NOTIFICATION FROM THE EUROPEAN COMMUNITIES

Attached is a notification received from the European Communities in response to the request in GATT/AIR/2087 that contracting parties make available any relevant information which would enable the secretariat to prepare basic documentation designed to facilitate discussion of the question of exports of domestically prohibited goods. The notification contains information supplied by the EC Commission and the following Community member states: Belgium, Denmark, Federal Republic of Germany, France, Netherlands and the United Kingdom.
NOTIFICATION FROM THE EUROPEAN COMMUNITIES

This communication is in response to the request addressed to contracting parties (GATT/AIR/2087) to make available to the secretariat any relevant information which would enable it to prepare documentation designed to facilitate discussion of problems relevant to the GATT in regard to exports of domestically prohibited goods.

The European Communities consider that the question of the marketing of products potentially harmful for human health or safety is a matter deserving of detailed examination.

Furthermore, the Community has participated actively in the work of several international organizations (FAO, UNEP, OECD, WHO) and intends to contribute to the rapid establishment of valid instruments in those organizations to allow identification of potentially dangerous products or substances.

There are no Community regulations wholly prohibiting the sale of certain products on the internal market. Such products are regulated at several levels:

- prohibition with specific exceptions;
- utilization authorized for certain purposes only;
- requirement of type-approval;
- sale on prescription only, etc.

Within the Community, stringent directives are in effect in regard to the placing on the market and use of two types of products:

(a) plant protection products containing certain active substances (pesticides) (Council Directive No. 79/117/EEC);

(b) certain dangerous chemical substances and preparations:

- PCB and PCT (Council Directive No. 76/769/EEC);
- benzene in certain toys (Council Directive No. 82/806/EEC);
- certain highly toxic liquid substances (Council Directive No. 79/663/EEC);
The Community is currently examining the implementing modalities for a system of notification to the authorities of third countries prior to the export of goods which are prohibited or strictly controlled on the Community market.

In addition, numerous decisions exist in the Community which prohibit the use of certain substances, or limit their concentration, for foodstuffs, pharmaceuticals and cosmetics.

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Contributions from Belgium, the Netherlands, France, the Federal Republic of Germany, the United Kingdom and Denmark are attached to this notification.
Principal Legal Provisions of the European Communities regarding Prohibition of the Placing on the Market and Use of Products Potentially Harmful to Human Health and Safety


This directive prohibits the placing on the Community market of certain pesticides containing one or more active substances.

The directive makes provision for temporary exceptions to this prohibition for very specific uses enumerated in the directive.

2. Directive on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations.

This directive prohibits the placing on the market of certain chemical substances. It has been the subject of several amendments enlarging the number of substances deemed harmful. At the present time, this directive concerns some ten chemical substances.

The directive allows temporary exceptions to this prohibition for certain very limited uses which are enumerated in the directive.

3. Directive on the supervision and control within the Community of transfrontier shipment of hazardous waste.

This directive establishes a system of notification prior to any shipment of toxic and dangerous waste, whether within the Community or to third countries. In the case of shipment to a third country, the consigner must notify his intention to the country of final destination and, where applicable, to the countries of transit.


This directive defines the procedure and criteria for the placing on the Community market of medicaments for human use.


This directive defines the procedure and criteria for the placing on the Community market of medicaments for veterinary use.

This directive defines verification procedures for the placing on the Community market of electrical equipment intended for use within certain voltage limits, in order to eliminate equipment that does not comply with certain safety criteria.
Principal International Organizations Having Studied the Problem of Trade in Domestically Prohibited Goods

Problems relating to trade in products prohibited for the domestic market for reasons of human health and safety have been examined by several international organizations which have special responsibilities in this regard. The Community has actively participated in these studies which are all oriented toward the establishment of notification schemes allowing importing countries to evaluate the risks inherent in the products concerned and to take precautionary measures with full knowledge of the facts.

1. United Nations

   Within the United Nations, two activities should be mentioned:

   (a) General Assembly Resolution providing for the establishment of a list of products whose consumption and/or sale are banned or severely restricted. It has been decided to update this list each year and to allow computer access to the relevant data.

   (b) The "provisional notification scheme for banned and severely restricted chemicals" of the Executive Board of the United Nations Environment Programme (UNEP).

       This scheme provides for two types of notification. A first notification to the authorities of other countries, when a country takes measures to prohibit or severely restrict a chemical; a second notification to the importing country to inform it, where applicable, that the export of such a product is envisaged.

2. OECD

   The Organisation for European Co-operation and Development (OECD) has adopted a recommendation which largely corresponds to the UNEP provisional notification scheme regarding arrangements for exchange of information on the export of banned or severely restricted chemical substances.

3. United Nations Food and Agriculture Organization (FAO)

   FAO is currently drawing up an international code of conduct on the distribution and the use of pesticides. In the context of this code, provision is made for establishment of an information exchange programme similar to those established by UNEP and OECD in respect of pesticides.
4. World Health Organization (WHO)

Since 1975, WHO has been applying its "certification scheme on the quality of pharmaceutical products moving in international commerce". This scheme allows any importing country to obtain from the competent authorities of exporting countries information on the type approval and detailed characteristics of any medicinal product intended for export.
NOTIFICATION FROM BELGIUM

1. The first characteristic of Belgium's legislation is that it does not lay down any general and absolute prohibition on the sale on the domestic market of products dangerous for human health and safety.

   The terms "authority empowered to ban the sale of products on the domestic market" and "reasons for prohibition of products" used in this notification in accordance with the outline proposed by GATT secretariat, must be understood subject to that reservation.

   The absence of any prohibition does not however imply complete freedom to place on the market products that are dangerous for health or safety.

   In fact, the marketing of these products is subject to a prior condition which, as the case may be, is termed registration (pharmaceutical products), inspection (foodstuffs) or approval or authorization (pesticides and plant protection products).

2. A second characteristic of Belgium's legislation is that it applies to exports to a varying extent.

   This is not the case for pesticides and plant protection products, animal feeding stuffs and fertilizers, which are specifically excluded from application of the regulations when intended for export, this exclusion being total in the case of the first group of products and only partial for the other two.

   On the other hand, the export of foodstuffs is authorized only if they comply with the legislation and regulations adopted with a view to consumer protection.

   In addition, the importing country can request a certificate of conformity from the exporting country.

   A similar system is in force for pharmaceutical products in that, in addition to the medicinal product certification under the WHO certification scheme, the importing country can obtain proof of registration of the medicinal product in the exporting country.

I. MEDICINAL PRODUCTS

A. Authority empowered to ban the sale of products on the domestic market

   Implementation of the legislation and regulations is the responsibility of the Ministry of Public Health and Family Matters.
B. Product designation

1. The legislation is mandatory in respect of medicinal products, i.e. any substance or compound presented as having curative or preventive properties in regard to human or animal disease, and likewise any substance or compound intended for administration to humans or animals with a view to establishing a medical diagnosis or to restoring, correcting or modifying organic functions.

2. It can be made applicable, wholly or partially:

(a) to objects and appliances presented as having curative or preventive properties or as having physiological effects in humans or animals;

(b) to objects, appliances, substances or compounds used in the art of healing or in veterinary medicine;

(c) to objects, appliances, substances or compounds designed to reveal data regarding the state of health or physiological or pathological state of humans or animals;

(d) to objects, appliances, substances or compounds designed to prevent or to encourage pregnancy in humans or animals.

C. Reasons for prohibition of products

In the interest of public health, the law authorizes the Executive to regulate and supervise the import, export, manufacture, preparation, transport, distribution, holding, storage, offer for sale, sale, transfer whether against payment or free of charge, packaging, presentation, denomination, content and labelling of packaging, and likewise the furnishing of medicinal products.

To this end, before being placed on the market, any medicinal product must be registered with the Ministry of Public Health and Family Matters, in the conditions and according to the modalities determined by the Executive.

In the interest of public health, the Executive may prohibit, wholly or partially, the above operations in the case of a medicinal product whose effects are deemed harmful or which is considered ineffective from the therapeutic aspect.

Lastly, in the context of the law, the Executive may take all necessary measures in the interest of public health to ensure implementation of international treaties and instruments adopted in pursuance of them; such measures may include the revocation or amendment of legal provisions.
It is on this basis that Belgium participates in the certification scheme for pharmaceutical products moving in international commerce, adopted by WHO in 1975. This scheme allows the importing country to obtain from the national services of the exporting country up-to-date information on the quality of a medicinal product and its type-approval in the exporting country.

E. **Other relevant information, in particular an indication of applicable laws and regulations**

The following are applicable in this regard:


II. **FOODSTUFFS AND OTHER PRODUCTS**

A. **Authority empowered to ban the sale of products on the domestic market**

Implementation of the legislation and regulations is the responsibility of the Ministry of Public Health and Family Matters.

B. **Product designation**

The legislation applies:

1. To foodstuffs, i.e., any product or substance intended for human feeding;

2. To the following other products:
   - additives;
   - materials and objects intended to be in contact with foodstuffs;
   - detergents and cleaning and maintenance products which, because of their normal use, can be incorporated in foodstuffs;
   - tobacco, tobacco products and similar products;
   - cosmetics;
   - commonly used products which, by reason of their use, can have a physiological effect either by absorption of some of their constituent parts or by contact with the human body;
- aerosol containers and propellant gases used for foodstuffs and other products mentioned above.

C. Reasons for prohibition of products

1. The legislation allows the Executive, in the interest of public health or with a view to preventing fraud or falsification, to regulate and prohibit manufacture, export and trade in respect of foodstuffs.

Inter alia, the Executive may determine the composition of foodstuffs, establish the corresponding denominations, and regulate the indications useful for information purposes.

In the interest of public health, the Executive may, in addition:

(a) regulate and prohibit trade, export and use of objects or materials intended to enter into contact with foodstuffs, in particular packaging;

(b) regulate and prohibit trade and export of detergents and cleaning and maintenance products which, by reason of their normal use, are likely to be incorporated in foodstuffs, and likewise their use in the foodstuffs industry;

(c) regulate and prohibit trade and exports of food additives, and likewise prescribe rules in respect of labelling.

2. The regulations stipulate that foodstuffs and the other products enumerated above may be exported only if they are in compliance:

(a) where appropriate, with legislation and orders adopted with a view to protecting consumer health and resulting from international treaties applicable in Belgium and international instruments adopted in pursuance of those treaties, provided they are also in force in the country of destination;

(b) with the provisions of the Royal Order of 3 January 1975 regarding foodstuffs and food substances deemed to have been declared harmful, except where such compliance is not required under the legislation and orders of the country of destination.

3. The regulations likewise stipulate that a certificate is issued on the occasion of the export of foodstuffs and other products if the authorities of the country of destination so require. This certificate bears various indications, including a statement to the effect that the product may be marketed freely in Belgium in the composition indicated (with the possible exception of certain ingredients) and that it is manufactured in Belgium in accordance with the public health standards in force.

It is stamped by the Ministry of Public Health, Foodstuffs Inspection Service.
D. Other relevant information, in particular an indication of applicable laws and regulations

The following are applicable in this regard:

- Law of 24 January 1977 on protection of consumer health in respect of foodstuffs and the other products enumerated;
- Royal Order of 6 March 1980 on the export of foodstuffs and other products.

III. PESTICIDES AND PLANT PROTECTION PRODUCTS

A. Authority empowered to ban the sale of products on the domestic market

Implementation of the regulations is the joint responsibility of the Ministry of Agriculture, the Ministry of Public Health and Family Matters and the Ministry of Employment and Labour.

B. Product designation

The regulations apply:

1. To pesticides, i.e. to substances and preparations designed to destroy or to prevent the action of harmful animals, micro-organisms or viruses;

2. To plant protection products, i.e.:

(a) pesticides for agricultural use;

(b) substances and preparations designed to encourage or regulate plant production or to ensure the preservation of plants, parts of plants and plant products;

(c) substances and preparations designed to combat weeds, lichens and algae;

(d) substances and preparations designed to destroy plants or parts of plants or to prevent or check undesired growth;

(e) substances and preparations designed to combat or eliminate ectoparasites of livestock, including pigeons;

(f) micro-organisms and viruses which are active agents in combatting parasites:

(g) dampening and adhesive agents or other additives designed to promote the action of the substances and preparations mentioned under (a), (b), (c), (d), (e), (f), provided they are traded for that purpose:
3. To pesticides for non-agricultural use, i.e. substances and preparations, and likewise micro-organisms and viruses, intended for use other than in agriculture in order to:

(a) combat or eliminate animals which can damage plant and animal products;

(b) prevent the decomposition of plant and animal products;

(c) combat or eliminate animals, plants or micro-organisms which are harmful in dwellings, buildings, means of transport, swimming pools, refuse dumps and sewers;

(d) treat materials and objects in order to combat or eliminate animals, plants or micro-organisms;

(e) combat or eliminate by the treatment of plants, soil or water, organisms which can cause human or animal diseases;

(f) combat or eliminate ectoparasites of small domestic animals.

4. To the toxic pesticides and plant protection products enumerated in Annex II to the Royal Order of 5 June 1975 and divided into three lists with an indication, where appropriate, of the percentage or weight of the active ingredient contained therein.

C. Reasons for prohibition of products

The regulations establish a general prohibition of the placing on the market, acquisition, offer, display or offering for sale, holding, preparation, transport, sale, transfer whether against payment or free-of-charge, import or use of plant protection products and pesticides for non-agricultural use which have not received prior approval or authorization from the competent Minister.

The grant of approval or authorization may be subject to chemical or physico-chemical analyses or to biological, toxicological or other tests. Standards with which the product must comply may likewise be fixed.

Similarly, the competent Minister may determine special conditions in regard to marketing or use of the product, and the designation under which it may be marketed.

The regulations do not apply, inter alia, to pesticides and plant protection products in transit or intended for export provided they are identified as such by a visible indication of their destination.
D. Other relevant information, in particular an indication of applicable laws and regulations

The Royal Order of 5 June 1975 on the preservation, trade and use of pesticides and plant protection products and the Royal Order of 22 October 1976 amending it are applicable in this regard.

IV. FERTILIZERS

A. Authority empowered to ban the sale of products on the domestic market

Implementation of the regulations is the responsibility of the Ministry of Agriculture.

B. Product designation

The regulations apply to trade in fertilizers and soil ameliorators, and likewise to any product having specific action conducive to plant production.

C. Reasons for prohibition of products

The regulations prohibit the marketing of products not included in the list of fertilizers annexed to the Royal Order of 6 October 1977. It establishes a prior approval requirement for any person who imports, manufactures, prepares or packages for marketing any compound fertilizer or mixed organic ameliorator.

The regulations do not apply to products in transit or intended for export provided they are identified as such by a visible indication of their destination.

It is stipulated, nevertheless, that such products must be free of toxic substances or other harmful substances.

D. Other relevant information, in particular an indication of applicable laws and regulations

The Royal Order of 6 October 1977 on trade in fertilizers and soil ameliorators and the Royal Order of 13 February 1981 amending it are applicable in this regard.

V. ANIMAL FEEDING STUFFS

A. Authority empowered to ban the sale of products on the domestic market

Implementation of the regulations is the responsibility of the Ministry of Agriculture.
B. Product designation

The regulations apply to substances intended for animal feed, in the form of feeding stuffs or additives, with certain exceptions.

C. Reasons for prohibition of products

The regulations prohibit the marketing of animal feeding stuffs which are not mentioned in Annex II to the Royal Decree of 13 November 1981 or are not compound feeding stuffs and ready-mixed feeding stuffs and do not comply with the special requirements of Annex I. They likewise prohibit the marketing of the feeding stuffs mentioned in Annex II if they fail to comply with the descriptions and requirements stipulated therein.

Provision is made for derogations subject to Ministerial authorization.

The same prohibitions apply to compound and ready-mixed feeding stuffs containing animal feed. In addition, it is prohibited to market or use animal feeding stuffs containing inter alia:

(a) any undesirable substance or product in a proportion exceeding the stated maximum;

(b) pesticide residues in excess of the same proportion;

(c) any substance which is toxic or harmful to human or animal health;

(d) any hormone-active or anti-hormone-active substance.

The regulations do not apply to products in transit or intended for export provided they are identified as such by a visible indication of their destination.

Nevertheless, the latter are subject to the general prohibition on the marketing of substances intended for animal feed which are not sound, genuine and of merchandizable quality, or which can constitute a danger for human or animal health.

D. Other relevant information, in particular an indication of applicable laws and regulations

The Royal Order of 13 November 1981 on trade and use of substances intended for animal feed is applicable.
NOTIFICATION BY DENMARK

Reference: Decision Taken by the GATT Council on 20 November 1984 (GATT/AIR/1885)

The protection of human health and safety against dangerous products is predominantly based on requirements as to marking of products and directions concerning their use. For specific products or additives marginal quantities or thresholds may be prescribed. Products of which marketing is directly prohibited are few (use of DDT as pesticide and blue asbestos (crocidolite)).

A system of positive lists is used to gain necessary insight into the use of products posing a potential hazard to human health and safety and to assess the need, if any, for directives as to use and marking, and quantitative limits to content of additives. This applies, for example to additives in food, pharmaceuticals, products for use in cosmetics, pesticides in agriculture (for DDT, see above comment). For entry on the positive list of products of specific types and uses, application for and grant of permission for marketing is required. Approval of a product for marketing may be restricted to specific forms of use and subject to marking regulations and marginal quantities of ingredients/components. On all existing products the authorities do not take a position without taking into account whether there is an industrial or commercial wish for access to marketing. Use of the opposite principle, negative lists of specific products excluded from marketing by explicit prohibition, would, in general, not be feasible in practice because of the rapid development of new, complex products in the chemical industry as well as in other areas.

The system applied in Denmark does not necessarily imply that products not on a positive list are assessed as posing a hazard to human health and safety. The reason may just as well be that enterprises - on commercial grounds, e.g. the suitability of the products for domestic marketing - have not wanted entry on the relevant list. Corresponding factors are taken into account in most other countries, and for that reason alone there are major differences between the contents of national positive lists and other forms of regulation. Disparities between national regulations may also be ascribable to differences in demand determined by natural and technical conditions or national authorities' assessment of the products.

The actually existing disparities between national regulations may be a technical obstacle to free international trade. It is obvious that this type of technical barriers to trade would be augmented if exporters, with regard to products for export, were to observe their own country's regulations for domestic marketing and thereby would prevent foreign importers from buying products which satisfied the importing country's specifications. Therefore observance of national regulations for domestic marketing is normally not required in international trade. Denmark does
not require such observance except, partially, with regard to some food products for whose production the Minister for Agriculture or the Minister for Fisheries may lay down regulations based on the positive list principle. For practical reasons it has been prescribed that regulations on processing shall be observed also for export products unless the producers provide documentary evidence of holding orders for products of other specifications which are in conformity with the requirements of the importing country. It is required that production for meeting such orders is kept separate from other production.

Denmark understands that the existing international régime may give rise to concern in countries which have been unable to establish adequate national regulations and provide for supervision of their observance. Against this background the Danish authorities place great weight on the ongoing international co-operation in the framework of the United Nations, WHO and the Codex Alimentarius Commission, inter alia in working out a Code of Ethics. Through this co-operation guarantees have been provided in important areas to ensure that human health and safety are not endangered through engagement in international trade. Denmark has consistently been and remains in favour of continuation and expansion of this co-operation.
NOTIFICATION BY FEDERAL REPUBLIC OF GERMANY

1. The Federal Government regards international transparency of the trade in such products as are prohibited in domestic markets for health and safety reasons as a legitimate objective. For this reason, it takes a basically positive outlook on pertinent activities by various international organizations and participates actively in the work done by various institutions in different areas in order to prevent damage that can be avoided through greater transparency in the trade in hazardous products. However, attention should be paid to the need for information that is clear and easy to understand. On the other hand, it would see little point in parallel discussions and work by international organizations on problems and products that are partly or wholly identical: potential users of the results of such activities would be faced with less rather than more transparency owing to overlapping and possibly contradictory information and notification systems.

2. Against this background, the Federal Republic of Germany co-operates inter alia on the "Provisional Notification Scheme for Banned and Severely Restricted Chemicals" of the United Nations Environment Programme (UNEP), on the OECD notification systems for consumer goods and chemicals, on the up-dating of the UN list of banned products published annually, on the development of an international code of conduct of the Food and Agriculture Organization (FAO) of the United Nations and on the "Certification Scheme for Pharmaceuticals Moving in International Commerce" of the World Health Organization (WHO).

3. In market economies such as the Federal Republic of Germany, producers have got an independent interest, as a rule, in avoiding and banning the circulation of dangerous substances. For, no producer or exporter of hazardous goods is in a position to survive in the market. Private-law liability regulations play their own part in this field. Those who are under an obligation to pay large amounts of compensation for the damage they cause, of necessity take appropriate precautions to avoid such damage.

   Nevertheless, governments cannot afford to rely exclusively on industry's own initiative or on damage prevention by private-law liability provisions. Rather, they must protect human health and safety from hazardous products also by legislative and administrative measures.

   Legal regulations exist for foodstuffs, cosmetics and articles in daily use, pharmaceuticals, motor vehicles, technical implements, radioactive substances, plant protectives, etc., for instance.

4. In the Federal Republic of Germany, exports of hazardous products are regulated by the legal regulations applicable in any one product field. There are no legal regulations banning or controlling exports of products harmful to human health or to safety that apply to all products across the board.
Export bans have been envisaged for the following individual fields:

The Act on protection from hazardous products (Chemicals Act) of 16 September 1980 (BGBl. I. S. 1718) allows (paragraph 17) restrictions to be decreed in the case of specific hazardous products and preparations that may affect exports through bans on production.

Paragraphs 8, 24 and 30 of the Act on foodstuffs and articles in daily use of 15 August 1974 (BGBl. I. S. 1946) bans the production and circulation of foodstuffs, cosmetics and articles in daily use insofar as these represent a potential threat to human health. Any violation of these bans is fined. Under paragraph 50, such bans also apply to exports.

Similar provisions apply to medicaments. Pursuant to paragraph 5 of the Act on Medicaments (AMG) of 24 August 1976 (BGBl. I. S. 2443) as amended by the First Act of 24 February 1983 (BGBl. I. S. 169) to amend the AMG, it is prohibited to circulate potentially hazardous medicaments. This prohibition basically applies to exports as well. Under Article 5 of the Convention of Pharmaceutical Products of 8 October 1970, together with the relevant Federal legislation ratifying the Convention of 10 March 1983 (BGBl. II.S. 158) the Federal Republic of Germany is obliged to make known without delay any deficiencies of pharmaceutical products that have come to its attention to the other Member States. Moreover, the responsible superior Federal authority co-operates under paragraph 62 of the Act on medicaments with the competent units of the World Health Organization and the pharmaceutical authorities of other countries on monitoring the medicaments in circulation and on fending off risks associated with medicaments. The Federal Republic of Germany will in the early future accede to the WHO certification system for the quality of pharmaceutical products in international trade.

Against this background, the Federal Government assumes that such products not approved for circulation domestically will not be exported either.

5. On the other hand, any general ban on exports on products the domestic circulation of which is prohibited would give rise to a number of problems from the point of view of the Federal Government, viz.:

- Not every product that does not comply with certain national standards and may therefore not be circulated in the domestic market represents a risk to human health and to safety. Its circulation may therefore be permitted in other countries which have adopted different standards and/or set different priorities.

Any general ban on exports in such cases would mean that the Federal Republic of Germany would force its own standards on other countries.
The countries having adopted the strictest safety standards would have to impose on their industries the obligation to comply with those strictest standards in the field of exports as well which would mean substantial drawbacks for them in terms of international competition, whereas producers in States with less strict safety requirements would enjoy competitive advantages.

For these reasons, the Federal Government does not see any possibility for a general ban on the exportation of domestically prohibited goods.

Since there is no outright ban on exports that would require monitoring of compliance, the Federal Government does not have any general export control instruments either.
NOTIFICATION FROM FRANCE

In France, chemical products are regulated by broad-ranging legislative provisions and regulations.

A first category of texts, of a general character, is designed to protect the population (Health Code), the worker (Labour Code), the consumer, and lastly the environment.

The second series concerns specific products: medicinal or quasi-medicinal products, agropharmaceuticals, food additives for human feeding.

The general principle is to develop the manufacturer's sense of responsibility so that he will pay appropriate attention to safety of a product before placing it on the market. In many cases, administrative control is exercised in detail on the occasion of declaration, authorization or type-approval before the product is placed on the market.

Some regulations, in pursuance of a fairly old law (dated 1 August 1905), are based on the principle of the positive list - i.e. whatever is not authorized is prohibited.

In regard to exports, the policy pursued is to apply the same rules as on the domestic market except where circumstances do not justify this. This means that in cases of obvious risk for the user (medicinal products, explosives, for example) it is essential that the rules be the same.

On the other hand, in the case of agropharmaceuticals or chemicals in relation to the environment, the advantage-risk comparison can vary according to the relevant geographical, climatic and industrial conditions. It is neither necessary nor even useful for the domestic rules to be applicable to exports, and certainly not in a systematic manner.

Since the chemical risk is the subject of special attention and vigilance in all countries, and in the first place in France, it is appropriate to draw attention to two necessary conditions for adequate control of this risk, without hindering international trade expansion and scientific progress.

It is not desirable to aim at a nil risk or to set unduly stringent requirements. Such an approach can conceal an incentive to domestic industry, if the latter has a substitute product, or protection of that industry if the maximum content levels imposed are below those normally accepted and virtually require local manufacture. And yet, apart from a few specific cases such as DJA (food additives, etc.) or pesticide residue content, the international approach is rather ineffective. It is therefore essential to establish and generalize admissible risk levels for other categories of chemicals.
In the second place, for a considerable number of chemical applications (pharmaceuticals, agropharmaceuticals, additives, etc.) the examination carried out with a view to type-approval, authorization or declaration for placing on the market is extremely strict. Once authorization has been granted to the first manufacturer, after lengthy and detailed expert examinations, imitations or counterfeit products appear on the market in misleading packaging. Apart from the danger for the user, since the copied product does not offer the same guarantees, this situation discourages serious firms whereas scientific progress must continue constantly in this biological field. After having studied the matter, the National Academy of Medicine expressed a recommendation at national and international level, proposing the fifteen-year rule. It would be desirable to adopt at international level a period of protection of property for data included in the type-approval submission, and to define possible conditions for sharing the costs among applicants; such participation could be imposed on the first applicant after a certain period of time.

I. GENERAL TEXTS

(a) Protection of health

Article R5168 allows the prohibition or regulation of the use of and trade in toxic and dangerous substances and preparations.

This was the basis, for example, for the Order of 8 July 1975 limiting the use of PCBs to closed systems.

It has never been deemed necessary to apply to exports the measures adopted in pursuance of Article R5168. Narcotic substances are covered by other articles. In such cases the regulations are applicable to exports in the same way as to purchase, sale or import.

In addition, at regional level France has departmental sanitary regulations in regard to drinking water, housing or other premises, waste, contagious diseases and hygiene in general (Circular of 9 August 1978 - Official Gazette of 13 September 1978).

In relation with other regulations not cited here, the above-mentioned regulation establishes prohibitions in certain areas (water-treatment products).

(b) Worker protection

The rules regarding labelling and safety tags are applied generally by the chemical industry, in respect of both exports and the domestic market.

Working conditions in respect of certain substances are subject to specific regulations (for example asbestos, monomer vinyl chloride).
Recommendations have been established fixing maximum average air-exposure limits for certain dangerous substances, for example cancerogenous substances.

The above-mentioned regulations and recommendations are within the framework of the authority of States on their own territory, and obviously cannot be made generally applicable to exports.

(c) Consumer protection


(d) Protection of the environment

Various provisions have been established in regard to chemical products in the following areas:

- safety of installations
- fight against water pollution
- fight against air pollution
- control of waste
- control of chemicals (see II(f))

In general, they are not applicable to exports, since pollution prevention conditions can vary according to the region concerned. In the case of waste, however, exports are subject to strict control.

II. SPECIFIC REGULATIONS

(a) Medicinal and quasi-medicinal products

Under Articles L511 and L601 of the Health Code, no pharmaceutical product can be sold unless authorized for placing on the market. Administrative control of the pharmaceutical industry is very stringent and applies to all manufactures, including those exported.

(b) Veterinary medicinal products

The French regulations, based on Articles L606 ff. of the Health Code, are similar to those adopted in respect of medicinal products for human use. The same principles are therefore applicable in respect of exports.

It should be noted, nevertheless, that the risk to human beings is not of the same order.
(c) Cosmetics and perfumery products

In regard to cosmetics and perfumery products, the French regulations are based on Law 75-604 of 10 July 1975, which has not been amended to date; certain obligations are laid down by the relevant implementing texts. Stringent controls are in effect, based on voluntary action by the sector concerned.

All manufacturers export products consistently with the French regulations, in pursuance of a collective undertaking by the firms concerned. On request, purchasers of products can obtain a certificate of conformity with the safety standards of the French legislation.

(d) Gunpowder and explosive substances

Law 70-575 of 3 July 1970 and its implementing texts are likewise applicable to exports.

The rules regarding approval and verification in respect of gunpowder, explosive substances, fireworks, etc. are accordingly identical in respect of exports and products for the domestic market.

(e) Anti-parasite products for agricultural use

The regulations are based on the Law of 3 November 1943, as amended, and its implementing provisions.

For reasons mentioned in the introduction, the rules applied on domestic territory are not applied to exports.

There are only very few manufactures intended for export which correspond to products not authorized in France.

(f) Miscellaneous chemicals


(g) Regulations based on positive lists

These regulations mainly concern food additives (Decree of 15 April 1912), materials entering into contact with foodstuffs and cleaning products for such materials (Decree 73-138 of 12 February 1973).

They are not applicable to exports, since in many cases they correspond to obligations existing only in France.
NOTIFICATION BY THE NETHERLANDS

In this contribution a categorization along the following lines is applied. Pharmaceuticals, food and non-food, labour and transportation means and pesticides.

Pharmaceuticals

It is not possible to draw up a list of pharmaceutical products, which are prohibited for sale in the domestic market as a pharmaceutical speciality, but which may be produced in the Netherlands for export purposes. It is not necessary to have licence for production for export.

Food and non-food

With regard to these two product-categories - food and non-food for consumptive use - it is also impossible to give a useful list of products which are prohibited in the domestic market, but are produced for export purposes.

National regulations are usually only meant for products, which are sold on the national market.

However, if a product is exported of a quality sub-national regulation, this does not necessarily mean that this product is unsafe or imposing a direct and immediate danger to health and safety of users.

Labour and transportation means

With regard to these two categories, labour and transportation means notification is practically not feasible; with regard to labour means the Netherlands Government imposes safety criteria, linked to a supervisory system. Those criteria can be lower in other countries, so the notification system as proposed cannot be reasonably applied to exported labour means, which do not comply to the Netherlands safety criteria.

In the Netherlands there are no cases of transportation means, transport services or loads which are considered too dangerous for the domestic market, but are produced for export.

Pesticides

As the paragraph on pharmaceuticals already stated, we can not give a synopsis of pesticides, which are not allowed for sale on the domestic market but are produced solely for the export. In principle importing countries can be informed of the Netherlands regulations regarding pesticides and can be informed of the freely available information on some basic characteristics concerning the pesticides which are allowed for sale.
in the Netherlands. As regards notification of national regulatory rules one should be aware that only in cases (countries) where more or less the same circumstances prevail, the same criteria can be applied as regards the admission to the market of pesticides. In particular this concerns applications of pesticides and cost/benefit analysis.

However, the Second Chamber of Parliament, has claimed by means of an amendment to the Bill on Hazardous Substances and Preparations ("Wet Milieuxgevaarlijke Stoffen") extra regulatory powers regarding exports of substances and preparations, the use of which impose a danger to man or the environment (mostly pesticides).

This section contains a prior-to-export notification to the Netherlands authorities of exports of hazardous products, as well as to the authorities of the importing countries. These exports may only take place when it can be certified that the authorities of the importing country agreed to the import of these goods and the importing country's government is known with the dangers connected with the products. If the exporter can not certify this, the Minister of Environment may prohibit the export.

During the coming two years this notification shall be voluntarily executed by the business community. After review (in 1988) the Government holds the option of transferring this voluntary agreement into an Order of the Minister of Environment.
NOTIFICATION BY THE UNITED KINGDOM

1. This note is provided as a contribution to the Work Programme established at the GATT Ministerial meeting, November 1982, and in response to the request to contracting parties (GATT/AIR/2087) to send the GATT secretariat relevant information to assist it to prepare documentation to facilitate discussion of GATT-related questions about the export of domestically prohibited goods. It should be read in conjunction with the notification presented by the Commission of the European Communities.

2. In the United Kingdom some goods may only be sold if they meet required health and safety standards, while others may only be used for certain specified purposes.

3. The notification by the Commission of the European Communities makes it clear that there are Community Directives prohibiting the marketing both of plant protection products containing certain active substances (pesticides) (Council Directive 79/115/EEC), as well as the following dangerous substances and chemicals:

- ornamental objects containing dangerous liquids (Council Directive 76/663/EEC),

4. In addition, the following legislation is in force in the United Kingdom.

   (i) Animal and public health

   The Animal Health Act 1981 provides the legal basis for United Kingdom animal health policy. Under this, all animals and animal products must conform with United Kingdom domestic animal or domestic standards; any animal product failing to meet these standards would fail our export health certification procedures. Ministry responsible: Ministry of Agriculture, Fisheries and Food.

   All outbreaks of notifiable livestock diseases must be reported immediately so that appropriate action is taken (e.g. imposition of movement restrictions) to prevent such diseases from spreading within Great Britain and to other countries. In addition, exports of cattle and pigs to Community countries must conform with health conditions for intra-community trade.
Production of red meat, poultry meat and meat products must also comply with public health requirements laid down by regulations made under the Slaughterhouses Act 1974 and the Food Act 1984. Exports of meat and meat products must satisfy United Kingdom domestic animal and public health requirements and any additional conditions imposed by the importing countries.

The Meat (Sterilization and Staining) Regulations 1982 (as amended) include controls on the disposal of "unfit" meat to prevent human consumption.

(ii) Carcinogenic substances

The Carcinogenic Substances Regulations 1967 and Carcinogenic Substances (Prohibition of Importation) Order 1967 proscribe the manufacture and use in premises subject to the Factories Act 1961 and the importation of four substances with limited powers of exemption:

2 - napthylamine and its salts; 4 - aminodiphenyl and its salts; 4 - nitrodiphenyl and benzidine and its salts. Also any substance containing these compounds, except as the by-product of a chemical reaction, in any other substance in a total concentration not exceeding one per cent. **Ministry responsible:** Health and Safety Executive.

(iii) Consumer goods

The Consumer Safety Act 1978 provides the authority for regulations to be made to ensure that goods sold in the United Kingdom are safe. Such safety regulations may prohibit the supply of unsafe goods or their component parts; require goods to conform to particular standards; require goods to be tested; or require goods to carry warnings or have instructions, and to avoid misleading marks. These provisions may be in respect of either the composition, contents, design, construction, finish or packing of goods. Instruments made under the Act normally apply to exports, unless there are special reasons for their exemption e.g. usefulness to importing countries. Examples of goods regulated are toys (required safety standards; Safety Regulations 1974, Statutory Instrument 1367), cosmetics (S/I 1260, 1984) and gas catalytic heaters (prohibition order; S/I 1802, 1984). The Act does not, however, apply to food, feeding stuff, fertilisers or medicines - all covered under separate legislation described elsewhere in this note - nor to drugs which are controlled under the Misuse of Drugs Act 1971. **Ministry responsible:** Department of Trade and Industry.

(iv) Fertilisers and feeding stuffs

The Agriculture Act 1970 (Part IV) provides for regulations to be made setting standards for the labelling and composition of fertilizers and animal feeding stuffs for sale in the United Kingdom. It also provides for the making of Regulations to enforce these standards. **Ministry responsible:** Ministry of Agriculture, Fisheries and Food.
(v) **Food standards**

The Food Act 1984 (Section 1) and similar legislation in Scotland and Northern Ireland makes it an offence to add any substance to food, use any substance as an ingredient in the preparation of food, abstract any constituent from food or subject food to any other process or treatment so as to render the food injurious to health, with intent that the food shall be sold for human consumption in that state. Under Section 8 of the Act it is an offence, *inter alia*, to have in possession for sale any food intended for, but unfit for, human consumption. Since these are offences relating to the preparation of food they are thus providing protection for foreign consumers - if the food is intended for export - as much as for domestic consumers. Specific compositional regulations made under the Act, however, normally exclude exports. This is because dietary preferences in different countries vary as do the need for and attitude towards food additives. Regulations made under the Food Act 1984 also make it an offence to sell or import various types of food additive unless the presence of these additives is permitted in food in the United Kingdom. These Regulations likewise do not apply to exports. **Ministries responsible:** Department of Health and Social Security and Ministry of Agriculture, Fisheries and Food.

(vi) **Medicine**

The Medicines Act 1968 and subordinate legislation provides for the control of medicinal products (including veterinary medicines) and certain other substances and articles by a system of licences and certificates. A product may not be placed on the United Kingdom market unless the Licensing Authority is satisfied on safety, quality and efficacy. The licence authorizes the use of the product for certain purposes only and stipulates the method of marketing, e.g. by prescription only. The Act contains powers to prohibit sale, supply, export or import. The permissible powers on exports have been implemented in the case of certain biological products only. **Ministries responsible:** Department of Health and Social Security for (human medicines) and Ministry of Agriculture, Fisheries and Food (veterinary medicines).

(vii) **Pesticides**

At present the supply of pesticides in the United Kingdom is controlled under the non-statutory Pesticides Safety Precaution Scheme. Under this scheme only pesticide products which meet United Kingdom safety standards are cleared for supply and use in the United Kingdom. This non-statutory system is seen to be replaced by statutory controls under the Food and Environment Act 1985.

The Food and Environment Protection Act does not provide powers to control the export of pesticides, but does enable Ministers to require from exporters whatever information is needed to meet international obligations such as the UNEP "Provisional Notification Scheme" for banned and severely
restricted chemicals. The United Kingdom Government expects to obtain the voluntary co-operation of exporters in implementing the UNEP scheme but the use of the Food and Environment Protection Act powers can be considered if necessary. **Ministry responsible:** Ministry of Agriculture, Fisheries and Food.

**(viii) Pollution control**

The Control of Pollution (Supply and Use of Injurious Substances) Regulations 1980 restrict the marketing and use of preparations containing more than 0.1 per cent by weight to polychlorinated biphenyls (PCBs) or polychlorinated terphenyls (PCTs). These Regulations prohibit the sale or use of PCBs/PCTs except in certain defined applications. The exemptions include use as dielectric fluids in electrical transformers and capacitors. **Ministry responsible:** Department of Environment.

Department of Trade and Industry
11 September 1985