WORLD TRADE ORGANIZATION

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EUROPEAN COMMUNITIES – MEASURES AFFECTING ASBESTOS AND ASBESTOS-CONTAINING PRODUCTS

Report of the Panel

Addendum

This addendum contains the annexes to the Report of the Panel to be found in document WT/DS135/R.

ANNEXES

ANNEX I

DECREE NO. 96-1133 OF 24 DECEMBER 1996

Concerning the ban on asbestos, implemented pursuant to the Labour Code and the Consumer Code

(Official Journal of 26 December 1996)

The Prime Minister,

Acting on the report of the Minister for Justice, the Minister for Equipment, Housing, Transport and Tourism, the Minister for Labour and Social Affairs, the Minister for the Economy and Finance, the Minister for Industry, Postal Services and Telecommunications and the Minister for Agriculture, Fisheries and Food,

Having regard to Council Directive (EEC) 76/769 of 27 July 1976 as amended, concerning restrictions on the marketing and use of certain dangerous substances and preparations;

Having regard to the Labour Code, in particular, Articles L.231-1, L.231-6, L.231-7 and L.263-2 thereof;

Having regard to the Consumer Code, in particular Article L.221-3 thereof;

Having regard to the Penal Code, in particular, Article R. 610-1 thereof;

Having regard to the Customs Code, in particular Article 38 thereof;

Having regard to the Traffic Law;

Having regard to Decree No. 88-466 of 28 April 1988 as amended, concerning asbestos-containing products;

Having regard to Decree No. 96-98 of 7 February 1996 concerning the protection of workers against the risks associated with asbestos dust inhalation;

Having regard to the referral of the matter to the Commission of the European Communities by the French Government on 29 October 1996, under the emergency procedure established under Article 9.7 of Directive (EEC) 83/189 as amended, providing for a notification procedure in the sphere of technical standards and regulations;

Having regard to the opinion of the National Commission for Occupational Health and Safety in Agriculture of 26 September 1996;

Having regard to the opinion of the Consumer Safety Commission of 2 October 1996;

Having regard to the opinion of the Senior Council for the Prevention of Occupational Hazards of 16 October 1996;

Upon consultation with the professional employer and employee bodies concerned;

Having heard the Council of State (Social Affairs Section),

Decrees:

Article 1

I. For the purpose of protecting workers, and pursuant to Article L. 231-7 of the Labour Code, the manufacture, processing, sale, import, placing on the domestic market and transfer under any title whatsoever of all varieties of asbestos fibres shall be prohibited, regardless of whether these substances have been incorporated into materials, products or devices.

II. For the purpose of protecting consumers, and pursuant to Article L. 221.3 of the Consumer Code, the manufacture, import, domestic marketing, exportation, possession for sale, offer, sale and transfer under any title whatsoever of all varieties of asbestos fibres or any product containing asbestos fibres shall be prohibited.

III. The bans instituted under Articles I and II shall not prevent fulfilment of the obligations arising from legislation on the elimination of wastes.

Article 2

I. On an exceptional and temporary basis, the bans instituted under Article 1 shall not apply to certain existing materials, products or devices containing chrysotile fibre when, to perform an equivalent function, no substitute for that fibre is available which:

- On the one hand, in the present state of scientific knowledge, poses a lesser occupational health risk than chrysotile fibre to workers handling those materials, products or devices;

- on the other, provides all technical guarantees of safety corresponding to the ultimate purpose of the use thereof.

II. The scope of application of paragraph I of this Article shall cover only the materials, products or devices falling within the categories shown in an exhaustive list decreed by the Ministers for Labour, Consumption, the Environment, Industry, Agriculture and Transport. To ascertain the justification for maintaining these exceptions, the list shall be re-examined on an annual basis, after which the Senior Council for the Prevention of Occupational Hazards and the National Commission for Occupational Health and Safety in Agriculture shall be consulted.

Article 3

I. The manufacture, processing, importation and domestic marketing of any of the materials, products or devices falling into one of the categories mentioned on the list envisaged under Article 2 shall be subject to a statement, signed, as appropriate, by the head of the business establishment, the importer or the party responsible for domestic marketing, which should be addressed to the Minister for Labour. This statement shall be filed in January of each year or, as appropriate, three months before the start of a new activity or the alteration of an existing production activity, by means of a form decreed by the Ministers for Labour, Consumption, Industry and Agriculture.

The statement shall be accompanied by all the supporting documents in the possession of the declaring party making it possible, considering the state of scientific and technological progress, to determine that as of the date of signature of the statement, the activity covered by the statement meets the conditions set forth in Article 2.I.

II. Activities that have not been the subject of a full statement submitted within the set time-frame may not benefit from the exception granted under Article 2.

III. The Minister for Labour may at all times convey to the author of the statement such information as may seem to him to establish that the material, product or device in question, although falling into one of the categories on the list mentioned in Article 2, does not meet the conditions laid down in paragraph I of that same Article. After requesting comments from the declaring party, he may serve notice to said party to cease manufacture, processing, importation or domestic marketing and to observe the ban instituted under Article 1. He may make such notification public.

Article 4

The manufacture and processing of the materials, products and devices falling into the categories on the list mentioned in Article 2 of this Decree must conform with the rules laid down under Chapters I and II and Chapter III, Section 1 of the aforementioned Decree dated 7 February 1996.

Labelling and marking shall conform with the requirements of Article L. 231-6 of the Labour Code and the rules established by the aforementioned Decree dated 28 April 1988.

Article 5

Without prejudice to the application of the penalties envisaged under Article L. 263-2 of the Labour Code in the event of violation of the provisions of Article 1.I of this Decree, the act of manufacturing, importing, introducing into the domestic market, exporting, offering, selling, transferring under any title or possessing for sale all varieties of asbestos fibres or any product containing asbestos fibres, in contravention of the provisions of Article 1.II shall be punishable by the fine prescribed for 5th class offences.

Article 6

I. Articles 1, 2, 3 and Article 6.I of the above-mentioned Decree No. 88-466 of 28 April 1988 are hereby repealed.

II. In the first subparagraph of Article 4 of the same Decree, the words: "bans envisaged in Article 2 above" shall be replaced by the word: "bans".

III. In Article 6.II of the same Decree, the words: "other than those envisaged under Article 2" shall be replaced by the words: "which are not subject to bans".

Article 7

Until 31 December 2001 and on a transitional basis, the ban on possession for sale, offering for sale and transfer under any title shall not apply to the used vehicles nor to the agricultural or forestry machinery put into circulation before the effective date of this Decree, and covered by Article R.138 of the Traffic Law.

Article 8

This Decree shall become effective on 1 January 1997.

Article 9

The Minister for Justice, the Minister for Equipment, Housing, Transport and Tourism, the Minister for Labour and Social Affairs, the Minister for the Economy and Finance, the Minister for the Environment, the Minister for Industry, Postal Services and Telecommunications, the Minister for Agriculture, Fisheries and Food, the Deputy Minister for the Budget, the Government Spokesperson, and the Deputy Minister for Finance and Foreign Trade shall be responsible, each in his own sphere of competence, for implementing the present Decree, which shall be published in the Official Journal of the French Republic.

Done at Paris, 24 December 1996.

By the Prime Minister — ALAIN JUPPE

The Minister for Labour and Social Affairs,
JACQUES BARROT

The Minister for Justice,
JACQUES TOUBON

The Minister for Equipment, Housing, Transport and Tourism
BERNARD PONS

The Minister for the Economy, and Finance,
JEAN ARTHUIS

The Minister for the Environment,
CORINNE LEPAGE

The Minister for Industry, Postal Services and Telecommunications
FRANCK BOROTRA

The Minister for Agriculture, Fisheries and Food,
PHILIPPE VASSEUR

The Deputy Minister for the Budget, Government Spokesperson,
ALAIN LAMASSOURE

The Deputy Minister for Finance and Foreign Trade,
YVES GALLAND

ANNEX II

QUESTIONS – REPLIES

At the First and Second Substantive Meetings
(1-2 June 1999 and 20-21 January 2000)

I. QUESTIONS TO THE PARTIES

A. QUESTIONS AT THE FIRST SUBSTANTIVE MEETING (1-2 JUNE 1999)

1. Questions by the Panel to Canada

Question 1: Canada states that "the risks to health associated with modern chrysotile products are undetectable". Does the concept of "undetectable" risk mean the same for Canada as no risk?

1. The term "undetectable" should not be interpreted as a subjective judgement with respect to risk management, but rather as a scientific term related to quantification of the risk. In the specific context of its submission, Canada could just as easily have used the expression "below detection limits" (BDL), which is commonly used by scientists. This expression means that as determined using the latest methods and techniques and the most rigorous statistical analysis, the risk (effect) related to exposure conditions (type of fibre, dose, duration) is so slight, if it exists at all, as to be "below detection limits". Scientists generally do not use the expression "zero effect" or "no risk" or any other similar expression to describe a level of risk. Rather, they use "below detection limits" (BDL). The term "undetectable" used by Canada and the scientific community at large should be interpreted in this specific sense. Canada considers that it is inappropriate to use expressions such as "zero risk" or "no risk". Canada thus adheres strictly to the scientific definition of the expression used, i.e., not "no risk", but "undetectable risk", as indeed do the European Communities. In fact, the European Communities themselves corroborate the validity of this concept when they state, with respect to ambient concentrations of asbestos in buildings, that "it is clear that the risk [thereof] is undetectable".

Question 2: In its oral submission (1 June) Canada indicated, with respect to encapsulated products, that chrysotile fibres are only released under certain conditions. What are those conditions?

2. Products in which chrysotile is an encapsulated component release virtually no fibres naturally, or, if they do so, in such minimal concentrations that they are below detection limits. In other words, only aggressive operations on products containing encapsulated chrysotile can lead to the release of a detectable quantity of fibres. Such operations may occur during installation, renovation or removal of such products.

Question 3: Do operations by professional workers or private individuals on asbestos-cement products (such as sawing, sanding or demolition) and erosion of the matrix over time have the effect of releasing chrysotile fibres at levels that present a "detectable risk"?

3. When asbestos products are installed in the workplace, be they asbestos-cement products (pipes, panels or tiles), friction products or other products containing encapsulated chrysotile, small quantities of fibres may be released. To mitigate this potential risk, numerous codes of practice such as Standard 7337 of the International Organization for Standardization (ISO) or the American Water Works Association Code have been developed in order to minimize the release of dust. These codes

of practice cover the tools and procedures for use with these products in detail. Recommended installation methods can eliminate the need to cut or drill basic chrysotile products at construction sites, since those products are distributed in various pre-cut and pre-drilled formats to buyers' specifications. Where products do have to be drilled or cut, the use of appropriate tools can minimize the release of dust and keep it well within the level considered safe by WHO. This has been confirmed by laboratory tests and testing at construction sites of release of fibres during the installation of asbestos products.[1]

4. These workers are subject to exposure peaks, the magnitude of which depends on the protective measures in place. However, aside from the intensity of exposure, the duration of exposure is also critical, for the risk is essentially determined by cumulative exposure. In the United States, according to the studies by CONSAD for OSHA (Occupational Safety and Hygiene Agency) between 1985 and 1990, the average annual exposure for such workers was 10 to 100 times higher than for occupants of buildings with asbestos insulation, which is corroborated by the WHO report EHC-203 (exposure of 0.002 to 0.02 f/ml). It can be inferred that the cumulative lifetime exposure for such workers is 2 to 30 times higher than for occupants of such buildings. These workers therefore appear to have a lifetime risk of some 20 to 300 per million, which is an "undetectable" risk, i.e. it cannot be shown or measured empirically.[2]

5. Unlike professional workers, private individuals probably work only very sporadically with chrysotile cement products. The exposure incurred by these do-it-yourself enthusiasts will only be a fraction of that of professional workers. Consequently, if professional workers working on a daily basis with chrysotile-cement products are not subject to any detectable risk, logically private individuals will be even less so. Generally speaking, private individuals will not perform any major operations such as sawing, sanding or demolition of materials. More likely, do-it-yourselfers will occasionally perform minor operations such as drilling a hole for a cable, for example. Finally, whenever they work with cement products, whether or not they contain chrysotile, do-it-yourselfers should use simple protective measures, if only because of the presence of other carcinogenic substances such as crystalline silica.

6. In the context of the general human environment, small quantities of fibres can also be released through natural wear and tear of the product during its life cycle, either by mechanical erosion of the product as a result of water or wind action or by the physico-chemical effects of changes in temperature. There has been extensive study of this matter, and it has been recognized that

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[1] See John A. Hoskins, *Chrysotile in the 21st Century*, (below "Hoskins") and his bibliographic references 103, 105, 109 and 110. These bibliographic references are reproduced in full in other Canadian annexes as follows:

- Vanherle HE: In: Proceedings of the 8th biennial conference of the AIA, Paris, 11-12 May 1993, (reference 103 in Hoskins);

- Equitable Environmental Health Inc., *Dust Exposures during the Cutting and Machining of Asbestos/Cement Pipe - Additional Studies* (reference 105 in Hoskins);

- Report of Industrial Hygiene Survey for Airborne Asbestos Fibers at 10233 Norton Rd., Potomac, MD, USA. Prepared for: Supradur Manufacturing Corporation, Rye, NJ. 1 December 1987 (reference 109 in Hoskins);

- Report of Industrial Hygiene Survey for Airborne Asbestos Fibers at J. Allocca Residence, 90 Lincoln Avenue, Florham Park, NJ, USA. Prepared for: Supradur Manufacturing Corporation, Rye, NJ. 16 August 1988 (reference 110 in Hoskins).

[2] CONSAD Research Corporation. *Economic Analysis of the Proposed Revisions to the OSHA Asbestos Standards for Construction and General Industry*, Washington, DC: OSHA, U.S. Dept. of Labor, 1990. These data and references are mentioned on page 4-74 of the HEI-AR report: Upton A. Barrett J. Becklake, MR. Burdett, G. Chatfield, E. Davis, JMG. Gamsu, G. Hoel, DG. Langer, A. Lee, RJ. Lippman, M. Mossman, BT. Morse, R. Nicholson, W. Peto, J. Samet, J. Wagner, JC, *Asbestos in Public and Commercial Buildings: A Literature Review and Synthesis of Current Knowledge - Final Report*, Cambridge, MA: Health Effects Institute - Asbestos Research 1991.

the release of fibres is at levels which do not measurably add to the chrysotile naturally present in the environment. The European Communities recognize that at such levels "it is clear that the risk is undetectable".

Question 4(a): What exactly does Canada mean by "modern chrysotile products" or "modern asbestos products"?

7. By "modern chrysotile products", Canada means the range of non-friable products where: (i) only chrysotile asbestos is used, but no amphibole asbestos (crocidolite and amosite); and (ii) in which the fibres are firmly bonded physically and chemically into the matrix (cement, asphalt, resins, plastic, etc.) of the compound (chrysotile-cement, friction material, asphalt road surfacing, etc.) and cannot easily be released in biologically significant concentrations. In this respect, the following observation seems germane:

> "Once an asbestos-containing product has been manufactured, whether or not it constitutes a source of asbestos in the environment will depend to a great extent on whether or not the asbestos is firmly "locked-in" the product with a binder, saturant, coating or bonding agent such that normal handling, application and use do not release it. Asbestos-cement products are a good example of "locked-in" products which probably do not constitute a significant source of asbestos to the environment under normal conditions of use."[3]

Question 4(b): Since when have "modern" asbestos processing techniques been in use?

8. The date of the shift to exclusive use of chrysotile asbestos in non-friable ("locked-in") products varies from country to country, as do the dates on which different countries banned asbestos flockings or the use of amphibole asbestos. ILO Convention 162 concerning Safety in the Use of Asbestos has now been adopted by over 20 countries. It should also be noted that many countries have banned or severely restricted and regulated the use of amphiboles or barred the spraying technique as required by Convention 162, without actually acceding to it.

Question 5: Canada observes that "the removal of most modern asbestos products should present little difficulty when a building is demolished". Can Canada expand on this assertion, and in particular develop the concept of "little difficulty"? In "everyday life", how can an individual who demolishes or works on a building containing asbestos-cement detect the presence of this material?

9. Demolition of a building is an operation which normally requires a permit and which is usually performed by professional workers. The issue of permits allows the authorities to ensure that the demolition is carried out by persons who are familiar with the appropriate working methods necessary to control all the risks associated with demolition activities including those involving the dust of all kinds which may be released during the works.

10. In the case of demolition of buildings, the first concern of the person responsible for the work should be to identify the presence of friable materials such as amphibole flocking, whether that person is a professional worker or a private individual. Indeed, when the demolished building contains flockings, their release into the open air will be the main source of contamination of the site by asbestos, much more so than the presence of asbestos-cement materials. The latter may be broken or crushed to a greater or lesser degree, but the concentration of respirable fibres thus released will be very much lower than concentrations of fibres originating from flockings.

[3] William J. Nicholson and F.L. Pundsak, *Biological Effects of Asbestos*, IARC Scientific Publications No. 8, pp. 126-127 Lyon (1973).

11. This observation demonstrates the importance of producing a register of buildings containing flockings and introducing regulations requiring consultation of the register and/or inspection of buildings to be demolished to determine whether or not flockings are present before a demolition permit is issued.

12. When it is determined that a building contains flockings, specific control measures must be followed if demolition is considered necessary.

13. Otherwise, demolition of structures containing products in which chrysotile is encapsulated (generally flat or corrugated sheeting and roof tiles) requires only elementary precautions since chrysotile-cement debris remains largely inert. In Quebec, for example, demolition is regulated by the Code of Safety for the Construction Industry issued by the Occupational Health and Safety Commission (Commission de la Santé et de la Sécurité du Travail). The debris resulting from demolition is disposed of in public landfill sites for solid wastes in the same way as other construction waste and coated with covering materials as a preventative measure, superfluous according to some, in order to ensure that no chrysotile dust is left suspended in the air. Under these conditions, chrysotile-cement debris causes little or no increase in natural concentrations of asbestos in the environment, levels which the European Communities, it should be recalled, consider "undetectable." Moreover, as chrysotile asbestos is not soluble and in any case constitutes no risk when ingested, it has no effect on the local or nearby water-table.

14. Private individuals who work on a construction containing chrysotile asbestos in everyday life run little risk since such work is very sporadic and generally of short duration, while chrysotile-related risks are primarily associated with prolonged occupational exposure to high concentrations of fibres.

15. It should also be noted that individuals should exercise equal care when working with any cement material, whether or not it contains chrysotile, because they are exposed to risks of the same magnitude due to the presence of other dust, such as crystalline silica or substitute fibres which may be released during the work. Crystalline silica is classified as a Group I carcinogen by the IARC and no study has yet been carried out on the health risks associated with the inhalation of dust from substitute fibres which may be released into the air during work of this type.

16. Wearing a "surgical" type mask would be a wise precaution whenever work by an individual on any form of material might result in the formation of respirable dust.

Question 6: International institutions such as WHO or ILO are encouraging a gradual switch to substitute products (see for example ILO Convention 162 concerning Safety in the Use of Asbestos; IPCS Environmental Health Criteria (203) on Chrysotile, WHO 1998). Does Canada subscribe to this approach?

17. Canada has itself ratified Convention 162 concerning Safety in the Use of Asbestos. The Convention should, however, be considered in its entirety, and it should be recalled that in Article 10, ILO encourages a gradual switch to substitute products "where necessary to protect the health of workers and technically practicable … by other materials or products or the use of alternative technology, scientifically evaluated by the competent authority as harmless or less harmful."

18. To date, no comparative scientific study has conclusively shown that, under similar conditions of production, manufacture or use, substitute products are harmless or less harmful than chrysotile asbestos. Indeed, some recent studies show that chrysotile displays lower biopersistence than the main fibrous substitutes such as refractory ceramic fibres, glass fibres, aramid fibres and cellulose fibres. There are also numerous scientific studies in existence which show that, at the low levels of exposure currently observed in the chrysotile products industry (generally less than 1 fibre/ml.), there is no measurable increase in the risk to human health.

19. The same argument applies to the IPCS *Environmental Health Criteria (203) on Chrysotile*, WHO 1998, which states: "where safer substitute materials for chrysotile are available, they should be considered for use."[4]

Question 7: What criteria should be used to determine the relative risk associated with substitute products and chrysotile asbestos?

20. Canada has referred to the consensus that the relative risk of fibrous materials varies according to three factors ("3 D"): dimension, durability and dose.

21. The dimension (length and diameter) affects "respirability". This is the factor which determines whether a fibre can actually penetrate the confines of the respiratory system: the alveoli.

22. However, the dimension factor is a necessary but not sufficient condition. An inhaled fibre must stay in the system long enough i.e. it must have sufficiently long (biopersistence) to exert its pathogenic effect. This is the durability factor. In this respect, Canada has submitted (and the latest data, which Canada can provide, confirms this) that in inhalation experiments with animals, chrysotile is very quickly eliminated from the lungs (within 24 to 48 hours), while amphiboles persist practically indefinitely, and then trigger the range of inflammatory reactions which precede and herald the known pathologies. The small quantity of data available on the biopersistence of certain substitute fibres (for example aramid fibres are more biopersistent than chrysotile) suggest that the durability factor should be seriously considered in evaluating the relative risk associated with fibres of substitutes for chrysotile asbestos. In this connection, the following quotation from a Scandinavian study bears repeating:

> "(…) adverse effects are associated rather with the fibres that are retained (amphiboles), than with the ones being cleared (largely chrysotile)".[5]

23. Another study, published in 1995, indicates that: "biopersistence of inhaled fibrous materials is a critical factor in determining carcinogenic potency." [6]

24. A recent report by Bernstein (1997) for *the Joint Research Centre, Environmental Institute, European Chemical Bureau* in Ispra (Italy) under the title *Correlation Between Short Term Biopersistence and Chronic Toxicity Studies* confirmed the relevance of the durability factor in evaluating the risk associated with substitute fibres and chrysotile asbestos.[7]

25. We had good reason to draw attention to the importance of the third factor, the dose. It introduces the phenomenon of the threshold of exposure above which harmful effects begin to appear, and below which (with obvious differences according to the type of fibrous material) the risk, if any, becomes undetectable.

26. Although the "3 D" are the recognized critical factors in the risk associated with respirable fibres, other factors; Such as the capacity to induce the production of reactive molecular forms may influence the degree of risk. Indeed, as several fibre toxicity mechanisms remain uncertain, it must be ensured that the experimental and epidemiological studies to evaluate the risk posed by the fibres to

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[4] IPCS *Environmental Health Criteria (203) on Chrysotile*, WHO, Geneva, 1998, p.144.

[5] Albin A., Pooley F.D., Strömberg U., Attewell R., Mitha R. and Welinder H., *Retention Patterns of Asbestos Fibres in Lung Tissue among Asbestos Cement Workers*, (1994) Occup. Environ. Med. 51: 05-211.

[6] Bellman and Muhle, (1995) Schriftenreihe der Bundesvanstalt für Arbeitsschutz (Federal Office for Worker Protection).

[7] *Bernstein, Correlation between Short Term Biopersistence and Chronic Toxicity Studies* (1997) Joint Research Centre, Environmental Institute, European Chemicals Bureau in Ispra (Italy).

humans are equally valid and comparable for chrysotile and its substitutes. It must also be ensured that the main comparability and validity criteria and principles for the design of such studies are established by recognized international bodies. We will not list these principles here, but we wish to emphasize that comparisons of the risk associated with different fibres need to satisfy the following conditions in order to be valid, i.e. unbiased: (i) analysis of the structural characteristics must be based on the "3 Ds"; (ii) the dose or exposure must be similar and must not overload the pulmonary macrophages; (iii) the observation periods must be similar and long enough to observe the effect of differences in biopersistence; (iv) the number of subjects and observations/studies must be sufficiently large to be able to detect even a slight risk; (v) the characteristics of the fibres studied must represent in the same way the real uses of chrysotile fibres and their real substitutes; and (vi) animal studies must study the effects of fibre inhalation in the same concentrations, under the same conditions of exposure and using the same experimental method.

27. Only on the basis of such criteria can the relative risk of chrysotile fibres and their substitutes be determined, and only a comparative risk analysis such as the one defined by the National Research Council in the United States can assess the quality and comparability of the data concerned and estimate the relative risk of the substances. For example, recent and incomplete toxicological data on substitute fibres cannot be compared with epidemiological studies based on 100 years of human exposure. It is necessary to compare data of the same type and of the same quality in order to have confidence that a proposed substitute is safer than chrysotile.

Question 8: What occupations are at greatest risk of exposure to asbestos at the present time? Can protection measures be instituted - and enforced - for all these occupations? Is controlled use of chrysotile asbestos and products containing it possible for occupations exposed to occasional but potentially high exposure, and exposure of a para-occupational and domestic nature?

28. In Canada's view, the occupations which run the greatest risk of exposure to chrysotile asbestos, are, in descending order: (i) chrysotile miners and employees of chrysotile-ore processing plants (mills); (ii) workers employed in the manufacture of chrysotile fabrics; (iii) workers employed in the manufacture of friction linings (brakes, clutches, etc.); (iv) workers employed in the manufacture of chrysotile cement products; (v) workers employed in asbestos removal; and (vi) workers employed in construction, renovation, maintenance and insulation.

29. While all workers in the above categories are more likely to be exposed to different types of asbestos fibres, it is most important to note that those in categories five and six may be exposed to amphiboles, while the others are not. In the case of workers in areas where chrysotile is used, effective protection measures have been put in place since the 1970s by the competent authorities, with the collaboration of manufacturers and trade unions, (ventilation, filtration, wet processes, mechanization, etc.). The methods used for this purpose rely on relatively simple technologies. They include the following: better ventilation of working areas; more effective filtration of dust-bearing air; crushing and processing under negative pressure to prevent the escape of dust; exhaust hoods in work stations directly exposed to fibre; wet manufacturing processes; mechanization, etc..

30. While workers in category 6 are exposed to friable asbestos products (of all kinds) on quite a regular basis in the course of their work, Canada is nevertheless of the view that the same information and training measures for employers and workers, combined with regular inspections and checks by occupational health and safety agencies, together with the compilation of registers of buildings containing asbestos, should give results similar to those obtained following the introduction of similar measures for the other five categories of workers. Prevention and protection measures (masks, dampening, ventilation, etc.) can considerably reduce occupational exposure to asbestos. It should be reiterated that these working conditions stem from uncontrolled use of asbestos (mainly flockings)

which has not occurred since the early 1980s, and a ban on chrysotile would not in any way alter the situation.

31. Controlled use of chrysotile asbestos and its modern products is possible for all occupations, even those where the workers may be subject to occasional exposure. It is a matter of establishing and enforcing an appropriate set of rules for their use, in the same way as is done for many other dangerous substances used in the workplace.

32. There are no conclusive studies of the risks associated with occasional but potentially high exposure, even the French study by Iwatsubo *et al.* quoted by the European Communities, concurs "(…) subjects with sporadic exposure were not at greater risk of mesothelioma than were controls."[8]

Question 9: Does Canada agree with the French experts' estimate (*Evolution of the annual incidence of mesothelioma in Canada and Quebec,* Section III.B.4), of the annual incidence of mesothelioma in Canada and Quebec? If not, what are the Canadian figures? Does Canada have statistics for deaths from lung cancer caused by chrysotile asbestos? If yes, what do they show?

33. The estimates of the incidence of mesothelioma in Canada and Quebec in the first written statement of the European Communities match the Canadian data, precisely because the International Agency for Research on Cancer data are taken from Canadian cancer records. The French experts' analysis however, requires further explanation in order to be correctly understood.

34. Unlike France whose cancer records cover only 9.5 per cent of the population (INSERM page 173), Canada is one of the few countries in the world whose cancer records cover 100 per cent of the population, with the consequence that its data are more reliable than those of France or most countries.[9] For this reason, and because Canada has a large number of studies on cohorts of asbestos workers, compiling a special registry of mesothelioma cases was less pressing than in other countries. It should be noted that France also does not have a central registry of mesothelioma.

35. Three caveats are necessary in order to interpret correctly the Canadian data summarized in the table produced by the European Communities: (i) Quebec cancer reports and likewise the Canadian totals that include Quebec are only reliable since 1984; (ii) as in most countries, mesothelioma was considerably underdiagnosed and under-reported until the mid-1980s, which falsely inflates the increase in the incidence of mesothelioma during the 1970s and 1980s[10]; (iii) data and trends prior to 1984 should therefore be treated with caution.

[8] Iwatsubo *et al. Pleural Mesothelioma: Dose-Response Relation at Low Levels of Asbestos Exposure in French Population-Based Case-Controlled Study*, Am. Journal of Epidemiology 1998, 148: 133-142.

[9] That is why Dr. Julian Peto had to estimate the incidence of mesothelioma in Western Europe from data on mortality from cancer of the pleura, a very imperfect indicator of the incidence of mesothelioma.

[10] Peto J. Hodgson JT, Matthews FE, Jones JR, *Continuing Increase in Mesothelioma Mortality in Britain*, Lancet 1995; 345:535-9.

36. Recent analyses of Canadian data on mesothelioma in Canada[11], British Columbia[12] and Quebec [13-14] agree that rates of incidence of mesothelioma have been stable in women of all age groups since 1984. In Quebec, the rates are 70 per cent higher than elsewhere in Canada, probably because of more frequent and more intense exposure in the workplace. In fact, Quebec produced about half of the world's commercial chrysotile until the 1950s. Quebec also used large quantities of amphiboles in various sectors, particularly in certain sectors in which many women were employed, especially during the Second World War.

37. According to a study by Schanzer, Semenciw and Ugnat (Health Canada, 1997), the incidence of mesothelioma in men in Canada increased by 22 per cent from 1984 to 1993, half the increase estimated by the French experts, and also half that in France.[15] Over the same ten-year period, the incidence of mesothelioma rose by 45 per cent in Quebec (the same as in France), 34 per cent in Ontario, 0 per cent in British Columbia and less than 10 per cent for the rest of Canada. These rates reflect wide disparities in Canada, contrary to the European Communities' assertion. The incidence in men also levelled off in 1984 in British Columbia (according to Coleman and Philips), and seems to have levelled off in Quebec after 1990.

38. Finally, the analysis of Canadian rates between 1973 and 1992 (Schanzer and colleagues, 1997) estimates that the risk is four times higher for men born before 1940 than for those born between 1951 and 1955. These analyses therefore suggest that the incidence of mesothelioma has levelled off in Canada is declining in British Columbia, and has levelled off in Quebec.

39. The following table, adapted from the one submitted by the European Communities, shows that despite the much higher asbestos production in Canada and Quebec than in France, the incidence of mesothelioma and the increase in that incidence were lower in Canada than in France. Thus, although Quebec produced almost half the chrysotile used in the world, the incidence of mesothelioma in Quebec was, surprisingly, no higher than in France.

A NUMBER OF CASES ANNUALLY PER MILLION PERSONS
1978 - 1992

Period	Canada		Quebec		France[16]	
	M	F	M	F	M	F
1978-1982	6	2	9	4	8	
1983-1987	9	2	11	3	12	
1988-1992	11	2	15	3	15	2

[11] Study by the Cancer Department of Health Canada (Schanzer, Semenciw and Ugnat, 1997) presented to the biennial conference of the Canadian Society for Epidemiology and Biostatistics.

[12] Study on mesothelioma and cancers of the pleura and peritoneum for the British Columbia Cancer Registry (Coleman and Philips, 1996).

[13] Study on mesothelioma and cancers of the pleura and peritoneum submitted to Health Canada's Environmental Health Directorate (Camus, 1997).

[14] Study of mesothelioma in Quebec from 1986 to 1993 and of pleural cancer and cancer of the peritoneum from 1986 to 1996 submitted to the Advisory Committee on Asbestos in the Ministry of Health and Social Services (Lebel, Gingras and Lévesque, Laval University Hospital Centre, 1998).

[15] Our comparison with France reflects the fact that the statement of the European Communities incorrectly calculated the rate of growth for Canada as "a particularly high rate". However, as shown on page 177 of the INSERM Report, the incidence of mesothelioma rose more rapidly in France than in Canada.

[16] From INSERM Report (page 177) using the published results of the FRANCIM network: Ménégoz F., Gosclaude P, Arveux P *et al., Incidence of mesothelioma in French cancer records: estimates for all France*, B.E.H. 1996:12.

40. With respect to the proportion of lung cancer cases attributable to occupational exposure to asbestos, no country in the world possesses such statistics. However, case-control studies of a number of cancers and types of exposure in the general population in Canada (some metropolitan regions or provinces) suggest an upper limit to the proportion of lung cancer cases attributable to asbestos, but they suffer from flaws which make it impossible to determine the specific proportion that is due to asbestos, independently of other major risk factors.

41. A case-control study of cancers in Montreal[17] suggests that the specific association between lung cancer and asbestos would explain at most 7.6 per cent of lung cancers in men between 1979 and 1985; but the real proportion is lower because part of the 7.6 per cent is attributable to concomitant exposure: PAHs (polycyclic aromatic hydrocarbons), solvents, alkanes, welding fumes, tobacco (residual effects after statistical control), etc.

42. Case-control studies in the United States, the United Kingdom and Sweden provide other estimates of the percentage of lung cancers attributable to asbestos. As the review of the studies[18] cited by INSERM (pages 10 and 179 of the Report) indicates, the enormous heterogeneity of these studies (e.g. the attributable percentage ranges from 0.6 per cent to 16.6 per cent in the United Kingdom alone) stems from variations in the prevalence of asbestos exposure (types of industry and proportion of workers exposed), which prevents any extrapolation of their findings to Canada (or to France).

Question 10: Canada refers to the WTO report *Environmental Criteria 53: Asbestos and Other Natural Mineral Fibres,* published in 1986, but does not mention a subsequent report by the same organization, IPCS Environmental Health Criteria (203) on Chrysotile, in 1998. In Canada's view, to what extent does the 1998 report confirm the findings of the 1986 report, particularly with regard to the dangers of chrysotile and risk management methods?

43. The reply to this question should be prefaced by two preliminary remarks. Firstly, it should be recalled that the forewords to the above-mentioned reports read as follows: "[T]his report contains the collective views of an international group of experts and does not necessarily represent the decisions or the policy of the United Nations Environment Programme, the International Labour Organization, or the World Health Organization." Secondly, Canada wishes to emphasize that the interpretation of the two reports, each over 150 pages long, in the limited context of the reply to this question will necessarily be incomplete.

44. That being so, this reply will address the question of the dangers of chrysotile before turning to risk management methods. Report 203 surveys the data on exposure to chrysotile and suggests among other things that: (i) in the mines and mills in Quebec, "the average fibre concentrations (…) are now generally well below 1 f/ml": (ii) in the production of asbestos cement in Japan, concentrations range between 0.05 and 0.45 f/ml in 1992; (iii) in the production of textiles in Japan between 1984 and 1986, the concentrations found were between 0.1 and 0.2 f/ml; (iv) in other countries and various other sectors: vehicle maintenance: "practically all measured levels after 1987 were less than 0.2 f/ml"; buildings maintenance: "[I]n buildings with control plans, personal exposure of buildings maintenance personnel in the USA … between 0.002 and 0.02 f/ml."[19] The trend towards lower concentrations is thus confirmed, and demonstrates the feasibility and benefits of applying controlled use policies.

[17] Siemiatycki J., *Risk Factors for Cancer in the Workplace*, Boca Raton: CRC Press, 1991.

[18] Vineis P, Simonato L., *Proportion of Lung and Bladder Cancers in Males Resulting from Occupation: A Systematic Approach [Review]*. Arch. Environ. Health 1991;46:6-15.

[19] Source; EHC No. 203, Summary, 1.3.

45. Report 203 also recognizes the difference in the dangers associated with chrysotile and amphiboles:

> "The mechanisms of the relatively more rapid clearance of chrysotile fibres compared to those of amphiboles (…)"
>
> "The more rapid removal of chrysotile fibres from the human lung is further supported by findings from animal studies (…)"[20]

46. Report 203 recognizes that the presence of chrysotile fibres in water is harmless:

> " … it was concluded that there was little convincing evidence of an association between asbestos in public water supplies and cancer induction. More recent identified studies do not contribute additionally to our understanding of health risk associated with exposure to chrysotile in drinking water."[21]

47. None of the IPCS reports (EHC No. 53 and 203) suggests any measures whatsoever with respect to risk management methods:

> The EHC monographs are intended to assist national and international authorities in making risk assessments and subsequent risk management decisions. They represent a thorough evaluation of risks and are not, in any sense, recommendations for regulation or standard setting."[22]

48. Thus among the conclusions in the 1998 report, we read: "[W]here safer substitute materials for chrysotile are available, they should be considered for use."[23] It is clear from this latter extract that the scientists who wrote the EHC 203 report refer to the consideration of safer and available substitute material. On the issue of proven safer substitute fibres, Canada has already indicated in its written and oral submissions that none of the fibrous materials that have been proposed as substitutes have undergone rigorous tests to show that they are harmless. The limited data at present available suggests that premature replacement could be a serious risk management error. This last extract refers to available substitutes. Experience shows that the mere fact that such materials are available does not mean that they are technically adequate. Finally, the recommendation does not say that asbestos should be replaced, rather that replacement "should be considered". The 1998 WHO report thus confirms the 1986 report. Both emphasize a reduction in fibre concentrations, recognize the difference between chrysotile and amphibole and suggest replacing chrysotile by safer substitutes. However, as Canada submits, the fibre substitutes have never been subjected to rigorous tests that demonstrate them to be harmless.

Question 11: Does Canada accept the logic that an increase in a country's imports of chrysotile asbestos is accompanied by a proportional increase in asbestos-related pathologies?

49. Canada does not accept the "logic" that an increase in a country's imports of chrysotile asbestos is accompanied by a proportional increase in asbestos-related pathologies. Indeed, this "logic" only holds up if one ignores the marked differences in risk between different types of asbestos, between friable and non-friable products, between sanitary and unsanitary conditions and between the production, use and presence of asbestos products.

50. It is recognized that the health risks associated with asbestos are primarily a function of the "three Ds": dose, dimension, durability (biopersistence). The volume of asbestos imports bears little

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[20] *Idem*, Summary 1.4.
[21] *Idem*, page 128.
[22] *Idem*, Preamble.
[23] *Idem.*, Conclusions, b.

or no relation to these risk factors. Rather, specific information should be provided for each country on the following: the proportion of workers exposed, the conditions of exposure (types of industry and products, workplace hygiene regulations) product uses and distribution in various population groups (brakes, flockings, construction materials, cement, public buildings, etc.), the types of asbestos used and their applications. These conditions vary greatly from country to country and over time.

51. No analysis can distinguish the impact of asbestos imports by type of fibre for the following reasons: (i) the available data do not normally allow us to distinguish retrospectively between the mineralogical types of imported asbestos; (ii) even if such information were available, it would not be possible to distinguish the effects based on mineralogical type of asbestos because the volumes of imports of chrysotile and amphiboles are closely correlated (i.e. historically, the more chrysotile that was imported, the more amphiboles were imported too); and (iii) there are paradoxes, such as countries which produced chrysotile while also importing amphiboles to satisfy their industrial needs of the time.

52. Furthermore, importing a small quantity of amphiboles for uncontrolled use, in flockings, for example, would probably lead to a measurable increase in pathologies. On the other hand, an increase in the chrysotile imports for controlled use in the manufacture of non-friable products in a context of controlled utilization would not result in any detectable additional risk.

53. As for the type of fibre, three recent studies examined the relationship between asbestos imports and mesothelioma in three countries: the United Kingdom[24], the United States[25] and France.[26] None of these studies addressed the link between chrysotile imports and mesothelioma. Moreover, in the most recent of these studies, conducted by French researchers, the authors explain that their estimate of the incidence of mesothelioma in France is much lower than that predicted using Peto's model for Great Britain because of the type of asbestos and not the imports:

> "a possible explanation can be found in the different fibres used in this country; France used a much smaller proportion of amphiboles than Great Britain."[27]

54. As for the level of exposure and the difference between workers and the general population, the French experts explain that there was no increase in mesothelioma among women, despite an increase in production and imports over time, because of the low levels of environmental exposure:

> "This does not support the hypothesis that current environmental exposure to asbestos could be associated with detectable risk of death."[28]

55. It should be noted, incidentally, that, like Canada, the French experts use the concept of "detectable risk". This "logic" also does not take account of the variety of ways that asbestos is used or the way its use has evolved. For example flockings in the 1960s and 1970s, must have significantly increased the risk of mesothelioma for a given volume of consumption or imports. Neither does this "logic" hold good for countries/regions such as South Africa, Brazil, Quebec and Western Australia, which are asbestos producers but import little, since the proportion of their populations exposed in the workplace and the levels of exposure were higher than in most importing

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[24] Peto J. Hodgson JT *et al.* (1995), *Continuing Increase in Mesothelioma Mortality in Britain*, Lancet 345: 535-539

[25] Price B., (1997) *Analysis of Current Trends in United States Mesothelioma Incidence*, Am. J. Epidemiol. 45: 211-218.

[26] Gilg AS, Bignon J and Valleron AJ (1998), *Estimation of the Past and Future Burden of Mortality from Mesothelioma in France*, Occup. Environ. Med. 55: 760-765.

[27] *Idem.*, page 765.

[28] *Idem.*, page 760.

countries and often led to higher risks of pathologies than in countries/regions that import more asbestos.

56. Technically speaking, what the Panel and the European Communities call "logic" consists of an error of inference which is classic in epidemiology, the social sciences and biostatistics: the ecological fallacy. This fallacy consists of confusing observations of large groups (aggregates) showing non-specific aggregate correlations with real individual effects. In particular, it consists of ignoring the fact that the conditions of exposure and "co-factors" (other risk factors) for individuals in the varions large aggregates vary enormously. These big observation units are so broad that they are in fact not comparable or similar when it comes to the factors which actually determine the risk.

57. Thus, in the case of chrysotile, the study and graph by Takahashi *et al* cited by the European Communities do not distinguish between the effects of chrysotile and those of asbestos; separate graphs are needed for the consumption of chrysotile and amphiboles. In fact, similar graphs and correlations to those of Takahashi would be obtained for the consumption of artificial fibres or consumption of cement. What should one deduce from that?

58. Crude ecological correlations lend themselves to arbitrary and contradictory interpretations. There are only ten countries in the graph, which is too few: the sample, selection criteria or their characteristics skew the analysis. If another twenty countries were added, including Quebec, South Africa and Western Australia, the picture would be more representative but much less coherent, the correlation would be weaker and the line would be flatter. Indeed, to fit a straight line between these ten points is arbitrary. The best correlation with Takahashi's ten points is not a straight line but rather an "S-shaped" curve (e.g. logistic or cumulative normal curve), with a practical risk threshold (no risk for consumption below 1 kg./capita/year) and a risk ceiling (no additional risk for consumption over 2.5 kg./capita/year). It is no more absurd to argue for this interpretation than for a linear relationship. We are not saying that these data show a risk threshold, but wish to underline the arbitrary nature of the European Communities' interpretation of these ecological data.

59. For lung cancer, the significance of smoking and other risk factors, means that there is even less reason to deduce a proportional risk relationship with a country's asbestos imports or consumption levels.

60. In short, there is no clear-cut link between asbestos imports (particularly chrysotile) and the incidence of asbestos-related pathologies.

Question 12: Does Canada agree with the European Communities that cellulose, polyvinyl alcohol and aramid fibres have been shown to be safe or of low toxicity?

61. No. Canada does not agree that cellulose, PVA and aramid fibres have low toxicity.

62. The European Communities claim that the diameter of these fibres is generally greater than that of chrysotile fibres. This can probably be explained by the data on "nominal diameter" supplied by the substitute fibre industry. For example, in the case of aramid fibres, the "nominal diameter" is from 12 to 15 microns. However, there are data which show that in commercial preparations of fibres labelled "nominal diameter: 12-15 microns", there is a significant proportion of fibres with a diameter within the range of respirable diameters.[29] The presence of such fibres has even been observed in the pulmonary alveoli of laboratory animals which have been exposed to commercial preparations.

63. Furthermore, as the IPCS-EHC Report No. 151 states on page 76:

[29] Dunnigan, J., Nadeau, D. and Paradis, D., (1984)., *Cytotoxic Effects of Aramid Fibres on Rat Pulmonary Macrophages: Comparison with Chrysotile Asbestos*, Toxicology Letters, 20, pp. 277-282.

> "All fibres that are respirable and biopersistent must undergo testing for toxicity and carcinogenicity. Exposures to these fibres should be controlled to the same degree as that required for asbestos until data supporting a lesser degree of control become available. The data available suggest that para-aramid fibres fall within this category. Furthermore, other respirable organic fibres should be considered to fall within this category until data indicating a lesser degree of hazard become available."[30]

64. In addition, the claim that the fibres are less "biopersistent" is arguable. As the authors of the INSERM report recognize, there are few verifiable data on this subject. As stated in INSERM's summary report - *Effects on Health of Substitute Fibres for Asbestos*:

> "The results of many studies suggest that the 'fibrous' structure of asbestos is a significant pathogenic factor in the same way as some of its chemical characteristics. Consequently, any new fibre proposed as a substitute for asbestos or for any other purpose, must be suspected, a priori, of being pathogenic because of its structure, which does not preclude the analysis of other possible consequences of its physical and chemical characteristics".[31]

65. This view is echoed by the Scientific Committee on Toxicity, Ecotoxicity and the Environment of the European Commission (DG XXIV) which stated: "for the substitute materials, with the exception of vitreous fibres, there is no significant epidemiology base to judge the human health risks".[32]

66. Canada is prepared to prove that, in fact, aramid fibres are more durable and biopersistent than chrysotile fibres.

67. Canada shares the opinion of the experts that fibres replacing chrysotile should not be assumed to be harmless until all relevant data have been collected. The authors of the INSERM Report are equally circumspect on this point.

Question 13: In paragraph 238 of its first written submission, Canada states that Article 2.4 of the Agreement on Technical Barriers to Trade lays down the principle that a Member "shall use relevant international standards, or the relevant parts of them, as a basis for their technical regulations". In paragraph 249 of its submission, Canada further states that the Decree does not comply with international standards (…)". Does Canada consider the concept of regulations "based on" or "in accordance with" an international standard to be equivalent to the concept of using international standards or relevant parts of them "as a basis" for their technical regulations, within the meaning of Article 2.4 of the Agreement on Technical Barriers to Trade?

68. No. Under Article 2.4 of the TBT Agreement, France is required to use relevant international standards or parts of them as the basis or foundation of its technical regulations. In paragraph 249 of its first written submission, Canada merely observes that the Decree does not comply with international standards. In paragraph 249 of its first oral submission presented at the first substantive meeting, Canada maintained that "Article 2.4 should not be interpreted as allowing a Member to circumvent a complete series of international standards that provide the foundations – sometimes quite specific – for a measure enabling Members to fulfil the alleged objective". In paragraph 250 of

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[30] IPCS-EHC No. 151, 1993.

[31] INSERM, Summary Report, *Effects on Health of Substitute Fibres for Asbestos*, Joint Study, INSERM, Paris, 1998, p. 2.

[32] Opinion on a study commissioned by Directorate General III (Industry) of the European Commission on *Recent Assessments of the Hazards and Risks Posed by Asbestos and Substitute Fibres and Recent Regulation on Fibres Worldwide*, Environmental Resources Management, Oxford (opinion expressed on 9 February 1998) page 1.

the same oral submission, Canada adds the following: "the French measure deviates significantly from the precepts of international standards". In other words, the French measure deviates to such an extent from the fundamental principles of international standards that the latter are no longer recognizable.

Question 14: Is there any difference between the concept of using international standards "as a basis" for a technical regulation within the meaning of Article 2.4 of the Agreement on Technical Barriers to Trade and the concept of a technical regulation "in accordance with relevant international standards" within the meaning of Article 2.5 of the same Agreement?

69. Yes. As the Appellate Body reported in its Report on European Communities *Measures Concerning Meat and Meat Products (Hormones)*, there is a difference between the meaning of the terms "based on" and "conform to". In paragraph 163 of the Report, the Appellate Body stated that: "[…] the ordinary meaning of 'based on' is quite different from the plain or natural import of 'conform to.' A thing is commonly said to be 'based on' another thing when the former 'stands' or is 'founded' or 'built' upon or 'is supported by' the latter. In contrast, much more is required before one thing may be regarded as 'conform[ing]' to 'another': the former must 'comply with' 'yield or show compliance' with the latter. The reference of 'conform to' is to 'correspondence in form or manner' to 'compliance with' or 'acquiescence', to 'follow[ing] in form or nature.' A measure that 'conforms to' and incorporates a [given standard] is, of course, 'based on' that standard. A measure, however, based on the standard might not conform to that standard, as where only some, not all, of the elements of the standard are incorporated into the measure." [Footnote omitted]

70. Article 2.4 of the TBT Agreement lays down the obligation to use relevant international standards or relevant parts of them as the basis of technical regulations. According to the ordinary meaning of words, this means that technical regulations must be founded on international standards or relevant parts of them. In other words, technical regulations must have as their fundamental principle or point of departure what is set out in international standards. This does not mean that the technical regulations adopted by a Member must be identical to international standards but where the latter are relevant, the technical regulations should be prepared on the basis of those international standards: the underlying international standard must be recognizable on a reading of the measure. Canada has established that the international standards concerning asbestos are relevant. The European Communities have not offered any convincing evidence to the contrary. In this instance, the French measure strays so far from the international standards that they are no longer recognizable as the foundation. The European Communities have not offered any reason to justify this departure and consequently the disputed measure is in contravention of Article 2.4 of the TBT Agreement.

71. Given that the Decree deviates to such an extent from the international standards that they are not evident as its basis, the European Communities cannot claim that "[…] it must be concluded (sic) that the international texts quoted, or sometimes not quoted, by Canada serve 'as a basis' for the French decree."

72. Furthermore, the obligation to use international standards as the basis for preparing technical regulations should not be interpreted as permission simply to ignore important aspects of those standards, as France has done. France is, in effect, forcing the replacement of asbestos by substitutes, ignoring the fact that it is only in the event of necessity that such replacement is recommended and only where the substitutes are harmless and safe. France has quite simply ignored the test of "necessity" required by the international standards and reports in order to operate a policy of banning asbestos. This is particularly disconcerting when it is considered that these are the same standards and reports that are cited by the European Communities to justify the French position in paragraphs 531 *et seq*. of their submission and that those standards and reports are very specific in this respect.

73. For its part, Article 2.5 of the TBT Agreement establishes a rebuttable presumption when the measure is in accordance with international standards. The French measure is clearly not in accordance with international standards. In this instance, therefore, the European Communities cannot rely on the presumption in Article 2.5 of the TBT Agreement.

Question 15: Canada states that it "will use the example of chrysotile fibre and chrysotile cement in order to show that chrysotile fibre and substitute fibres are similar and products containing chrysotile and those containing substitute fibres are like products". In the light of this paragraph and the overall arguments presented by Canada in its analysis of the similarity of products under Article III:4 of GATT 1994, is our understanding correct that Canada does not allege any likeness between chrysotile fibres and products containing chrysotile and any possible non-fibrous substitute products?

74. Yes. Both under Article III:4 of GATT 1994 and Article 2.1 of the TBT Agreement, Canada is not invoking the argument of the likeness of non-fibrous substitute products (PVC, ductile iron). Nor does Canada extend the likeness argument to substitute fibres other than glass, cellulose and PVA fibre or fibro-cement products containing these types of fibre.

75. Canada does not need to invoke all products like to chrysotile or chrysotile cement products to demonstrate a violation of Article III:4 of GATT 1994 and Article 2.1 of the TBT Agreement. For there to be a violation, it simply has to show that for a given product or series of given products there are one or more like products which enjoy more favourable treatment.

76. We wish to point out that in rejecting the analysis of likeness advanced by Canada, the European Communities go to great pains to affirm that PVC and ductile iron are not products "like" chrysotile fibre and chrysotile cement products. Interesting as it may be, however, this analysis is in no way relevant to the issue of whether glass fibre, cellulose fibre, PVA fibre and fibrous-cement products incorporating these types of fibres are "like" chrysotile fibre and chrysotile cement products.

Question 16: In its argument concerning Article 2.2 of the Agreement on Technical Barriers to Trade, Canada maintains that the ban on asbestos and products containing asbestos has no "rational link" with the objective pursued by France. Could Canada provide additional clarification on the distinction between this concept of "rational link" and the test of necessity which it defines as the second test of a measure's conformity under Article 2.2?

77. Canada maintains that a technical regulation creates an unnecessary obstacle to international trade if the objective of the regulation is not legitimate or if the regulation is more restrictive than necessary to fulfil its objective, taking account of the risks non-fulfilment would create.

78. Once an objective is recognized as legitimate, it is then a matter of determining whether the technical regulation is a rational and necessary measure. The nature of the "rationality" and "necessity" of a technical regulation may vary according to the circumstances.

79. In our view, rationality and necessity entail the following elements. Firstly, the technical regulation must be carefully conceived to fulfil the objective concerned. It must be neither arbitrary, nor founded on irrational considerations. That is the rational link. Secondly, even supposing that there is a rational link, the technical regulation must be such that it is not more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create. These are the risks entailed by the absence of a technical regulation and minimum prejudice to trade.

80. With regard to the rational link, the point is whether the technical regulation is rationally linked to the fulfilment of the objective. In other words, is the technical regulation carefully designed to fulfil the objective in question. We feel that this stage of the analysis is essential in order to avoid

justification of technical regulations which have tenuous links with the intended objective or even none at all. If this were not a necessary stage, a great many technical regulations could be justified without the slightest link with the objective.

81. With regard to the risks of having no technical regulations and minimal effect on trade, it is first necessary to try and establish if the absence of a technical regulation would create risks that the objective would not be fulfilled. To evaluate these risks, the relevant factors to be considered include scientific and technical data available and the intended end-uses of the products. One must then ask whether the prejudicial effects of the technical regulation are appropriate given the objective, in short, whether there is a less trade-restrictive alternative solution which would allow the intended objective to be fulfilled equally well.

82. It is only once the rational link between a technical regulation and the legitimate objective has been established that there is reason to examine the risks that might be created by the absence of that technical regulation and the existence of an alternative measure.

2. Questions by the Panel to the European Communities

Question 17: The EC states that "between 1945 and 1988, some 97 per cent of the asbestos consumed by France was chrysotile asbestos. From 1988 onwards, all the asbestos consumed in France was chrysotile asbestos". What has been the pattern of consumption of hard and friable forms of chrysotile asbestos in France since 1945?

83. The question contains an ambiguity that needs to be removed. Thus, it is necessary not to confuse: (i) the variety of the fibres: there are different natural varieties of asbestos, in particular, the chrysotile variety which should be distinguished from the amphiboles. These fibres are incorporated in materials: (ii) the "friability" of materials containing asbestos: these materials may be hard or friable, in varying degrees, depending on the application. In the French regulations, the friability of a material containing asbestos is defined as follows: "A friable material is any material liable to emit fibres under the influence of impact, vibration or air currents." Flocking (material composed of a mat of blown fibres) and lagging consisting of asbestos wadding or felt are typical friable materials. Asbestos-filled plastics and asbestos-cement products are non-friable materials. Before amphiboles were banned in the countries of the European Union, as in many other countries, there may have been friable products based on chrysotile and non-friable products based on amphiboles, and vice versa. It would be quite mistaken to associate amphiboles exclusively with friable products such as flocking and lagging and chrysotile exclusively with non-friable products such as asbestos cement. Since amphiboles were banned, all products containing asbestos - both friable and non-friable - have been based on chrysotile.

84. With regard to trends in asbestos fibre consumption and the division of the market between friable and non-friable products, the data supplied by the asbestos-processing industry indicate that over the period 1970-1975 (when both amphiboles and chrysotile were in use): (i) asbestos intended for very friable products (flocking, wadding), which do not form part of the statistics of the asbestos-processing industry, accounted for 10 to 20 per cent of imports; (ii) the remaining imports (80 to 90 per cent of the total), intended for processing, can be broken down as follows:

Non-friable products:

- 73 per cent for asbestos cement (compared with over 75 per cent in 1950);
- 8.4 per cent for floor coverings (production increased seven-fold between 1950 and 1975);
- 3 per cent for brakes (production increased seven-fold between 1950 and 1975);
- 1.9 per cent for mouldings (stable between 1950 and 1975);

- 1.3 per cent for gaskets;
- 2.4 per cent for miscellaneous applications (adhesives, mastics, mortars, etc.).

Friable products:

- 7 per cent for asbestos board and paper;
- 3 per cent for textile products (braiding, tape, coverings, etc.).

85. The use of very friable products (asbestos flocking and wadding) ended in France in 1978. No more asbestos fibres were incorporated in floor coverings after 1984. In the 90s (before the ban), asbestos-cement products, brakes and mouldings accounted for more than 90 per cent of the asbestos imported. Friable products such as textiles and board consumed less than 10 per cent.

Question 18: The European Communities state that Canada "consumes little asbestos and thus exports the bulk of its production". The European Communities also note, in paragraph 53: "... the fact that the increase in the frequency of mesothelioma-type cancers can be seen throughout Canada shows that the risk of death from chrysotile is not confined to the asbestos mining industry ... but that it affects all sectors of the economy". To which sectors of the economy do the European Communities refer? Are statistics and studies available?

86. Per capita consumption in Canada is among the highest in the industrial world. Canada exports most of its chrysotile asbestos production (400,000 tonnes out of 450,000 in 1990). Thus, the proportion reserved for home use is very small. Nevertheless, Canada's consumption is very considerable compared with other industrialized countries. Thus, in 1990, per capita consumption in Canada was distinctly higher than in France: (i) Canada: 2.05 kg per capita; (ii) Brazil: 1.26 kg. per capita; (iii) France: 1.11 kg per capita; (iv) United States: 0.13 kg per capita. This high level of asbestos consumption in Canada explains the high and steadily increasing incidence of mesothelioma in that country.

87. There are studies available which show that in Quebec and the other areas investigated a wide range of economic sectors is affected by mesothelioma. Thus, a study by Siemiatycki[33] in Montreal shows that the workers mainly at risk of mesothelioma are those exposed while working with materials containing asbestos. The results of the study show that construction sector workers run a risk of developing mesothelioma almost 12 times higher than the average. Another study[34] by the Quebec Occupational Health and Safety Commission (CSST), reveals that the risk of mesothelioma has increased steadily in Canada since 1967. The study notes that the incidence of this disease is increasing especially rapidly in the maintenance sector.

Question 19: **With respect to substitute products, INSERM has stated, in particular, that "suitable research work should be carried out and developed as a matter of urgency, before substitute fibres are generally introduced" (Effects on health of the main types of asbestos exposure, INSERM, 1997, p. 434) and that "taking into account the present uncertainties concerning the effects on humans of exposure to fibres used as a substitute for asbestos, it is important to ensure that the levels of exposure among users of products containing fibre substitutes for asbestos are as low as possible" (Effects on health of fibres used as a substitute for asbestos, INSERM, 1998, p. 34). In the light of these observations, can the European Communities explain the statement in paragraphs 140 et seq. of their written submission according to which "there are no data giving rise to concern as to the carcinogenicity of fibres used as a substitute for asbestos in cement fibres"?**

[33] Siemiatycki J., *Risk Factors for Cancer in the Workplace*, Boca Raton, Florida, CRC Press, 1991.

[34] R. Bégin *et al. Work-Related Mesothelioma in Quebec*, 1967-1990, American Journal of Industrial Medicine 22:531-542 (1992).

88. There are no data giving rise to concern as to the fibres used as a substitute for asbestos in cement fibres. First of all, it should be noted that asbestos cement is often replaced by products from another branch of technology (PVC plastics, ductile iron, various metals, etc.). This is the case, in particular, with pipes and roofing. In France, industry had decided to stop producing asbestos-cement pipes before the ban, because of the competition from PVC and ductile iron. When asbestos is replaced in fibro-cement, it is replaced by PVA, para-aramid or cellulose. It is never replaced in fibro-cement by man-made mineral fibres. PVA, cellulose and para-aramid fibres have been used for a very long time without any sort of health warning having been given by occupational health specialists. PVA fibres have been used since 1930, para-aramid fibres for 30 years or so. As for cellulose, it has been in use for several centuries.[35]

89. In 1996, these substances gave no cause for concern, and this has since been confirmed by studies conducted by CSTEE DG XXIV of the Commission of the European Communities and COC[36] in the United Kingdom.[37] Moreover, by the time the decision to ban asbestos was taken (July 1996), key facts had become available as a result of the G2SAT report on the comparative harmfulness of asbestos and man-made mineral fibres.[38] This report established a hierarchy of risks as between chrysotile asbestos, ceramic fibres and mineral wools (glass wool, rock wool, slag wool) which made it impossible to avoid a global ban with exceptions.[39] Thus, in 1996, France had to choose between asbestos, a known and proven human carcinogen, and substances used for decades without any problem ever having been reported.

90. INSERM's concerns relate to certain man-made mineral fibres rarely used as substitutes for asbestos and France has taken INSERM's recommendations into account. The expert opinion requested from INSERM related mainly to the fibres most under suspicion, i.e. man-made mineral fibres (ceramic fibres and mineral wools), whose harmfulness had been stressed by the opponents of a ban on asbestos. It confirmed the results of the G2SAT Report, as well as the classification adopted at the European level for ceramic fibres and mineral wools. France took into account the recommendations to proceed with caution and proposed an action plan for consideration by the social partners as soon as the results were published: (i) reminder of the regulations applicable, given the European classification; (ii) controls on fibre labelling; (iii) package of measures to monitor exposure levels, in particular among secondary users; (iv) establishment of groups of workers exposed to man-made mineral fibres for epidemiological follow up purposes.

Question 20: **Why did asbestos cement remain outside the scope of Directive 91/659/EEC (paragraph 82 of the first submission of the European Communities)?**

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[35] We recall that, where asbestos is concerned, the first findings of its harmful effects on health go back to 1906, as attested by the report of a French labour inspector who drew attention to the number of deaths among workers who had worked in factories making asbestos-based products.

[36] Opinion on chrysotile asbestos and possible substitute products, Scientific Committee on Toxicity, Eco-toxicity and the Environment (CSTEE), 19 September 1998; Statement for Health and Safety Executive (HSE) on Carcinogenic Risks of Three Chrysotile Substitutes, Committee on the Carcinogenicity of Chemicals in Food, Consumer Products and the Environment (COC), July 1998.

[37] At this point, we note that asbestos cement accounted for 90 per cent of the asbestos imported into France at the time of the ban. Thus, in accordance with INSERM's recommendations, France has not generalized the use of man-made mineral fibres in place of asbestos.

[38] Used much less frequently as a substitute for asbestos (less than 10 per cent of the asbestos used in France).

[39] This hierarchy of risks showed that chrysotile asbestos (a proven human carcinogen) poses a much greater threat than ceramic fibres (a suspected animal carcinogen) and *a fortiori* mineral wool (no carcinogenic effect on animals, no effect on the human lung).

91. The purpose of the 1991 Directive 91/659/EEC was to ban, on the basis of the epidemiological data available at the time[40], all varieties of asbestos other than chrysotile, which was then considered less dangerous than amphiboles. This directive also restricted the use of chrysotile to those products which were incapable of releasing asbestos fibres spontaneously into the air without special intervention and for which the possibilities of replacement had not yet been fully established. Since the publication of that directive, our understanding of the risk and the international database have expanded considerably[41] and research on the replacement of the asbestos in asbestos cement products has led to solutions that pose no threat to the health of the user and are technically and economically viable.

Question 21: Is it possible to estimate the number of deaths, since 1945, due to chrysotile asbestos occurring in the categories which the submission of the European Communities described as "secondary" occupational, para-occupational and domestic? What type of exposure is responsible for the 25 per cent of mesothelioma cases in the building sector mentioned in paragraph 413 of the submission of the European Communities (construction, occasional handling, de-flocking, demolition, etc.)?

92. The number of deaths by mesothelioma among "secondary" users can be estimated at between 10 and 15 per million inhabitants per year. For mesothelioma, the spontaneous death rate, i.e. other than by exposure to asbestos, is about one to two cases per million inhabitants per year. It is true that, up to about the 1970s, the great majority of these deaths occurred among primary users (asbestos mining and processing).[42] During that period the rate reached about five cases per million inhabitants per year in most of the industrial countries for which reliable health data are available (see Table 4, page 166 of the INSERM Report. All the studies show that those affected were almost exclusively so-called "secondary" users.[43] The study by J. Peto *et al.*[44] analyses mesothelioma mortality in England and Wales during the years 1979 to 1990. It shows that about 95 per cent of all the deaths that occurred during that period concerned workers belonging to the "secondary" user group. In the industrial countries, this proportion of 95 per cent of all asbestos-related deaths has applied to this category of workers since about the 1970s. At present, among men, the mesothelioma death rate stands at about 15 to 20 deaths[45] per million inhabitants per year: thus it may be estimated that in these countries 10 to 15 deaths per million inhabitants per year occur among male workers in the "secondary" user category.[46] Even if a small fraction of these deaths can be attributed to exposure to amphiboles, it is none the less true that the number of deaths due to chrysotile is quite considerable.

93. The overwhelming majority of mesotheliomas occurring among construction workers are the result of occasional exposure to high peaks of asbestos. This can be illustrated by reference to the table headed "Distribution of Deaths from Mesothelioma by Occupation (Section III.B.4)" which gives a breakdown of the occupations most affected: the construction sector trades most affected are the carpentry, plumbing, electrical and related trades. Typically, workers in these trades have to

[40] The data on which an international concensus was reached in 1991 came from studies and observations made at least four or five years earlier.

[41] With the exception of the G2SAT study, the scientific studies appended to the first written submission of the European Communities are all post-1991.

[42] In fact, because this disease has a very long latency period, the deaths that occurred up to the 1970's correspond to exposures suffered prior to about the 1940's, when asbestos was still little used.

[43] Because of the long latency period, it took several decades for the asbestos marketed on a large scale after the Second World War to produce its effects on large numbers of "secondary" users.

[44] J. Peto *et al., Continuing Increase in Mesothelioma Mortality in Britain,* The Lancet, vol. 345, page 535 (1995).

[45] It should again be pointed out that this estimate should be at least doubled to take into account the deaths by lung cancer and the cases among women, which are less numerous.

[46] According to recent estimates, in the next 30 years about 500,000 men will die in Western Europe and 95 per cent of these will be workers in the "secondary" user category.

handle asbestos-containing materials only intermittently. This is because of the numbers involved.[47] To the workers in these construction trades it is necessary to add the workers in many other occupations: welders, dockers, laboratory technicians, fitters, upholsterers, power station workers, etc., who are only occasionally exposed to high peaks of asbestos and, taken together, account for the majority of deaths by mesothelioma.

Question 22: The article annexed by the European Communities (A. Gilg*, et al., Estimation of the Past and Future Burden of Mortality from Mesothelioma in France,* Occupational Environmental Medicine, 1998; 55: 760-765) estimates that between 1996 and 2020, about 20,000 men will die of mesothelioma. Is it possible to determine the different circumstances of exposure to asbestos that will have induced these 20,000 cases of mesothelioma?

94. Occupational exposure to asbestos in France concerns the approximately 20-25 per cent of men who have been exposed at least once in the course of their working life.[48] This reflects the enormous variety of exposures. In France about 85 per cent of all the men exposed work in industrial production (mainly metallurgy, machines and appliances), building and public works or services, sectors characterized by occasional exposure to asbestos. It is these types of exposure that will cause the 20,000 deaths expected to occur among men in France between now and the year 2020.

Question 23: Have cases of death clearly attributable to occasional, but high exposure ("of the exposure peak" type) been documented?

95. All the studies based on the individual examination of mesothelioma cases, documented by a detailed study of the patient's work history, have shown that since the 1970s the great majority of cases have occurred among workers who have never had any type of exposure other than occasional exposure with pollution peaks. The studies are mainly of two kinds:

- Studies relating to cases of acknowledgement of occupational illnesses, which always involve an in-depth examination of the circumstances of exposure, in particular, because of the financial consequences of acknowledgement (payments of benefits and pensions). Thus the above-mentioned study[49] by the Quebec Occupational Health and Safety Commission (CSST) shows that during recent times the cases of mesothelioma acknowledged as being an occupational illness generally correspond to short-term exposure and most frequently involve servicing and maintenance workers.
- Epidemiological studies of the "case-control" type, in which each case of mesothelioma considered forms the subject of an in-depth examination of the victim's entire working life by industrial health experts. Because of their high scientific quality, studies of this kind are particularly suitable for assessing the circumstances of exposure. The recently published study by Iwatsubo *et al.*,[50] concerning cases that occurred between 1987 and 1993 in France, is of this type. It, too, shows that almost all the mesotheliomas reported in France were observed in patients who had been subjected to only occasional exposure with pollution peaks. The previously

[47] Far fewer workers (about 1,500 in France) are employed in de-flocking and demolition than in "secondary" user occupations (several hundred thousand people exposed daily).

[48] Goldberg M. *et al., Past Occupational Exposure to Asbestos Among Men in France.* Scand. J. Work Envir. Health, 1999 (in press).

[49] Bégin R *et al., Work-Related Mesothelioma in Quebec,* 1967-1990, American Journal of Industrial Medicine 22: 531-542 (1992).

[50] Iwatsubo Y *et al., Pleural Mesothelioma: Dose-Response Relation at Low Levels of Asbestos Exposure in a French Population-Based Case-Control Study,* American Journal of Epidemiology, 1998, 148: 133-142.

mentioned study by Siemiatycki[51] in Montreal, which is of the same case-control type, yielded similar results.

Question 24: The *Comparative Table of the Characteristics of the Fibres Studied by the CSTEE* (Section III.B.6) submitted by the European Communities, seems to indicate that the diameter of PVA, para-aramid and cellulose fibres could be greater than their length. Could the European Communities clarify these figures.

96. The fibres which must be taken into account in making a metrological assessment of a working environment have been defined by WHO[52] in accordance with the following dimensional parameters: (i) more than 5 microns in length; (ii) less than 3 microns in diameter; (iii) ratio of length to diameter greater than 3 microns. The table in question is intended to show that the polyvinyl alcohol, cellulose and para-aramid fibres generally used in France for replacing chrysotile asbestos all have lengths distinctly greater than the 5 microns indicated by WHO; in any event, all the fibres in question have a length that is greater than the diameter. The diameters of these fibres are greater than 10 microns. This physically prevents them from penetrating into the pulmonary alveoli, which are accessible only to fibres less than 3 microns in diameter. Hence this characteristic of the substitute fibres eliminates the risk of their penetrating deep into the lungs. It is important to note that, generally speaking, unlike chrysotile fibres which have a diameter of between 0.1 and 1 micron and which separate lengthways into even finer crystalline fibrils (0.020 microns), the synthetic fibres used as substitutes, whether of organic or mineral origin, retain the diameter resulting from the manufacturing process throughout the life cycle of the fibre, even when released into the air from a material undergoing machining.

Question 25: The European Communities indicate that the substitute products using fibres shown to be harmless or less harmful include cellulose, PVA or aramid fibres. Could the European Communities give further details of the harmlessness or low toxicity of these products?

97. Cellulose, polyvinyl alcohol and aramid fibres have been used for a very long time, since well before asbestos was banned in France. There has been nothing to give cause for concern, (in particular, reports of cases of cancer among the workers exposed) which might have led to extensive research, whereas asbestos has been the subject of numerous scientific studies because of the large number of cases of disease found in workers over the last 70 years. The CSTEE committee of DG XXIV of the Commission of the European Communities and COC in the United Kingdom have made in-depth assessments of the comparative risks of asbestos and the fibres used to replace it, particularly in asbestos cement.

98. On the basis of an analysis of the studies and reports supplied by the Health and Safety Executive, COC[53] concluded: (i) with regard to polyvinyl alcohol fibres, "these fibres will have no potential for the induction of lung cancer or mesothelioma" (...). The information on PVA suggests a low carcinogenic hazard"; (ii) with regard to para-aramid fibres, "although there is some evidence of adverse biological effects with para-aramids, there is no convincing evidence to suggest a carcinogenic hazard (...). The evidence suggests a lower carcinogenic risk than chrysotile"; with regard to cellulose fibres, "a recent investigation with cellulose fibres had documented evidence of a long biopersistence in the rat lung. However, the COC agreed that this study was not relevant to consideration of the question [... and] that it was unlikely [to] identify a carcinogenic response

[51] Siemiatycki J., *Risk Factors for Cancer in the Workplace*, Boca Raton, Florida CRC press, 1991.
[52] Determination of airborne fibre number concentrations. WHO, Geneva 1998.
[53] Statement for Health and Safety Executive (HSE) on Carcinogenic Risks of Three Chysotile-Substitutes, Committee on the Carcinogenicity of Chemicals in Food, Consumer Products and the Environment (COC), July 1998.

attributable to cellulose fibres." The COC concluded from its study that "the evidence presented to the committee on fibre dimensions, studies in animals including that of biopersistence in the lung, indicate that the carcinogenic risk posed by PVA fibres, para-aramid fibres or cellulose fibres is likely to be less than that posed by chrysotile". These conclusions are shared by CSTEE of DG XXIV[54] which found that "there is sufficient evidence that all forms of asbestos, including chrysotile, are carcinogenic in humans. There is no evidence of the occurrence of cancer induced by fibres in humans with respect to any of the three substitute products [investigated]". CSTEE also notes that "pulmonary fibrosis is a well-known consequence of exposure to chrysotile [whereas], so far, no case has been reported among workers exposed to any of the three substitute products".

Question 26: The European Communities maintain that the Agreement on Technical Barriers to Trade does not cover general prohibitions on the use of the product. In the present case, Decree No. 96-1133 provides for the possibility of exceptions to the ban. Do the European Communities consider that the Agreement on Technical Barriers to Trade is also inapplicable to these exceptions and to the provisions relating to them?

99. The French Decree provides that in certain circumstances a limited number of products may contain asbestos (see Art. 2(I) of the Decree). The European Communities consider that, like the general ban, the exceptions to the general ban do not constitute "technical regulations" in the meaning of the TBT Agreement. The reason is that the definition of a "technical regulation" requires that the document concerned must "lay down product characteristics or their related processes and production methods." Article 2(I) of the French Decree does not lay down any particular characteristics. In particular, it does not stipulate any performance or design characteristics that such products must meet. All it does is to permit, provisionally and under justified conditions, the use of asbestos (in a general sense, not as a specific characteristic), in the absence of a substance that ensures equivalent performance. The exceptions in the French Decree deal with or are based on the specific characteristics of asbestos, not of the products that are allowed provisionally to contain it.

100. The provisions of the French Decree, which lay down the procedures for establishing which products may be allowed under an exception, also do not qualify as a technical regulation. Contrary to what Brazil argues, the inclusion of the term "applicable administrative provisions" in the definition of a "technical regulation" does not give independent meaning and existence to the term "applicable administrative provisions", but simply clarifies that the definition includes such legislative provisions.

Question 27: The European Communities state that "many substitute products are not fibrous in texture". Could the European Communities indicate, within the context of their analysis of "likeness" within the meaning of Article III:4, which parts of their argument relate to substitute products containing fibres and which to non-fibrous substitutes?

101. See paragraphs 102 and 103 below.

Question 28: The European Communities indicate that "Canada mentions only fibrous substitute products (cellulose, para-aramid, PVA), making no reference at all to non-fibrous products." In the opinion of the European Communities, is it appropriate to take into account non-fibrous substitute products for the purpose of examining, in the present case, the likeness of the products under Article III:4 of GATT 1994 or Article 2.1 of the Agreement on Technical Barriers to Trade?

102. The European Communities have explained in their submissions (and in their reply to written question No. 29 of the Panel) that it is essentially the morphology of the chrysotile fibres (in terms of

[54] *Opinion on chrysotile asbestos and likely substitute products*, Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE), 19 September 1998.

length and diameter/thickness) that determines their carcinogenic effects. As the mode of action of the fibres is through inhalation, the fibrous nature of the chrysotile asbestos is essential. In legal terms, the fibrous nature relates directly to the product's properties, nature and characteristics and, probably, end-use. That probably explains why Canada has claimed "likeness" only with regard to substitute fibrous products. It is, therefore, probably not necessary for the Panel to determine whether non-fibrous substitute products are "like" products to chrysotile or chrysotile containing products.

103. The arguments in the European Communities' first written submission relate primarily to the fibrous nature of chrysotile and chrysotile-containing products, on the one hand, and the fibrous substitute products, on the other. The European Communities have demonstrated that the fibrous substitute products are not like products to chrysotile or chrysotile-containing products on the basis of the four criteria normally used by Panels.[55] It follows that, *a fortiori*, non-fibrous substitute products are also not "like" products, an additional reason being the even more marked difference in the physical characteristics or nature of the products concerned.

3. Questions by the Panel to both parties

Question 29: Does the term "chrysotile" cover a product of uniform quality (in particular, in terms of the length and quality of the fibres) or should it be assumed that there are different qualities of chrysotile and, therefore, different levels of risk?

(i) Reply by Canada

104. In strictly technical and commercial terms, there are various groups of chrysotile fibres which are classified according to their length. The method developed by the Association of Asbestos Mines of Quebec has been adopted by the majority of producer countries for the classification of chrysotile and lists the groups of fibres from the longest fibres (Group 1) to the shortest (Group 7). The length of fibre is normally measured in millimetres (10^{-3} metres). This classification is used to determine the strength of the fibre used; the longest groups of fibres are used for the manufacture of chrysotile cement products, while the shortest fibre groups are used for the manufacture of friction products, mastics and roof coatings.

105. This technical and commercial classification, however, has nothing to do with the level of risk to health, which should be evaluated on the basis of the criteria of durability (biopersistence), dose and dimension. The pathogenicity of the fibres is examined on the basis of their dimension: for a natural or synthetic fibre to be potentially harmful, it must have a length greater than five microns, a diameter less than three microns and a length to diameter ratio over 3:1 (a micron is equal to 10^{-6} metres).

(ii) Reply by the European Communities

106. Chrysotile, a natural mineral of the asbestos group, is a magnesium silicate of crystalline structure with the empirical formula "$Mg_3 (Si_2 O_5) (OH)_4$". In chrysotile, as in all silicates, chemical elements other than magnesium may be present in low concentrations and variable proportions. Thus the chemical analysis of different samples of chrysotile may yield results which vary over the following ranges:

[55] That is the product's properties, nature and quality, tariff classification, the product's end-uses given market and consumers' tastes and habits.

Silica (SiO_2)	38 to 42%
Alumina (Al_2O_3)	0 to 2%
Ferric oxide (Fe_2O_3)	0 to 5%
Ferrous oxide (FeO)	0 to 3%
Magnesium oxide (MgO)	38 to 42%
Calcium oxide (CaO)	0 to 2%
Sodium oxide (Na_2O)	0 to 1%
Nitrous oxide (N_2O)	11.5 to 13%

107. Finally, at the same geological site, the purity of a vein of chrysotile in the process of being mined may vary from one point to another. It may also differ between sites. A deposit of chrysotile asbestos (like any natural ore) is never perfectly pure and may contain various types of impurities which will still be present, in whole or in part, in the asbestos-containing end-products. This applies, in particular, to quartz (silica) and other non-fibrous or fibrous silicates, such as amphibole asbestos.

108. Incidentally, chemical composition alone is not sufficient to identify a mineral; the physical structure is equally important. Thus, minerals such as lizardite and antigorite have exactly the same chemical composition as chrysolite but are not fibrous.

109. Under the heading "chrysotile" it is possible to distinguish between the forms that contain impurities (that is, a small proportion of tremolite, an asbestos of the amphibole type) and those that contain no impurities or only very small amounts. Despite attempts to show that only the traces of tremolite present in Canadian chrysotile are responsible for the numerous mesotheliomas among workers exposed to it, no difference in toxicity between these two forms of chrysotile has ever been proved. This theory of chrysotile being "inoffensive" with respect to mesothelioma has, moreover, been rejected by the scientific community[56] as noted in the written submission of the European Communities.[57] As far as we know, there is only one epidemiological study concerning Zimbabwe's chrysotile which is reputed not to contain amphiboles: it shows a net excess of mesothelioma among the workers in chrysotile mines and mills.[58] Thus, from the standpoint of the composition of chrysotile, there is no reason to believe that the toxicity of the pure forms with respect to mesothelioma would be any different from that of the forms that contain impurities.

110. It appears to be clearly established that it is essentially the morphology of the fibres, rather than their geological origin, that determines their carcinogenicity with respect to the lungs. These conclusions stem from observation of the very high risks to which groups of textile asbestos workers handling fine fibre chrysotile are exposed. (It should be noted that the asbestos used by some of these groups comes from Canada.) For their part, chrysotile "mine and mill" workers exposed to thicker fibres present clear but much lower risks.[59]

111. As Landrigan[60] notes, the risks of cancer of the lung can vary by a factor of 50 between a group of chrysotile miners and a group of industrial workers handling chrysotile asbestos from the same mines. Reference may also be made to the INSERM Report[61] which compares the risks of

[56] Stayner LT *et al., Occupational Exposure to Chrysotile Asbestos and Cancer Risk: A Review of the Amphibole Hypothesis*, Am. J. Public Health. 1996, 86:179-186. Smith *et al*., *Chrysotile Asbestos, the Main Cause of Pleural Mesothelioma*, American Journal of Industrial Medicine, 1996, 30:252-266.

[57] Other scientific publications may also be consulted on this point.

[58] Cullen MR, Baloyi RS, *Chrysotile Asbestos and Health in Zimbabwe, I: Analysis of Miners and Millers Compensated for Asbestos-Related Diseases Since Independence* (1980), Am. J. Ind. Med., 1991, 29:161-169.

[59] The main data are summarized in the INSERM Report, pages 262-264.

[60] Landrigan PJ. *Asbestos - Still a Carcinogen*, New Eng. J. of Medicine, 338, 22, 1628-1629, 1998.

[61] Figure 1, page 198, Figure 2, page 199; Table 3, page 200.

cancer of the lung according to the industry using the chrysotile. The very considerable differences in risks observed are mainly attributable to differences in the morphology of the fibres, which are subjected to different forms of physical processing depending on the end-use: generally short and thick when mined, they may undergo changes in morphology and be made finer to adapt them better to particular uses.

Question 30: What are the output and import and export volumes of substitutes for chrysotile asbestos products, particularly asbestos cement, in France and Canada respectively?

(i) Reply by Canada

112. Without wishing to offer a full review of all the substitute products individually, the following is an indicative summary of the value of the products used as substitutes for chrysotile asbestos products (1997 data):

PRODUCT	PRODUCTION	IMPORTS	EXPORTS
Concrete pipe	$212,055M	$0,426M	$22,846M
Forged pipe and steel tubing	$2381,270M	$1174,0M	$727,282M
Plastic pipe (PVC)	$794,000M	$305,000M	$271,000M
Structural cement products	$314,732M	$3,708M	$60,996M
Vinyl cladding	$400,000M	$14,000M	$83,000M
Steel plate and sheet	$279,387M	$4,958M	$63,368M
Asphalt roofing products	$520,278M	$53,746M	$110,752M

(ii) Reply by the European Communities

113. In France, more than 90 per cent of imported chrysotile asbestos fibre was used for making asbestos-cement products. Since asbestos was banned, the market in asbestos cement products and materials has shifted towards: (i) materials and technologies which have existed for a very long time (for example, PVC and ductile iron for making pipes, aluminium for roofing); (ii) fibre substitutes for asbestos: mainly cellulose fibres and, to a lesser extent, polyvinyl alcohol and polypropylene fibres.

114. The first submission of the European Communities provides some statistical data on cellulose and polyvinyl alcohol fibres. Cellulose fibres are mainly intended for the textile and paper (pulp) industries. Each year, the fibro-cement industry uses less than one per cent of the total volume of cellulose fibres consumed in the various industrial sectors. In 1998, France produced 2,660,000 tonnes of cellulose fibres and imported 2,030,000 tonnes (including 660,000 tonnes from countries of the European Union and 740,000 tonnes from North America, of which 380,000 tonnes from Canada). It should be noted that imports of cellulose fibre from Canada increased by 14,000 tonnes between 1996 and 1998.

115. Polyvinyl alcohol fibres, which are mainly used in the textile and packaging industries, are made by only two factories in the world, one in China and the other in Japan. In 1998, France recorded a trade deficit of 700 tonnes or 115 million francs. In 1998, deliveries from French manufacturing units amounted to 4,200 tonnes and imports to 11,400 tonnes. As far as other products are concerned (the remaining ten per cent of chrysotile asbestos fibres consumed), the most popular substitute has been man-made mineral fibres of the glass or rock fibre type (the great majority of applications), with very limited use being made of para-aramid and ceramic fibres (these two products

are very expensive as compared with asbestos fibres). With regard to para-aramid fibres, in 1998, France recorded a trade deficit of 400 tonnes or 26 million francs. Man-made mineral wools and fibres are mainly produced in France and principally intended for insulating buildings. It should be noted that less than one per cent of the output of these man-made mineral wools and fibres is now being used in products previously manufactured with asbestos.

Question 31: Are there statistical data available which indicate what are the positive effects of controlled use, the use of encapsulated products and the banning of chrysotile asbestos, respectively, as regards reducing the number of mesotheliomas and cancers of the lung?

(i) Reply by Canada

116. The sources of asbestos-related pathologies have been identified as utilization of amphibole varieties in friable products such as flocking or cases of exposure to high quantities of chrysotile. Controlled use, a practice that was gradually introduced in the 1970s, has eliminated these dangerous sources. However, since there is a latency period of some decades between exposure to asbestos and the appearance of disease, pathologies related to uncontrolled exposure occurring up to the 1970s will continue to appear for a few decades yet, even if the sources of that exposure have now disappeared. Furthermore, as long as the competent authorities do not ensure appropriate and systematic management of the flockings installed during the years of uncontrolled use, the associated problems will not be completely eliminated.

117. There are few statistics on the prohibition of flockings and the exclusive use of chrysotile at low levels of exposure. Data collected and compiled by the Asbestos International Association (AIA) in 1995 cover 28 countries with some 25,000 workers employed.[62] In these countries, because of the introduction of controlled-use procedures and measures, the A.I.A. surveys show that 97.3 per cent of workers are exposed to less than 1.0 f/ml. These exposure levels satisfy the recommendations on worker protection made by the Group of Experts which met under the auspices of the WHO in Oxford, England, in April 1989. The findings of a similar survey conducted in 1997 will be available in the summer of 1999.

118. It should also be made clear that there is little data for assessing the positive effects of controlled and exclusive use of chrysotile asbestos, and that the reference period does not begin until the late 1970s when the current workplace controls were implemented (plants in a few countries for the manufacture of asbestos cement and friction materials).

119. Other data have also been published on groups of workers in chrysotile asbestos mines in Quebec, which feature both a sufficiently high number of workers and a sufficiently long observation period to measure the effects of asbestos exposure. The study covers cohorts formed in 1966 and monitored since then[63], including more than 11,000 workers born between 1891 and 1920. The most recent update, published in 1997, reports data until 1992. The findings for workers in this group who were exposed to chrysotile concentrations of up to 22f/ml for 40 years led the authors to conclude "from the point of view of mortality that exposure in this industry to less than 300 mpcf. years [i.e. equal to about 22f/ml over 40 years] has been essentially innocuous."

[62] A.I.A., *A.I.A. Dust Measurement Records Report*, Paris (March 1997).

[63] Liddell FDK, McDonald AD and McDonald JC (1997), *The 1891-1920 Birth Cohort of Quebec Chrysotile Miners and Millers: Developments from 1904 and Mortality to 1992*, Ann. Occup. Hyg.41:13-35.

(ii) Reply by the European Communities

120. To the best of our knowledge, the only published study that enables the effectiveness of controlled use to be measured is that issued in 1996 by the Health and Safety Executive[64] in the United Kingdom concerning the risks of cancer incurred by asbestos workers after 1969, when the "safe" use of asbestos was adopted by the United Kingdom. This study shows that, despite strictly "controlled" use (since the study relates exclusively to workers making asbestos-based products), there is a significant net excess of cancers among those who worked only under the "controlled" use regime. It follows from this finding that "controlled" use does not make it possible to prevent deaths from cancer, even in specific industrial manufacturing sectors with a workforce which is relatively small and a priori easy to train and supervise.

121. For at least 40 years, the manufacture of asbestos cement has involved "encapsulating" asbestos in cement. This encapsulation does not guarantee the harmlessness of asbestos cement during use: in practice, when asbestos cement is used, in an occupational, para-occupational or domestic environment, it is generally sanded, crushed or sawn and releases carcinogenic fibres in the form of dust. The occurrence of mesotheliomas among workers exposed to asbestos fibres which, in the manufacturing stage, were encapsulated in cement clearly shows that this process offers absolutely no protection against the carcinogenic effects of chrysotile fibres released when products and materials containing "encapsulated" asbestos are worked. This is perfectly understandable considering the very high levels of exposure measured under these conditions. It is possible to encounter concentrations several tens, even several hundreds of times higher than the national statutory limits[65] and the internationally recommended levels.[66]

122. The number of asbestos-related illnesses in a country is very strongly correlated with the amount of asbestos imported into that country. The most effective way of reducing, in the future, the number of asbestos-related illnesses is therefore to reduce asbestos imports. A ban with exceptions is the most effective means of achieving that result. France has demonstrated this, since imports fell very rapidly after the implementation of the ban (an estimated 1,200 tonnes in 1997, 200 tonnes in 1998, and a projected 55 tonnes in 1999 as against 35,000 tonnes in 1995). Thus, France could not afford to wait another 30 years in order to verify whether tighter controls on so-called "safe" use would make it possible to achieve the same results.

Question 32: With regard to substitute products is there a difference in potential or proven risk between fibrous and non-fibrous products?

(i) Reply by Canada

123. The replacement of fibre products with products containing no fibre might imply that the manufacture and use of the latter are risk free. This is not the case, at least for certain non-fibrous products being proposed as substitutes for chrysotile asbestos products. Only a comparative, case-by-case evaluation can yield relevant information. For example, let us take the alternative of PVC pipes. It should be realized that manufacture of the vinyl chloride monomer (a proven carcinogen which is later polymerized in PVC) involves the use of chlorine, an element which is later incorporated in an organic molecule. It has been well established that the synthesis of organo-chlorines is a significant source of dioxins, substances whose medium to long-term effects are very harmful, and regarding

[64] *Asbestos-related Disease*, S. Hutchings, J. Jones, J. Hodgson, Occupational Health Decenal Supplement, London, Health and Safety Service, 1996, pp. 127-152.

[65] A roofer using a grinder on corrugated asbestos-cement sheeting in the open air is subjected to a maximum exposure peak of 41 f/ml, i.e. 410 times greater than the French limit value.

[66] The permissible limit values under ISO 7337 are very considerably exceeded.

which the WHO has recommended a threshold of exposure not exceeding 10pg/kg./day (approximately 220ng/year).

124. The fact that the production of ductile iron also poses health risks recognized by the IARC as Group I is something which should not be concealed, since it entails greater energy consumption leading to the emission of carcinogens such as polynuclear aromatic hydrocarbons (PAH), etc.. These two examples clearly show that there are virtually no products or technologies that offer zero risk: one must learn to control and manage the risks within the framework of a policy of controlled and disciplined use. In any case, only a case-by-case analysis can answer the question asked.

(ii) Reply by the European Communities

125. The carcinogenic effect of asbestos is linked with its inhalation. In fact, not only does asbestos have a length to diameter ratio that enables it to penetrate into the pulmonary alveoli[67] but, in addition, asbestos fibres are all capable of separating lengthways into even finer crystalline fibres, including inside the bronchial tree, which helps them to penetrate into the deepest recesses of the lungs. Many of the products used to replace asbestos cement rely on alternative technologies which do not use fibres. Accordingly, these products, which cannot be inhaled, do not carry any threat of carcinogenicity. Non-fibrous products such as ductile iron and PVC have never been suspected of being carcinogenic and no case of cancer among the workers exposed has been recorded, although the products have been used for a very long time for a wide variety of purposes. The dust released when they are machined (against which protection should in any case be provided) is considered to be without specific toxicity for the human organism (ductile iron or plastic dust).

126. In assessing the carcinogenicity of fibrous products, WHO takes into consideration, in particular, the ratio of length to diameter[68] which makes it possible or impossible for the fibres to penetrate into the pulmonary alveoli. Fibres are used to replace asbestos in asbestos cement. With the exception of man-made mineral fibres, none of the fibres used to replace chrysotile has a length to diameter ratio that enables them to penetrate into the lungs. In fact, polyvinyl alcohol and para-aramid fibres are 2 to 8 mm. (i.e. 2,000 to 8,000 microns) in length and 10 to 16 microns in diameter. Only cellulose fibres, which are 12 to 40 microns in diameter, can give rise to finer particles which are said to irritate the respiratory pathways, but which are never carcinogenic. None of the fibres sometimes used to replace chrysotile asbestos (glass or rock man-made mineral fibres, organic fibres such as aramid fibres, plant fibres such as cellulose) are capable of separating lengthways: fibres extracted from the material retain their original diameter, which is almost always greater than the basic diameter of asbestos fibres.

127. Thus, scientifically, a consensus exists in favour of the following classification based on risk: (i) asbestos, of both the amphibole and chrysotile varieties, is a proven human carcinogen[69]; (ii) some fibrous substitute products, such as ceramic fibres, are suspected[70] of being carcinogenic: their carcinogenicity has been revealed by animal studies, but there is no evidence of their being carcinogenic in humans; (iii) the other fibrous products used instead of asbestos (PVA, cellulose, para-aramids, glass and rock fibres) are not human carcinogens.[71] There have been no studies designed to determine whether or not they are carcinogenic in animals; (iv) the non-fibrous products have never been suspected of being carcinogenic. It should be noted that the use of the substitute

[67] See the reply to question 24 of the Panel.

[68] *Idem.*

[69] See IARC classification in the *List of Products Recognized as Carcinogenic for Man, Global Evaluation of Carcinogenicity in Man*, monographs of the International Agency for Research on Cancer, Volumes 1 to 63.

[70] IARC Group 2-b.

[71] See the reply to question 25 of the Panel.

products which are suspected of being carcinogenic (ceramic fibres) is strictly limited to applications for which there is at present no less dangerous substitute that would ensure equivalent performance. In any case, their use is regulated.

Question 33: Is the concept of necessity in Article XX:(b) of GATT the same as that in Article 2.2 of the Agreement on Technical Barriers to Trade?

(i) Reply by Canada

128. With regard to 'necessity', the text of Article 2.2 of the TBT Agreement is not identical to the text of Article XX:(b) of GATT 1994. Article XX:(b) uses the phrase, "necessary to protect […]". Article 2.2 of the TBT Agreement evokes the concept of necessity in a more specific context: "not more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create". Article 2.2 in particular prescribes that account be taken of available scientific and technical information and the intended end uses of the products.

129. Despite the differences in textual formulation, the case law that has developed around analysis of Article XX:(b) can be helpful in determining the substance of the concept of necessity in Article 2.2. Conversely, the avenues for evaluating the 'necessity' of the measure contained in 2.2 (i.e. use of scientific information and consideration of end uses) may be relevant to analysis of necessity under Article XX:(b).

(ii) Reply by the European Communities

130. All the Panel reports that have examined the concept of necessity in the context of Article XX:(b) of GATT have concluded that it was not the necessity of the policy goal pursued by the measures at stake that was to be examined, but whether or not it was necessary to subject the imported products to the legal regime of the contested measure. In all cases a measure inconsistent with another provision of GATT was found to be not "necessary" if an alternative measure which the defending Member could reasonably be expected to employ and which was not inconsistent (or less inconsistent) with other GATT provisions was available to it.[72] The same should apply as regards the concept of necessity in the context of Article 2.2 of the TBT Agreement. This results clearly from the ordinary meaning of the terms of Article 2.2 in their context, which state that: "For this purpose, technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create". The sixth preambular paragraph to the TBT Agreement clarifies that Members have the autonomous right to determine the level of human health protection they consider appropriate in their territory. The necessity test, therefore, in Article 2.2 may only be applied in order to examine whether the technical regulations have been prepared, adopted or applied "with a view to or with the effect of creating unnecessary obstacles to international trade". An obstacle to trade will be found to be unnecessary, if another measure consistent (or less inconsistent) with GATT is reasonably available to the defending Member, to enable it to achieve the level of health protection which it has determined.

131. The fact that, in substance, the necessity test should be applied in the same way in both provisions does not, however, have the same procedural implications as regards, for instance, the burden of proof. Unlike Article XX:(b) of GATT 1994, where initially the burden is on the Member claiming its application to prove it, in the context of Article 2.2 of the TBT Agreement, the burden is initially on the plaintiff Member to establish that there has been a violation. Indeed, the plaintiff

[72] *See United States - Section 337 of the Tariff Act 1930*, BISD 36S/386, paragraph 5.26 (adopted on 7.11.89); *Thailand - Restrictions on Importation of and Internal Taxes on Cigarettes*, BISD 37S/214, paragraph 75 (adopted on 7.11.90); *United States - Standards for Reformulated and Conventional Gasoline*, WT/DS2/R of 29.01.96, paragraph 6.22 to 6.24.

Member must first demonstrate the availability of an alternative consistent or less inconsistent measure which can achieve the level of health protection determined by the defending Member.[73] The European Communities have already explained that so-called "controlled use" is not "an alternative measure" because, *inter alia*, it does not provide the same level of protection as the French Decree. The European Communities would, moreover, recall that, as is clear from the factual part of their two written submissions, it is "in the real world" not feasible to make sure that controlled use is applied in all circumstances where people work with asbestos in such a way as to achieve the level of sanitary protection determined by France.

Question 34: Is the notion of "like product" within the meaning of Article III:4 of GATT 1994 identical with that of "like product" within the meaning of Article III:2, first sentence of GATT 1994?

(i) Reply by Canada

132. The case law of GATT and the WTO indicates that the concept of "like product" in Article III:2 is to be construed narrowly. However this narrow interpretation does not apply to Article III:4 where the concept of likeness must be construed more broadly, given the purpose and context of Article III:4. Consequently, Article III:4 encompasses a more extended "range of like products" than does Article III:2, first sentence.

133. The report of the Appellate Body in *Japan – Taxes on Alcoholic Beverages*, in its discussion of Article III:2 commented precisely on the relative character of likeness under various articles and under various agreements.

> "No one approach to exercising judgement will be appropriate for all cases. The criteria in border tax adjustments should be examined, but there can be no one precise and absolute definition of what is "like". The concept of "likeness" is a relative one that evokes the image of an accordion. The accordion of "likeness" stretches and squeezes in different places as different provisions of the WTO Agreement are applied. The width of the accordion in any one of those places must be determined by the particular provision in which the term "like" is encountered as well as by the context and circumstances that prevail in any given case to which that provision may apply."[74]

134. In the same report, the Appellate Body commented on the helpfulness of a "case-by-case" examination and pointed out the narrowness of the "accordion of likeness" in the first sentence of Article III:2

> "This approach should be helpful in identifying on a case-by-case basis the range of "like products" that fall within the narrow limits of Article III:2, first sentence in GATT 1994. Yet this approach will be most helpful if decision-makers keep ever in mind how narrow the range of "like products" in Article III:2, first sentence, is meant to be, as opposed to the range of "like" products contemplated in some other provisions of GATT 1994 and other multilateral trade agreements of the WTO Agreement."[75]

135. Using the analogy of the accordion of likeness, the Panel in *Japan – Taxes on Alcoholic Beverages* pointed out that the same interpretation of the term "like product" in Article III:2 and Article III:4 would give a different scope to two paragraphs in the same Article. Two paragraphs of the same Article designed to protect the conditions of competition for products imported into the territory of a WTO Member should not have a different scope. Since the terms "directly competitive"

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[73] See on this point, by analogy, the Appellate Body Report in *Japan - Measures Affecting Agricultural Products*, AB-1998-8, para. 126.

[74] *Japan – Taxes on Alcoholic Beverages*, Appellate Body, 4 October 1996, WT/DS11/AB/R, page 18.

[75] *Idem.*, p. 18.

or "directly substitutable" add to the term "like product" in defining the scope of Article III:2, interpreting "like product" in III:4 in the same way as in III:2 would give a narrower overall scope to Article III:4 than to Article III:2. In *Japan – Taxes on Alcoholic Beverages*, the Panel wrote:

> "6.20 The Panel noted that the term "like products" appears in various GATT provisions. The Panel further noted that it did not necessarily follow that the term had to be interpreted in a uniform way. In this respect, the Panel noted the discrepancy between Article III:2, on the one hand, and Article III:4 on the other: while the former referred to Article III:1 and to like, as well as to directly competitive or substitutable products (see also Article XIX of GATT), the latter referred only to like products. If the coverage[76] of Article III:2 is identical to that of Article III:4, a different interpretation of the term "like product" would be called for in the two paragraphs."

136. What emerges from this Panel report is that the overall scope of paragraphs 2 and 4 of Article III should be identical. The Panel continues in paragraph 6.20:

> "Otherwise, if the term "like product" were to be interpreted in an identical way in both instances, the scope of the two paragraphs would be different. This is precisely why, in the Panel's view, its conclusions reached in this dispute are relevant only for the interpretation of the term "like products" as it appears in Article III:2."

137. It is therefore clear that the analysis of the term "like product" was valid only for III:2, because the Panel did not want to give a different overall scope to the two paragraphs. The concept of "likeness" must therefore have a broader scope under Article III:4 than under III:2. To maintain the same scope in the two paragraphs, the accordion of "likeness" must be tightly squeezed in Article III:2 and stretched in Article III:4. In *Japan – Taxes on Alcoholic Beverages*, the Appellate Body supports the Panel's analysis and rejects the appellants' interpretation that the scope of Article III:2 (first and second sentences) and of Article III:4 is not identical:

> "We note the argument on appeal but the Panel suggested in paragraph 6.20 of the Panel report that the product coverage of Article III:2 is not identical to the coverage of III:4. That is not what the Panel said."[77]

138. This interpretation of Canada's is consistent with doctrine on the subject. For example, Edmund McGovern observed:

> "[…] the Appellate Body in the 1996 Japanese Alcohol case doubted whether [similar products] has the same meaning even among the various paragraphs of Article III. In particular, the narrow interpretation appropriate in the first sentence of paragraph 2 (concerning internal taxation) does not necessarily apply in the context of paragraph 4 (concerning internal regulations), and it is possible that "like products" in paragraph 4 might even have the same scope as "directly competitive and substitutable products" in paragraph 2. […] Consequently, the point has to be discussed separately with regard to each provision." [78]

139. Canada therefore maintains that the test of likeness in Article III:4 is different from and broader than that developed in Article III:2.

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[76] Canada notes that, in using the term "coverage", the Panel wondered whether Article III:4 governed the treatment of both the categories of products mentioned in III:2, namely both "like" products and "directly competitive or directly substitutable" products.

[77] *Japan – Taxes on Alcoholic Beverages*, (Appellate Body) 4 October 1996 WT/DS11/AB/R, page 18, note 44).

[78] McGovern B., *International Trade Regulation*, Exeter, Globefield, 1995 (loose-leaf edition) in paragraph 8.12 on page 8.12-1.

(ii) Reply by the European Communities

140. The European Communities consider that for the purpose of the present dispute the reply to this question is of theoretical relevance only. Canada does not claim a violation of Article III.2 of GATT and it is clear from the submissions of the European Communities that only paragraph 4 of Article III of GATT might be of relevance in this case. The European Communities have demonstrated, however, that the French Decree does not discriminate either *de jure* or de facto between national and imported products. It has been consistently held by Panels and the Appellate Body that the concept of "like product" does not necessarily have the same meaning in all GATT provisions in which it occurs and that its meaning "must be determined by the particular provision in which the term "like" is encountered as well as by the context and the circumstances that prevail in any given case to which that provision may apply."[79] The European Communities have explained in their submissions that asbestos and asbestos-containing products have very different physical characteristics from products that do not contain asbestos and, therefore, cannot be considered "like products." Article III:4 does not cover "directly competitive or substitutable" products and, according to the Appellate Body, such an omission must have some meaning.

Question 35: What is the relationship between GATT 1994 and the Agreement on Technical Barriers to Trade? Does the nature of this relationship have any effect on the order in which a panel should examine a measure alleged to constitute a violation of both GATT 1994 and the Agreement on Technical Barriers to Trade? Does this relationship have any particular bearing on the present dispute?

(i) Reply by Canada

141. The nature of the relation between the different agreements in Annex 1A to the Agreement Establishing the World Trade Organization can be determined on the basis of the wording of the General Interpretative Note to Annex 1A (Annex 1A). This Interpretative Note was introduced in order to reflect the relation between GATT and the 12 other Agreements constituting Annex 1A. This Note is directly modelled on the customary rule of interpretation of international public law whereby, in the event of conflict, specific provisions prevail over more general rules. The Note recognizes that the 12 Agreements are, relative to GATT, provisions concerned with the detailed preparation and application of the more general provisions of GATT. These Agreements constitute the most recent and most specific expression of the WTO Members as to what the interpretation and application of these disciplines should be.

142. In the case of the Agreement on Technical Barriers to Trade, this is confirmed by the wording of its Preamble, which states, among other things: "Desiring to further the objectives of GATT 1994".[80] In this sense, then, the TBT Agreement is the most recent and the most specific expression of the WTO Members as to the necessary interpretation and application of the general disciplines of GATT (e.g. the obligations of Article I, III, X and XI in view of the exceptions provided for in Article XX) in the context of technical regulations and standards. The more specific character of the TBT Agreement does not have the effect of setting aside the more general applicable disciplines of GATT, and hence the two Agreements apply simultaneously and must be examined separately. This rule was clearly recognized by the Appellate Body in the *Bananas III* case where it stated that:

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[79] Report of the Appellate Body in *Japan – Taxes on Alcoholic Beverages*, AB-1996-2, DS 8, 10, 11, p. 18.

[80] See the reports of the Appellate Body: *European Communities – Regime for the Importation, Sale and Distribution of Bananas (Bananas III)*, AB-1997-3, WT/DS27/AB/R (9 September 1997), paragraph 204; *Brazil – Measures Affecting Dessicated Coconut*, AB-1996-4, WT/DS22/AB/R (21 February 1997), pp.14 and 15; and the report of the Panel in: *Indonesia – Certain Measures Affecting the Automobile Industry*, WT/DS54/R, WT/DS55/R, WT/DS59/R, WT/DS64/R (2 July 1998), paragraphs 14.62 and 14.63.

> "Although Article X:3(a) of GATT 1994 and Article 1.3 of the Licensing Agreement both apply, the Panel, in our view, should have applied the Licensing Agreement first, since this Agreement deals specifically, and in detail, with the administration of import licensing procedures".

143. The same idea was revisited by the Panel in the *Indonesian Automobiles* case, when it was dealing with the issue of simultaneous application of the Agreement on Trade-Related Investment Measures and Article III of GATT (see the report, paragraph 14.62). With regard to the order in which the Agreements should be considered by the Panel, since Article 2 of the TBT Agreement deals in a more specific and detailed fashion with the preparation, adoption and application of technical regulations and standards, giving due regard to what WTO Members consider to be an acceptable balance between the various interests protected by the general provisions of GATT 1999, it seems to us that the TBT Agreement must be examined first. This position is in keeping with the approach adopted by the Appellate Body in the *Bananas III*[81] case and by the Panel in the *Indonesian Automobiles* case.[82] Therefore the TBT Agreement should be examined first.

(ii) Reply by the European Communities

144. GATT and the TBT Agreement are two legally distinct Agreements. The General Interpretative Note to Annex 1A to the WTO Agreement clarifies that, in the event of conflict between the two, the provisions of the TBT shall prevail to the extent of the conflict. The object and purpose of the TBT Agreement, like its predecessor Agreement, is "to further the objectives of GATT 1994" (second preambular paragraph) in the areas of international standards and conformity assessment systems so as to ensure that technical regulations and standards do not create unnecessary obstacles to international trade (third to fifth preambular paragraphs). The European Communities consider that the legal relationship of the two agreements as explained above does not dictate any particular order in which the Panel should examine the claims and arguments of the parties in this dispute. The two options of examining first GATT and then the TBT Agreement or vice versa are both theoretically available.

145. The European Communities note, however, that several important concepts (such as the concept of like products, the principle of non-discrimination or the concept of necessity) are found in both Agreements, but there is very little case law and practice of the Members under the TBT Agreement on which the Panel may draw. It may therefore be more prudent, from the interpretative point of view, to proceed first with an analysis under GATT, especially when the two parties disagree on the applicability of one of the two agreements, in this instance the TBT Agreement. This approach is, in any case, not unusual, as is shown by the *US Gasoline* Panel and Appellate Body reports. The choice of the order by which the claims of the parties under these two Agreements will be examined does not appear to have any particular or significant implication for this dispute, other than that the Panel should ensure consistent interpretation of the provisions of the two Agreements. As regards the separate issue of allocation of the burden of proof, see the European Communities' reply to Canada's written question No. 8.

Question 36: Do the exceptions provided for in Article XX of GATT 1994 apply to violations of provisions of the Agreement on Technical Barriers to Trade? Could this question have any bearing on the present dispute?

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[81] *European Communities – Regime Applicable to the Importation, Sale and Distribution of Bananas (Bananas III)*, op. cit., paragraph 204.

[82] Report of the Panel in: *Indonesia – Certain Measures Affecting the Automobile Industry*, op. cit. paragraph 14.63.

(i) Reply by Canada

146. No, the exceptions provided for in Article XX of GATT are not intended to apply to violations of the provisions of the TBT Agreement. Article XX is not applicable outside GATT 1994 unless there is a specific stipulation to the contrary, as in the TRIMs Agreement. The text of the TBT Agreement makes no reference to Article XX of GATT.

(ii) Reply by the European Communities

147. Yes, the European Communities consider that the basis of the exceptions in Article XX are applicable under the TBT Agreement. This means that the substantive grounds on which an exception can be based under Article XX(b) of GATT 1994 are also available under the TBT Agreement. This derives from a systematic interpretation of the TBT Agreement and GATT, in particular the sixth preambular paragraph of the TBT Agreement, and the history of the preparatory work. The European Communities consider that the availability under the TBT Agreement of the reasons behind the exceptions in GATT Article XX(b) does not appear to have any particular or significant implication for this dispute, other than that the Panel should ensure consistent interpretation of the provisions of the two Agreements. As regards the separate issue of allocation of the burden of proof, see the European Communities' reply to Canada's written question No. 8.

Question 37: What are the factors that determine the "relevance" of an international standard within the meaning of Article 2.4 of the Agreement on Technical Barriers to Trade?

(i) Reply by Canada

148. The "relevance" of an international standard is a question of fact which must be determined on a case-by-case basis.

149. The ordinary meaning of the word *"pertinent"* is given in Larousse as *"approprié, qui se rapporte exactement à ce dont il est question."* The English version of the TBT Agreement uses the word "relevant", which is defined by the *Concise Oxford Dictionary* as: "bearing on or pertaining to the matter at hand."

150. In this case, the international standards cited by Canada are relevant since they relate to the same product, namely asbestos, and to the same regulatory purpose, namely protection of the health of workers and individuals. The international standards all deal with the use of chrysotile in a controlled and safe manner.

151. The Panel must also be aware that the relevance of the international standards invoked by Canada has never been challenged by the European Communities. Rather, the European Communities confine themselves to attempting to demonstrate that the international standards cited by Canada are not "international standards" within the meaning of the TBT Agreement.

(ii) Reply by the European Communities

152. The phrase in question reads: "[w]here technical regulations are required and relevant international standards exist or their completion is imminent (…)." The ordinary meaning of "relevant" is bearing on or pertaining to the matter at hand.[83] The context of this provision, however, makes it clear that the substantive requirement to judge the relevance of an international standard is

[83] The Oxford English Reference Dictionary, 1995.

that the latter should meet the requirements of the definition of "technical regulation" in Annex 1 to the TBT Agreement (see Article 1.2 of the TBT Agreement).

153. In the present case, none of the international standards invoked by Canada define the characteristics which asbestos or products containing asbestos must have. They deal, for instance, with the way in which asbestos and asbestos-containing products must be handled in the workplace and the relationship between employers and employees. They are, therefore, not "relevant" in the meaning of Article. 2.4 of the TBT Agreement. In any case, even if they were relevant (which they are not) they would be completely ineffective and inappropriate to fulfil the legitimate objective of France, which is to protect human health in its territory.

Question 38: In the context of the Agreement on Technical Barriers to Trade, is a Member free to determine, for the purpose of drafting and adopting a technical regulation, the level of protection it considers appropriate?

(i) Reply by Canada

154. Yes, but in compliance with the obligations of the TBT Agreement. For example, a Member's freedom to adopt a regulation for the protection of human health, at the levels it considers appropriate, is mentioned in paragraph 6 of the preamble to the TBT Agreement. However, this freedom is circumscribed. First, it is subject to the requirement that the technical regulation does not constitute either a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail or a disguised restriction on international trade. Second, it is subject to the technical regulation being otherwise in accordance with the provisions of the TBT Agreement.

(ii) Reply by the European Communities

155. Yes. Article 2.2 of the TBT Agreement provides that protection of human health and safety is a legitimate objective. The preamble to that agreement confirms that "no country should be prevented from taking measures necessary to … protect human … life or health, at the levels it considers appropriate (…)".

Question 39: Article 2.4 of the Agreement on Technical Barriers to Trade envisages the situation in which the relevant international standards or the relevant parts of them would be "an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued, for instance because of fundamental climatic or geographical factors or fundamental technological problems". What other types of situation would be liable to make the standards or some of their parts "ineffective or inappropriate" within the meaning of this article?

(i) Reply by Canada

156. Situations that might render international standards or certain parts of them ineffective or inappropriate, other than those situations explicitly mentioned in Article 2.4, should be examined in the light of the ordinary meaning of the terms in this article, taken in their context. The text of Article 2.4 states that they must be "fundamental" factors or problems.

157. For Article 2.4 not to be stripped of its meaning, it requires that, in order to set aside an otherwise relevant international standard, the Member must provide real and tangible evidence of a "fundamental" consideration and not a mere allegation that certain standards are not appropriate.

(ii) Reply by the European Communities

158. The most obvious examples are when the latest scientific evidence suggests that the scientific basis of an international standard is inaccurate or obsolete, or when the level of protection that could be achieved by the international standard is lower than that determined by a Member in its territory. In the present case, the relevant scientific evidence that became available, in particular in the late 1980s and early 1990s, indicates that: (i) there is no doubt at all that chrysotile asbestos is a proven carcinogen; (ii) there is no safe exposure limit (threshold) for chrysotile asbestos and products containing asbestos; (iii) so-called "controlled use" is not applicable in all circumstances and for all types of persons that may come in contact with asbestos or asbestos-containing products and, in addition, does not eliminate all the risks; and (iv) there are substitute products that are safe, or safer than chrysotile asbestos.

159. Under these circumstances it is clear that an international standard that would permit the use of asbestos or asbestos-containing products or would set an exposure limit or would recommend "controlled use" would be ineffective or inappropriate to achieve the level of health protection determined by France.

4. Questions by Canada to the European Communities

Question 1: The first written submission of the European Communities states that "mesothelioma is a pleural cancer for which the only known cause is the inhalation of asbestos". Are we to take this assertion to mean that the European Communities are unaware of the scientific data identifying x-rays and erionite, *inter alia*, as causes of mesothelioma?

160. Erionite is indeed an indisputable cause of mesothelioma (as was made clear in the INSERM Report: see pages 125-126); however, exposure to the fibres of erionite, a mineral of natural origin, has to our knowledge been documented only in the Turkish region of Cappadocia. For that reason, in Section 4(a) of the first submission by the European Communities, a more complete form of words was used: "apart from exposure to asbestos, no other causal factor present in the industrialized countries has been established or even seriously suspected". As for the other factors mentioned by Canada, such as x-rays, none has been positively confirmed up to now, even though presumptions exist in the case of some; none of them is classified in Group 1 of the International Agency for Research on Cancer as a proven carcinogen with regard to mesothelioma.

Question 2:

> **(a) In paragraph 238 of their first written submission, the European Communities conclude that the controlled use policy is inapplicable. Was France applying a policy of controlled use of asbestos at the time when the workers referred to in the study by Y. Iwatsubo were exposed? If not, how can this policy be found to be inapplicable?**

161. The study by Iwatsubo *et al*. concerns workers who developed mesothelioma in recent years (1987-1993) and who have therefore been exposed to asbestos during a period dating back at least 20 or 30 years, when so-called controlled use was not applied. However, the study in question (like others cited in the European Communities' submission, which were carried out in different countries), confirms that the vast majority of such cases of mesothelioma occurred in a wide variety of trades, particularly in the construction sector, where workers are in most cases unaware of their sporadic exposure due to having to handle a wide range of materials that have frequently been in place over a very long period of time without anyone knowing of their asbestos content.

162. The study by Iwatsubo *et al*., like similar studies, has the advantage of showing clearly that "controlled use" procedures would have to be applied on so wide a scale (several hundred thousand

workers a day in France carry out isolated operations on materials containing asbestos) that they are in practice largely unrealistic although every effort must be made to encourage such procedures given the enormous quantities of asbestos that have been imported for decades and which remain in place. Moreover, the prevailing unawareness that the materials concerned contain asbestos makes it even more difficult to introduce such work procedures systematically; it would mean in practice putting a supervisor behind every worker in the construction trade and numerous other sectors of activity which use heavy equipment covered by the ISO 7337 Standard, and prohibiting any operation until checks have been carried out on the presence of asbestos. Specifically, that would mean having to send a sample of the material on which a sometimes very brief operation is to be carried out (such as drilling or sawing) to an approved laboratory and awaiting the laboratory findings. It is clear that the procedures described above cannot be applied on such a broad scale, uniformly and continuously, i.e. over a period of decades given the continued presence of asbestos.

Question 2:

(b) Could the European Communities specify the varieties of asbestos to which the persons covered by the study by Y. Iwatsubo *et al.* were exposed?

163. The study by Iwatsubo *et al.* does not distinguish between the varieties of asbestos to which workers suffering from mesothelioma were exposed. However, France has used chrysotile almost exclusively: the share of amphiboles in asbestos imports into France has not exceeded 3 per cent since 1945, and France has never produced amphiboles domestically. Amphiboles were used mainly for specific purposes: it is therefore highly likely that the great majority of workers with mesothelioma covered by the study by Iwatsubo *et coll.* were never exposed to any variety of asbestos other than chrysotile.

Question 3: The European Communities acknowledge in Section 4(a) of their first written submission that there is a difference between the toxicity of chrysotile and that of amphiboles. Do the European Communities therefore acknowledge that assessment of the risk from exposure to chrysotile exclusively must be based solely on data concerning chrysotile exposure, and not on data concerning exposure to amphiboles or mixtures of asbestos containing amphiboles?

This question calls for two preliminary comments:

- The European Communities pointed out in their first written submission that, while it is true that amphiboles appear to be a more important cause of mesothelioma than chrysotile, that is not the case for lung cancer. However, lung cancer has caused a higher number of asbestos-related deaths than mesothelioma (many authors consider that for every death from mesothelioma there is at least one or even possibly two deaths from cancer of the lung due to asbestos). It is therefore impossible to accept the wording of the question by Canada which, once again, seems to be seeking to ignore this fact.

- Canada does not explain what is meant by *"exposure to chrysotile exclusively"*: the chrysotile produced by Canada is contaminated by tremolite (a variety of amphibole asbestos with a very strong carcinogenic potential in respect of mesothelioma). This argument has also been widely used by the "defenders" of chrysotile to dispute the fact that the latter could cause mesothelioma (the reasoning being that the traces of tremolite contained in Canadian chrysotile were solely responsible for the many cases of mesothelioma observed among workers exposed to Canadian chrysotile asbestos). This theory of the harmlessness of chrysotile in relation to mesothelioma has been rejected by the scientific community, as is pointed out in the submission of the

> European Communities. It is hard to see what Canada is recommending when it suggests that assessments of the risk associated with *"exposure to chrysotile exclusively"* should not be based on exposure to mixtures of asbestos containing amphiboles.

164. Canada suggests in its question that the assessments of the risk from exposure to asbestos carried out up to now (by INSERM and by all the other official bodies which have performed such assessments) are wide of the mark as they are all based on increases in cancer risk observed in different studies where workers were exposed to different types of asbestos. The models used are in fact based on the average dose-risk ratios observed in the main studies available, the validity of which has been deemed adequate. Those ratios differ widely in "extreme" studies, and this may reflect the statistical uncertainty associated with each study and/or genuine differences in risk due, for example, to the conditions of exposure or the nature or morphology of the fibres.

165. The decision to use a single average value in order to set up a dose-dependent risk model is the most realistic option when it is wished to assess the risk to the general population of a country, which is exposed under highly variable conditions, particularly in terms of the nature and morphology of the asbestos fibres encountered. While a "detailed" assessment may be justified in specific and well-known exposure situations, a "universal" risk assessment is broadly speaking a more plausible option in most situations. If it was nevertheless wished to assess the risk associated with *"*exposure to chrysotile exclusively*"*, difficult problems would be faced. The dose-risk ratios observed in the main studies available on exposure to chrysotile are extremely variable: for example, in the case of lung cancer, the dose-risk ratios are more than twenty times higher in the textile asbestos industry than in the asbestos mining and milling industry. Generally speaking, higher lung cancer risks are found in studies concerning exposure to chrysotile than in those concerning amphiboles.[84] Which of the dose-risk ratios does Canada consider should be chosen for risk assessment purposes?

Question 4: Do the data from the study by Peto *et al.* (1998) cited by the European Communities concern exposure to chrysotile only or exposure to amphiboles or mixtures containing amphiboles?

166. The data from the study by Peto *et al.* concern none of the specific varieties of asbestos: they are based exclusively on statistical models for mesothelioma mortality data actually observed in the European countries concerned. The study therefore deals with the fatal effects of asbestos in all its forms. However, in order to evaluate the role of each of the different varieties of asbestos in this health catastrophe, it should once again be recalled that chrysotile accounts for the overwhelming majority of asbestos imports, particularly in France where the share of chrysotile has never been lower than 97 per cent of all asbestos. For that reason, chrysotile must be considered to be responsible for most cases of mesothelioma, as is demonstrated in detail in the article by Smith *et al.*[85], the very title of which is unambiguous: "*Chrysotile asbestos, the main cause of pleural mesothelioma*".

Question 5: Did the INSERM researchers study the question of exposure from sporadic work on materials in which chrysotile fibres are firmly embedded in a binding agent, so that no dust can be formed, such as chrysotile cement?

167. This type of exposure was analysed in the INSERM report[86], together with the range of occupational exposures to sporadically high levels of pollution, which are responsible for the vast

[84] A detailed analysis of these figures will be found in the INSERM report, pages 193 to 214; see in particular table 3, page 200.

[85] Y. Iwatsubo, *et al., Pleural Mesothelioma: Dose-Response Relation at Low Levels of Asbestos Exposure in A French Population-Based Case-Control Study,* Am.J. of Epid., 1998;148:133-142.

[86] INSERM Report, pages 69-71.

majority of cancers due to asbestos. Moreover, an Annex[87] to the first written submission of the European Communities sets out exposure values measured in connection with such work, which show that levels tens or even hundreds of times higher than the prescribed limit values can be encountered. For example, a roofing worker using a grinder out of doors to repair corrugated roof sheeting made of asbestos-cement is subjected to a maximum exposure level of 41 f/ml, 410 times the limit value. It is worth noting that the authorized limit values are substantially exceeded when the ISO 7337 standard is applied.

Question 6: Since the INSERM Report acknowledges a latency period of some decades for asbestos-related illnesses, how can the European Communities assert that controlled use does not work, when fewer than 25 years have elapsed since the effective implementation of controlled use?

168. The assertion that "controlled use does not work" is based essentially on the finding that extremely high levels of asbestos fibre are released into the atmosphere during operations on asbestos-containing materials carried out in accordance with the ISO 7337 Standard, as well as the practical impossibility of ensuring that the Standard is observed at all times in operations on such materials.[88] As it is clearly established that such levels of exposure provoke cancers, it is obvious that fatal illnesses will occur in the future as a result of such exposures. What Canada is suggesting in this question is a waiting period of 25 years (and a considerable number of deaths) to confirm this patent fact which is based on indisputable data. Furthermore, it should be noted that the HSE (Health and Safety Executive) study[89] carried out in the United Kingdom on a population of workers in the asbestos-processing industry, which was subjected to strict rules of "safe use" from 1969, shows that the application of those rules does not enable a significant excess of cancer to be avoided, even in a sector which appears to be easy to demarcate and control.

Question 7: Did INSERM itself estimate the risk level for lung cancer or did it use the 1986 EPA estimates?

169. It should first of all be pointed out that the "risk levels" referred to indicate the increase in the relative risk of lung cancer mortality for each additional unit of exposure to asbestos. These levels were estimated by neither INSERM nor the EPA: they were actually observed in the epidemiological studies carried out among workers in the asbestos industry. Canada no doubt wishes to draw attention to the "average" level (derived from all those observed in different epidemiological studies) which is used for risk assessments and which represents the average risk. This value serves to calculate "theoretical" numbers of deaths that would be caused under various scenarios of exposure to asbestos in a population; the higher the level, the greater the calculated number of deaths. The aim therefore is to use epidemiological models to measure the theoretical impact of such levels of exposure in the population, for scoping purposes. Such models based on uncertain scenarios are commonly used in many areas relating to health or the economy, for instance in order to inform decision makers about the possible consequences of their decisions. This is what was done by the INSERM researchers.

170. It is important for the Panel to be aware that, prior to the INSERM study in 1996, the very basis of which is challenged in the Canadian submission, six other official expert groups (including a Canadian group) had done similar work:

- Consumer Product Safety Commission (USA, 1983)

[87] Memo setting out the guidelines of the Conseil supérieur de prévention des risques professionnels, of 3 July 1995.

[88] See our reply to Questions 2(a) and 5 by Canada.

[89] Hutchings, S., *et al.*, *Asbestos-Related Disease*, Occupational Health Decenal Supplement, London, Health and Safety Executive, 1996, pp. 127-152.

- National Research Council (USA, 1984)
- Ontario Royal Commission (Canada, 1984)
- Health and Safety Commission (United Kingdom, 1985)
- Environmental Protection Agency (EPA, USA, 1986)
- Health Effects Institute (USA, 1991)

171. INSERM carried out a thorough review and careful analysis of the risk levels used by these different groups of experts, who had already made assessments of the risk of lung cancer caused by exposure to asbestos.[90] Selecting an average level is a complex matter given the sharp variations observed in the different epidemiological studies (once again, it should be noted that the highest values are usually observed in studies concerning workers exposed to chrysotile asbestos). It is observed[91] that four of them selected the same value as INSERM (+1 per cent); another selected a lower value, albeit combined with a range of variation with a very high upper limit; another selected a higher value (+ 2 per cent). It can be seen, therefore, that the choice made by INSERM is consistent with that of the expert groups of other countries, and no attempt was made to exaggerate the risks from asbestos.

Question 8: Do the European Communities acknowledge that they bear the burden of proof under Article XX(b) of GATT 1994 and Article 2.2 of the TBT Agreement?

172. The burden to establish a prima facie violation of a provision of the GATT Agreement is on Canada. When the prima facie case has been made, the burden of proof passes to the defending Member, which must in turn counter or refute the alleged inconsistency, for instance by claiming the application of Article XX(b) of GATT. The burden of proof and the concomitant burden of persuasion continue, however, to shift back and forth ("like a pendulum") throughout the entire Panel proceedings. The case law on the burden of proof that has been developed under Article XX(b) is not, however, applicable in the context of the TBT Agreement (in particular Article 2.2 thereof), as Canada's question seems to suggest. Article 2.2 cannot be described as an exception to another provision of the TBT Agreement. The case law of the Appellate Body in the *Hormones* case (paragraphs 99 to 109) is more relevant in this context[92], taking into account the structure and context of Article 2.2 of the TBT Agreement.[93]

Question 9: Do the European Communities maintain that the chemical composition of fibres is a relevant criterion in determining the likeness of products under Article III:4 of GATT?

173. Chemical composition is certainly relevant to the extent it affects or influences the nature, properties and qualities of the product in question. According to GATT practice and case law, a product's properties, nature and quality are extremely important in determining "likeness" under Article III:4 of GATT. Since the chemical composition of the fibres contained in a product is almost certain to influence its characteristics (including its potential health effects), the European Communities consider that criterion indeed relevant. In addition, it is not unreasonable to assume that the chemical composition may also affect or influence the nature or quality of the product and, consequently, consumers' tastes. It is hardly open to doubt that any informed consumer would very probably refuse a product proved to be carcinogenic. Please see also the European Communities' reply to question 27 of the Panel.

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[90] See pages 193 to 202 of the INSERM Report – see also our reply to question 3 by Canada.

[91] INSERM Report, Table 4, p. 202.

[92] AB-1997-4.

[93] The European Communities note that the case law of the Appellate Body in the case *Japan – Measures Affecting Agricultural Products* (AB-1998-8, paragraph 126) is also relevant by analogy, where it was held that the burden lies on the Plaintiff Member to establish that the measure at issue is more trade-restrictive than necessary to fulfil the legitimate objective, taking account of the risks non-fulfilment would create.

Question 10: Do the European Communities recognize the relevance of international standards for the establishment of technical regulations on the use of asbestos fibres?

174. Please refer to the European Communities' reply to question 37 of the Panel.

5. Questions to Canada by the European Communities

Question 1: On what facts does Canada base its claim that cases of mesothelioma in France are due solely to amphibole asbestos, not to chrysotile asbestos?

175. Canada has never stated that cases of mesothelioma in France are due solely to amphibole asbestos and not to chrysotile asbestos; science has not yet proved beyond a shadow of a doubt that chrysotile cannot cause mesothelioma. There is, however, a great deal of scientific evidence that this is, in fact, the case. On the other hand, the link between exposure to amphibole fibres, particularly crocidolite, and development of mesothelioma has been clearly established. Since the disease was identified in the late 19th Century, there have been many reported cases which could not be linked to exposure to asbestos. According to Dr. Premysl V. Pelnar in a study published in the *Scandinavian Journal of Work, Environment & Health* in 1988, it has been proved that many agents other than asbestos cause mesothelioma in laboratory animals, including biological agents (e.g. the SV 40 virus), chemicals (e.g. polysilicone plastics and diatomaceous earth), physical chemical products (glass fibre, erionite-zeolite, tremolite and attapulgite), and physical agents such as x-rays. It has also been proved that exposure to some of these agents (erionite-zeolite, tremolite and x-rays) causes mesothelioma in humans.[94] See also the answer to question 3 by the European Communities to Canada.

Question 2: Can Canada give its figures for amphibole asbestos imports and consumption before the ban?

176. First of all, the question contains an error of fact concerning the ban on use of amphiboles in Canada that needs to be rectified. Under the *Hazardous Products Act/Hazardous Products (Crocidolite Asbestos) Regulations*, "The importation of crocidolite asbestos fibres shall be (…) restricted and regulated", but not banned. Under the regulations, the importation of crocidolite asbestos fibres for the manufacture of diaphragms, chloralkali and certain acid and temperature resistant products (e.g. waterproof seals) and of certain products containing the fibres (e.g. asbestos cement pipes) is permitted subject to the following conditions: (i) a notice must be sent to the Federal Department of Industry, which informs the provincial organization responsible for enforcing the *Occupational Health and Safety Act*; (ii) the notice must include the import date, the port of entry, the quantity being imported, the address of the premises where the product is to be used, etc.; (iii) the product must be labelled appropriately.

177. However, Canadian statistics on asbestos imports do not differentiate among the various types of asbestos fibres, so imports of chrysotile, amosite and crocidolite are combined in one figure in the available data. Data on Canadian consumption of asbestos fibre have been available since 1982, the year that annual surveys began. Low levels of amosite fibre consumption were reported for the period 1982-85, but no crocidolite consumption was reported.

Question 3: Does Canada have any scientific evidence to suggest that materials other than asbestos may cause mesothelioma in industrialized countries?

178. Canada has access to the same scientific data that is available to the international community at large, including France on "other potential causes of mesothelioma in industrialized countries".

[94] Pelnar, V., *Further Evidence of Non-asbestos-Related Mesothelioma; A Review of the Literature*, 1988, 14 Scand. J. of Work, Environment and Health, 141.

Canada feels compelled to inform the European Communities of the considerable body of evidence contradicting their statement that "asbestos in all forms (amphibole and chrysotile) is the only known factor that can cause mesothelioma or pleural cancer". A number of studies suggest other potential risk factors that may have been underestimated in epidemiological studies in industrialized countries. We take this opportunity to correct the European Communities' simplistic definition of mesothelioma: "mesothelioma is a cancer of the pleura … ". In fact, malignant diffuse mesothelioma is a cancer of the mesothelial cells of the pleura, the pericardium and the peritoneum. Furthermore, peritoneal mesothelioma is much more typical of exposure to amphiboles than pleural mesothelioma.

179. A number of artificial fibres cause mesothelioma when they are injected into the pleura and peritoneum of laboratory animals. It should also be noted that the International Agency for Research on Cancer (IARC) has classified refractory ceramic fibres as probable carcinogens, partly because of instances of mesothelioma induced by inhalation and injection in animal studies. The SV 40 virus readily induces mesothelioma when injected into animals; studies suggest that the virus contaminated anti-polio (poliomyelitis vaccines) from 1955 to about 1963 and may induce mesothelioma with or without the help of asbestos fibres. Some studies of humans report the presence of the simian SV 40 virus in the biological tissue of mesothelioma victims. Ionizing radiation used in cancer therapy, as well as, perhaps, occupational exposure to radiation have induced mesothelioma.[95] In addition, a large proportion of mesothelioma cases (as high as 25 per cent) are not attributable to exposure to asbestos; they may have been caused by hidden (unidentified but real) exposure to asbestos, but the figures suggests that there are other significant causes that cannot be countered by targeting exposure to asbestos alone. For example, erionite has been shown to be even more toxic than crocidolite in causing mesothelioma: it has killed large numbers of villagers in Turkey. Erionite is a mineral fibre but does not belong to the asbestos family, which suggests that fibres with similar physical characteristics could pose a health threat to other population groups. Finally, we wish to remind the European Communities that the issue at hand is the ban on chrysotile products and that there are mesothelioma risk factors other than chrysolite, particularly all the amphibole fibres and flockings placed around furnaces, boilers and high-temperature pipes.

Question 4: Does Canada dispute that chrysotile asbestos is a proven carcinogen in humans - in general? In the case of lung cancer? In the case of mesothelioma?

180. Canada does not dispute that chrysotile causes lung cancer. However the way in which exposure to chrysotile asbestos may increase the risk of lung cancer has not yet been fully explained, and might only be indirect. First of all, Canada maintains that the risk is dependent on the intensity and duration of exposure and that there is a level of risk below which the risk, if any, is undetectable. According to Churg on this subject:

> "As a practical matter, the data indicate that chrysotile will not produce mesotheliomas in those exposed to any current or recently regulated numbers of chrysotile, and certainly not in those exposed to chrysotile encountered at environmental levels".[96]

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[95] See the following studies: Tassile, D. Roth AD, *et al*., *Colon Cancers and Peritoneal Mesothelioma Occurring 29 Years after Abdominal Radiation for Testicular Seminoma - A Case Study and Review of the Literature*, Oncology 1998, 55: 289-292; Antman, KH, Corson JM *et al*., *Malignant Mesothelioma Following Radiation Exposure*, J. Clin. Oncol. 1983, 1:695-700; Kawashima, A., Libshitz, H. *et al., Radiation-Induced Malignant Pleural Mesothelioma [Case Report]*, Can. Assoc. Radiol. J. 1990, 41:384-386; Hofmann, J. Mintzer D., Warhol M.J. *Malignant Mesothelioma Following Radiation Therapy*, American Journal of Medicine 1994, 97:379-382; Gold B. Kathren R.L., *Causes of Death in a Cohort of 260 Plutonium Workers*, Health Physics 1998, 75:236-240; Huncharek M. The Epidemiology of Pleural Mesothelioma: Current Concepts and Controversies. *Cancer Invest* 1989, 7:93-99.

[96] Churg A. (1988) *Chrysotile, Tremolite, and Malignant Mesothelioma in Man*, Chest: 93: 621-628.

181. The risk may become detectable in cases of long-term exposure to high levels, but it is then by no means certain whether the chrysotile acts as a direct carcinogen or by causing the formation of pulmonary fibrosis, which would be a precursor of neoplasia. In other words, exposure must be sufficient in intensity and duration to induce pulmonary fibrosis, which predisposes the pulmonary parenchyma to a higher risk of cancer. Regarding asbestos-related mesothelioma, a number of studies have demonstrated cogently that this type of cancer is almost exclusively linked to exposure to amphiboles. Cases of mesothelioma in chrysotile asbestos miners in Quebec are relatively rare - in a cohort of 11,000 workers who were very carefully monitored (in the McDonald study), there were at most fifty or so cases over several decades. Exhaustive research into their employment history revealed that most of the cases were related to short-term exposure to commercial amphiboles. For example, during the Second World War, some of the miners with mesothelioma had worked in plants manufacturing products for the allied forces and amphiboles imported into Canada had been used to make a variety of products, including gas masks, to assist in the war effort.[97]

Question 5: How does Canada explain the fact that the risk of mesothelioma is seven times higher than average for women living near chrysotile mines in Quebec? (Note that this population group was the subject of a special study because, in its case, the exposure is environmental, not directly occupational).

182. The women in the towns of Thetford Mines and Asbestos have been continuously exposed from birth to asbestos concentrations of 1 f/ml. or more. Given that the risk of mesothelioma increases by approximately the power of 3 in relation to the time that has elapsed since exposure, these women have had more time to develop a detectable risk of mesothelioma than many workers in other parts of the asbestos industry. Even so, their risk level seems to be at least 20 times lower than predicted by the Environmental Protection Agency (USA) and INSERM models.

183. More specifically, it should be borne in mind that some 75 per cent of the women in this study[98] lived with an asbestos worker, of whom a small minority worked with amphiboles, particularly crocidolite. Furthermore, some 5 per cent had themselves already worked in the asbestos industry as "sheddeuses" or "gobeuses" or had worked in workshops for repairing jute sacks which had contained crocidolite or had worked at home for the asbestos industry repairing jute sacks used to transport amphiboles. Finally, the results to which the EC refers concern deaths from pleural cancer. Since then, researchers have compiled and checked the diagnosis in pleural mesothelioma cases, thus providing a better measurement of the risk arising from asbestos. The authors of the study have collected but not yet analysed the exposure histories of cases of pleural mesothelioma in women (more than ten so far, and not merely the seven mentioned in the 1997 publication).

184. Preliminary analyses indicate that a certain number of mesothelioma cases were exposed to crocidolite or amosite more than thirty years before the onset of the disease (Camus and Siemiatycki, personal communication, 1999). The other mesotheliomas may be attributable to a long period of induction, following a massive build-up since childhood, of continuous environmental exposure or exposure in the home (living with an asbestos worker) to commercial chrysotile exceeding 1 f/ml. The women's cumulative exposure was equivalent to between 100 and 300 fibre years/ml. for asbestos workers.

Question 6: Does Canada disagree that most cases of mesothelioma occur in industrialized countries in occupations involving intermittent exposure to asbestos, specifically those where the worker has to work with asbestos containing materials?

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[97] McDonald JC *et al* (1989) *Mesothelioma and Asbestos Fibre Type*, Cancer 63: 1544-1547.

[98] Camus M. Siemiatycki J., Meek B., *Non-occupational Exposure to Chrysotile Asbestos and the Risk of Lung Cancer, N. Eng.l J. Med*. 1998; 338: 1565-71.

185. Nowadays, most cases of mesothelioma in the industrialized countries occur in occupations other than mining and manufacture of asbestos products because workers in those occupations are exposed to amphiboles in poorly controlled work areas. The workers who remain at risk, working in the construction sector, are specifically those who are most exposed to flocking and friable products made of asbestos mixes containing amphiboles or composed entirely of amphiboles. This situation is completely different from the case of workers in chrysotile mines and in manufacturing plants where only chrysotile is used.

Question 7: Because Canada did not provide the health statistics requested at the consultative meetings in July 1998, France used gross data on the worldwide situation published by the WHO to calculate the incidence of mesothelioma in Canada and Quebec from 1978-1992. Could Canada provided its own recent health statistics (since 1992) on mesothelioma deaths in Canada and Quebec?

186. See above, reply to question 9 by the Panel to Canada.

Question 8: Can Canada explain how the safe use of chrysotile can have resulted in the following observations from a study conducted in the Montreal area:

- **A risk of mesothelioma more than 14 times higher than the average for persons "significantly" exposed to chrysotile asbestos?**

- **A risk of lung cancer 2.3 times higher than the average for people "significantly" exposed to chrysotile asbestos?**

- **A risk of mesothelioma almost 12 times higher than the average for construction workers?**

187. The purpose of this major case-control study, which was conducted on 4,500 cancer cases diagnosed in hospitals in the Montreal area between September 1975 and June 1985, was to identify potential associations for follow-up from among the tens of thousands of possible associations between 23 groups of cancer, 98 occupational groups and 293 substances. As the authors state, the study and the analysis were designed to establish hypotheses, not to verify specific hypotheses. The downside of this greater sensitivity is a tendency to overestimate associations and to obtain more "false positives" The authors therefore recommend that each reported association should be interpreted with prudence and caution (page 304).

188. The main limitation of the reported analyses is that they are "univariate": they consider only one occupational exposure at a time and do not evaluate the effects of other concomitant occupational exposures (page 119). This problem is particularly significant in the case of chrysotile. The workers in the study who were exposed to chrysotile were also exposed to amphibole fibres, crystalline silica, cement dust, PAH's and alkanes, wood dust, solvents and pyrolysis fumes (pages 50-51). Seven of the ten substances in the study were associated with mesothelioma and all ten were associated with lung cancer. Thus the reported associations between mesothelioma, lung cancer and chrysotile do not isolate the level of risk associated with chrysotile itself from the compound effect of several other risk factors. The authors thus caution against oversimplified interpretations (page 301): "[A] much more important problem is the fact that the association between cancer and one occupational substance may be confounded by other occupational substances." The problem may be even more serious in respect of mesothelioma, because the study included only a very small number of cases (12 cases).

189. Regarding lung cancer, the study also recognizes the possibility of a residual effect of smoking and a paradox that the researchers cannot explain: the absence of an association between lung cancer and exposure to amphiboles. This anomaly illustrates the difficulty in population case-

control studies of distinguishing between past exposure to chrysotile and amphibole. The same problem was underlined in the article by Iwatsubo *et al.*, cited by the European Communities[99] and in the preface[100] by Siemiatycki and Boffetta (IARC) to the Iwatsubo study. Finally, because the study was restricted to cancers occurring between 1979 and 1985, and the induction/latency periods for lung cancers and mesothelioma are several decades, the exposures that may have caused the cancers occurred before controlled use measures were applied. This data can, therefore, in no way provide a basis for assessing the affect of controlled use of chrysotile which was introduced in the 70's.

Question 9: Why does Canada think that the controlled use of amphiboles is not technically feasible (since it has banned this type of asbestos)?

190. The distinction is based on the proved lower toxicity of chrysotile compared with amphiboles and the application of principles inherent in international standards on the controlled use of asbestos.

Question 10: In its submission, Canada acknowledges that "certain uses for which exposure cannot be controlled to an acceptable degree should be banned". Could Canada specify to which uses it is referring?

191. The guiding principle in controlled use is the elimination of any use involving a risk that cannot be adequately controlled. Thus the Canadian *Hazardous Products Act* prohibits the use of the following:

(a) Textile fibre products that are to be worn on the person and that contain asbestos fibres, other than products that are designed for the purpose of affording protection from fire and heat hazards and constructed in such a way that ensures that the asbestos fibres will not, on reasonably foreseeable use, become separated from the products;

(b) asbestos in spray form except products composed of a mixture of asbestos fibres and bituminous and resinous-based binding materials where the fibres are encapsulated with the binding during spraying and the resulting materials are not friable after drying;

(c) products composed of or containing asbestos for use by a child in learning and playing and made in such a way that asbestos may become separated from the products;

(d) products composed of or containing asbestos for use in modelling or sculpture;

(e) dry-wall joint cements or compounds or sprackling or patching compounds, composed of/or containing asbestos, that are made in such a way that airborne asbestos may become separated from the products during the preparation of the products, other than preparation at the manufacturing level, or during the application of the products or at any time thereafter up to and including the repair and removal of the products;

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[99] Iwatsubo Y, Pairon JC, Boutin C, Ménard O, Massin N, Caillaud D, Orlowski E, Galateau-Salle F, Bignon J, Brochard P, *Pleural Mesothelioma: Dose-Response Relation at Low Levels of Asbestos Exposure in a French Population-Based Case-Control Study* [see comments]. American Journal Of Epidemiology 1998; 148(2): 133-142.

[100] Siemiatycki J, Boffetta P. Invited commentary: *Is it Possible to Investigate the Quantitative Relation between Asbestos and Mesothelioma in a Community-Based Study?* Am. J. Epidemiol., 1998; 148(2): 1-5, (preface to the Iwatsubo study).

(f) products composed of or containing asbestos for use to simulate ashes or embers.

Question 11: The enormous amount of work in France on airborne particles in the workplace has shown no evidence of chemical changes in chrysotile asbestos fibres released during high-speed machining of materials containing asbestos. Can Canada provide evidence of changes in the chemical composition of chrysotile asbestos during high-speed machining?

192. Canada is surprised that this question should be asked, because the answer was given at the first substantive meeting of the Panel, with relevant supporting references. In any case, given that the question concerns fibres released during dry, high-speed machining of high-density materials, the operations concerned clearly do not comply with controlled-use safety procedures.

Question 12: Can Canada state exactly when the "modern" use of asbestos began? How does Canada characterize the so-called "modern" characteristics of chrysotile cement products?

193. The advent of the use of "modern" asbestos products was a gradual process that began in the 1970s with the phasing out of uses in which asbestos fibres could readily be separated from the finished product, as in the case of friable insulating materials and flockings, toys and unprocessed textiles. The manufacture of products containing amphibole-type fibres was also phased out because they were recognized as more harmful. In short, a distinction must be made between two periods: the first is characterized by the use of amphibole fibres and uses in which asbestos fibres could be easily separated from the finished product; the second is characterized by the prohibition or restricted use of amphibole asbestos and by the advent of non-friable products, i.e. products in which fibres are firmly bound to a matrix and are highly unlikely to be released in biologically significant concentrations. The distinction is a fundamental one. It should nonetheless be noted that non-friable products in which chrysotile is encapsulated in a matrix, as in the case of chrysotile cement, were manufactured and used during both periods.

194. The industrial diseases attributable to asbestos that are now occurring in Europe and North America are associated with so-called "old-style" products and amphiboles. This fundamental distinction has been recognized by the International Labour Organization in Convention 162 concerning Safety in the Use of Asbestos, by the World Health Organization and in the regulations of most countries. Even though they have been manufactured for nearly 100 years, chrysotile cement products meet the "modern use" criterion because the fibres are encapsulated in a cement matrix and are not released in significant quantities as long as simple controlled-use procedures are followed. More recently, new procedures have been introduced to eliminate the use of crocidolite fibres in the manufacture of pipes, and countries such as Japan and France have developed new chrysotile cement products manufactured by extrusion or covered with a lustre coating. These advances have in no small measure helped to make products not only safe but also more attractive.

Question 13:

(a) Has Canada established a monitoring enforcement mechanism for the application of "controlled" use measures, including maintenance work?

195. In Canada, controlled use has entailed the prohibition of friable products containing asbestos and the adoption of measures to protect the health and safety of workers exposed to asbestos. In general, the protective measures are a provincial responsibility, and in Quebec they come under the Regulation on the Quality of the Work Environment and the Safety Code for the Construction Industry, which are administered by the Occupational Health and Safety Commission (CSST). Both sets of regulations cover working conditions in chrysotile mines, asbestos product manufacturing plants, and firms specializing in maintenance and removal of asbestos flockings in Quebec.

196. Regarding the health and safety of workers specializing in maintenance and repairs (plumbing, electricity, air-conditioning, etc.) in buildings containing asbestos flockings, the CSST is in the process of implementing a programme for the prevention of occupational diseases associated with exposure to asbestos. The programme is aimed at management and employees in this sector of activity and its purpose is to inform them about the required prevention measures and give them the appropriate training.

197. In addition, the Regulation on Air Quality and the Regulation on Solid Waste, issued by the Department of the Environment of Quebec, state respectively the environmental measures to be taken regarding airborne asbestos and the standards governing burial of waste containing asbestos. Officers of the CSST and the Department of the Environment monitor and enforce the application of all these measures as part of their regular duties, in the same way as they enforce provisions for the control of other substances considered to pose a public health risk and a threat to the health of workers. The measures make it possible to control asbestos throughout its useful life, from the time it is mined to the time it is buried.

(b) What monitoring mechanism did Canada set up to check whether the applicable ISO standards were being followed in Canada and in countries with companies that signed the "Agreement"?

198. In their respective areas of jurisdiction, the regulations of the Canadian Government and the provincial governments provide that the use of chrysotile, at all stages from extraction to use of the finished product, is to be controlled in such a way as to minimize exposure to fibres. Furthermore, they cover the maintenance of buildings containing various types of asbestos and provide for a variety of measures based on the type of work being done and the type of asbestos fibre involved. In most provinces and in buildings under the jurisdiction of the Canadian Government, property owners are required to maintain friable materials in good condition and to inform employees in advance in the event that they may be exposed to such products during maintenance work, repairs or renovations.

199. In the Agreement on the responsible use policy, there is no question of any intent to check how each business uses its products containing chrysotile. The aim of the Agreement is to ensure that users manufacturing finished products, where the health risk is the highest, comply with national and international occupational health standards. The relevant passage of the Canadian submission, concerning standards for installing asbestos cement products, was intended to show that the safe use of asbestos cement products is possible and that this fact is recognized by international organizations such as the International Organization for Standardization. So Canada is surprised at European claims that safe use is impossible, particularly in a country like France.

Question 14: Could Canada clarify whether asbestos producers have already had occasion to stop exports to countries after determining that businesses using their products were not complying with the "Agreement"?

200. Stopping chrysotile sales by producers from signatory countries is the measure of last resort in cases where a consumer is not complying with national regulations and makes no effort to improve working conditions in the business concerned. Under the Agreement, producers must first provide businesses with technical support in order to reduce concentrations of airborne respirable fibres. Measures include the implementation of working procedures, the installation of dust collectors, and the purchase of air sampling and analysis equipment. To enhance the effectiveness of their actions, Canadian chrysotile producers have also used the services of international organizations such as the Asbestos Institute and the Asbestos International Association for plant inspections, training and the collection of data on airborne fibre rates on a continuing basis. In this context, more than 100 technical visits have been made over the last five years, along with training courses in Canada and in a number of consumer countries.

201. Numerous contacts have been established with the governments of chrysotile importing countries to raise their awareness of the work being done by the producers, often with the assistance of trade unions and the Government. In this way, signatories to the Agreement can be assured that non-compliant businesses cannot obtain supplies from other sources. As a result, some countries have decided to issue import licences so as to ensure that every user complies with national regulations. However, in the few cases where users do not follow controlled-use procedures, Canadian producers refuse to sell or stock shipments of the fibre. This has been the case, in particular, of certain users in Mexico, Argentina, Korea, China and Egypt.

Question 15: How can Canada claim, on the one hand, that amphibole-asbestos and chrysotile-asbestos are very different products and, on the other, claim at the end of its submission, that chrysotile-asbestos and substitute products are like products?

202. The distinction made by Canada between amphibole fibres and chrysotile fibres is intended to differentiate between the fibres according to their pathogenicity, on a medical and scientific basis. The objective is not to determine whether they are "like" for the purposes of any provision in the TBT Agreement or GATT but to determine whether one is more dangerous than the other. In this context, the capacity for inducing mesotheliomas and the carcinogenicity of the different types of fibres are clearly relevant to determining the respective pathogenicity levels of amphiboles and chrysotiles.

203. Regarding Canada's arguments on like products under Article III:4 of GATT and Article 2.1 of the TBT Agreement, the scientific question of pathogenicity opens the door to consideration of broader factors such as the properties, nature and quality of the product, its tariff classification and end use. Canada sees no contradiction between making a distinction between two types of fibre to provide a scientific demonstration of differences in pathogenicity, on the one hand, and applying criteria based on WTO and GATT decisions for the purposes of a legal argument on like products on the other. Canada is of the opinion that likeness under GATT or the WTO is a different issue from the assessment of pathogenicity.

Question 16: If Canada were to admit that there was a difference in toxicity between two products, would it accept the idea that they were not like products?

204. No. First, it should be noted that the toxicity of a product is not a recognized criterion for analysis of likeness. In Canada's opinion, the fact that two products have similar toxicities is not an element of their likeness under Article III:4 of GATT or Article 2.1 of the TBT Agreement. Benzene, for example, is not "like" crystalline silica just because they are both carcinogens.

205. Conversely, where it is clearly established that the toxicities of two products are different, it is not inconceivable that the two products could still be "like" for the purposes of Article III:4 of GATT or Article 2.1 of the TBT Agreement. By way of example, wine and vodka, in equal quantities, have very different effects on health and yet they are considered to be "like" products.[101]

Question 17: On what scientific basis did Canada decide not to follow the recommendations made by the ILO in 1986 and those made by WHO in 1998 for asbestos, including chrysotile asbestos, to be replaced with less hazardous products?

206. To answer this question, we would first like to quote Article 10 of ILO Convention 162, to which the European Communities refer in discussing substitute products: "where … technically feasible, national laws or regulations shall provide for … the replacement of asbestos or of certain

[101] *Japan – Customs Duties, Taxes and Labelling Practices on Imported Wines and Alcoholic Beverages*, L/6216, adopted 10 November 1987, BISD 34S/92, paragraph 5.6, page 131.

types of asbestos or products containing asbestos by other materials or products or the use of alternative technology, scientifically evaluated by the competent authority as harmless or less harmful; ….". The concept of substitution approved by WHO is identical to the one conveyed here: it must be proven that the substitute products are harmless or less harmful. The fact is that the scientific community still questions the harmlessness of most of the substitutes. Thus, INSERM stated that "any new fibre proposed as a substitute for asbestos or for any other use must be suspected, a priori, of being pathogenic because of its structure but that this does not preclude [the requirement] for analysis of the possible consequences of its physico-chemical characteristics."[102]

207. Given the substantial latency period (between 15 and 45 years for asbestos) between exposure to a pathogen and the development of disease, it is impossible to make a definitive assessment of the carcinogenic potential of substitute fibres which came on to the market only recently. However, a number of recent studies cast doubt on the harmlessness of these fibres. As long ago as 1993, in a report entitled *Selected Synthetic Organic Fibres*, the World Health Organization's International Programme for Chemical Safety (IPCS) identified the para-aramid fibre as being respirable and biopersistent, two criteria associated with toxic potential in a substance. The same applies to most replacement fibres. Given the lack of knowledge on the subject, it would be premature to press on blindly with substitution.

Question 18: Why has Canada not instituted similar proceedings against other countries that have imposed similar bans on asbestos, such as Iceland, Norway, Denmark, Switzerland and New Zealand?

208. Canada could have taken action and is entitled to take action against similar measures previously introduced by other countries, and in particular by seven other members of the European Communities. However, it has decided, for the time being, to confine itself to the "model case" of France, basically for the following reasons:

- France is the first European country to have banned asbestos since the creation of the WTO and the introduction of the new dispute settlement rules;
- France has switched from a policy of controlled-use of asbestos (precisely the one advocated by Canada) to a diametrically opposite one – a total ban – even though there is no new scientific data; and
- the procedures under the Agreement do not include any mechanism for combining similar or identical legal action.

B. QUESTIONS AT THE SECOND SUBSTANTIVE MEETING (20-21 JANUARY 2000)

1. Questions by the Panel to both parties

Question 1: Is the concept of "like product" in the meaning of Article III:4 of GATT identical to that contained in Article 2.1 of the TBT Agreement? In this context, what precisely, in your opinion, is the relevance of the criterion of the effects of the product on human health in the context of the two provisions?

(i) Reply by Canada

209. Article 2.1 of the TBT Agreement reaffirms the obligation concerning national treatment (Article III:4 of GATT) and the obligation of most-favoured-nation treatment (Article I:1 of GATT).

[102] See INSERM, *Summary Report – Effects on Health of Asbestos Substitute Fibres, page 2.*

In the case of the obligation concerning national treatment, we consider that Article 2.1 of the TBT Agreement and Article III:4 of GATT contain the same type of prescription: not to treat imported products less favourably than like national products. The only difference between the two provisions is that Article 2.1 applies only to technical regulations while Article III.4 of GATT applies to "all laws, regulations and requirements […]". From that it follows that the concept of like products in the meaning of Article 2.1 of the TBT Agreement is identical to that contained in Article III:4 of GATT and that the criteria which are used to identify the range of like products under Article III:4 of GATT are the same as those which are used to identify the range of like products in Article 2.1 of the TBT Agreement. These criteria do not include the effects of the product on human health and we consider that they are not relevant in this case.

210. According to the Appellate Body in the case of *Japan – Taxes on Alcoholic Beverages*[103], the report of the working group on *Border Tax Adjustments* set out the principle for interpretation of the formula "like products" in general in the various provisions of GATT 1947. It must be interpreted on a case by case basis using criteria such as the product's end-use in a given market, consumers' tastes and habits, which change from country to country, and the products properties, nature and quality.[104] This approach has been followed in almost all Panel reports which have been adopted since the one concerning border tax adjustments.[105] We have followed this principle in developing our arguments that chrysotile fibre and cellulose, PVA, glass fibres as well as chrysotile-cement and fibro-cement are like products pursuant to Article III:4 of GATT and Article 2.1 of the TBT Agreement.[106] In the same case, *Japan Taxes on Alcoholic Beverages*, the Appellate Body implied that other criteria can also be utilized to identify the range of like products within the context of a particular provision of the multilateral trade agreements of the WTO Agreement.[107]

211. The example of another criterion frequently used in previous Panel reports to determine whether products are like is the tariff classification.[108] We have followed this example in the present case and invoked the uniform classification in the tariff nomenclatures of the harmonized system as a criterion to confirm that chrysotile fibre and cellulose, glass and PVA fibres, as well as chrysotile-cement and fibro-cement, are like products. The toxicity of a product, however, has never been taken as a criterion for determining whether products are like. Moreover, in this case, the effects of the substitute fibrous products on human health are too little known and uncertain to constitute a criterion which could assist the Panel in identifying the range of like products. Consequently, we are of the opinion that the Panel should only examine the criteria defined by previous practice of GATT on which we have relied in our arguments. We refer the Panel to our second written submission in which we stated that the effect of a product on human health is not a criterion that should be used to determine whether products are like.[109] Two products may be similarly toxic and not be like in the meaning of Article III:4 of GATT or Article 2.1 of the TBT Agreement. Conversely, assuming that it is clearly established that two products do not share the same toxicity, they may still be like for the purposes of Article III:4 of GATT or Article 2.1 of the TBT Agreement.

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[103] Report of the Appellate Body, page 20.

[104] Report of the Working Group on *Border Tax Adjustments*, BISD 17S/110, paragraph 18.

[105] *Australian Subsidies on Ammonium Sulphate*, BISD II/204; *EC - Measures on Animal Feed Proteins*, BISD, S25/53; *Spain – Tariff Treatment of Unroasted Coffee*, BISD 28S/108; *Japan – Customs Duties, Taxes and Labelling Practices on Imported Wines and Alcoholic Beverages*, BISD S34/92; *United States – Taxes on Petroleum and Certain Imported Substances*, BISD 34S/154. See also *United States – Standards for Reformulated and Conventional Gasoline*, WT/DS2/9, report adopted on 20 May 1996.

[106] See Section III.C.2.(b)(i).

[107] *Japan – Taxes on Alcoholic Beverages*, Report of the Appellate Body, page 20.

[108] *EC – Measures on Animal Feed Proteins*, BISD 25S/53; *Japan - Customs Duties, Taxes and Labelling Practices on Imported Wines and Alcoholic Beverages*, BISD 34S/92; *United States – Standards for Reformulated and Conventional Gasoline*, WT/DS2/9, reported adopted on 20 May 1996.

[109] See Section III.C.2(b)(i).

212. We reiterate our replies to questions 15 and 16 by the European Communities in which we explain that the scientific question of the pathogenicity of the fibres has no place in the context of an argument to show what is like pursuant to Article III:4 of GATT 1994 or Article 2.1 of the TBT Agreement. Instead, the broadest and most general criteria contained in the case law, such as characteristics, nature and quality of the product, tariff classification and product's end use should be applied.[110] Chrysotile fibre is indisputably different from amphibole fibres when it comes to toxicity[111], but we consider that chrysotile fibre and amphibole fibres are like products. Just as chrysotile fibre and amphibole fibres are like products although amphibole fibres are much more toxic, so PVA, glass and cellulose fibres and chrysotile fibres are like products by virtue of their characteristics, nature and quality, even if we do not know, given the present state of scientific research, the actual toxicity of each of these substitute fibres.[112] In our view, the effects of chrysotile fibre on human health, in the same way as those of substitute fibres, which in most cases are not known, are not relevant to the issue. The Panel should not take them into account in the context of its examination of the various characteristics of these products to establish whether they are like pursuant to Article III:4 of GATT or Article 2.1 of the TBT Agreement.

(ii) Replies by the European Communities

(a) No, the concept of "like products" in Article III.4 of GATT is not identical to the concept of "like products" contained in Article 2.1 of the TBT Agreement for the following reasons.

213. The concept of "like products" has to be interpreted in accordance with the customary rules of interpretation of public international law, that is in accordance with the ordinary meaning to be given to this concept in its context and in the light of its object and purpose.[113] It should also be recalled that the Appellate Body has held that the concept of "likeness" is a relative one that evokes the image of an accordion. The accordion of "likeness" stretches and squeezes in different places as different provisions of the WTO Agreement are applied. The width of the accordion in any one of those places must be determined by the particular provision in which the term "like" is encountered as well as by the context and the circumstances that prevail in any given case to which that provision may apply. No one approach to making a judgement will be appropriate for all cases.[114]

214. First of all, the context in which this term appears is different in the two Articles. The context of GATT Article III.4 is clearly different from that of Article 2.1 of the TBT Agreement. The TBT is a specific Agreement that elaborates further on the objectives of GATT 1994. Whereas the obligation of national treatment and the concept of "likeness" in Article III.4 of GATT 1994 have a fairly wide application "in respect of all laws, regulations and requirements affecting internal sale, offering for sale, purchase, transportation, distribution or use", the obligation of national treatment and the concept of "likeness" in Article 2.1 are confined by the specific object and purpose of the TBT Agreement, that is it applies only "in respect of technical regulations". Thus, Article 1.2 of the TBT Agreement provides that for the purposes of that Agreement the meaning of the terms given in Annex 1 thereto applies. Also the title of Article 2 reads "Preparation, Adoption and Application of Technical Regulations by Central Government Bodies". These phrases may not be read so expansively as to subvert the purpose and object of Article 2.1 and of the TBT Agreement in general. It follows that because the TBT Agreement deals only with technical regulations, standards and conformity

[110] Replies by Canada to the questions posed by the Panel and the EC at the first substantive meeting of the Panel on 1 and 2 June 1999.

[111] See Canada's observations on the replies by the experts to question 3 of the Panel.

[112] See Canada's observations on the replies by the experts to question 6 of the Panel.

[113] Article 3.2 of the Understanding on Dispute Settlement and Article 31.1 of the Vienna Convention 1969.

[114] *Japan – Taxes on Alcoholic Beverages*, AB-1996-2, WT/DS8/AB/R, p. 18.

assessment procedures related to products or processes and production methods[115] the concept of "likeness" is by definition narrower than that of Article III.4 of GATT as regards the legal context within which and the object and purpose for which the determination of "likeness" is to be made. In other words, the legal context as well as the object and purpose determine inevitably the coverage of the term "like": not all like products are covered by Article 2.1 of the TBT Agreement, but only those to which the technical regulation was intended to apply.

215. Secondly, the European Communities dispute Canada's claim that the French Decree in question lays down a technical regulation in the sense of the TBT Agreement. This is clearly not the case of the general, horizontal prohibition of any kind of asbestos as well as of the limited and transitional exceptions laid down in Article 2 thereof, as shown in our written and oral submissions. However, if we suppose, for the sake of argument, that the French Decree did lay down a technical regulation, such a regulation would only have been applicable to asbestos as such and to asbestos-containing products. Indeed, the French Decree in question has laid down no technical regulation whatsoever for the so-called "substitute" products as claimed by Canada. Canada's argument that the so-called "substitute" products are, for the purpose of Article 2.1 of the TBT Agreement, "like" asbestos and asbestos-containing products runs counter to the very object and purpose of the TBT Agreement and leads to unacceptable results from the regulatory point of view. This is because such an interpretation is likely to restrict unreasonably the regulatory freedom of the WTO Members and would introduce uncertainty and unpredictability into international trade for no valid reason. As a general rule, Members introduce technical regulations, standards and conformity assessment procedures for the purpose of achieving a legitimate objective (e.g. safety). The object and purpose of the TBT Agreement is to guard against "unnecessary obstacles to international trade" (fifth preambular paragraph) in the products covered by the technical regulation, not in the potentially vast category of alternative/substitute products, because normally no government is in a position to know in advance the category of products that are likely to be affected by the adoption of the technical regulation.[116] The concept of "like" products cannot be given so broad a reach as effectively to underline the autonomous right of Members to determine their level of health protection. In other words, to interpret so broadly the concept of "like" products is bound to present Members' regulatory authorities with the dilemma of abandoning the pursuit of a legitimate objective (e.g. safety) for the sake of avoiding a possible adverse finding under Article 2.1 of the TBT Agreement, even if there exist only a few alternative/substitute products of national origin. Such a paradoxical result can surely never have been intended by the WTO Members. It is contradictory and unreasonable to judge "likeness" on the basis of the possible effects of the technical regulation on the imported (prohibited) product, as compared to the alternative/substitute products of national origin, because a technical regulation by definition, almost always, entails different effects (negative or positive) on those products (of whatever origin) which do not conform with the technical regulation in question.

216. Thirdly, since the context, object and purpose of Article 2.1 of the TBT Agreement is different from that of Article III:4 of GATT, the four criteria usually used by panels to judge "likeness" on a case-by-case basis in the context of Article III of GATT (i.e. the product's end uses, consumers' tastes and habits, the product's properties, nature and quality, and tariff classification) may be applied in the context of Article 2.1 of the TBT Agreement but only in the light of the purpose of the technical regulation under consideration, i.e. in order to identify only whether the imported asbestos and asbestos-containing products receive, in respect of the technical regulation in question, treatment less favourable than that accorded to various asbestos (different types of amphibole asbestos, chrysotile, etc.) and asbestos-containing products (brakes, various asbestos-containing cement products, etc.) of national origin.

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[115] See Annex 1, point 2 of the TBT Agreement.

[116] The European Communities note that, as a matter of fact, a general and horizontal prohibition of a given product (as in this case) is by definition likely to increase (rather than restrict) trade in alternative/substitute products regardless of their origin.

(b) As the European Communities have explained[117] when it has been scientifically established that a product is dangerous to human health, this finding attributes a special internal and/or external characteristic to the product in question that should be taken into account in defining "likeness" in both Articles. Indeed, the scientifically established dangerous nature of a product (like that of any kind of asbestos) necessarily affects the normal criteria used by panels to define "likeness", because:

- The product's very properties, nature and quality are necessarily affected, in the sense that they are not the same as those of a safe or safer identical or alternative or substitute product. For example, an apple that contains a poisonous pesticide can never be "like" a safe apple of the same or different variety or a safe orange, when one would otherwise consider apples and oranges "like" products for the purpose of Article III:4 of GATT.

- The product's end uses are also different, because a product that has been scientifically shown to be dangerous to human health (e.g. an apple that contains a poisonous pesticide or any type of asbestos) usually does not have the same end uses as those of a safe or safer identical or similar or substitute product.

- The consumers' or end-users' tastes and habits are also bound to differ in the case of a product that has been scientifically shown to be dangerous to human health (e.g. an apple that contains a poisonous pesticide or any type of asbestos) and a safe or safer identical or similar or substitute product.

217. In reality, a product that has been scientifically shown to be dangerous to human health attributes to that product a specific characteristic that makes it unlike any other product of the same family or category (e.g. apple or asbestos) or similar or alternative or substitute products (e.g. orange or PVC fibrous product). That kind of dangerous product should not be put into international trade and no importing country should have to rely on Article 2.2 of the TBT Agreement, for example, or the exception provisions of Article XX to justify any restriction on imports.[118] It follows that the dangerous character of a product to human health is of particular relevance in the context of Article III:4 of GATT in deciding "likeness". In the context of Article 2.1 of the TBT Agreement, the dangerous character of a product to human health is also highly relevant because, in the light of the object and purpose of a technical regulation, the protection of human health is a legitimate objective that may be taken into account in the course of its preparation. This is particularly true, if the concept of "like" products in the context of Article 2.1 of the TBT Agreement is to be given the very wide meaning advocated by Canada.

Question 2: Is it possible for a measure to fall partly within the scope of the TBT Agreement while other elements of the same measure would come under GATT?

(i) Reply by Canada

218. As the Appellate Body indicated in *EC - Regime for the Importation, Sale and Distribution of Bananas*[119] and in *Canada - Certain Measures Concerning Periodicals*[120], it is possible that a measure, because it has several aspects, could be examined under more than one WTO agreement.

[117] See above Section III.C.2.(b)(I) above.

[118] The European Communities note that if such a dangerous product to human health is allowed to be imported by a Member, this is most likely because either the dangerous nature of the product is not known, not detectable or not visible, or the importing Member has a level of health protection that can cope with a risk of human health of this nature or degree.

[119] Report of the Appellate Body, para. 221.

[120] Report of the Appellate Body, page 19.

Conceptually, then, it is possible that certain aspects of a particular measure are covered by the TBT Agreement, while other aspects of the same measure, which are not covered by the TBT Agreement, are covered by GATT. However, taking account of the facts of this case, Canada is of the opinion that the French measure is a technical regulation and that all aspects of it come under the TBT Agreement. It seems to us, that in terms of methodology, the whole French measure should initially be examined in relation to the TBT Agreement; subsequently, it could be examined in relation to GATT.

219. In the above cases, the question of whether the *General Agreement on Trade in Services (GATS)* and GATT 1994 were mutually exclusive was raised because GATS does not cover the same subject as GATT. The Appellate Body decided at that time that the agreements were not mutually exclusive. The situation in this case is different. Indeed, the respective areas of application of the TBT Agreement and GATT 1994 overlap. In our reply to question 35 by the Panel, we said that "the TBT Agreement is the most recent and most specific expression of the WTO Members as to what the interpretation and application of the disciplines under GATT 1994 […] should be in the context of technical regulations and standards".[121] The two agreements cover the same subjects, the TBT Agreement being a development of GATT disciplines. It is therefore difficult to see how in practice certain specific aspects of the French measure would come under the TBT Agreement while other aspects would be governed by GATT. The TBT Agreement is more specific than GATT 1994 in the area of technical regulations. As the French measure is a "technical regulation" in the meaning of the TBT Agreement, it would seem to us appropriate first to examine the measure in the light of the disciplines in that agreement, with particular reference to the GATT disciplines. This methodological approach flows from the most recent case law on relations between the WTO Agreements, which requires that claims should first be examined under a more specific agreement rather than GATT 1994.[122] Canada maintains that the Panel should first examine all the disputed elements and aspects of the French measure in the light of the TBT Agreement.

(ii) Reply by the European Communities

220. In general, the question of deciding which WTO Agreement applies to a given measure is a problem of determining the character of the measure. In the absence of a specific provision in the relevant WTO Agreements[123], one has to examine essentially the aim and content of the measure in question. A measure that has a single and uniform aim and content should fall under one agreement. Equally, a measure that pursues several distinct or heterogeneous aims can potentially fall under several, different agreements. But not every element in a measure attributes a different, multiple aim to the measure under examination. Secondary, accessory or ancillary provisions do not necessarily alter the essential aim of the measure for the purpose of determining its legal character.[124] Therefore, the essential or principal purpose of the measure, as this is objectively expressed in its design, architecture and structure, determines its character and the applicable agreement. In defining the essential or principal objective of a measure, one has to look at the centre of gravity or predominant

[121] Replies by Canada to the questions posed by the Panel and the EC at the first substantive meeting of the Panel on 1 and 2 June 1999.

[122] *Indonesia - Certain Measures Affecting the Automobile Industry*, Report of the Panel, paragraph 14.63: "On the question of whether the allegations should first be examined under Article III:4 of GATT or Article II of the TRIMs Agreement, we believe that we should begin by examining the claims under the TRIMs Agreement since that is more specific than Article III:4 in relation to the claims under consideration. A similar question arose in the *Bananas III* case, in which the Appellate Body examined the relationship between Article X of GATT and Article 1:3 of the Agreement on Import Licensing and concluded that, since the Agreement on Import Licensing was more specific, it should be applied first."

[123] See, for example, Article 1.5 of the TBT Agreement and Article 1:4 of the SPS Agreement.

[124] See, by analogy, the findings of the Appellate Body in the *Reformulated Gasoline Case*, in which the "substantial relationship" of two positions of the gasoline rule was decided in the light of the overall aim of the basic gasoline rule: AB-1996-1, pages 17 to 18.

component of the aim pursued by the measure in question, as this emerges or becomes apparent from the measure itself.[125]

221. Therefore, the reply to the question would depend on how significant and independent the "other elements" of the measure are, in other words, whether they are capable of attributing a distinct, different and additional aim to the one principally pursued by the measure in question. Only in such a situation may some elements of a measure fall under the provisions of GATT and other elements of the same measure fall under the provisions of the TBT Agreement.

222. Applying the above principles to the French Decree in question, the Panel should conclude that it pursues only one, single, uniform aim, that is to ban the use of any kind of asbestos for the purpose of protecting human health. As the European Communities have explained at length in their written and oral submissions, this sole object of the Decree flows from the ordinary meaning of its terms in their context, the design and structure of the measure and the history of the preparatory work. The essential object and purpose of the Decree is to lay down a general, horizontal ban on the use of asbestos and asbestos-containing products. It does not relate to the preparation, adoption, and application of a technical regulation of any kind, in the sense of the TBT Agreement. Neither does it lay down a process and production method for asbestos and asbestos-containing products, simply because it bans their use.

223. One may wonder whether the limited and temporary exceptions laid down in Article 2 *et seq.* are a sufficiently important or independent element as to attribute another, separate and different aim to the Decree. As the European Communities have already explained, this is clearly not the case. Article 2 *et seq.* of the Decree state expressly that "exceptionally and on a temporary basis" certain products may continue to use chrysotile asbestos in order to ensure "an equivalent function" and so long as there exists "no substitute" for chrysotile which can ensure a lower level of risk and guarantee the same level of safety to users. This is an exception to the general ban, and exceptions by definition are to be interpreted narrowly. Article 2 *et seq.* explicitly state that the exception is temporary and will be phased out when substitute products become technically available. As the European Communities have already shown, the practice followed since the adoption of the Decree in 1996 confirms the ephemeral nature of these exceptions.[126] Consequently, these exceptions are not an essential, but rather an ancillary, accessory or subsidiary element of the Decree. They lay down no technical regulations or standards in the sense of the TBT Agreement and, therefore, cannot render the entire Decree subject to the TBT Agreement. And even if we were to assume that the exceptions do lay down technical regulations (which they do not), at best only those exceptions would fall under the scope of the TBT Agreement. But Canada does not claim that those exceptions constitute a violation of the TBT Agreement. Therefore, the question of whether some elements of the Decree (in this case the temporary exceptions) can fall within the TBT Agreement is, from a strict legal point of view, totally irrelevant to the outcome of this case.[127]

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[125] This is, for example, the way the issue of the relevant legal basis and of the applicable EC treaty provisions are determined in European Community law: see, for example, judgement of 11 June 1991, Case C-300/89, Titanium Dioxide [1991] ECR I-2867. For the problem of characterization in general under international law see, for example, J.A. Salmon, *Some Observations on Characterisation in Public International Law*, in UN Law/Fundamental Rights, Two Topics in International Law (ed. A. Cassesse, 1979), page 3 *et seq.*

[126] The EC notes, that in fact, the number of exceptions has fallen rapidly since the adoption of the French Decree prohibiting all kinds of asbestos. Thus, in 1997, 87 enterprises used 1,200 tonnes of asbestos under all the permitted exceptions. In 1998, only 63 enterprises used 200 tonnes, 40 per cent of which was used by a single enterprise to produce "waterproof seals" (Latty-Soffa seal). In 1999, the number of enterprises fell to 25 with a volume of only 50 tonnes, 80 per cent of which was used by a single enterprise to produce chlorine (chloride).

[127] According to the EC, this proposition finds implicit support in the decision of the Appellate Body in the *Reformulated Gasoline* case, where it discussed the term "measures" for the purpose of deciding whether the

Question 3:

(a) In assessing the conformity of a measure with Article XX of GATT, what would be the relevance of any practical difficulties encountered by a country in implementing a measure, in assessing whether the measure was reasonably capable of achieving the objectives of its health policy?

(b) In assessing the conformity of a measure with Article 2.2 of the TBT Agreement, what would be the relevance of any difficulties in the practical implementation of a measure in evaluating whether it was less trade-restrictive than the measure in place?

(i) Reply by Canada

Reply 3(a)

224. Canada is of the opinion that any claims of practical difficulties inherent in the implementation of a measure are not a factor to which any weight should be given in assessing the reasonable availability of a measure as a less trade-restrictive alternative. In considering a measure in the light of the criteria of necessity in Article XX of GATT, the practical difficulties of implementing an alternative to the measure under dispute – if such exist – do not detract from the alternative or exclude it as a less trade-restrictive alternative. In the context of the test of necessity, assessing the legality of a measure in the light of so-called practical difficulties encountered in implementing it would be to reward laxity in implementing a measure and compensate administrations for their inefficiencies. It would then become easy for Members to evade the GATT disciplines, because they would simply have to allege practical difficulties in implementation – i.e. the inefficiency of their own administration – to exclude a less trade-restrictive alternative measure, and thus escape the GATT disciplines. In the light of the application of the test of necessity in Article XX of GATT, a Member that generally devotes significant resources to overcoming practical difficulties in implementing a regulation and which can pride itself on the efficient administration of its regulatory framework would be penalized vis-à-vis a Member who decided to deploy few resources to implement regulations or which proved to be lax in that regard. To assess, in the context of analysing Article XX of GATT, whether an alternative measure is reasonably available in the light of the existence or otherwise of practical difficulties in implementing it would be a dangerous precedent which would weaken the test of necessity, produce Kafkaesque results and lead to pernicious effects on a systemic scale. In this respect, the decisions of the Panel and the Appellate Body in the case of *United States – Standards for Reformulated and Conventional Gasoline*[128] support Canada's position. In that case, Venezuela and Brazil complained about the discriminatory nature of the American standards on gasoline, which were aimed at environmental protection. The United States unsuccessfully used as a defence the general exceptions in Article XX of GATT. It is clear from both the decision of the Panel and of the Appellate Body that under the regime of the test of necessity in Article XX of GATT, practical difficulties in the implementation of an alternative measure do not exclude that measure as a less trade-restrictive measure.

225. In the case of *United States – Standards for Reformulated and Conventional Gasoline*, the United States pleaded, as in this case do the European Communities, that the alternative measure

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entire Gasoline Rule or only the baseline establishment rules fell within the scope of Article XX(g). It explained that "*The Panel report did not purport to find the Gasoline Rule itself as a whole, or any part thereof other than the baseline establishment rules, to be inconsistent with Article III.4; accordingly, there was no need at all to examine whether the whole of the Gasoline Rule or any of its other rules, was saved or justified by Article XX(g)*". See AB-1996-1, p. 12.

[128] *United States – Standards for Reformulated and Conventional Gasoline*, WT/D52/R (decision of the Panel), adopted 20 May 1996.

invoked – the establishment of individual baselines for foreign refiners – was not reasonably available and could not be upheld because it presented practical difficulties in implementation. In support of their argument under Article XX of GATT, the United States submitted to the Panel that the application of an individual baseline to foreign refiners was not feasible for three reasons: (i) the impossibility of determining the refinery of origin of each imported cargo; (ii) the temptation for exporters and importers to "manipulate" the system; (iii) the difficulty for the United States of assuring compliance by foreign refineries with the Gasoline rule, since, to be effective, that, it was supposed, would require penal and civil sanctions.[129] In its communication to the Appellate Body, the United States reiterated its positions:[130]

> "The impracticability of verification and enforcement of foreign refinery baselines in this instance shows that the 'discrimination' is based on serious, not arbitrary or unjustifiable concerns stemming from different conditions between enforcement of its laws in the United States and abroad. (Footnote omitted)."

226. The Panel rejected the American argument based on the practical difficulties of implementing individual baselines for foreign refiners.[131] The Appellate Body, for its part, although its decision mainly related to Article XX(g) of GATT and the introductory paragraph of Article XX of GATT, cited and approved the reasoning of the Panel concerning the incidence of practical difficulties in implementing individual baselines for foreign refiners on the application of the test of necessity in Article XX. Thus, the Appellate Body states:[132]

> "The United States stated that verification and enforcement of the gasoline rules requirements for imported gasoline are 'much easier when the statutory baseline is used' and that there would be 'a dramatic difference' in the burden of administering requirements for imported gasoline if individual baselines were allowed.
>
> While the anticipated difficulties concerning verification and subsequent enforcement are doubtless real to some degree, the Panel viewed them as insufficient to justify the denial to foreign refiners of individual baselines permitted to domestic refiners. (Footnotes omitted)".

227. It is interesting to note that the Appellate Body, like the Panel, recognizes that the practical difficulties of implementing the alternative measure are indeed real. That does not prevent them from considering it as a measure reasonably available to achieve the environmental objectives pursued by the United States. The Appellate Body thus confirms the reasoning and conclusions of the Panel whereby the existence of practical difficulties in implementing an alternative measure do not disqualify it as a less trade-restrictive alternative, under the test of necessity.[133] For the Appellate Body and the Panel, an alternative measure fulfils the test of necessity even if the measure preferred by the defending party is "much easier" to implement than the alternative measure, and that there is "dramatic difference" in the administrative burden between the measure under consideration and the alternative. For the Appellate Body and the Panel, the alternative measure will be excluded only if it is clearly impossible to implement it.[134] The decision of the Appellate Body and the Panel in *United States – Standards for Reformulated and Conventional Gasoline* clarify the principles outlined by the Panel in *United States – Section 337 of the Tariff Act of 1930*.[135] The decisions of the

[129] Report of the Panel, paragraph 3.42 and 6.23.

[130] Paragraph 55 of the appellant's communication, dated 4 March 1996, cited in the report of the Appellate Body on page 24.

[131] Report of the Panel, paragraph 6.26 to 6.29.

[132] Report of the Appellate Body, page 24.

[133] Report of the Appellate Body, pages 24-25.

[134] Report of the Panel, paragraph 628: "(…) the statutory baselines would only be applied if it was impossible to determine the source of the imported gasoline or to establish a baseline for lack of data" Report of the Appellate Body, page 25: "we agree with the finding made in the Panel report".

[135] L/6439, BISD 6S/386 to paragraphs 5.30 to 5.35 of the Panel Report adopted on 7 November 1989.

Appellate Body and the Panel *in United States – Standards for Reformulated and Conventional Gasoline* can be seen also as an extension of the Panel's decision in *United States – Section 337 of the Tariff Act of 1930.* It should be recalled that in that case, the Panel had rejected the basic American claims that the disputed provision met the test of necessity under Article XX(d) of GATT 1947 "because of difficulties with service of process on and enforcement of judgement against foreign manufacturers."[136]

228. Concerning the dispute between Canada and the European Communities regarding measures concerning asbestos and products containing asbestos, Canada's position in relation to the problem of practical difficulties in implementation hinges on two points. Firstly, we maintain that to achieve its objective of protecting human health, the French Government had available to it an alternative less trade-restrictive measure. Instead of acting in haste and under pressure from its public opinion, it could have introduced a regulatory framework under which prohibitions and authorizations of products containing asbestos would have been established in a rational manner on the basis of two guiding principles: (i) assessment of the risks on a product-by-product and use-by-use basis; (ii) analysis of the feasibility and effectiveness of controlled use for each product. Canada maintains that such a regulatory framework would not be difficult to implement in practice and that it would not be impossible to introduce. In that light, Canada maintains that there is a less trade-restrictive and reasonably available alternative measure to achieve the objectives pursued by France. Secondly, Canada maintains that in any case and as a general rule, any practical difficulties in implementing a measure are not a factor to be considered in assessing whether the measure is reasonably available and applying the test of necessity under Article XX of GATT, unless it is clearly established that these practical difficulties make implementation absolutely impossible. Canada's position relies partly on the cases of *United States – Standards for Reformulated and Conventional Gasoline* and *United States – Section 337 of the Tariff Act of 1930* and, secondly, on the conviction that taking account of the practical difficulties of implementation in applying the test of necessity would weaken the GATT disciplines by indirectly rewarding laxity and inefficiency.

Reply 3(b)

229. The European Communities and Canada agree that: (i) Article 2.2 of the TBT Agreement contains a test of necessity; (ii) the analysis involved in this test of necessity is similar to that relating to the test of necessity in Article XX:(b) of GATT. Consequently, our reply to question 3(a) on Article XX of GATT applies equally to Article 2.2 of the TBT Agreement. In particular, the principles formulated by the Panel and the Appellate Body in *United States – Standards for Reformulated and Conventional Gasoline* cited in Canada's reply to question 3(a) are wholly applicable in the context of the test of necessity in Article 2.2 of the TBT Agreement.

(ii) Reply by the European Communities

230. All the Panel and Appellate Body reports that have examined so far the test of "necessity" under Article XX:(b) of GATT have come to the conclusion that a restrictive measure taken by a Member is not necessary if an alternative measure, which that Member could reasonably be expected to employ and which is not inconsistent with other GATT provisions, is available to it.[137] A careful look at the rationale of the Panels demonstrates that the alternative measure must be: (i) effectively available to the Member in question; (ii) reasonably expected to be employed; (iii) not inconsistent or less inconsistent with other GATT provisions; (iv) capable of ensuring the Member's desired level of health protection. Thus, in the *Section 337* report the Panel held that " neither Article III:4 nor Article XX:(d) puts obligations on contracting parties specifying the level of protection that they

[136] Report of the Panel, paragraph 5.30.

[137] See, e.g, *Section 337* Panel report, BISD 36S/345, para. 5.26; *Thai Cigarettes* Panel report, BISD 37S/200, paragraph 75; *Reformulated Gasoline* Panel report, WT/DS2/R, paragraph 6.22-6.28.

should accord to patents or the effectiveness of procedures to enforce such protection".[138] Consequently, the Panel held that:

- A different scheme for imports alleged to infringe process patents established by *Section 337* was not necessary because the alternative of granting jurisdiction to civil courts over imports of products manufactured abroad was available and actually applied both in third countries and by the United States (paragraph 5.28);

- Presidential review in order to secure compliance with United States patent legislation and the difficulties with service of process on and enforcement of judgments against foreign manufacturers was not objectively necessary mainly because no equivalent requirements were applicable involving products of domestic origin (paragraphs 5.29 and 5.30);

- a system for the enforcement of *in rem* orders was necessary because it would "generally be more difficult" and "seldom feasible" to secure enforcement of the rulings of a court in the country of production. The alternative measure (i.e. an action *in personam*) was judged to be not "an adequate substitute … in all cases" because, *inter alia,* importers might be "very numerous and not easily" brought into a single judicial proceeding (paragraph 5.31). For these reasons the panel concluded that there could be "an objective need" in terms of Article XX:(d) to apply limited *in rem* exclusion orders to imported products only. On this point, therefore, the lack of an alternative feasible and equally efficient measure played an important role in deciding "necessity";

- exclusion orders which were automatically enforced by the United States customs service were also found to be necessary because such enforcement at the border was considered to be "a means necessary to render such orders effective" (paragraph 5.33).

231. In the *Thai Cigarette* case the Panel found that the reasons advanced by Thailand to justify the import restrictions at issue were to protect the public from harmful ingredients in imported cigarettes and to reduce the consumption of cigarettes. So the measures were intended to ensure the quality and reduce the quantity of cigarettes sold in Thailand. But the Panel found that the Thai concerns about the quality of cigarettes consumed could be met "with strict, non-discriminatory labelling and ingredient disclosure regulations … coupled with a ban on unhealthy substances" (paragraph 77). As regards the Thai concerns about the quantity of cigarettes consumed, the Panel noted the view expressed by WHO that demand for cigarettes, in particular by the young, was influenced by cigarette advertisements and that bans on advertisements could therefore curb demand, and that Thailand could also restrict the supply of cigarettes by maintaining governmental monopolies on the importation and domestic sale of products. Consequently, the Panel concluded that Thailand's practice of permitting the sale of domestic cigarettes while not permitting the importation of foreign cigarettes was not necessary within the meaning of Article XX:(b) of GATT (paragraphs 78-81) .

232. In the *Reformulated Gasoline* case, the Panel examined carefully all the arguments of the United States in order to determine whether it was practically feasible to assign to foreign producers an individual baseline so as to enable imported gasoline to benefit from the same favourable sales conditions under the *Gasoline Rule* as domestic gasoline. The Panel held that preventing imported gasoline from benefiting from as favourable conditions of sale as domestic gasoline was not necessary to achieve the stated goals of the *Gasoline Rule*, that is to reduce air pollution resulting from the consumption of gasoline. The reasons on which the Panel based its findings were that the

[138] Panel report on Article 337, *supra,* paragraph 6.1.

United States had not satisfied its burden of proving that it was "not feasible" to establish individual baselines for foreign producers, or that there were any reasons that "precluded the effective use" of individual baselines, or that there were "any particular difficulty" sufficient to warrant the method of establishing baselines used by the United States (paragraphs. 6.23-6.26). It also found the that United States did not meet its burden of showing whether the "gaming" concern "would actually occur", and that slightly stricter overall requirements on non-degradation of gasoline could not be implemented by the United States "at any time" (paragraph 6.27). The Panel also found that "the imposition of penalties" on importers was "an effective enforcement mechanism" used by the United States in other settings, because the United States had not demonstrated that the data available from foreign refiners was "inherently less susceptible" to established techniques of checking, verification, assessment and enforcement than data for other trade in goods subject to United States regulation (paragraph 6.28).[139]

233. In consequence, in order to decide whether an alternative measure is reasonably available, panels have looked at the specific facts of each individual case. In all the three Panel Reports mentioned above, the Panels identified specific alternative measures that were objective, effective and constantly available to the Member applying the inconsistent measure in question. They also found that theoretical or potential measures, i.e. measures that were not real, feasible and as effective in practice as the measure applied, were not enough. The Panels and the Appellate Body appear, almost invariably, to have judged a measure not necessary, simply on the grounds that the same or an equivalent measure was not applied to products of domestic origin. They also found that the effective alternative measure should be clearly capable of achieving the pursued legitimate objective (i.e. achieve the desired level of health protection). It follows that objective difficulties in the effective application of the possible alternative measure that risk compromising the desired level of protection render the measure in question not reasonably available and one not reasonably expected to be employed by the Member.

234. To reply specifically to the Panel's question, objective difficulties in the practical application of a measure play a crucial and determining role in deciding whether that measure is a reasonably available alternative measure to the one actually applied by a Member. As the European Communities have already explained in their written and oral submissions, the possible difficulties in the practical application of a measure may be of a wide and diverse nature, e.g. practical, technical, legal, economic, scientific or a combination of two or more of these reasons. The European Communities have already identified in its submissions a large number of such objective difficulties. The scientific experts have also confirmed those difficulties, in writing and orally. The outcome of their evaluation was that all these difficulties render "controlled use" not feasible or practicable. In deciding whether an alternative measure is reasonably available, Panels have to examine whether it is objectively available, feasible, effective and proportional to the pursued legitimate objective of protecting human health. In so deciding, one should always keep in mind that Article XX:(b) of GATT clearly allows contracting parties to give priority to human health over trade liberalization.[140] Therefore, the result in this particular case is that so called "controlled use" does not achieve the level of health protection desired by France.

235. The same applies in the context of Article 2.2 of the TBT Agreement. Possible objective difficulties in the practical application of a measure play an equally crucial and determining role in deciding whether that measure is less restrictive on trade than the one actually applied. The text of Article 2.2 is clearer on this point because it provides that when applying the necessity test ("creating unnecessary obstacles to international trade" and "more trade-restrictive than necessary"), panels should take into account "the risks that non-fulfilment of the legitimate objective would create". This clarification imparts meaning to the concept of necessity and indicates the nature of the measure under examination, because the mere existence of a possible alternative measure will not render the measure

[139] The findings of the Panel on these points were confirmed on appeal, pages 29-30.
[140] See, for example, the Panel Report in *Thai Cigarettes*, paragraph 73.

actually applied more trade-restrictive if the former cannot achieve the desired level of health protection.

236. Under Article 2.2 of the TBT Agreement, as under Article XX:(b) of GATT, the possible objective difficulties in the practical application of a measure may be of a wide and diverse nature, e.g. practical, technical, legal, economic, scientific or a combination of two or more of these reasons. Article 2.2, *in fine*, provides some examples, *inter alia*, of the elements that Members (and Panels) may take into account in deciding the less trade-restrictive nature of the measure actually applied and whether an alternative measure, which can fulfil the pursued legitimate objective, is reasonably available to the Member in question.

237. Without going as far as Article 5 of the SPS Agreement, Article 2.2 of the TBT Agreement nevertheless goes textually further than Article XX:(b) of GATT, because it explicitly links the necessity test with an assessment of the risks to human health and the design and structure of the measure under examination. Moreover, by analogy, Article 5.6 of the SPS Agreement and the notes thereto clarify that "a measure is not more trade-restrictive than required unless there is another measure, reasonably available taking into account technical and economic feasibility, that achieves the appropriate level of sanitary or phytosanitary protection and is significantly less restrictive on trade". Although the principles and provisions of the SPS Agreement are not applicable in the context of GATT and the TBT Agreement, the underlying philosophy of these provisions may nevertheless assist us in interpreting Article XX:(b) of GATT and Article 2.2 of the TBT Agreement as regards the need, for the purpose of judging the necessity of a measure, to take into account the risks to human health arising from difficulties in the practical application of a measure.

238. Applying the above principles to the facts of the present case, it is clear that a number of practical, technical, legal, economic and scientific reasons do exist such that there is no alternative measure reasonably available to France to the total ban on all kinds of asbestos. The European Communities have discharged their burden of proof, because the reports of numerous competent international institutions (e.g. the WHO Environmental Health Criteria Report Number 203 and the IARC Monographs) clearly confirm the findings of the INSERM Report, and the scientific experts chosen by the Panel fully endorsed INSERM's findings and the arguments of the European Communities. In the case of a substance that has been classified officially as a proven human carcinogen and for which it is impossible to establish scientifically an exposure threshold and when there is a vast category of persons that may be exposed to it because of the diverse nature of their activities, difficulties in the practical application of so-called "controlled use" make it clearly not a reasonable alternative measure for France, in the sense explained above, to the total ban on any kind of asbestos. Canada's belated attempt to limit the scope of this dispute to high density chrysotile-containing cement products flies in the face of the available scientific evidence.[141] For example, the WHO Report Number 203 states:

> "Some asbestos-containing products pose particular concern and chrysotile use in those circumstances is not recommended. These uses include friable products with high exposure potential. Construction materials are of particular concern for several reasons. The construction industry work force is large and measures to control asbestos are difficult to institute. In-place building materials may also pose risk control to those doing alternations, maintenance and demolition. Minerals in place have the potential to deteriorate and create exposures."[142]

[141] The European Communities note that Canada has never claimed in its request for consultations or in its request for the establishment of the Panel that the scope of this dispute is about high density chrysotile-containing cement products. Also, the terms of reference of the Panel do not contain such a provision. Furthermore, Canada has been exporting only chrysotile asbestos as a raw material, not high density chrysotile-containing cement products.

[142] Point 3 of the conclusions and recommendations, WHO Report Number 203.

239. These WHO findings have been fully endorsed by all four scientific experts chosen by the Panel. The available evidence and the experts consulted by the Panel concur with the European Communities in saying that so-called "controlled use" is not really feasible or practicable. Moreover, it is important to emphasize that the available evidence and the experts also confirm that even if "controlled use" were feasible in practice, in those cases where it might be applicable it is still inherently not effective because it cannot eliminate all risks. Canada has never argued that there was "no risk" at low levels of exposure, but merely that it becomes "undetectable". The available evidence and the experts consulted by the Panel (including one of the experts of Canada, Dr. McDonald) confirmed during the meeting with the experts on 17 January that the linear model is appropriate and that there is no scientifically established threshold of exposure below which there is no risk. The experts also agree with the European Communities that to apply "controlled use" would entail very serious health risks as well as technical, administrative and economic costs to France. They also agree that the application of administrative controls and fines do not act as a real deterrent, because too many and serious violations still occur very frequently in countries which do not prohibit asbestos completely but simply try to control its use. Therefore, the risks associated with asbestos in place and the measures taken to deal with them are not relevant in deciding whether the "controlled use" proposed by Canada is a reasonable alternative measure to the total prohibition of asbestos. In the absence of any discrimination in the application of the total ban, the legitimate health objective pursued by France by far outweighs any economic benefits to Canada. Once again, the European Communities would like to emphasize that under Article XX(b) of GATT a WTO Member has the right to determine its level of protection as it considers appropriate. The European Communities would also like to emphasize that under Article 2.2 of the TBT Agreement a WTO Member is entitled to take measures "taking account of the risks non-fulfilment would create", and that the ultimate risk in the case of asbestos is death. The European Communities have established in their submissions and oral statements that lung cancers, mesotheliomas and other asbestos-related diseases occur despite the appropriate use of adequate protection. Hence, the European Communities' objective to eliminate the risks induced by asbestos cannot be met by so-called "controlled use", even if it were feasible in practice.

Question 4: Can Canada and the European Communities expand on their arguments concerning the implementation of measures relating to the use of chrysotile asbestos and its various applications (i) in Canada; (ii) in France prior to the prohibition imposed by the Decree. In particular, for France and Canada respectively, are there any data on the effectiveness of inspection and surveillance measures designed to ensure compliance with the regulations concerned, in particular in the various activities relating to the building industry? If yes, what do they show?

(i) Reply by Canada

240. Controlled use in Canada involves strict control of average concentrations of asbestos fibres in the workplace, the prohibition of friable products containing asbestos and the adoption of measures to ensure the health and safety of workers exposed to friable asbestos in place and chrysotile in high density products. Thus, controlled use consists of regulation, workplace inspections (especially construction sites), prevention through information and training and registration and monitoring the health of workers exposed to asbestos. In Canada, these measures normally come under the responsibility of the provinces and as the only Canadian asbestos mines are in Quebec and that is where the bulk of the chrysotile industry is located, our analysis focused on the situation in Quebec.

Existing legislation and regulations

241. The Quebec system of health and safety at work is the result of a broad consensus; it is the social contract which binds over two million workers and their employers in relation to occupational health and safety. In order to establish the rights and obligations of each, and to put in place the means to exercise them, Quebec passed the *Occupational Health and Safety Act* (LSST)[143], which covers prevention and the *Occupational Accidents and Diseases Act* (LATMP)[144], covering workers compensation and rehabilitation. This legislation makes employers and workers responsible for health and safety in their workplace. The Occupational Health and Safety Commission (CSST) is responsible for enforcing it. There are several implementing regulations under this legislation concerning the whole raft of pollutants present in the workplace. In the case of the LSST, we would draw attention in particular to the *Regulation on the Quality of the Workplace* (Regulations)[145] and the *Code of Safety for Construction Works (the Code)*.[146] In 1989, the Quebec Government amended all the legislation and regulations covering the workplace in order to take account of the provisions of Convention 162 of the International Labour Organization (ILO) concerning Safety in the Use of Asbestos.[147] The Regulations and the Code govern working conditions in chrysotile mines, in plants manufacturing asbestos products, in enterprises specializing in maintenance of buildings and removal of asbestos flockings in Quebec and in the construction sector. Among other things, Section 3 of the Regulations governs air quality by prescribing the applicable standards, protective equipment and control measures for some 600 air pollutants in the workplace, including chrysotile asbestos. Annex A of the Regulations sets out the acceptable levels of exposure to dust. The weighted average exposure level for chrysotile asbestos is 1 f/ml. Article 5 of the Regulations provides that any establishment whose operations may lead to the emission of dust in the workplace must be operated so as to ensure that the concentration of dust, in the workers' respiratory area, does not exceed the levels laid down in the regulations for any indicated period of time. Article 5 of the Regulations also provides that the use of crocidolite, amosite or a product containing either of these substances, is prohibited unless there is no reasonable and practicably feasible alternative.[148] Subsection 3.23 of the Code applies to any construction site where work is carried out that may lead to the emission of asbestos dust.

242. The Code prohibits the spraying of a surface with a mixture of friable materials containing asbestos and the installation of friable insulation materials containing asbestos. In order to ensure the application of adequate protection measures, construction sites are divided into three categories: (1) low risk; (2) moderate risk; and (3) high risk. Sites where low risk work is carried out include installation, handling or removal of manufactured articles containing asbestos, provided that they are and remain in a non-friable condition, such as an asbestos-cement product. They also include sawing, cutting, machining and drilling of an asbestos-cement product with manual tools or electric tools equipped with a dust extraction system with a high performance filter. The Code provides that on a site where low risk works are carried out, such as sawing, cutting, machining, drilling of an asbestos-cement product with manual tools or electric tools equipped with a dust extraction system with high-performance filter, the employer must ensure that any worker present in the working area wears a breathing mask. The wearing of breathing masks is, however, not required for work such as installation, handling or removal of an asbestos-cement product. Sites where high risk work is carried out, include, for example, handling or removal of friable materials containing asbestos, by spraying a binding agent, and utilization of electric tools, not equipped with a dust extraction system with a high

[143] *Loi sur la santé et sécurité du travail,* L.R.Q., c. S-2.1.
[144] *Loi sur les accidents du travail et les maladies professionnelles,* L.R.Q., c. A-3.001.
[145] *Règlement sur la qualité en milieu de travail.*
[146] *Code de sécurité pour les travauxs de construction.*
[147] Convention concerning Safety in the Use of Asbestos (Convention 162), adopted on 24 June 1986, International Labour Conference, Geneva.
[148] See also Article 3.23.3.1 of the *Code of Safety for Construction Works*.

performance filter, for grinding, cutting, drilling or sanding an asbestos-cement product. On sites where high-risk work is carried out on friable materials in place, the employer must comply with much stricter requirements. These include wearing breathing apparatus of the semi or full mask type, sampling of the concentration of respirable asbestos fibres in the air in the working area at least once a shift, provision of protecting clothing to workers, providing workers with lockers for work clothing and personal clothing, provision of a shower room, isolation of the working area and the locker room for work clothes from the remainder of the building by a sealed partition equipped with an extraction ventilation system. The Code also provides that before work is commenced that might result in the release of asbestos dust, the employer must train and inform workers on the risks, methods of prevention and safe working methods. The training and information programme must include the employers general obligations, the effects of asbestos on health, the applicable standards and the sampling to be carried out, the workers rights and obligations, personal and collective protection measures and equipment, tasks to be carried out and the equipment or tools to be used, safe working methods and procedures, and methods of prevention and control.

Role of the Occupational Health and Safety Commission (CSST)

243. The Occupational Health and Safety Commission (*Commission de la Santé et de la Sécurité au Travail*) fulfils its administrative functions in a variety of ways. It is concerned, *inter alia*, to prevent occupational injuries while at the same time playing the role of public guarantor for employers and workers alike. In addition, the CSST provides workers and employers with the services to which they are entitled. In the case of prevention it is involved in promoting occupational health and safety, assistance to workers and employers in their efforts to improve their working environment and eliminate hazards, and workplace inspections. The role of the CSST is mainly focused on prevention, specifically through the comprehensive analysis of the causes of occupational accidents and diseases. Consequently, when it investigates a work place, all the chemical and physical pollutants, including chrysotile asbestos, and all working constraints are taken into account. The CSST requires the employer to implement a prevention programme. The prevention programme also includes a health programme, which involves monitoring workers' health for the prevention and early detection of any medical condition caused or aggravated by work.

Implementation of controlled use

244. In workplaces where, *inter alia*, chrysotile asbestos is found, a variety of actions for implementing the legislation and regulations under ILO Convention 162 has been carried out in recent years. More specifically, we present data for which we have performance indicators relating to inspection, health services, training and information for workers in a variety of environments, in particular, the construction industry.

245. Inspection: When an inspector investigates a construction site or an industrial establishment, he opens an investigation file and visits the work site on one or more occasions. During his visit, he may find various breaches of the regulations concerning chemical and physical pollutants and other provisions on occupational health and safety. He may take a number of actions, including closing the site which means halting the work until the appropriate remedial measures are put in place. The record of activities of the inspection service of the CSST in the construction sector show that in Quebec in 1999, 14,928 inspections were carried out in all areas of economic activity, including 5,171 inspections of construction sites. These inspections gave rise to 234 occupational health and safety proceedings relating to asbestos. The main reasons for proceedings were the following: lack of lockers or showers, failure to isolate the working area and the locker room from the remainder of the building by means of a sealed partition equipped with a dust extraction and ventilation system (37 cases)[149], failure to dampen friable materials containing asbestos during removal works and failure

[149] *Code of Safety for Construction Works*, Article 3.23.16.

to use a dust extraction system equipped with a high-performance filter to remove debris containing asbestos (28 cases)[150], failure to provide disposable protective clothing or reusable protective clothing (27 cases)[151], and failure to take daily samples of the concentration of respirable asbestos fibres in the air in the working area (5 cases).[152] Eighteen sites were closed for non-compliance with standards. We should emphasize that in 1999, all asbestos-related occupational health and safety proceedings on building sites concerned exclusively friable asbestos products and not asbestos-cement products.

246. Training and information: The various training sessions developed and delivered by partner bodies in the occupational health and safety network are targeted at several types of client and, for that reason, the content and length varies. In 1997, the CSST took stock of its continuous training programmes for its inspectors and that led to the development of a specific training module on asbestos. As a result, in 1998 and 1999, the CSST delivered two types of training on chrysotile asbestos, a three-day course aimed at inspectors in the construction sector and specialists in the health network, and a two-day course for inspectors in industrial establishments. So far, the CSST has delivered eight two-day courses in which 77 inspectors participated. The three-day training sessions provided training for 80 construction sector inspectors and some 30 people from the health network. At the beginning of June 1999, in collaboration with its partners, the CSST launched the programme for the prevention of occupational diseases related to asbestos exposure. Aimed this time at workers and employers, the programme focuses on prevention measures to be taken not only on renovation and demolition sites, but also in repair and maintenance work. The objectives are to inform about appropriate working methods and suitable protective equipment for all work, which may give rise to the release of asbestos dust and ensure that they are used.

247. For its part, the joint sectoral association for occupational health and safety in the construction sector (ASP-Construction) has, since 1992, been offering a four-hour training course for construction workers. The course on asbestos safety meets the requirements on Article 3.23.7 of the Code. The participants in this course are mainly general labour, insulation appliers, pipe fitters, electricians, fire protection engineers, demolition workers etc.. The following table shows the annual distribution of data for this course provided by the ASP-Construction Consultants:

Year	Number of Courses	Number of Participants
1999	67	946
1998	34	509
1997	60	532
1996	31	350
1995	36	407
1994	12	136
1993	39	698
1992	16	245
TOTAL	295	3,828

248. Concerning information activities, the following table shows the annual breakdown of ASP-Construction data for the distribution of the *Prevention Guide for Asbestos* and notices to be placed at the entrance to every site when moderate or high risk works are carried out:

[150] *Idem.*, article 3.23.9 and 3.23.10.
[151] *Idem.*, article 3.23.15 and 3.23.16.
[152] *Idem.*, article 3.23.16.4.

Year	Number of Guides	Number of Notices
1999	2,044	931
1998	936	410
1997	1,342	811
1996	857	415
1995	855	415
1994	614	560
1993	1,002	349
1992	1,272	723
TOTAL	8,922	4,614

249. A few firms specializing in occupational health and safety also provide eight-hour training sessions on chrysotile asbestos. The data for 1997, 1998 and 1999 are as follows:

Number of Sessions	Number of Participants	Type of Enterprise
350	4,600	GOVERNMENTAL INSTITUTIONS BOARDS OF EDUCATION UNIVERSITIES HOSPITALS ALUMINIUM WORKS PULP AND PAPER FACTORIES PRIMARY SECTOR FACTORIES SECONDARY SECTOR FACTORIES

250. Health services: In the Montreal region, in September 1998, there were 23 establishments using chrysotile in their processes or operating plants which could cause occasional exposure of workers to chrysotile:

Establishments using Chrysotile in 1999

Economic Sector	Number of Establishments	Total Number of Workers
Rubber products	1	8
Manufacture of metal products	5	225
Transport components (wheels and brakers)	6	803
Rail components (reconditioning)	2	1,728
Refitting of ships	3	91
Waterproof seals	2	21
Chemical industry	1	10
Storage (other)	1	50
Adhesives	1	70
Corrugated cardboard cartons	1	238
TOTAL	23	3,244

251. The preventative measures in place in these establishments include regular medical supervision, environmental monitoring, respiratory protection and information on health risks. All of these actions are encompassed in each establishment's prevention programme.

Controlled use in France and the United States

252. We note that the French system for registering asbestos in place does not require the inclusion of chrysotile cement products.[153] It appears that France, in its approach to management of the risks related to the use of asbestos, is not concerned with chrysotile cement products which do not present any detectable risk to health. The INSERM data are quite clear about the efficiency of controlled use in the French manufacturing industry. Of 2,480 people working in the asbestos processing sector in France in 1994, only two (0.1 per cent of workers) were exposed to concentrations of over 0.6 f/ml.[154] Consequently, it is difficult to talk of the impossibility of controlled use in the processing industry when compliance with exposure standards throughout the territory of France required only one intervention concerning two workers. The American experience also shows the effectiveness and practicability of implementing a controlled use policy. As pointed out by Canada at the second substantive meeting, the OSHA in the United States only recorded 16 cases of exceeding the maximum exposure levels of 0.1 f/ml throughout America in the year 1998-1999.[155] It should be noted, furthermore, that those exposures were related to friable materials, whose use is proscribed under the principles of controlled use as set out in international standards and by Canada. Yet again, hard to speak of ineffectiveness and the impossibility of controlled use.

Conclusion

253. All the above data shows that here have been many and varied preventative activities relating to chrysotile asbestos used in various working environments, including the construction sector. They effectively take account of the various provisions contained in the legislation and regulations. It is difficult in the case of asbestos to use medical performance indicators because of the latent period of the various pathologies related to exposure to chrysotile. But all these preventative measures make it possible to monitor exposure and to react in cases where limits are exceeded as the result of an incident, of whatever nature, in the working environment.

(ii) Reply by the European Communities

254. In France, the implementation of measures relating to the use of chrysotile asbestos and its various applications was completed in several stages, starting from the date when the carcinogenic nature of asbestos was recognized by the IARC (International Agency for Research on Cancer), in 1977. The first phase, covering the 1970s, was centred on the production sector, in the course of which France: (i) laid down specific rules for the use of asbestos in the manufacturing sector and transformation of asbestos-based products; (ii) restricted its use with a view to protecting the population. A second phase, covering the period of the 1980s and the first half of the 1990s centred on restrictions on use, during which the European directives came in: (i) strengthening workers' protection in the manufacturing and transformation sectors; (ii) setting down rules for protection in the case of removal of asbestos; (iii) progressively eliminating the most dangerous varieties of asbestos; (iv) prohibiting the most dangerous uses; (v) restricting the use of asbestos in general, including the use of chrysotile. A third phase, from 1995 onwards, is centred on the repair and maintenance sectors, in the course of which France is concerned to: (i) take into account the risks

[153] See Decree 97-855 and Decree 97-1219.
[154] INSERM, *Report on the Effects on Health of the Main Types of Exposure to Asbestos*, page 73.
[155] See [OSHA, 3349 standards cited, 19101001 or 19261101 issued FY (October 1998 to September 1999), Nationwide].

faced by repair and maintenance workers; (ii) strengthen workers' protection on sites where asbestos is removed and in certain residual asbestos processing centres; (iii) strengthen protection of the public.

First phase (1970s)

255. Following the recognition by the IARC, in 1977, that asbestos was carcinogenic, the French authorities issued specific regulations in order to ensure protection of workers against asbestos-related risks (Decree No. 77-949 of 17 August 1977 on Specific Hygiene Measures Applicable in Establishments where the Workforce is Exposed to the Action of Asbestos Dust, hereinafter "the 1977 Decree")[156]. The provisions of that Decree supplemented the general measures on protection of workers and sanitary conditions in occupational premises and general rules of hygiene applicable to all places of work. During the same period, asbestos flockings were prohibited in buildings (Decree No. 78-394 of 20 March 1978 on Prohibition of Flockings in all Buildings). The overall provisions of the 1977 Decree imposed constraints on employers both in terms of collective protection of workers (for example: encasing of industrial systems and devices, humidification, dust extraction and ventilation of premises, compulsory monthly or quarterly removal of dust, maintenance of common protection equipment), and individual protection of workers (in particular, free provision of breathing apparatus). These provisions applied to all occupational activities involved in handling asbestos or products containing asbestos and compliance was monitored by labour inspectors along with all other measures relating to protection of health in the workplace.

Second phase: the 1980s and the period 1990-1995

256. During the second phase, French regulations developed in line with the provisions of the new European directives on asbestos. This development was also in step with progress in scientific knowledge, and international recommendations (in particular, ILO Convention No. 162 concerning Safety in the Use of Asbestos.[157] In particular, the 1977 Decree was amended twice in order to translate the relevant European directives into French domestic law:

- The first modification of the 1977 Decree, by Decree 87-232 of 27 March 1987 was to incorporate the provisions of European Directive 83/477/EEC of 19 September 1983, which set the following limits for occupational exposure: 0.5 fibre/cm^3 measured over eight hours for crocidolite, and 1 fibre/cm^3 for all other varieties of asbestos, including chrysotile.

- Second amendment of the 1977 Decree, by Decree 92-634 of 6 July 1992, to incorporate the provisions of European Directive 91/382/EEC of 25 June 1991, which lowered the limits of occupational exposure to 0.6 fibre/cm^3 for chrysotile, and 0.3 fibre/cm^3 for all other varieties of asbestos. The European directive also introduced provisions for protection of workers and the environment specific to sites of removal of asbestos.

257. Parallel to the translation of the above-mentioned directives into French domestic law, the French authorities adopted measures to restrict sales which progressively prohibited the use of crocidolite, then all varieties of amphiboles. The use of chrysotile was also restricted: the use of

[156] This Regulation was repealed by Decree No. 96-98 of 7 February 1996 on protection of workers against risks related to the inhalation of asbestos dust, cf page 62 (Article 33) of the collection of French regulatory texts on asbestos, in *Recueil des textes français dans le domaine de l'amiante*, Official Journals, Ministry of Employment and Solidarity, 1998.

[157] International Labour Organization, Convention concerning Safety in the Use of Asbestos, (Convention 162), adopted 24 June 1986.

chrysotile asbestos was prohibited in the manufacture of certain products such as toys, smokers articles, paint and varnishes, liquid filters, mortars, plaster, mastics, sizes, low-density insulating or soundproofing materials, bituminous roofing felt, and textiles susceptible of releasing fibres (Decree 88-466 of 28 April 1988 on Products Containing Asbestos).[158] In any case, since the beginning of the 1990s, the risks for users of products containing asbestos were clearly emerging from the cumulative data. A database, called "EVALUTIL" was set up to evaluate exposure to asbestos among users of products containing asbestos. This database showed up the very high level of exposure of certain construction workers in the course of operations ("exposure peaks" during operations such as cutting asbestos cladding containing 5 per cent chrysotile, cutting up fireproof doors coated in asbestos, for example). Following the publication of certain studies[159] which showed the increase in the number of mesotheliomas and the significant risk to the population of workers in the maintenance and repair sectors, the French authorities convened an expert group in 1994. The deliberations of these experts highlighted, firstly, a number of scientific doubts and, secondly, a number of loopholes in the French regulations then in force.[160] The expert group's conclusions led the authorities to draw up its first "asbestos plan" which was presented in outline on 6 July 1995 to the Council for the Prevention of Occupational Risks.[161] The plan reflected the determination of the French authorities to strengthen the existing preventative measures and to equip itself with the means to obtain more detailed knowledge of the risks related to asbestos.

Third phase: the asbestos plan of December 1995

258. The asbestos plan of December 1995 contained immediate measures for the protection of workers and the public, as well as initiating a joint independent scientific report on the effects on health of various varieties of asbestos. This plan, whose measures are still in force today, is intended to reinforce the protection of workers in the asbestos industry, and also, above all, to take into account the risk inherent in asbestos in place for the public and workers in the repair and maintenance sectors. The asbestos plan of December 1995 contains the following provisions, in particular:

- The requirement for owners of buildings to identify flockings and laggings containing asbestos before 31 December 1999, and to have the condition of the flockings and lagging surveyed by a competent body in order to undertake the necessary works in the event of deterioration[162];

- reduction of the occupational exposure limits in activities involving work in contact with asbestos, to the lowest level technically possible, i.e. 0.1 fibre/cm^3 (Decree 96-98 of 7 February 1996).[163] The difference between the limit for "pure" chrysotile (0.3 fibre/cm^3 and amphiboles (0.1 fibre/cm^3) which only concerned the production sector, was abolished by Decree 96-1132 of 24 August 1996, with effect from 24 December 1996;

[158] The EC point out that the Decree of 28 April 1988 prohibits the sale of crocidolite, subject to limited exceptions, and certain products containing chrysotile, and makes it mandatory to label products containing asbestos accordingly. The Decree of 28 April 1988 was subsequently amended by Decrees No. 94-645 of 26 July 1994, No. 98-668 of 26 July 1996 and No. 96-113 of 24 December 1996. The Decree of 26 July 1994 prohibits the use of all varieties of asbestos, except for chrysotile asbestos. It also extends the list of products containing asbestos which are prohibited from sale.

[159] See in particular Peto J., *et al, Continuing Increase in Mesothelioma Mortality in Britain*, The Lancet, vol 345, p. 535 (1995).

[160] Summary of the principal conclusions of the meeting of French asbestos experts on 20 December 1994.

[161] Outline note of the *Conseil supérieur de prévention des risques professionnels* of 3 July 1995.

[162] Collection of French regulations on asbestos, Official Journals, Ministry of Employment and Solidarity, 1998, page 3.

[163] *Idem.*, page 53.

- improved procedures for asbestos removal: the power conferred on labour inspectors to close sites where asbestos is being removed where the protective measures do not seem to them to be adequate (amendment of Article L 231-12 of the Labour Code by Law 92-1446 of 31 December 1992, Article 35 and Law 96-452 of 28 May 1996, Article 39)[164]; prohibition on the use of casual workers to carry out the work of removing asbestos, introduction of a procedure of accreditation of firms (Decree No. 96-98 of 7 February 1996);

- elaboration of specific rules for prevention suited to repair and maintenance situations: the need to enquire of the owner whether asbestos is present, mandatory individual protection whenever the presence of asbestos is suspected (Decree 96-98 of 7 February 1996).

259. These provisions completed the general arrangements for information and training of workers set out in the French Labour Code, by adapting them to the risks related to the inhalation of asbestos dust and the type and method of use of individual and collective means of protection. The regulations thus put in place satisfy the objective of reducing to the lowest level possible the risk presented by asbestos in place. In technical terms, they contain the tightest possible protection measures.

260. The introduction of French regulations on asbestos was accompanied by information campaigns directed at trade federations and, more particularly, the construction sector. All the French regions and all those involved in the prevention of occupational risks prepared numerous methodological guides, information leaflets, audiovisual programmes and training. To increase knowledge about the risks related to asbestos in the repair and maintenance sectors, the "EVALUTIL" database, which can evaluate asbestos exposure of users of asbestos-containing products, has been made accessible via the Internet. The Labour Inspectorate has been heavily involved and specially trained in the context of the Ministry of Labour's priority actions. Sites where asbestos is being removed or sealed are strictly monitored: all removal plans are studied, all sites where"friable" asbestos and the vast majority of other asbestos removal sites are monitored by the Labour Inspectorate. For example, of 2,344 declared sites, 70 per cent were controlled *in situ.* Apart from their persuasive effect, the extent of which is difficult to measure, these inspections led to work being stopped on 114 sites because the protection measures were judged by the Labour Inspectorate to be inadequate, and have led to more than 3,000 notifications of failure to comply with French regulations.

261. The labour inspectors observe, in regional reports of priority actions, that the regulations are relatively well respected and that the asbestos risk is investigated and taken into account in major works such as large-scale renovation, demolition and works carried by out large companies. On the other hand, in regional reports of priority actions, the labour inspectors also note, objective and serious difficulties in enforcing the regulations in many small operations, particularly by private individuals. Indeed, the labour regulations are mandatory for employees and self-employed workers but not for individual do-it-yourself enthusiasts. In such situations, which by their nature are extremely diverse, little notice is taken of the need to investigate the presence of asbestos and take the necessary protection measures.

The French decision to impose a ban

262. The INSERM report, which was submitted at the end of June 1996, to the Minister of Labour and Social Affairs, showed the need to supplement the existing protection arrangements, as an essential step to reduce the risk of asbestos in place to the lowest possible level, by a ban which would

[164] *Idem.*, page 79.

stop the risk spreading. The reasons for this are as follows: (i) chrysotile is carcinogenic and it has not been shown that there is a threshold below which it is harmless; (ii) the vast majority of mesotheliomas appear among "secondary users", particularly, in the construction sector, which means a very large number of people exposed in a very wide variety of situations in which the so-called "safe" use is inapplicable. Protection measures in force prior to the decision to impose the ban, even if technically the tightest possible, proved inadequate to reduce the risks in all situations to the lowest possible level. That being the case, if the French authorities had not imposed a ban, they would have knowingly allowed the volume of asbestos in place to increase, thereby increasing the risk to workers' health, particularly that of "secondary users" (workers in the repair and maintenance sector and do-it-yourself enthusiasts).

2. Question by the Panel to Canada

Question 5: With respect to Articles III:4 of GATT and 2.1 of the TBT Agreement, Canada states that it is not invoking the argument of likeness of non-fibrous substitute products and neither does it extend the argument of likeness to substitute fibres other than glass fibre, cellulose fibre, PVA fibre and fibro-cement products containing such fibres (reply to question 15 of the Panel). Could Canada clarify if it considers that the Panel should limit its findings and conclusions to the effect of the regulations in relation to these three substitute fibres?

(i) Reply by Canada

263. Canada reiterates its reply to Question 15 of the Panel, as set out above in paragraph 74 and 75.

264. In the case of *Indonesia – Certain Measures Affecting the Automobile Industry*, it was clearly established that it was not necessary, for the purposes of Article III:2 of GATT, to determine whether the Honda Civic was like the Indonesian Timor since the demonstration of the likeness between he Toyota Corolla and the Timor was enough to establish the violation of Article III:2 of GATT.[165] We note that the recent INSERM study on substitute fibres, *Effects on Health of Fibres Replacing Asbestos*, dwells specifically on the fibres mentioned by Canada as being like in the meaning of Article III:4 of GATT and 2.1 of the TBT Agreement, namely, glass fibres, cellulose fibre and polyvinylalcohols (PVA). INSERM states in its study:

> "This study covered the main fibres used to replace asbestos: artificial mineral fibres (glass, rock and slag wool, continuous thread glass fibre, glass microfibres, refractory ceramic fibres), organic fibres (para-aramid, cellulose). The case of polyvinylalcohols (PVA) has not been considered because of the dearth of scientific literature on them".[166]

265. For the purposes of Canada's argument under Article III:4 of GATT and 2.1 of the TBT Agreement, Canada is of the opinion that the findings and conclusions of the Panel should consider the effect of the regulations in relation to these three substitute fibres and fibro-cement products incorporating them.

3. Questions by the Panel to the European Communities

Question 6: Could you describe the type of measures applicable, in France, to substitute fibres, in particular glass, cellulose, PVA, para-aramid and refractory ceramic fibres?

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[165] *Indonesia – Certain Measures Affecting the Automobile Industry*, Report of the Panel, paragraph 14.110.

[166] INSERM, *Effects on Health of Fibres to Replace Asbestos*, November 1999, page v.

(i) Reply by the European Communities

266. Substitute fibres are considered to be chemical substances. As such, their manufacture, use and sale are governed by a mass of complex European regulations which have been incorporated into French domestic law. In particular, both consumers and workers must be informed of the intrinsic danger of such fibres by means of labelling and "risk warnings" based on the European classification of their risk to human health.[167] This requirement to provide information also exists at international level. Discussions are currently taking place in an endeavour to harmonize classification systems at international level. At the moment, the European Union has a system of classification of chemicals and chemical preparations which is applied uniformly throughout the member States, and consequently in France too. The preventative measures applicable to chemicals and chemical preparations vary according to the level of risk as determined by their classification. The applicable regulations depends on the level and type of hazard. The following regulations, in rising level of risk are applied cumulatively, depending upon the particular characteristics of the chemical or chemical preparation: (i) for chemical agents not classified as dangerous, reference must be made to the traditional regulations on ventilation and air quality in the workplace[168]; (ii) for chemical agents classified as dangerous the regulation on chemical risks has to be applied[169]; (iii) for chemical agents classified as proven human or animal carcinogens, the regulations on carcinogenic risks applies.[170] Furthermore, breaches of these provisions, like all breaches of the provisions of the Labour Code and implementing legislation are criminal offences pursuant to Article L. 263-2 which lays down financial penalties (25 000FF per employee) and, in appropriate cases, a term of imprisonment.

267. Of the fibres mentioned in question 6, three fibres are not classified as dangerous: PVA, para-aramid and cellulose. Nonetheless, the general regulations on ventilation and air quality in the workplace apply and mean that: (i) systems for ventilation and dust capture at source must be installed; (ii) dust levels must be below the thresholds set out in the Labour Code.

268. Glass fibres are classified as irritant and carcinogenic "Group 3" (i.e. suspect in animals under the IARC classification); in this case the regulations on prevention of chemical risks apply, which means that the employer must satisfy the following requirements: (i) risk assessment (levels of collective and individual exposure, methods envisaged to reduce them); (ii) installation of collective protective equipment; (iii) supply and maintenance of individual protective gear; (iv) training and information for workers; (v) signposting of premises where the substances are used; (vi) an explanatory notice on the risks and means of protection specific to each work place. For this purpose the employer has safety information sheets provided by the manufacturer, which give details of the composition of the product, the hazards and the prevention measures to be taken.

269. As ceramic fibres are classified carcinogenic "Group 2" (proven risk to animals under the IARC classification), their use is subject to the regulations on prevention of carcinogenic risks, which incidentally is more restrictive than that concerning chemical risks mentioned above, because in addition it requires: (i) substitution by a less dangerous product when that is technically possible; (ii) use of a closed system when that is practicable; (iii) limitation of the quantities used and the number of workers exposed; (iv) reduction of exposure to the lowest level technically possible; (v) special medical monitoring of workers.

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[167] Directive 67/548/EEC on Chemical Substances and Directive 88/379/EEC on Chemical Preparations.

[168] Articles R. 232 etc. of the Labour Code.

[169] Articles R. 231-51 et seq., R. 231-52 et seq., R. 231-53 et seq., R. 231-54 et seq., R231-55 et seq. of the Labour Code.

[170] Articles R. 231-56 et seq. of the Labour Code.

270. Following the results of the collective INSERM report on asbestos substitute fibres, the French authorities launched a plan of action on artificial mineral fibres (in particular glass wool and ceramic fibres) which provides for: (i) monitoring of the compliance of labelling of the various fibres, in particular, glass wools; (ii) monitoring of exposure levels; (iii) improving knowledge in the area of toxicology and epidemiology.

Question 7: Canada claims that France should have used two guiding principles to determine which chrysotile asbestos products should be used: (i) risk assessment product by product and use by use, and (ii) demonstration of the feasibility and effectiveness of "controlled use" for each product. Could the European Communities comment on these arguments?

(i) Reply by the European Communities

271. Both Canada's arguments are incorrect for the following reasons.

272. First, neither GATT nor the TBT Agreement lay down any rule whatsoever on how to perform a risk assessment. Even the SPS Agreement, which is not applicable in this case and which contains specific provisions on risk assessment, does not require the performance of a risk assessment in the way suggested by Canada.[171]

273. Secondly, there are in fact no internationally agreed and binding rules on how to conduct a risk assessment for dangerous substances like asbestos. In addition, neither national nor international practice (e.g. by WHO, IARC, FAO/Codex Alimentarius, etc.) support the views of Canada on the two "guiding principles". It is common practice to assess the risks posed by chemical substances or other potentially dangerous products by evaluating in general the physico-chemical properties, toxicological and other relevant data on the pharmacologically active parent compound and its metabolites, and the possible ecotoxicological effects where this is likely to be relevant to the assessment of the risks posed by the substance in question. When the risk assessment indicates that an Acceptable Daily Intake (ADI) and a Maximum Residue Limit (MRL) can be set for the substance or product in question, they can subsequently be used without further examination on a product by product and use by use basis, contrary to what is incorrectly suggested by Canada.[172] Risk assessment, however, is a very complex and interactive process and no one particular technique or methodology is always appropriate for all cases. Epidemiological data and occupational exposure data may also be used to support toxicological data from *in vitro* or *in vivo* studies.

274. Thirdly, the WHO and IARC Reports that evaluated asbestos, including chrysotile asbestos, do explain the methodology they used.[173] A close look at them shows that, in fact, they evaluated the risks posed by chrysotile asbestos to a very large extent in a way similar to the one suggested by Canada but have arrived at conclusions opposite to those of Canada.

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[171] See, e.g., Article 5.1-5.2 SPS and the Appellate Body report in the *Hormones* case, AB-1997-4, paragraph 187.

[172] The European Communities note that a general overview of the principles applied by WHO and its specialized agencies in the evaluation of food additives and contaminants in food may be gained by looking at the WHO Environmental Health Criteria no. 70, *Principles for the Safety Assessment of Food Additives and Contaminants in Food*, Geneva, 1987. A study by the US General Accounting Office on pesticides has also demonstrated serious differences in the way a risk assessment is carried out by several industrialised nations: see US General Accounting Office, *Pesticides – A Comparative Study of Industrialised Nations' Regulatory Systems*, Washington, 1993.

[173] See WHO Environmental Health Criteria 203, Geneva, 1998, pp. 1-9, and IARC Monographs, Supplement 7, Lyon, 1987, pp. 19-28 and 38-40.

275. Fourthly, the risk assessment carried out by WHO is very similar, if not identical, to the one performed by INSERM and confirms on all essential points the results of the INSERM Report.

276. Fifthly, as regards substances that have been classified as proven human carcinogens, such as chrysotile asbestos, and for which there is no scientifically established threshold of exposure, the two guiding principles suggested by Canada are in fact totally irrelevant, because any exposure to chrysotile or any kind of chrysotile-containing product may pose a risk to human health (because there is no safe exposure threshold). Therefore, the nature and number of the final products and their use does not matter as such. What is important is the fact that they contain the very carcinogenic substance that has been evaluated, i.e. chrysotile asbestos.

277. Sixthly, it is not correct to suggest that France and the other competent international organisations that have evaluated chrysotile asbestos failed to demonstrate the lack of feasibility and effectiveness of the so-called "controlled use". As the European Communities have explained in detail in their written and oral statements, cases of lung cancer and mesothelioma have been observed or reported even in cases where strict measures have been taken to control exposure to asbestos. It is interesting to note that during the meeting of the Panel with the scientific experts on 17 January 2000, none of the experts was aware of any specific case where the so-called "controlled use" advocated by Canada was applied. And even Canada, in the same meeting, failed to provide a specific example of a country where such "controlled use" has ever been effectively applied.

278. To sum up, the existing rules permit France to apply its own, customary and normal rules on risk assessment to asbestos. This is what France did in this case. The methodology applied by France is similar, if not identical, to the one usually applied internationally and actually used by WHO and the IARC in the case of asbestos. It is up to Canada, not France, to perform the different, novel type of risk assessment it now advocates in order to demonstrate the accuracy of its claims. That Canada has failed to do.

II. QUESTIONS TO THIRD PARTIES

C. FIRST SUBSTANTIVE MEETING - SESSION WITH THE THIRD PARTIES (2 JUNE 1999)

1. Questions from the Panel to Brazil

Question 1: Could you please develop or expand upon the argument you make concerning developing countries in paragraph 4.23 of your written submission, particularly in light of the fact that this is not a point that has been raised by either party to the dispute?

279. In the Marrakech Declaration of 15 April 1994, adopted at the time of signature of the Uruguay Round Final Act, Ministers welcomed the notably active role of developing countries in the negotiations, declaring that "[t]his has marked a historic step towards a more balanced and integrated global trade partnership." (Paragraph 4.) Ministers also recalled that the results of the negotiations embodied provisions conferring differential and more favourable treatment for developing economies. (Paragraph 5.) These Ministerial statements reflect the achievement of the goal set out in Part I, Section B, Paragraph (iv) of the 20 September 1986 Punta del Este Declaration launching the Uruguay Round negotiations. As set out in Brazil's third party submission,[174] this commitment to special and differential treatment is embodied in Article 12 of the TBT Agreement. The issue was not raised by Canada because it is not a developing country. It was not raised by the EC because, as responding party, it has no interest in acknowledging its higher level of obligation to Brazil (and Zimbabwe). But, this does not detract from the EC' obligation to respect the special and differential treatment obligations established at Articles 12.2 and 12.3. A Member's obligations do not depend on

[174]See Section IV.A of this Report.

the procedural aspects of dispute settlement; rather, they are set out in the texts of the WTO agreements, in this case the TBT Agreement, in particular. In imposing the ban, France did not "take into account the special development, financial and trade needs" of Brazil or Zimbabwe, as required by Article 12.2. Nor did France ensure that the ban "[did] not create unnecessary obstacles to exports" of chrysotile from Brazil, as required by Article 12.3. This is why Brazil has asked the Panel to scrutinize the ban closely, especially as it applies to the chrysotile exported by Brazil. The ban's unwarranted effects on Brazil and Zimbabwe provide a supplemental reason why the ban is inconsistent with France's obligations under the TBT Agreement.

Question 2: To what extent can modern controlled use in both current and recent past practice ensure adequate safety standards throughout the life-cycle of products containing chrysotile asbestos?

280. Current controlled-use policies are available to guarantee safety throughout the life-cycle of chrysotile products. First, as a preliminary matter, Brazil notes that the most current research indicates that chrysotile alone does not present significant health risks. (Please refer below to Brazil's response to the EC Questions 22 and 23.) Second, an examination of the life cycle of chrysotile products indicates that procedures can be adopted to guarantee safe use of chrysotile. The following discussion breaks the life-cycle into three stages: (i) manufacture; (ii) use and maintenance; and (iii) disposal. The product used as an example is chrysotile cement because it accounts for such a large portion of the market.

(a) Manufacture

281. The safety of workers manufacturing chrysotile cement and chrysotile cement products can be guaranteed through proper controls. The following controls have been demonstrated to reduce chrysotile concentrations to 0.1 f/ml: (i) wet-process treatment (asbestos is mixed with water to make a slurry from which fibres and dust cannot escape); (ii) closed-process treatment (after workers load airtight bags of asbestos into machines, the process is air-tight through the point where the final product (in which the fibres are encapsulated) is produced); (iii) filtered ventilation systems (to remove from the air those few fibres that escape the wet, enclosed process); (iv) special treatment of workers' clothing (because those few fibres that do remain often cling to clothing, Brazilian cement plants provide special work clothes and launder them appropriately on-site); and (v) personal hygiene measures (supply shower facilities and double dressing rooms for workers to further address fibre deposition).

(b) Use and Maintenance

282. By "use and maintenance," Brazil refers to the installation and maintenance of chrysotile cement products. The "waste" from use is discussed below under the heading "Disposal/Recycling." For chrysotile cement products, the procedures set out in ISO-7337 guarantee a high level of safety in installation and use. ISO-7337 establishes guidelines for breaking/cutting/drilling cement products so that they can be installed with minimal release of fibres. In general, ISO-7337 requires breaking or cutting with special saws, using wet process and/or vacuum dust extractors. Brazil also would recommend proper training. Perhaps licensing is appropriate for certain procedures (e.g., removing flocking). At all other points during use, the fibres are encapsulated. However, in certain climates, regular inspection (e.g., every 5 years) of exposed products (roofing tiles, in particular) may be appropriate. Any exposure from degradation of the product can be halted by using the spray sealant currently recommended for application to flocking.

(c) Disposal/Recycling

283. Disposal/recycling of asbestos cement products and "waste" should be handled with measures similar to their manufacture end-use - proper wet controls and cutting or breaking methods. Please recall that the EC focus on remediation of flocking is not at issue. Rather, the issue here is the disposal/recycling of encapsulated used chrysotile cement products and waste. In cement products, the chrysotile remains encapsulated. Indeed, when buried, for example, in a landfill, the fibres are as inert (or more inert) as they are in naturally appearing ores containing asbestos.

(d) Personal Protection Equipment

284. At each stage, proper controls reduce exposure and health risks to *de minimis* levels. With the use of personal protection equipment (PPE), exposure can be reduced to zero. PPE absolutely guarantees no exposure and thus no risk to health. PPE could constitute "deep sea diver suits." However, for any modern application involving chrysotile products, a simple air filter, coupled with proper working procedures, will eliminate exposure. In addition, Brazil refers the Panel to Brazil's answers to EC Questions 10 (flaws of the linear risk model), 16 (safety of modern uses) and 22 and 23 (chrysotile that is not mixed with or accompanied by any amount, even a trace amount, of amphibole or substitute fibres presents no risk; modern uses of chrysotile present no risk).

2. Questions from Canada to Brazil

Question 1: What is Brazil's position on the relative health effects of chrysotile, amphiboles and man-made fibres?

285. In considering the question of relative health effects, one must keep in mind four basic truths. First, as accepted and employed by the EC in its rulemaking (see Brazil's response to EC Question 7), the toxicity of fibres is defined primarily by reference to the size, shape and durability and duration in the lung of the fibre in question. Thus, experts posit that any fibre with characteristics similar to chrysotile (due to its having been engineered to substitute for chrysotile) must be a suspected carcinogen.[175] Chrysotile has been proven safer than amphibole asbestos. As INSERM concedes and the studies cited by Brazil in response to EC Question 5 establish, this fact is not subject to question. Equally incontrovertible is the proposition that some man-made fibres have been proven more dangerous than chrysotile or even amphibole. See the discussion and the studies cited at Brazil's response to EC Question 7. Recent research demonstrates that chrysotile presents no health risk. Please refer to the discussion and studies presented at Brazil's responses to EC Questions 22 and 23. Scientists now suspect as a result of recent studies that health effects once associated with chrysotile are due to the fact that the past studies examined subjects exposed to chrysotile and amphibole and that the amphibole was responsible for the health effects.[176]

[175] Pott, F. and Roller, M., *Relevance of Nonphysiological Exposure Routes for Carcinogenicity Studies of Solid Particles*, International Life Sciences Institute Monographs, Toxic and Carcinogenic Effects of Solid Particles in the Respiratory Tract, Washington, DC, at 112 (1994).

[176] See, e.g., Churg, A. and Vedal, S., *Fiber Burden and Patterns of Asbestos-related Disease in Workers with Heavy Mixed Amosite and Chrysotile Exposure* , Am. J. Resp. Crit. Care Med., Vol. 150, No. 3 (1994); Albin, M. *et al.*, *Retention Patterns of Asbestos Fibres in Lung Tissue among Asbestos Cement Workers*, Occ. Env. Med., Vol. 51, No. 3 (1994); McDonald, J.C. and McDonald, A.D., *Chrysotile, Tremolite and Carcinogenicity*, Ann. Occup. Hyg., Vol. 41, No. 6 (1997); Davis, J.M.G., *Animal Inhalation Studies with Fibers, International Life Sciences Institute Monographs, Toxic and Carcinogenic Effects of Solid Particles in the Respiratory Tract*, Washington, D.C. (1994). See also McDonald, J.C., *Unfinished Business: The Asbestos Textiles Mystery*, Ann. Occup. Hyg., Vol. 42, No. 1 (1998).

Question 2: What is Brazil's position as to whether and how chrysotile use can be controlled to guarantee safety?

286. For years, Brazil has controlled the mining, production and use of chrysotile and chrysotile products to guarantee safety. As explained by Brazil in response to Panel Question 2, controls exist for every part of the life cycle, from the time chrysotile is mined until chrysotile cement products are disposed of. Even as the EC presents the grossly exaggerated picture of workers equipped as "veritable deep sea divers," the EC provides the seed of an admission which, germinated, compromises its position. The EC concedes that use can be safe and, in doing so, admits that a ban is not the least trade restrictive remedy required to achieve its desired level of protection. But, in any case, the EC's picture is quite distorted. For a country that chooses to disturb flocked asbestos, guaranteeing worker safety by equipping workers as veritable deep sea divers may be rational; however, for modern controlled uses of chrysotile, the only relevant personal protective equipment (PPE) is a simple air filter, which reduces already safe exposure levels to zero.

Question 3: How does Brazil interpret the expression "current controlled use"?

287. The expression "current controlled use" is the key to this proceeding. Brazil is not defending past uses, e.g., flocking, the use of amphibole, or the use of naturally exposed asbestos in solution as a white-wash for buildings. Brazil is defending against France's ban a limited range of beneficial, safe uses: the use of chrysotile in asbestos cement products and friction products. Brazil has demonstrated that these uses, which compose the majority of the market, are safe. Exposure can be controlled so that PPE is not needed to guarantee worker safety. In these limited applications, safety is guaranteed by controls, but PPE can be used to reduce exposure to zero.

3. Questions from the European Communities to Brazil

Question 1: Brazil alleges in a number of instances (e.g. in paragraph 4.28 of its written submission) that in the past France imported and used mainly amphibole asbestos. On what factual and/or statistical data are these allegations based? Could Brazil provide them to the Panel?

288. Brazil's understanding that France once imported much larger amounts of amphibole than it now does is based on the history of world use of asbestos, not on French import statistics. For some time, countries did not distinguish between imports of chrysotile and the far more dangerous amphibole asbestos. During this period, the two types were used virtually interchangeably and countries, even Brazil, imported substantial amounts of amphibole. As the EC likely is aware, French import statistics do not distinguish chrysotile and amphibole.

Question 2: Could Brazil define what it means by "uncontaminated" chrysotile?

289. By "uncontaminated", Brazil means chrysotile that is not mixed with or accompanied by any amount, even a trace amount, of dangerous amphibole or substitute fibres. An attached scientific assay demonstrates that the chrysotile that Brazil mines and exports is uncontaminated.[177] Moreover, as discussed in detail in the answer to EC Question 5, INSERM also recognizes that chrysotile is less hazardous than amphibole. Nonetheless, INSERM did not address the health effects of exposure to chrysotile alone. The distinction is quite important. As McDonald (1998) concludes " … it now seems fairly widely accepted that the carcinogenicity of the amphiboles, crocidolite in particular, is

[177] Miriam Cruxên Barros de Oliveira *et al.*, Technical Report Nr. 36 889, Instituto de Pesquisas Tecnológicas, São Paulo (Brazil), 1998.

appreciably greater than of chrysotile …"[178]. Thus, amphibole is viewed widely as the source of toxicity that at one time in the past was associated with the use of chrysotile.

Question 3: Could Brazil provide concrete written evidence supporting its allegation (e.g. paragraphs 4.3 and 4.9 of its written submission) that the French Decree at issue aims to deal exclusively with a public outcry, public pressure and to appease domestic sentiment and is not based on any scientific evidence, given the volume of internationally available scientific evidence documenting the risks of asbestos to human health?

290. Obviously, the French Government did not accompany the Decree with an official statement admitting the Decree was passed to appease the French public. No government would do such a thing. However, the facts preceding and surrounding the Decree and the INSERM Report, as well as the timing of the decisions taken, demonstrate that the Decree was not aimed primarily at protecting public health (for if it was, why are substitutes that are Class II carcinogens not banned?), but was designed to quiet a disturbed populace. In this regard, Brazil refers to Canada's arguments (contained in Section III.B.3 of this Report) which set out a chronology showing how a series of unfortunate decisions, coupled with the public's strong response, led the French Government to ban chrysotile, without scientific basis. The text of the INSERM Report also supports this conclusion. At page 140, INSERM notes that exposure to flocked asbestos in buildings is the "core of the current concerns," and emphasizes that the subject is "extremely controversial." INSERM states that French courts had wrestled with the issue and ignored science in tying sickness to indoor exposure. *Id*. at pages 141-2. Ironically, INSERM concludes that the data "do not confirm" that maintenance and service personnel in "asbestos-sprayed buildings" (flocked buildings) experienced an increased risk of respiratory abnormalities. *Id*. at pages 143-4.

Question 4: Could Brazil provide concrete evidence supporting the allegation (paragraph 4.3 of its written submission) that the INSERM report was merely a scientific "cover" for a previously taken political decision?

291. Brazil refers to the answer to EC Question 3. In addition, Brazil notes that the fact that the INSERM Report was merely scientific cover for the political decision is confirmed not merely by reference to the events of the time, but also by a review of the Report itself. Even a cursory review shows that INSERM ignored evidence that did not conform to the opinion it apparently was instructed to reach.

Question 5: Could Brazil provide written evidence supporting the allegation (paragraph 4.3 of its written submission) that "especially the spraying of brittle amphibole" caused the asbestos-related health problems in France?

292. Flocked asbestos led to the health problems that most concerned the French officials contemplating a ban. That is incontrovertible as a review of the INSERM Report and the answer to EC Question 3, above, demonstrates. Likewise incontrovertible is the fact that flocking occurred during the time prior to any ban on amphibole asbestos. Indeed, INSERM states (page 18) that chrysotile fibres commonly were mixed "with up to 40 per cent amphibole fibers," due to the different properties of the two types of fibres. The Report prepared by INSERM at the request and under the direction of the French Government recognizes that chrysotile is much safer than amphibole and thus that amphibole is of primary concern for negative health effects. INSERM concedes this point throughout the Report. For example, at page 102, INSERM states, "subjects exposed mainly to chrysotile have a lower risk of mesothelioma than subjects exposed to amphiboles or a mix of fibers. " Later, discussing Hughes *et al.* (1987) and Weill *et al.* (1977), INSERM reports that the "prevalence

[178] McDonald, J.M., *Unfinished Business: The Asbestos Textiles Mystery* (invited editorial), Ann. Occup. Hyg., Vol. 42, No. 1 at 3 (1998).

of radiographic asbestosis was found to be higher in the plant that handles more amphibole asbestos. " *Id*. at page 323. INSERM further concedes that "crocidolite has a greater fibrogenic effect than chrysotile." *Id*. at page 326. INSERM concludes that the studies demonstrate that the dose-effect relationship is much stronger with amphibole fibres than with chrysotile, as regards both asbestosis and the other pathogenic effects of asbestos. *Id*. at page 327. Anecdotal evidence supports the conclusion. INSERM explains the higher incidence of sickness in Australia and New Zealand by reference to the "widespread use of the crocidolite these two countries produce." *Id*. at page 158; [*sic*] *see also id*. at page 171 (concluding that, in Australia, "the incidence of mesothelioma is particularly high due to widespread crocidolite use"). This view is widely shared. In 1996, Health and Safety Executive of Great Britain concluded that:

> "[v]ery few cases of mesothelioma can be reliably attributed to chrysotile despite the many thousands of workers who have had massive and prolonged exposures … In contrast, mesotheliomas have been observed among some workers who experienced only brief exposures to amphiboles."[179]

293. A U.S. Government official has expressed a similar view. According to Malcolm Ross, mineralogist for the U.S. Geological Survey, scientific studies show chrysotile is not as great a health risk as amphibole: "[t]here's no non-occupational risk with chrysotile. … In the workplace, chrysotile should not show any noticeable increase of disease if it is controlled."[180] These studies and conclusions demonstrate that the primary concern regarding risk to human health is exposure to amphibole, most of which occurred during past uses.

Question 6: Could Brazil provide a copy of the full American Society of Mechanical Engineers (ASME) study it has cited (paragraph 4.5 of its written submission), as well as a reference to where it has been published?

294. Brazil does not cite the ASME study anywhere in its submission. Rather, Brazil cites the Fifth Circuit's recounting and analysis of the testimony during the court proceeding of one of the study's authors.

Question 7: In paragraph 4.6 of its written submission, Brazil claims that "available scientific data" would show that, compared to chrysotile, man-made fibers produced in France present greater risks when use is not controlled? Could Brazil provide copies of the relevant scientific articles and/or other data?

295. The available scientific literature demonstrates that chrysotile is safer than many if not all substitutes. Indeed, recent research suggests that chrysotile poses no health risk. In this respect, Brazil attached the following papers and studies: (i) Cossette (1998), concluding that iron ductile and PVC pipe present health risks far greater than that presented by chrysotile cement pipe; (ii) Hesterberg (1992), reporting that 35 per cent of hamsters treated with a variety of ceramic fibres developed mesotheliomas; and (iii) Peraud *et al.* (1994), concluding that, as compared to all types of asbestos, the man-made mineral fibres *silicon carbide*, *JM 104/475*, *B1M*, and *B3K*, have a "moderately higher toxic effect" (pages 570-2). In addition, the scientists and doctors attending *The Proceedings of the Workshop on Health Risks Associated with Chrysotile Asbestos* (1994) concluded that:

> "With the exception of the textile industry, the slopes of the exposure response curves for lung cancer in the various chrysotile industry sectors were shallow, with no detectable risk of an extremely low level of risk of lung cancer associated with exposure to chrysotile asbestos at and below lifetime

[179] Meldrum, M., *Review of Fibre Toxicology*, Health & Safety Executive (1996) at 1.

[180] Los Angeles Times, *Link to Lung Disease Traced to 1906, but Asbestos' Strengths Spurred Use*, Part 1, page 2, column 1 (13 July 1986).

> cumulative exposures of 30 fibres/ml-years. No chrysotile related increased risk was detected at considerably higher exposures in the mining sector."[181]

296. Moreover, in his report to the EC (EC document number ECB/TM/15(97)), Dr. Bernstein analysed statistically all available biopersistence studies, chronic intraperitoneal [injection] studies (IP) and chronic inhalation studies on fibres. This and subsequent research demonstrates that chrysotile is safer than refractory ceramic fibres (RCF), glass fibres, p-aramid fibres and cellulose fibres. Dr. Bernstein's analyses for the EC were reviewed and accepted by the Ad-Hoc Group of Experts commissioned by the EC and consisting of scientific experts from EC member states and industries. The results of the analysis clearly showed that one can use inhalation biopersistence clearance half-times to predict IP tumour results, the number of long fibres remaining at 24 months in the Chronic Inhalation Studies and a score of pulmonary fibrosis in the Chronic Inhalation Studies (tumours were not used as an endpoint as only a single fibre type (RCF) was tumorigenic in these studies). Based upon this scientific analysis, the EC Fiber Directive included in Note Q the provision that:

> "The classification as a carcinogen need not apply if it can be shown that the substance fulfils one of the following conditions: (i) a short-term biopersistence test by inhalation has shown that the fibres longer than 20 µm have a weighted half-life less than 10 days; or (ii) a short-term biopersistence test by intratracheal instillation has shown that the fibres longer than 20 µm have a weighted half life less than 40 days, or (iii) an appropriate intra-peritoneal test has shown no evidence of excess carcinogenicity; or (iv) an absence of relevant pathogenicity or neoplastic changes in a suitable long term inhalation test."

297. The results from Dr. Bernstein's chrysotile biopersistence study show that chrysotile fibres are rapidly removed from the lung. Fibres longer than 20 µm are cleared with a half-time of 1.3 days, most likely by unravelling into shorter fibrils. This is consistent with the known chemistry of chrysotile. Shorter fibres also are cleared rapidly from the lung, with fibres 5-20 µm clearing even faster ($T_{½}$ = 2.4 days) than those < 5 µm in length. These short fibres were never found clumped together but appeared as separate, fine fibrils, occasionally unwound at one end. Short free fibres appeared in the corners of alveolar septa, and fibres or their fragments were found within alveolar macrophages. The same was true of fibres in lymphatics, as they appeared free or within phagocytic lymphocytes. These results support the evidence presented by McDonald and McDonald that the carcinogenicity of chrysotile largely depends on whether it is mixed with amphibole.[182] Thus, chrysotile clears faster than most current glass fibres for which in the EC system, the clearance half-time of long fibres must be less than 10 days in order to be exonerated. In addition, chrysotile clears substantially faster ($T_{½}$ = 1.3 days) than long p-aramid fibres which following a 90-day inhalation exposure cleared with a half-time of 95 days.[183] Finally, chrysotile clears considerably faster than cellulose fibres for which the clearance half-time of WHO fibres was between 1046 days and infinity.[184] One should note that the INSERM Report ignores the above analysis by Dr. Bernstein, as well as other studies comparing chrysotile to p-aramid and cellulose, even though they pre-date the INSERM Report.

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[181]Executive Summary, Workshop on Health Risks Associated with Chrysotile Asbestos, St. Helier, Channel Islands (1994) at page 2. Brazil also notes that most of this data is from exposure to chrysotile mixed with amphibole.

[182] McDonald, J.C. and McDonald, A.D., *Chrysotile, Tremolite and Carcinogenicity* , Ann. Occup. Hyg., Vol. 41, No. 6 at 699-705 (1997).

[183] Final Report on an Inhalation Tolerance Study for p-Aramid Respirable Fiber-Shaped Particulates (RFP) in Rats, Fraunhofer-Institut für Toxikologie und Aerosolforschung, Germany (1998).

[184] Muhle, H. *et al.*, *Investigation of the Durability of Cellulose Fibres in Rat Lungs*, Ann. Occup. Hyg., Vol. 41, Supplement 1 at 184-8 (1997).

Question 8: In footnote 11 of paragraph 4.10 of its written submission, Brazil states that "because only the INSERM report preceded the Ban, the Ban must be supported by the report alone." Could Brazil explain why the INSERM report alone should support the ban given the volume of internationally available scientific evidence clearly documenting the risks of asbestos to human health? What provisions of the GATT 94 and/or the TBT Agreement (assuming this is applicable) support this proposition?

298. First, the Government of France ordered the INSERM Report precisely for the purpose of conducting a risk assessment and supporting the ban. In promulgating the ban, it relied on the INSERM Report as the risk assessment. For the ban to be legitimate, it must be supported by the risk assessment upon which it is based. That is a matter of logic, not of WTO rules. More importantly, however, INSERM and the French Government failed to conduct an unbiased risk assessment. The EC now appears before this Panel, suggesting that the actual risk assessment was not published, but occurred behind closed doors in a process in which French Government officials reviewed the INSERM Report and all of the relevant studies the EC concedes with this question that INSERM ignored. Then, and only then, suggests the EC, did the French Government issue its decision to ban chrysotile. There is no evidence that any such complex, thorough process occurred in the 24 hours between delivery of the INSERM Report and the issuance of the ban. Moreover, to countenance the EC's attempt to insulate the French risk assessment from examination would be to make a mockery of the TBT Agreement. It would allow any Member to conduct a secret analysis and issue its foregone conclusion that a ban was necessary, without any oversight or discipline, whatsoever.

Question 9: In paragraph 4.11 of its written submission, Brazil states: "Finally, INSERM concedes that, although the health data it applied to chrysotile is from past, massive and prolonged exposure to amphibole (…)". Could Brazil provide the exact location (page number) where INSERM has stated this?

299. Throughout the Report INSERM relies on data from human exposure and animal exposure (mostly rats and hamsters). All of the studies of human exposure focus on exposure that occurred 20, 30, 40, 50 and 60 or more (for the earliest studies) years ago. *See, e.g.*, INSERM Report at Tables 1 and 2 to Chapter 13, pages 321 through 323; Table 2 to Chapter 8, page 164; and Table 4 to Chapter 8, page 166, summarizing data on past exposure of workers in various asbestos product plants and other occupations, and comparing the incidence of disease in men and women. This point is not subject to debate. The primary fact differentiating current exposure from these older periods of exposure is that, during the older periods of exposure, amphibole was commonly used, and had not yet been banned. See Brazil's answer to EC Question 5; INSERM Report at page 18. Nowhere does the INSERM Report distinguish between exposure to chrysotile only and to chrysotile mixed with carcinogenic amphibole. Another difference is that, in contrast to current practices, the work processes were not controlled and workers had little personal protective gear, much less safety accommodations such as showers and special clothing. A review of the dates of the studies summarized in the tables referred to above, and of the ages of the subjects and the length of exposure indicates that many of the exposures studied were quite dated. See also the discussion of latency periods and disease onset at pages 156-59 of the INSERM Report.

300. Moreover, even in plants using "chrysotile," studies suggest that a significant amount of the asbestos used was amphibole. For example, INSERM reports that the asbestos used in the Casale Monferrato plant was "chrysotile, but approximately 10 per cent of the total amount of asbestos was crocidolite." INSERM Report at page 137. Further to the point, INSERM concludes regarding exposure from industrial sources, that "in all positive studies reported, when asbestos fibre type was specified, the fibres involved were from the amphibole group, or fibres containing some amphiboles (amosite, tremolite or crocidolite)." *Id*. at 140. This applies even to the animal studies INSERM relied on. According to INSERM:

> "Animal experiments also make it possible to evaluate the dose-effect relationship. Most of the studies have used massive quantities of fibers at concentrations far higher than seen clinically in humans. Recent work by Quinlan *et al* (1994) analysed the effects of lower concentrations, ranging from 0.1 to 10 mg of crocidolite per cubic meter of air."[185]

Question 10: In paragraph 4.12 of its written submission, Brazil criticises the use of the "linear risk model" used by France. Could Brazil provide scientific evidence explaining why this model, which is a very widely used one, is unfounded or inappropriate?

301. Brazil already has introduced scientific evidence regarding the limitations of the linear risk model as applied to chrysotile. Brazil assumes that a statement by INSERM would qualify, at least for France and the EC as "scientific." As INSERM itself conceded, but apparently the EC wishes to ignore, the linear risk model cannot produce "scientifically certain knowledge" (INSERM Report at 239). Moreover, much of the research upon which INSERM relies for other propositions demonstrates that a safe threshold exists. For example: (i) at Table 2 to Chapter 6, page 88, INSERM reports that Wistar rats exposed to chrysotile in the amount of 6 fibres mg/m^3 developed no lung tumours, in contrast to rats exposed to higher amounts or to other fibres; (ii) at pages 88-89, INSERM recounts that hamsters exposed to various amounts of chrysotile in three separate studies (Lee *et al.* (1981), Smith *et al.* (1987) and Hesterberg *et al.* (1991)) did not develop lung tumours; and at page 104, INSERM recounts a study of intermittent exposure at high concentrations and continuous exposure at lower concentrations (Davis *et al.* (1980)), and concludes that "the authors found no significant effect on the tumour rate in the different treatment groups." In spite of these and other studies, INSERM supported the linear risk model. But when it came time to state why, INSERM (page 408), equivocated:

> "No argument based on the analysis of existing epidemiological data, direct or indirect, supports the belief that no-threshold linear extrapolation based on data corresponding to higher levels of asbestos exposure (adopted in this report to quantify the risks associated with low-level exposure) is not the most plausible uncertain model."

302. The conclusion, confused as it is, is utterly implausible given the evidence cited above from the Report itself, much less that discussed below. Moreover, earlier in the report, INSERM concedes that, even if one adopts a linear risk model, a safe threshold nonetheless exists. According to INSERM (page 104), if a:

> " … straight-line relationship is maintained for smaller doses, it means there is no minimum below which all risk disappears. However, the tumour latency period increases in animals as the dose falls. This means that a threshold value should exist in practice, corresponding to a dose for which the latency period is greater than the "natural" life expectancy of the animal in question."

303. Thus, INSERM concedes that, even assuming that all exposure is dangerous, at some lower exposure level, the latency period would be so long that no tumour would occur before death from natural causes. The most recent literature on the subject rejects outright the linear risk model. For example, Mossman and Churg now conclude that "asbestosis does not appear until a threshold exposure level has been reached …" and "[e]pidemiological studies indicate very clearly that the development of asbestosis requires heavy exposure to asbestos and provide strong evidence that there

[185] INSERM Report at page 275; see also *id*. at pages 86-7; *id*. at page 155 (asbestos-related disease is linked to "massive use"). The effect of massive doses is well documented in the scientific literature on "lung overload" Thus, one might question how the dose-effect relationship can be defined by studying the effects of "massive quantities of fibers at concentrations far higher than those seen clinically in humans." At the least, one would not expect such data to define the safe threshold. The existence of a safe threshold for chrysotile is discussed at length in Brazil's response to EC Question 10.

is a threshold fibre dose below which asbestosis is not seen …".[186] In 1994, Churg *et al.* concluded that:

> "Our results show clearly that, despite known historic exposure to amosite and chrysotile, amosite is by far the predominant residual fiber, and there are correlations between amosite measures and disease. Chrysotile was present inconsistently and in relatively small amounts, and no correlations were found between chrysotile measures and disease."[187]

304. According to Professor Patrick Brochard of the Pellegrin Hospital in Bordeaux, France, "chrysotile is carcinogenic, but not below a certain dosage level, unlike amphiboles".[188] Health and Safety Executive concludes in the Review of Fibre Toxicology that, for chrysotile, "the balance of toxicological evidence does not support the non-threshold model for asbestos-induced lung cancer. A practical threshold is likely".[189] Even the WHO suggests that a threshold exists for chrysotile. In discussing the incidence of mesothelioma in workers exposed to chrysotile, the WHO concluded in 1998 that "[n]one occurred in workers exposed for less than two years."[190] And this statement was in regard to workers in the mining and milling sectors, likely handling chrysotile and amphibole fibres.

Question 11:[191] **Has the article of Brazil's Law No. 9055, cited in paragraph 4.17 of its written submission, according to which miners and wholesalers are prohibited from supplying chrysotile or substitute fibers to any company that does not comply with any provision of the law, already been put in practice? Could Brazil provide written evidence thereof, including copies of all relevant court or administrative decisions, statistics on the number of cases in which the article has been applied, etc.?**

305. There has been no occasion to enforce this or any other article. As demonstrated in a document provided by Brazil to the Panel,[192] supplies are immediately withdrawn as soon as non-compliance is discovered. The supply resumes only after compliance measures demanded by ABRA have been implemented. More importantly, the question is irrelevant to this proceeding. Brazil describes its own practice merely to show the Panel that exposure can be controlled. France's obligation is to adopt the least restrictive means of achieving its own level of safety. That might require controls or restrictions in addition to those imposed by Brazil.

Question 12: Has the article of Brazil's Law No. 9055, cited in paragraph 4.17 of its written submission, according to which there should be prompt Department of Justice enforcement against infractions of that law, already been put in practice? Could Brazil please provide written evidence thereof, including copies of all relevant court or administrative decisions, statistics on the number of cases in which the article has been applied, etc.?

306. See Brazil's response to EC Question 11.

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[186] Mossman, B.T. and Churg, A., *Mechanisms in the Pathogenesis of Asbestosis and Silicosis*, Am. J. Respir. Crit. Care Med., Vol. 157 at 1667 (1998).

[187] Churg, A. and Vedal, S., *Fiber Burden and Patterns of Asbestos-Related Disease in Workers with Heavy Mixed Amosite and Chrysotile Exposure*, Am. J. Respir. Crit. Care Med., Vol. 150, No. 3 at 667 (1994).

[188] Le Monde, *The Dangers of Asbestos*, (7 December 1994).

[189] Review of Fibre Toxicology at 1 (1996).

[190] *IPCS Environmental Health Criteria (203) on Chrysotile Asbestos*, WHO, Geneva, 1998, at 8.

[191] Brazil notes that EC Questions 11 through 15 are irrelevant to this proceeding. Brazil nonetheless supplies following answers in order to be as responsive as possible to the EC.

[192] Letter from ABRA (Associação Brasileira do Amianto) to SAMA, dated 16 March 1999.

Question 13: Could Brazil please provide all available information on the results of its "research into and confirmation of the health effects of chrysotile and its substitutes" foreseen in its Law No. 2350 (paragraph 4.18 of its written submission)? Please provide copies also of those results.

307. Two types of research are under way: epidemiological research and research on bio-persistence. The epidemiological research is far from completion, but tracks the health of thousands of asbestos workers in Brazil. Results or a summary thereof will be provided as soon as they are available. The preliminary findings on bio-persistence are presented in Dr. Bernstein's study,[193] provided by Brazil to the Panel. Moreover, as discussed in response to EC Question 7, research performed in the EC and elsewhere demonstrates that substitute fibres present significant health risks.

Question 14: The so-called Tripartite Agreements (paragraph 4.19 of its written submission), "make ABRA", the Brazilian Asbestos Association "responsible for providing the companies with technical assistance regarding controls and preventive measures." Has ABRA ever provided such assistance to French client companies of Brazilian chrysotile producers? If so, please provide evidence thereof.

308. Yes, ABRA provides assistance to those companies that join as members and request assistance. As the French Government well knows, among ABRA's members is Brasilit S/A, a French company that is one of the largest cement fibre producers in Brazil. (Other ABRA members are German and United States companies.) Moreover, ABRA is available to assist any French or EC company needing assistance after the ban is lifted.

Question 15: Brazil's written submission does not clearly explain what the Brazilian legal requirements and practices are regarding the waste generated by end-users of products containing asbestos, for instance when parts of asbestos-containing-products have to be cut off to fit certain uses or when buildings, installations, and other structures containing asbestos are demolished? Could Brazil please provide detailed information, including references to legislation, on this question?

309. Brazilian environmental legislation addresses "residues," including chrysotile residues. The Tripartite Agreements require zero residue or complete recycling of residues in the industrial processes for producing chrysotile cement products. Also, imports of amphibole were banned years ago and the asbestos Brazil produces is chrysotile. Because Brazilian asbestos use is limited to chrysotile and chrysotile products, no health effects have been associated with disposal of cut-off pieces of asbestos cement pipe or roofing. However, cement companies have adopted procedures where they accept and recycle "waste." End users are directed to return the waste to the point of purchase, which then returns it to the producer. The producer recycles the waste in its industrial process. Certainly, France has the ability to regulate chrysotile "waste," just as it regulates wastes from many other production processes.

Question 16: In paragraph 4.33 of its written submission, Brazil claims that what it calls "modern-day" products containing chrysotile do not contain loose, friable chrysotile fibres. Could Brazil provide the data it possesses on exposure levels occurring when these products are actually used in practice (for instance when cutting or sawing these products in workplaces or homes, or when demolishing the buildings and other structures in which they are present)?

310. The Brazilian Government has not conducted or sponsored any studies on workplace exposure levels. However, as the EC well knows, many studies document that exposure levels

[193] David M. Bernstein, *Summary of the Final Report on the Chrysotile Biopersistence Study*, 2 October 1998.

depend upon the controls used. Brazil directs the EC to the INSERM Report at page 70. There, INSERM sets out exposure levels for uncontrolled activities. The levels range from 10 f/ml for a person silly enough to change a friction element on a machine for making corrugated fibreboard and then clean it with a blow gun, to 0.15 f/ml for a person removing a false ceiling. Do-it-yourself activities such as cutting an asbestos seal, and drilling holes in sprayed asbestos fall in between these levels and for the most part are under 1 f/ml. But these value are for uncontrolled use. Controlled use would yield much lower exposure rates. Moreover, controlled use, plus, as INSERM terms it "protection measures" would yield no or *de minimis* exposure. Indeed, at page 70, INSERM refers briefly to a study (CORN) in which the concentrations of fibres for "work in buildings" ("dismantling false ceilings, cable passageways, electrical work and encapsulation"), ranged "between 0 and 0.228 f/ml." On the related topic of the safety of controlled use, INSERM makes several interesting points. These data are relevant, INSERM states at page 71, because:

> "In the area of para-occupational exposure, related in particular to do-it-yourself activities, there are no data in the literature allowing documentation of the subject. In each basic operation - welding, cutting asbestos board, cutting or drilling asbestos cement and so on - it seems justifiable to consider the emission peaks to be identical to those found during industrial operations of the same type. The possible differences in exposure levels, in terms of inhaled doses, are eventually to be found in exposure times, as the do-it-yourselfer does not perform such operations as often as occupational workers."

311. Thus, experience with occupational exposure to asbestos is applicable to do-it-yourselfers, provided one recalls that exposure times are far less for do-it-yourselfers than for asbestos workers. The following discussion recounts INSERM's conclusion regarding occupational exposure. First, INSERM notes that mesothelioma stems from past occupational exposure. According to INSERM (page 182), "stringent worker protection measures" can eradicate mesothelioma: "[b]ecause of the occupational source of asbestos exposure, mesothelioma incidence is not rising in a few countries that implemented stringent worker protection measures at an early date." Regarding asbestosis, INSERM (page 327) notes that "[t]he current levels of exposure in industries that use asbestos directly should lead to an end of confirmed cases of asbestosis (Doll *et al.*, 1985)." INSERM (page 327) also cites the Peto study, which the EC heavily relied on, for the proposition that "[e]xposure prevention measures have removed this disease [asbestosis] from the list of the causes of death at a British Textiles firm." Thus, contrary to the conclusion reached by the French Government and the position adopted by the EC in this proceeding, chrysotile can be safely used, and even INSERM concedes this fact.

Question 17: In footnote 42 of paragraph 4.27 of its written submission, Brazil seems to imply that the TBT Agreement would require a "rational link" between the measure and the risk assessment, in apparently the same sense as the case law cited therein from the SPS Agreement requires. Could Brazil identify the provision of the TBT-Agreement that justifies this allegation?

312. A rational link requirement is implicit in the text of the TBT Agreement. Article 2.2 states that a technical regulation "shall not be more trade restrictive than necessary to fulfil a legitimate objective." The risk assessment is the basis of the level of safety chosen, which, in turn, is the basis of the measure taken. Absent any rational link between the measure taken and the risk assessment, this chain breaks. Thus, there must be a rational link to ensure that the measure taken is not more trade restrictive than necessary to fulfil the legitimate objective, the general statement of the level of safety, which is based on the risk assessment. Moreover, the very nature of the WTO agreements suggests that a rational link is necessary. One does not find in international agreements a "rationality clause." Rather, the parties to the agreement understand that the provisions are to be interpreted rationally. Does the EC here suggest that a measure with no rational link to a risk assessment should be found WTO consistent? Brazil notes that it presented the panel reports addressing the SPS Agreement to

ensure that the Panel was informed that a similar issue already had been addressed and resolved under the SPS Agreement.

Question 18: Has the study by Dr. David M. Bernstein, cited by Brazil, been published in a peer-reviewed journal?

313. The study by Dr. D. Bernstein was planned in two phases. The first phase (now complete) involved the evaluation of the biopersistence and morphological disposition of chrysotile fibres following inhalation exposure. Dr. Bernstein presented portions of the first phase 10 November 1998 at the Giornata Scientifica sulle Fibre di Vitro in Rome. The second phase is currently under way and involves a similar study of biopersistence and morphological disposition of both short and long tremolite fibres following inhalation exposure. Dr. Bernstein has confirmed that these studies will be published in a peer-reviewed scientific journal when the results from Phase Two are available. In the interim, Dr. Bernstein has published or presented the following reports: (i) a publication providing the scientific basis leading the European Communities to incorporate fibre biopersistence as a key parameter in assessing fibre toxicity[194]; a presentation of the chrysotile biopersistence and morphological disposition results at a scientific colloquium presented at the Universidade Federal de São Paulo (Brazil) 19 March 1999; and an abstract by Dr. Bernstein entitled *The Inhalation Biopersistence and Morphologic Lung Disposition of Pure Chrysotile Asbestos in Rats* has been accepted for presentation at the "7th International Symposium on Particle Toxicology" which will be held in Maastricht 12-15 October 1999.

314. More fundamentally, however, Brazil disputes the relevance of the EC' question. What matters is the soundness and relevance of the research, not whether it has been published yet. These facts INSERM concedes at page 135 of its Report. There, INSERM discusses a study by Camus *et al.*, describing it as "an as yet unpublished study whose preliminary results have been communicated to us." INSERM notes that, although unpublished, the study is particularly valuable because it was prepared, in part, by "particularly competent experts." *Id.* Dr. David M. Bernstein is a particularly competent expert. As the EC well knows, the EC has hired him (as has the Government of Germany) to study and develop recommendations concerning the proper control of fibres. Indeed, he is still in the employ of the EC.

Question 19: In paragraph 4.28 of its written submission, Brazil refers to the "modern-day internationally recognised controlled-use level of 1f/ml," based on a reference to a 1991 document. Is Brazil aware that in 1998 the WHO concluded that no threshold has been identified below which asbestos, including chrysotile, can be considered to be safe (see Annex II-1 of first written EC submission)?

315. Yes. Many different organizations have reached different conclusions about safe exposure levels. The United States and Canada, for example, have adopted exposure levels that are significantly higher than those of Brazil. A careful review of the WHO study indicates that the WHO conclusion was based on concern regarding chrysotile mixed with amphibole:

> "The more rapid removal of chrysotile fibres from the human lung is further supported by findings from animal studies showing that chrysotile is more rapidly cleared from the lung than are amphiboles including crocidolite and amosite."[195]

[194] *The Scientific and Health Related Reasons for Fiber Classification by the EC*, D.M. Bernstein in VDI Berichte 1417 published by *the* Verein Deutscher Ingenieure, VDI Verlag GmbH, Düsseldorf, 1998 (ISSN 0083-5560, ISBN 3-18-091417-3).

[195] *IPCS Environmental Health Criteria (203) on Chrysotile Asbestos*, WHO, Geneva, 1998, at 4-5.

316. These conclusions led the WHO to recommend research on the effects of exposure limited to chrysotile without any exposure to amphibole.[196] This is precisely the type of research Dr. David M. Bernstein is conducting.

Question 20: Could Brazil elaborate on the relationship and possible limits of Article 12, in particular 12.3, of the TBT Agreement with the right of Members to take measures to protect human health in their territory?

317. No relationship exists, but this is not an issue in the present case. Brazil totally agrees that protecting public health is a legitimate objective. However, here France has taken a measure that is more trade restrictive than necessary to fulfil the purported objective of protecting public health. Moreover, France did not even consider the fact that Brazil mines and exports only chrysotile, not amphibole or a chrysotile/amphibole mixture. This is inconsistent with the TBT Agreement. (Please refer also Brazil's response to Panel Question 1.)

Question 21: Could Brazil please provide data, including scientific evidence, of the number of cases of mesothelioma observed and their evolution during the last 20-30 years in its territory?

318. No case of lung cancer or mesothelioma from exposure only to chrysotile has been reported (this currently is being confirmed in the epidemiological study). Only three cases total of mesothelioma have been reported in Brazil. All of these were in individuals with substantial exposure to amphibole.

Question 22: In paragraph 4.14 of its written submission, Brazil states that "Recent research focusing on uncontaminated chrysotile demonstrates why it presents no health risk whatsoever". Could Brazil provide copy of this scientific evidence?

Question 23: In its oral presentation, Brazil stated that INSERM has not taken account of studies which show that there is no risk associated with what it calls "modern" use of chrysotile. Could Brazil provide copies of the studies concerned, including references to the relevant paragraphs?

319. Brazil has addressed these questions with one answer because they raise similar issues.

320. Brazil has provided a copy of Dr. Bernstein's study.[197] Please also refer to three other studies presented by Brazil,[198] which, in sum, " … support the hypothesis that adverse effects are associated rather with the fibres retained (amphiboles), than with the ones being cleared (largely chrysotile)."[199] These studies show that, and explain why, modern uses of chrysotile alone present no health risk. In addition, please recall that in 25 years of operation, the Capivari Chrysotile Cement Plant in Brazil has not experienced one case of mesothelioma (please refer to Brazil's presentation in Section IV of this Report). This health history is similar to that at other work sites using chrysotile (and even some in which chrysotile was predominant in a mix of chrysotile and amphibole). In the Executive Summary of The Workshop on Health Risks Associated with Chrysotile Asbestos,

[196] Id. at 145.

[197] David M. Bernstein, *Summary of the Final Report on the Chrysotile Biopersistence Study*, 2 October 1998.

[198] Cossette M., *Substitutes for Asbestos*, 4 December 1998; Brown *et al.*, *Mechanisms in Fibre Carcinogenesis*, Proceedings of a NATO Advanced Research Workshop on Mechanisms in Fibre Carcinogenesis, 22-25 October 1990, New Mexico, United States; Peraud A. and Riebe-Imre M., *Toxic and Chromosome-Damaging Effects of Natural and Man-Made Mineral Fibers in Epithelial Lung Cells in vitro*, Institute of Experimental Pathology, Hannover Medical School, Germany.

[199] Albin, M. *et al.*, *Retention Patterns of Asbestos Fibres in Lung Tissue among Asbestos Cement Workers*, Occup. & Env. Med., Vol. 51, No. 3 at 211 (1994).

Dr. Graham W. Gibbs emphasized the importance of the "absence of lung cancer and mesothelioma risks in workers exposed to reportedly high concentrations of chrysotile in a UK asbestos cement plant in which silica was not used, as well as two similar plants in Zimbabwe …".[200] A clean bill of health also has been assigned to chrysotile as used by shipyard workers and insulators in the Pacific Northwest of the United States. According to Churg and Vedal (1994):

> "Our results show clearly that, despite known historic exposure to amosite and chrysotile, amosite is by far the predominant residual fiber, and there are correlations between amosite measures and disease. Chrysotile was present inconstantly and in relatively small amounts, and no correlations were found between chrysotile measures and disease."[201]

4. Questions from the European Communities to the United States

Question 1: In paragraph 4.47 of its submission, the US states that chrysotile asbestos is no less toxic than other forms of asbestos. Could the US please develop this statement further, including, if possible, references to and/or copies of the scientific grounds on which it is based?

321. The United States refers the Panel to its third party presentation in this case (see Section IV of this Report). In addition, the United States points out that a review of lung burden studies in human subjects and mechanistic studies does not provide convincing evidence for the "amphibole hypothesis" that chrysotile may be less potent than amphiboles in the induction of mesothelioma.[202] Animal studies support the conclusion that all types of asbestos should be considered equally potent with respect to the production of either lung cancer or mesothelioma.[203] For instance, in an inhalation study in which groups of rats were exposed to the five UICC asbestos fibre types[204], amosite, anthophyllite, crocidolite, Canadian chrysotile, and Rhodesian chrysotile, comparable incidences of lung tumours and mesotheliomas were induced by all types of asbestos fibres.[205] While epidemiological studies clearly demonstrate a link between asbestos exposure and increased risk of lung cancer and mesothelioma, most of the studies involve workers that were exposed to mixed fibre types. Nevertheless, there are a number of epidemiological studies of workers that were exposed predominantly to chrysotile and one study in which the exposure was solely to amosite.[206] There is no statistically significant difference in the risk of lung cancer seen in the group of workers exposed only to amosite compared to those exposed predominantly to chrysotile in textile production or to mixed fibres in manufacturing.[207] In addition to evidence showing the causal relationship of exposure to chrysotile asbestos and cancer, ample evidence shows that exposure to chrysotile asbestos poses a significant risk of non-malignant respiratory disease.[208] One study, which reported mortality and

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[200] Workshop on Health Risks Associated with Chrysotile Asbestos, held at St. Helier, Channel Islands, 14-17 November 1993, Executive Summary, at page 2.

[201] Churg, A. and Vedal, S., *Fiber Burden and Patterns of Asbestos-Related Disease in Workers with Heavy Mixed Amosite and Chrysotile Exposure*, Am. J. Respir. Crit. Care Med., Vol. 150, No. 3 at 667 (1994).

[202] Stayner, L.T., Dankovic, D.A., and Lemen, R.A., *Occupational Exposure to Chrysotile Asbestos and Cancer Risk: A Review of the Amphibole Hypothesis*, 86 American Journal of Public Health 179-186 (1996), republished at http://www.cdc.gov/niosh/pdfs/97-162-d.pdf .

[203] *Airborne Asbestos Health Assessment Update* (EPA, June 1986) at 126-132.

[204] The United States notes that these represent the most important types of asbestos fibres, as recognized by the International Union Against Cancer (UICC).

[205] Wagner, J.C., Berry, G., Skidmore, J.W., and Timbrell, V., *The Effects of the Inhalation of Asbestos in Rats*, 29 Br. J. Cancer 252-269 (1974); *Airborne Asbestos Health Assessment Update*, (EPA, June 1986) at 128 and 130.

[206] According to the United States, no data exist, from any studies, concerning risks to workers exposed solely to crocidolite.

[207] *Airborne Asbestos Health Assessment Update*, (EPA, June 1986) at 53, 80-82, 106-108.

[208] In the mid-1980s, OSHA performed a quantitative risk assessment to justify amendments to its standards. This risk assessment was published in 1986 as "Occupational Exposure to Asbestos, Tremolite,

assessed dose-response relationship for asbestosis in a cohort of asbestos textile workers exposed only to chrysotile, found that 17 (5.5 per cent) of 308 deaths were due to asbestosis or pulmonary fibrosis. A second study reported data showing a linear relationship between cumulative fibre dose and morbidity. A third study reported a linear dose-response relationship between asbestosis and levels of asbestos dust. These data also support the hypothesis of no threshold, or low threshold for asbestos, since there is increased risk at cumulative exposures as low as 37 fiber-years/cc.[209]

322. Because of the carcinogenicity and asbestosis-producing effects of all asbestos types, the U.S. Environmental Protection Agency (EPA) and the Occupational Safety and Health Administration (OSHA) of the U.S. Department of Labor do not distinguish among asbestos fibre types in their regulations.[210] In testimony in 1990, Richard Lemen, Assistant Director of the U.S. National Institute for Occupational Safety and Health, summed up the case against distinguishing among asbestos fibre types in public policy. We quote from his testimony:

> "Recent reports have appeared in the scientific literature to suggest that different forms of asbestos are not equally pathogenic. … However, there is a great deal of uncertainty associated with these findings and equally important contradictory evidence. Results from research involving animal bioassays present a strong case that there is no safe form of asbestos. … Not only has chrysotile been found to be as potent as crocidolite and other amphiboles in inducing mesotheliomas when injected intrapleurally. … it has been found equally potent in inducing pulmonary neoplasms through inhalation exposures (Wagner *et al.*, 1974). Chrysotile also appears to be more potently fibrogenic and carcinogenic than amphiboles, in relation to the quantity of dust deposited and retained in the lungs of rats (Wagner et al, 1974).
>
> … In fact chrysotile fibers are much more chemically and biologically reactive than amphibole fibers. … These fibers are less readily detected in the tissue after the damage is done. …
>
> At this time, there is no compelling evidence to justify different public health policy for different asbestos fiber types…".

323. Lemen also notes that the Royal Commission study submitted by Canada to the Panel recommended that textile manufacturing using chrysotile be banned, and concluded that "all fibre types can cause all asbestos-related diseases."[211]

Question 2: In paragraph 4.47 of its submission the United States writes: "[s]pecification of work practices and other controls does not avoid all the risks associated with a hazardous materials such as chrysotile asbestos." Could the US please expand on this statement, and if possible provide (references to) the facts and data that support this viewpoint?

Anthophyllite and Actinolite: Final Rules", in volume 51 of the U.S. *Federal Register* at pp. 22615 to 22650 (51 FR 22615-22650) and has been submitted as U.S. Exhibit 38.

[209] Studies by Dement et al (1983) referred to at 51 FR 22624, Finkelstein (1982) discussed at 51 FR 22645 and Berry *et al.* discussed at 51 FR 22645, in OSHA risk assessment submitted as U.S. Exhibit 38.

[210] At the Panel's meeting with third parties, Brazil alleged that worker exposure standards of the U.S. Department of Health and Human Services differ for chrysotile and other asbestos. EPA and OSHA are not aware of any such standards. A 1996 HHS Public Health Service report referred to an exposure standard of the American Conference of Governmental Industrial Hygienists (ACGIH), but it should be clear that the ACGIH is *not* a U.S. government agency and its threshold values are *not* regulatory standards.

[211] Statement by Richard Lemen before the Subcommittee on Toxic Substances, Environmental Oversight, Research and Development, Committee on Environment and Public Works, April 26, 1990, p. 104-105, Item E in *Asbestos Bibliography (Revised)*, Sept. 1997, DHHS (NIOSH) Publication No. 97-162, published at http://www.cdc.gov/niosh/97-162.html; Lemen testimony is in document http://www.cdc.gov/niosh/pdfs/97-162-d.pdf and is submitted as U.S. Exhibit 44.

324. In response to the statements throughout the Canadian submission that "controlled use" will bring the risk associated with chrysotile asbestos to "undetectable" levels, in its third party's submission to the Panel the United States has discussed the fact that "controlled use" will not completely eliminate the risk caused by asbestos. In 1994 OSHA reduced its permissible exposure limit for occupational exposure to asbestos to 0.1 fibres per cubic centimeter (f/cc) as a time-weighted average measured over 8 hours. Based on its risk assessment OSHA found that the excess cancer risk at that level would be a lifetime cancer risk of 3.4 cases per 1,000 workers and a 20 year exposure cancer risk would be 2.3 per 1000 workers. OSHA found that this risk is still significant and the United States Court of Appeals for the D.C. Circuit affirmed this finding. OSHA set this limit because it believed that it was the lowest exposure level using feasible engineering and work practice controls. It is not a risk-free limit. In other words, there is a still significant health risk at or below OSHA's permissible limit. For this reason, and because some employers do not adequately implement the work practices, many asbestos workers rely on respirators (masks). Asbestos removal work often is done by poorly paid and poorly trained workers. OSHA has found that respirator effectiveness depends on how well the masks fit, how often they are replaced, cleaned and repaired, and how well employees are trained. In spite of rules requiring good respirator practices, studies show that many employers do not comply and that respirator-wearing employees still get high exposures. OSHA recently calculated, based on studies of respirator effectiveness, that up to 40 per cent of employees who wear respirators get essentially no protection when their employers do not adequately fit, clean and replace the respirators they wear.[212] Also, where employees are protected solely by masks, the uncontrolled asbestos dust released during their work is airborne and contaminates the work-site. A major work practice in asbestos handling is wetting the tool used to cut or disturb the asbestos material or wetting the material itself. When the material dries, the dust becomes airborne.

325. Most asbestos-containing products are installed, disturbed or removed on construction work-sites. Construction jobs typically involve transient employees who may work for many different employers; short term work; and lack of training opportunities compared with factory employment. These factors make enforcing work practices and good respirator practices difficult. Another problem is that renovation work occurs in buildings that may or may not contain asbestos. This uncertainty leads to under-protecting the workers. Also, construction worksites have many immediate safety hazards. Employers and employees may concentrate on avoiding these immediate hazards and pay less attention to the risks of chronic hazards caused by asbestos. The difference between exposure levels when employers use available controls and when they do not is striking. During OSHA's rulemaking, the U.S. Argonne National Laboratory (ANL) reported to OSHA concentrations during cutting operations of asbestos-cement sheet that ranged from 8 to 14 f/cc without local exhaust as compared to 0.04 to 0.15 f/cc when local exhaust was used. Similarly, sampling data collected by the U.S. National Institute of Occupational Safety and Health (NIOSH) during the installation of asbestos-cement sheet ranged up to 0.32 f/cc when local exhaust ventilation was not being used. Similarly, when cutting asbestos-cement pipe with an abrasive disc saw and cutting and machining pipe without a shrouded tool or without using wet methods, exposures exceeded OSHA's exposure limit of 0.1 f/cc. Many asbestos product manufacturing and installation jobs expose workers to over the OSHA permissible exposure limit of 0.1 f/cc when dry operations take place. For example, OSHA determined in 1986 that "it is generally not feasible for the dry operations of carding and spinning (in textile operations) to comply with" the then permissible limit of 0.2 f/cc. OSHA also found that in the asbestos reinforced plastic manufacturing process, the "problem exposure areas" appear to be in dry finishing operations. These operations are similar to dry mechanical operations in other asbestos products manufacturing industries and include grinding and sanding, which OSHA has determined may not be feasible to achieve exposure levels below 0.2 f/cc

[212] 63 FR 1164-71, January 8, 1998.

without the use of respirators.[213] Based on OSHA 's risk assessments, lifetime cancer risks at these levels are 6.7 per 1000 exposed workers.

326. Moreover, as discussed in both the U.S. and EC submissions to the Panel, the steady enlargement of the stock of asbestos and asbestos-containing materials in society, which results from failure to ban further use of asbestos, may engender substantial risks where demolition or maintenance takes place and the composition of materials is not obvious. As indicated in the U.S. third party's submission, EPA has asbestos regulations in place which govern work practices and other controls to be used during the demolition of buildings[214], and maintenance activities in schools.[215] These regulations require those engaging in such activities to identify asbestos-containing materials, or to assume that certain materials are asbestos-containing, prior to commencement of the work. If the composition of the material is unknown, in the absence of such regulatory requirements concerning work practices and controls, workers could be unprotected. The United States believes that unprotected workers who undertake building demolition or maintenance activities involving asbestos-containing materials would be subject to the exposure levels set forth by OSHA in Table 6 of the preamble to its final rule governing occupational exposure to asbestos.[216] Table 6, entitled "Estimated Occupational Exposure to Asbestos and Reduction in Cancer Risk in General Industry and Shipyards as a Result of the Final Revision to the Standard",[217] presents average baseline exposure levels in the absence of respiratory protection and other primary controls and work practices.[218] These figures are given in the third column of the table, entitled "Potential mean fiber exposure with minimal controls (f/cc)".[219] Such exposure levels would be expected to occur for unprotected workers. Based on this table, the exposure level for an unprotected worker involved in a demolition project would be 9.9 f/cc, or almost one hundred times the permissible exposure limit of 0.1 f/cc established by OSHA.[220] The 1991 Health Effects Institute-Asbestos Research report estimates that the lifetime risk to workers historically exposed to levels of that magnitude is approximately 200,000 per million, or 1 in 5.[221]

327. EPA has issued public guidance concerning asbestos-containing products and their management.[222] In addition, EPA has issued lists of suspect asbestos-containing materials.[223] But it cannot be assumed that many "Sunday carpenters" know about such guidance, especially since they may not even be aware that they are working with asbestos-containing materials. The data in Table 6

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[213] *Occupational Exposure to Asbestos, Tremolite, Anthophyllite and Actinolite: Final Rules*, at 51 FR 22659-22660.

[214] Asbestos National Emission Standards for Hazardous Air Pollutants (NESHAP), 40 CFR 61.145. This standard applies to demolition or renovation of a "facility", defined at 40 CFR 61.141 to mean "any institutional, commercial, public, industrial, or residential structure, installation, or building (. . . excluding residential buildings having four or fewer dwelling units). . . .", thus excluding single-family homes. (Asbestos National Emission Standards for Hazardous Air Pollutants (NESHAP), 40 CFR 61.141.

[215] These regulations, which relate to operations and maintenance activities in school buildings, are at 40 CFR 763.91, contained within 40 CFR part 763, subpart E.

[216] OSHA Final Rule on Occupational Exposure to Asbestos, 59 FR 40964, 41036-38, August 10, 1994.

[217] Ibid. at 41036-37.

[218] Ibid. at 41038, col. 1.

[219] Ibid. at 41036-37.

[220] See, e.g., 29 CFR 1926.1101(c)(1).

[221] HEI, *Asbestos in Public and Commercial Buildings: A Literature Review and Synthesis of Current Knowledge* (Health Effects Institute-Asbestos Research Report 1991) at 1-11.

[222] For example, *Managing Asbestos in Place: A Building Owner's Guide to Operations and Maintenance Programs for Asbestos-Containing Materials* (EPA, July 1990).

[223] *See, e.g., Guidance for Controlling Asbestos-Containing Materials in Buildings* (EPA, June 1985) at Appendix A. "Asbestos-Containing Materials Found in Buildings".

of the preamble to the OSHA rule[224] could be used to estimate exposures to these unprotected persons as they periodically engage in repair activities such as those involving ceiling tiles, plumbing, roofing, and drywall, based on such factors as the frequency and length of these intermittent exposures.

Question 3: In paragraph 4.51 of its submission the US states: "The use of a linear model is appropriate for a quantitative estimation of the risks associated with low levels of exposure to asbestos ….". Could the US further elaborate on this statement, explaining why it considers the use of a linear model – which implies that there is no threshold below which there is no carcinogenic risk – appropriate?

328. As indicated in the U.S. third party's submission (footnote 4, paragraph 8, and Exhibit 15), studies of workers exposed to asbestos in the workplace (occupational exposures) link such exposures to high incidences of lung cancer and mesothelioma. However, since workplace exposures to asbestos are higher than general environmental exposures, these occupational exposures lead to an incidence of disease that is considerably higher than for the general population. The International Agency for Research on Cancer (IARC) and the World Health Organization's International Programme on Chemical Safety (IPCS) recognize that there is no conclusive evidence to demonstrate that there is an exposure level for asbestos below which there is no risk, i.e., there is no "threshold" for asbestos. Even the Report of the Royal Commission on Matters of Health and Safety Arising from the Use of Asbestos in Ontario stated: "Most epidemiological studies of asbestos workers that have demonstrated an excess lung cancer risk associated with the inhalation of asbestos have produced results consistent not only with a linear relationship between cumulative dose and mortality, but also consistent with the absence of a threshold."[225] EPA uses a linear model to estimate the risks associated with low levels of exposure to asbestos because of the observed linearity of the response in occupational studies and because of the incomplete understanding of how asbestos causes diseases in humans. In order to estimate and project excess risks at the low level of exposures to which the general public is subject for asbestos, EPA utilizes a mathematical model that shows excess risks as simply proportionate to exposures at low levels (low-dose linearity). This procedure uses a curve to describe the excess incidence of disease observed at higher exposures (in the occupational setting) and takes a straight line to project from this excess to the lower-exposure environment of the general public. EPA believes that this approach is a reasonably protective way to address the issue of effects associated with low levels of exposure to asbestos.

329. Furthermore, as the United States points out in its submission, the limited data that exist for low levels of exposure to asbestos relating to the incidence of mesothelioma also indicate a linear relationship. In addition, the following should be noted, as indicated in the U.S. submission. Canada's statement that "no epidemiological study to date has detected a higher health risk [than the linear model] resulting from low levels of exposure"[226] does not take into account that, by their very nature, epidemiological studies are capable of detecting only relatively large incidences of cancer. Null results from epidemiological studies conducted at low exposure levels do not prove the absence of carcinogenic effects at such levels because such results can arise from such factors as inadequate study design or small population size. In 1986, OSHA also published a quantitative risk assessment of asbestos, as a basis for amendments made in 1986 and 1994 to the OSHA asbestos standards. The risk assessment made the following key findings concerning the dose-response relationship in the case of asbestos. With regard to lung cancer, the data from several well-conducted epidemiologic studies show that a linear model best describes the dose-response relationship. With regard to mesothelioma,

[224] OSHA Final Rule on Occupational Exposure to Asbestos, 59 FR 40964, 41036-38, August 10, 1994 at 41036-37.

[225] *Report of the Royal Commission on Matters of Health and Safety Arising from the Use of Asbestos in Ontario*, p. 281.

[226] See Section III.B.7 of this Report.

a linear model is reasonable, fits the data well, and is the best estimator of risk.[227] As noted in the U.S. submission, IPCS found a linear dose-response relationship for mesothelioma in its 1998 risk assessment on chrysotile.

330. OSHA conducted a public hearing in 1984 with participation by major scientists and researchers in the field, including Dr. Kenny Crump, who testified that the linear model "has been widely used … for asbestos and lung cancer." Dr. William Nicholson and Dr. Hans Weill also supported the use of the linear model to predict lung cancer risk. Dr. Weill testified: " … as far as the shape of the curve for the important malignant consequences of asbestos exposure, I think we are all in agreement. . . that the evidence does not permit us, nor does concern for public health or prudence permit use . . . (of) risk analysis on any basis other than linearity of exposure and response and in a no threshold model."

Question 4: Does the US consider that any of the currently used substitutes in the US for chrysotile asbestos are as dangerous or more dangerous than chrysotile?

331. The big picture of asbestos is that asbestos-exposed workers are right now being diagnosed with disabling asbestosis and mesothelioma that has clearly been caused by asbestos exposure. Asbestos-exposed workers are also being diagnosed with lung cancer. Because lung cancer is also caused by exposure to other toxic agents, it is sometimes difficult to prove that it was the asbestos exposure that caused the lung cancer in these individuals. However, looking at the epidemiological studies of workers, there is no doubt that the asbestos exposure causes lung cancer, and that the workers' exposure either caused the lung cancer or played a large part in causing lung cancer (as discussed above, no significant difference exists between the toxicity of chrysotile asbestos and other asbestos). The question above asks whether there is an equivalent or stronger causal relationship to human disease or death in the case of substitute fibres or products containing them.

332. To begin with, as stated in the U.S. submission, in some instances asbestos use in a product (e.g. an asbestos-lined hot pad) is not essential, and the "substitute" consists of simply subtracting asbestos from the product, or using other materials such as iron or ceramic for the same purpose (e.g. an iron or ceramic trivet) or otherwise reformulating the product so that neither asbestos nor substitute fibres are used. In this case the health effects of substitutes are nil or trivial. As indicated in the U.S. submission, there is no evidence that any of the currently used substitutes in the U.S. for chrysotile are as dangerous or more dangerous than chrysotile. The only fibre that has been shown to be more hazardous than chrysotile is another naturally occurring fibre, erionite.[228] However, erionite is not currently used in commerce. Based on the current understanding of how fibres can cause adverse health effects, available data indicate that the differences in physical structure and properties between substitute man-made mineral fibres (MMMFs) and chrysotile, such as the larger diameter of MMMFs and the fact that they break transversely rather than longitudinally to shorter fibres, may render some MMMF substitutes less dangerous than chrysotile. No MMMF has the same magnitude of carcinogenic potential as asbestos. A man-made mineral fibre, refractory ceramic fibre, has been shown to have considerable potency in some laboratory animal studies, but the legacy of suffering and death found with asbestos has not occurred. The high cost of refractory ceramic fibres has limited their use to high-temperature industrial operations. As a general matter, exposures to fibreglass have been lower than asbestos fibres. This may be due to the inherent property of fibrous glass to have fewer airborne fibres of a size that is deposited in the lungs.

[227] This risk assessment has been submitted by the United States in *Occupational Exposure to Asbestos, Tremolite, Anthophyllite and Actinolite*: *Final Rules*, 51 CFR 22615-22650.

[228] *Asbestos and other Natural Mineral Fibers* (IPCS 1986), Environmental Health Criteria 53, International Programme on Chemical Safety, World Health Organization, Geneva at 131, 139-140.

5. Questions from the European Communities to Zimbabwe

Question 1: In its oral statement, Zimbabwe appears to argue that the so-called controlled use, including all the protective measures relating thereto, is capable of "minimizing" risk to human health. Could Zimbabwe expand on what it means by "minimize", i.e. which level of risk – and thus chrysotile-caused diseases – would still remain and how much of that risk would be acceptable to Zimbabwe?

333. Zimbabwe first of all wishes to state that, being a natural product, chrysotile asbestos is present, for example, in the air we breathe and that some exposure is thus inevitable. There is therefore no question of eliminating exposure altogether. This said, Zimbabwe recalls that the 1998 Task Group has clearly stated that the risks to humans are conditional on exposure. The goal for responsible governments must therefore be to reduce exposure. It is the contention of Zimbabwe that as a result of the application of risk control measures the risk of exposure to asbestos dust can be minimized - so much so that the use of chrysotile asbestos can be considered safe. There is therefore no justification for a complete ban on the use of chrysotile asbestos. Zimbabwe submits that this conclusion is valid for both "primary" and "secondary" users of chrysotile asbestos. Regarding the former, Zimbabwe notes that the 1998 Task Group has confirmed that:

> "Data from industries where control technologies have been applied have demonstrated the feasibility of controlling exposure to levels generally below 0.5 fibres/ml. Personal protective equipment can further reduce individual exposure where engineering controls and work practices prove insufficient."

334. In Zimbabwe the fibre levels at workplaces where chrysotile asbestos is mined, milled or processed are indeed below 0.5 fibres/ml/eight-hour period. The aim is to bring those levels down even further to 0.3 fibres/ml. It is thus entirely possible for a developed country like France to achieve its target level of 0.1 fibres/ml. As concerns "secondary" users of chrysotile asbestos, Zimbabwe recalls that it has stated in paragraph 4.82 of its written submission that the:

> "Combined use of high-density products made from asbestos-cement, which inherently are low-risk products, coupled with adequate risk control measures minimize the risk of exposure to asbestos dust".

335. Zimbabwe thus believes that the combined use of inherently safe products and adequate risk control measures would enable France to achieve the maximum exposure level it deems acceptable. Zimbabwe finds itself in agreement on this point with Canada and the supporting evidence adduced by it.[229]

Question 2: In paragraph 4.98 of its written submission Zimbabwe suggests putting "asbestos warning messages" next to buildings. Can Zimbabwe explain why there would still be a need for this type of warning if, as it alleges, controlled use results in encapsulating indefinitely chrysotile in cement?

336. Zimbabwe wishes to remind the EC that the relevant part of paragraph 4.98 of Zimbabwe's written submission states as follows:

> "While Zimbabwe recognizes that it may not be readily apparent to an inexperienced person whether or not he/she is handling a product containing asbestos fibres, it is by no means justification for instituting a far-reaching ban on products which might contain asbestos fibres. […] Where the materials have already been installed or incorporated, say, in a building, Zimbabwe does not see why there could not

[229] Baujon et Authier, *Détermination des concentrations de fibres d'amiante dans l'atmosphère lors de la pose sur chantier de plaques ondulées et d'ardoises an amiante-ciment (Rapport 93.189)*, Laboratoire d'hygième et de contrôle des fibres minérales, Paris, 1993, referred to by Canada (see Section III.B.7).

be, for instance, an asbestos warning message next to the evacuation instructions on a notice board of that building."

337. Zimbabwe has also stated in paragraph 4.81 of its written submission that:

"… products made from asbestos-cement are products of high density and thus chrysotile asbestos fibres are firmly blended into the final product [footnote omitted]. This reduces to a minimum the likelihood of fibres being released into the air and thereby posing a health hazard to human beings."

338. Contrary to what the EC tries to suggest, there is no contradiction between the two above-mentioned statements made by Zimbabwe in its written submission. The EC has contended that no measure was available to France other than a complete ban of chrysotile asbestos and of products containing chrysotile asbestos, if France were to achieve its public health objective. The EC relies, *inter alia*, on the argument that it may not be readily apparent to an inexperienced person whether he/she is handling or dealing with a product containing asbestos fibres. In its submission, Zimbabwe addressed this argument put forward by the EC and Zimbabwe pointed out to the Panel that France could have very easily required asbestos warning messages to be posted in buildings, for example, so as to alert "secondary users" of the presence in buildings of chrysotile asbestos, if and where appropriate. The EC' argument does therefore not provide a justification for a ban on chrysotile asbestos. It is true, as the EC rightly points out, that asbestos warnings in buildings are in principle unnecessary in view of the fact that chrysotile asbestos fibres today are encapsulated permanently in cement products. The EC nevertheless asserts that there could still be a risk of exposure to asbestos dust whenever the cement-products are installed, maintained or repaired. Zimbabwe has not contested this. Zimbabwe has, however, pointed out that there is a range of measures which would be available to France to effectively control such risks of exposure. All of these measures stop short of imposing outright bans. Thus, Zimbabwe's submissions are by no means internally inconsistent.

Question 3: Could Zimbabwe explain whether training courses and the certification referred to in paragraph 4.98 of its written submission are the only elements of the so-called "controlled use" which can minimize risk, or does the postulated "controlled use" require also other types of measures?

339. In a sweeping and grossly exaggerated statement the EC has claimed that "Once on the market, there is no further reasonable means of controlling the use of asbestos and, in particular, controlling commonplace operations (cutting, sawing, …) that many persons may have to carry out".[230] Zimbabwe refutes this argument in its third party submission and cites specific and less trade-restrictive measures which could have been used by the French Government. Even assuming *arguendo* that the EC' concern about control were justified with regard to *do-it-yourself users* of asbestos-containing products, Zimbabwe has submitted that, if indeed the French Government was so concerned about those users of asbestos-containing products, it could have easily banned the sale of such products in all do-it-yourself outlets. As an additional measure, the French Government could also have restricted the handling of asbestos-made products to certified experts, thus eliminating exposure of inexperienced private users to asbestos. Through certification the Government could ensure that training meets certain minimum standards and thus enables the individuals concerned to engage in safe work practices.

340. Zimbabwe also addressed the question of how the French Government could have sufficiently protected occupational "secondary users" of chrysotile asbestos other than through an outright ban on asbestos. As explained in Zimbabwe third party's submission, the French Government "could have, for example, required certification, which would only be bestowed upon an individual once he/she had successfully followed information and training courses on the use and handling of asbestos-

[230] See arguments of the EC in Section III.C.1.(c)*(ii)*.

containing products. The French Government could also have laid down the precise work practices and technical appliances that must be used in all contacts with asbestos-containing products. To ensure compliance, the regulations could authorize the imposition of heavy fines or a custodial sentence in the event of a wilful disregard of the government's regulations. Needless to say, it is also open to a Member to run information campaigns. Thus, it emerges clearly from this statement that certification, which would be conditional upon completion of, *inter alia*, training courses, is not the only element of "controlled use". In any event, this statement must be read together with the paragraphs where Zimbabwe has set out the types of measures that together make up "controlled use". It might be added here that in Zimbabwe's view, periodical medical surveillance of workers can and should be an integral part of "controlled use", notably in the case of "primary" and occupational "secondary" users of chrysotile asbestos.

Question 4: Could Zimbabwe comment on the findings of the study by Cullen *et al., Chrysotile Asbestos and Health in Zimbabwe, 1991 Am. J. Int. Med. 19, 171-182,* which establishes a net excess of mesothelioma cases of workers in mines and mills of chrysotile in Zimbabwe?

341. Zimbabwe disputes the assertion by the EC that the study by Cullen *et al.* establishes a net excess of mesothelioma cases of workers in chrysotile mines and mills in Zimbabwe. At page 178 of the study referred to it is stated that "[m]ajor x-ray abnormalities were rare in the population, with only four having evidence of TB and three having nodules or masses that potentially represented cancer." This could hardly amount to conclusive evidence in support of the assertion by the EC. In fact, pleural disease was also surprisingly uncommon in the population which was examined. Eighty-five of the subjects had parenchynal changes of whom 65 were in grade 0/1. The fact that the study in question does show a relationship between parenchynal change and cumulative doses merely confirms the need for risk control measures. In no way does it establish a case for a complete ban on the use of chrysotile asbestos. It is worth noting here that there is another study by Cullen *et al.* entitled *Chrysotile Asbestos and Health in Zimbabwe - Analysis of Miners and Millers Compensated for Asbestos-Related Disease Since 1980* (1991 Am. J. Int. Med. 19, 161 – 169). This study was not, however, specifically on workers of chrysotile mines and mills in Zimbabwe. This was a case study on cases certified as having pneumoconiosis by the Pneumoconiosis Board in Zimbabwe.

342. The fact that this study showed cases of asbestos-related disease does not mean that the origin of those cases can be traced back to chrysotile mines and mills in Zimbabwe. The two cases referred to in the study (numbers 19 and 20), where the histological examination confirmed mesothelioma, were cases of individuals who had also worked in South African crocidolite asbestos mines. They were thus not exposed exclusively to chrysotile asbestos dust. Another case referred to in the study (number 12) had also worked in a crocidolite mine in South Africa for five years. This finding is confirmed by the records of the National Cancer Registry, which have been carefully maintained since 1940 in Bulawayo. The records show no more than 15 cases of mesothelioma. In a detailed study undertaken by Dr. Baloyi *et al.* of those 15 cases, 14 were found to involve individuals who have had mixed exposures, i.e. exposure to both crocidolite and chrysotile asbestos dust. In the remaining case, no exposures could be established. It is very important to note in this connection that in any event all the findings referred to were the result of past exposures. The control measures which have been put in place at the chrysotile mines, mills and manufacturing units in Zimbabwe since then mean that comparable exposure levels will never occur again.

6. Questions from Brazil to the European Communities

Question 1: In regard to the INSERM Report: (a) does it contain any original research (research performed by INSERM during the time the report was prepared)? (b) does it review any study regarding current controlled uses (post 1990 uses of chrysotile products)? (c) does it purport to review all available scientific studies? (d) does it review the then current research performed on the subject by and for the EC, in particular, that regarding bio-persistence and its relationship to disease? (e) if the answer to any of these questions is "no", the report cannot support the ban, can it?

343. The INSERM Report bases its conclusions on the analysis of 1200 international scientific studies, and reviews the status of international scientific knowledge concerning asbestos-related risks at the time of its adoption. It should be pointed out that all the studies on so-called controlled use and on bio-persistence available in 1996 were examined and taken into account in the INSERM Report. The French ban is thus fully justified scientifically. In addition, we do not understand Brazil's reasoning, which amounts to saying that one negative reply, for example to the question in subparagraph (a), would deprive the French Decree of a scientific basis in the light of the large volume of scientific data from the international sources existing on the subject.

Question 2: Why has France not banned all Class I carcinogens?

344. Brazil appears to be referring to an obligation of consistency which does not exist either in the GATT 1994 or in the TBT Agreement. It should be noted that, to our knowledge, no country has imposed a general ban on all Class I products (proven human carcinogens), but several have already banned asbestos. There is no international text imposing a general ban on all Class I products. France imposed a general prohibition on asbestos as a result of a risk assessment. Risk assessment must be specific to each product, and the ensuing national risk management decisions are different according to each product concerned. Of the Class I carcinogens, none has been used in such a widespread way, in products, spreading the carcinogenic risk when they are used, and sold to the general public. Most of these products are subject to very strict marketing restrictions and are usually used in an isolated environment as synthesis intermediates. Thus, they are no longer present in the finished products and hence do not spread the carcinogenic risk when the end-product is used. Besides, none of these products has caused as many deaths or occupational illnesses.

Question 3: How will the ban protect handymen from existing asbestos?

345. The French measure by prohibiting the use of any type of asbestos, including chrysotile asbestos, provides effective protection by stopping future human exposure to risk from this substance. The fact that quantities of asbestos, because of past use, remain and thus may continue to provide a source of risk, does not diminish at all the right of France to take the measure in question to stop further exposure to the risk from new applications. The implicit logic in Brazil's question is that because of possible risks from existing asbestos France should continue adding further risks. This type of reasoning the EC contests. In any case, France has taken indeed very serious and strict measures to protect handymen from existing asbestos. They have been communicated to the Panel[231].

Question 4: Does not France regulate the use of pesticides through use restrictions, labelling and disposal requirements and the like? Are not many of these pesticides extremely toxic? If these types of dangerous products can be regulated to control risk and avoid improper use and disposal during the entire product life cycle, how can France maintain that chrysotile in contrast cannot be regulated?

[231] Affections professionnelles consécutives à l'inhalation de poussières d'amiante, Tableau n° 30 (document submitted by the EC to the Panel).

346. The rationale of regulating the use of pesticides is completely different from that of the ban on the use of asbestos. Use of pesticides is allowed, after proper evaluation, in order to protect human, animal or plant life or health from pests, diseases, illnesses, etc. So although toxic, they serve a specific purpose and their use is authorized under well-specified quantities and conditions. The use of asbestos is not comparable to the controlled use of pesticides, as its use is proposed by Canada exclusively for commercial and economic reasons. To clarify even better the point, the parallel should be drawn with human medicinal products which are allowed to be used under strictly controlled conditions. Taking Brazil's logic to its extreme, it would also suggest prohibiting human medicinal products because asbestos is also prohibited.

Question 5: Have substitute fibres been subject to the same close scientific scrutiny as asbestos? Do not the relevant studies conclude that many of the fibres cause cancer in rats and thus are suspected carcinogens? Does not IARC specify several of them as Class II carcinogens, including glass fibres, rock wool and slag wool?

347. The products used as substitutes for asbestos have been the subject of scientific studies like asbestos. Among all the products that may be used as asbestos substitutes, no fibre has been recognized as a proven human carcinogen (Class I - International Cancer Research Centre), unlike asbestos, which is a proven carcinogen. Only ceramic fibres are classed as Class II carcinogens, i.e. proven for animals, but they are used only in very limited and carefully controlled cases.

Question 6: If France were to remove from the first submission all reference studies that do not distinguish chrysotile and amphibole, is it true that no studies would remain? If some studies would remain, how many would remain?

Question 7: If France were to remove from the first submission all references to studies that do not directly address the risk of current controlled use of chrysotile, isn't it true that no studies would remain? If some studies would remain, how many would remain?

348. Those questions of Brazil are purely rhetoric. Brazil appears to ignore the fact that the WHO Health Criteria 203 of 1998 (point 3 of Recommendations and Conclusions) have confirmed that:

> "Exposure to chrysotile asbestos poses increased risks for asbestosis, lung cancer and mesothelioma in a dose dependent manner. No threshold has been identified for carcinogenic risks"…"Where safer substitute materials are available for chrysotile, they should be considered for use"…"Some asbestos containing products pose particular concern and chrysotile use in those circumstances is not recommended. These uses include friable products with high exposure potential. Construction materials are of particular concern for several reasons. The construction industry work force is large and measures to control asbestos are difficult to institute. In-place building materials may also pose risk control to those doing alterations, maintenance and demolition. Minerals in-place have the potential to deteriorate and create exposures".

349. It follows that the WHO, like so many other scientific publications cited in the report of INSERM, consider that chrysotile asbestos poses similar risks and the same type of problems as regards controlled use to those posed by amphiboles asbestos. So, all the references in the scientific literature in the INSERM report remain valid and pertinent.

Question 8: Does the EC not recognize that amphiboles is more toxic than chrysotile? If so, shouldn't the EC focus only on studies that at least attempt to distinguish the two? If not, how does the EC explain its position in light of the conclusions of relevant studies, including the INSERM report itself, concluding that amphiboles is more toxic?

350. Lung cancer is caused, with a comparable carcinogenic effect, by chrysotile asbestos and by amphiboles asbestos. Chrysotile asbestos, on the other hand, presents a lesser risk than amphiboles as regards mesothelioma. In both cases these diseases are currently untreatable and fatal, and it is no less serious to die of lung cancer than to die of mesothelioma.