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Committee on Sanitary and Phytosanitary Measures

SUMMARY REPORT ON THE SPS RISK ANALYSIS WORKSHOP 19-20 JUNE 2000

Note by the Secretariat

1. The WTO Secretariat organized a workshop on Risk Analysis on 19-20 June 2000, in conjunction with the 18th meeting of the Committee on Sanitary and Phytosanitary Measures (the "SPS Committee"). The workshop was chaired by Dr. Alejandro Thiermann (United States) and attended by 130 participants, mainly capital based experts.[1] The programme is attached.

2. In welcoming the participants, Mr. Frank Wolter, Director of the Agriculture and Commodities Division, stressed the fundamental right of all WTO Members to protect their consumers, animals and plants from health risks. The basic obligation under the Agreement on the Application of Sanitary and Phytosanitary Measures ("SPS Agreement") was to ensure that trade measures aimed at protecting health were based on scientific principles and not maintained without sufficient scientific evidence, except in the special circumstances addressed in Article 5.7 of the SPS Agreement. Mr. Wolter noted that basing sanitary and phytosanitary measures on science was an important implementation issue for WTO Members, in particular for developing countries.

3. The objective of the workshop was to shed light on the complex relationship between risk analysis, the disciplines of the SPS Agreement, the work of the relevant standard-setting organizations and actual policies of WTO Members.

4. As the workshop was scheduled to immediately precede the 18th regular meeting of the SPS Committee, it enabled many capital-based experts, who might not otherwise have had the opportunity, to participate in the regular meeting of the SPS Committee as well. In this regard, Mr. Wolter thanked the United States Department of Agriculture for providing funds which had enabled the WTO to cover the costs of participation for six least developed countries in both meetings.

5. After these introductory remarks, the workshop followed the programme set out below:

[1] A list of participants is contained in document G/SPS/INF/13, dated 19 June 2000.

Relevant negotiating history of the SPS Agreement

6. Ms Gretchen H. Stanton[2], Secretary of the SPS Committee, noted that as early as 1974 members of the GATT were discussing the need for clear rules to deal with sanitary and phytosanitary measures. They wanted to make sure that restrictions on trade, while permitted for the purpose of protecting health, were justified and not disguised restrictions on trade.

7. The link to the international standard-setting organizations arose early in the negotiating process. When the negotiations on the Uruguay Round ("UR") began in September 1986, the mandate for the negotiations in the Ministerial Declaration included a reference to the aim that countries achieve greater liberalization in agriculture trade by, *inter alia*, minimizing the adverse effect of sanitary and phytosanitary measures on trade, taking into account the relevant international agreements.

8. The first formal negotiating proposal was tabled by the United States in July 1987. It proposed that laws and regulations necessary to protect the health and safety of food, plants and animals as well as the agricultural environment, should conform to recognized international standards, and recognize equivalency of laws and regulations in supplying countries. A recognition of the need for putting in place procedures for consultations and notifications also came early. In April 1988, the European Communities proposed that national regulations that complied with international standards should be considered to conform to the GATT Article XX(b) exception. They also suggested (i) that these regulations should be the least restrictive on trade, (ii) that they should be adapted to the risks involved – and in particular the risk assessed on a regional basis – and, (iii) that the measure should be limited to the minimum strictly necessary "to guard against actual risks occurring in modern conditions of production and trade, rather than the theoretical risk of transmission". Thus, as early as 1988, there were already negotiating proposals essentially referring to the need to assess risk in establishing SPS measures.

9. In September 1988, the Negotiating Group on Agriculture agreed to create a Working Group on Sanitary and Phytosanitary Measures. The Working Group on SPS measures was mandated to find a common approach to the promotion of greater international harmonization and to strengthen the GATT rules and disciplines, recognizing the need to rely on scientific evidence and to apply the principle of equivalence. The Working Group on SPS measures met for the first time in October 1988. In April of 1989, the mid-term review Ministerial Declaration endorsed harmonization of national regulations as a long-term goal. It also set out a work-programme to develop harmonization of sanitary regulations on the basis of the standards of the Codex Alimentarius Commission (Codex), of the Office international des epizooties (OIE) and the FAO International Plant Protection Convention (IPPC).[3] By April 1990, proposals had been tabled and a first draft of an SPS Agreement was being discussed in detail; it was circulated in June 1990. The draft text proposed that SPS measures should be necessary for health protection and consistent with available scientific evidence, and that there be harmonization on as wide a basis as possible. It also encouraged the standard-setting organizations to develop and publish, *inter alia*, methodologies and criteria for risk assessment to ensure that SPS measures were based on adequate risk assessment procedures.

[2] Senior Counsellor, Agriculture and Commodities Division, WTO Secretariat.

[3] These three organizations are directly referenced in the SPS Agreement as the "relevant standard-setting organizations", and referred to more informally as "the three sisters".

10. Hence, the link between the SPS Agreement, the requirement that SPS measures be based on an assessment of risk and that one look to the three relevant standard-setting organizations explicitly identified in the SPS Agreement for guidelines and methodologies on how to go about assessing risk, has a long history. After 1990, work focused on finalizing the legal text of the SPS Agreement, including Article 5 of the Agreement ("Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection").

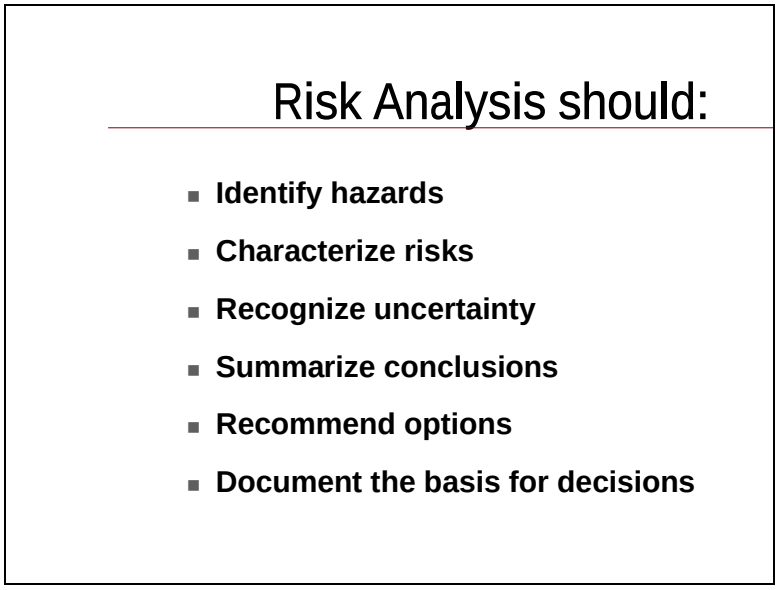
The fundamentals of risk Analysis and its practical application

11. Mr. Robert Griffin[4] began by noting that the discipline of risk analysis was not a new concept introduced in 1995 with the SPS Agreement. It had existed for over a century and was widely used in such diverse fields as insurance, investment and engineering. He described the broad concept of risk analysis as a systematic way of gathering, evaluating and recording information which would lead to recommendations, positions or actions in response to an identified hazard.

12. Risk was composed of two main elements: the probability or likelihood – that is the chance – of an adverse event occurring, and the magnitude of the consequences. The latter element was important and often not considered. For example, in walking across the street the probability of being hit by a pedestrian, a bicycle or a car could be the same yet the consequences would be very different, and therefore the risks were different. Two further elements were implicit in risk. For a risk to exist, there had to be a hazard, an adverse event, or something harmful that one feared. Second, there had to be some level of uncertainty associated with what was known about the probability and the consequences of the adverse event.

13. Mr. Griffin noted that risk analysis was not designed to provide a decision but was instead a tool to support decision-making. In most countries, the decision concerning whether a risk was acceptable and what would be done to reduce or eliminate risk was taken at a political level. Risk analysis provided the mechanism for evaluating the risk and developing recommendations on which a decision could be based. It was an analytical tool that arose from the need to characterize and manage risk. In Figure 1, Mr. Griffin illustrated the steps a risk analysis should follow.

Figure 1

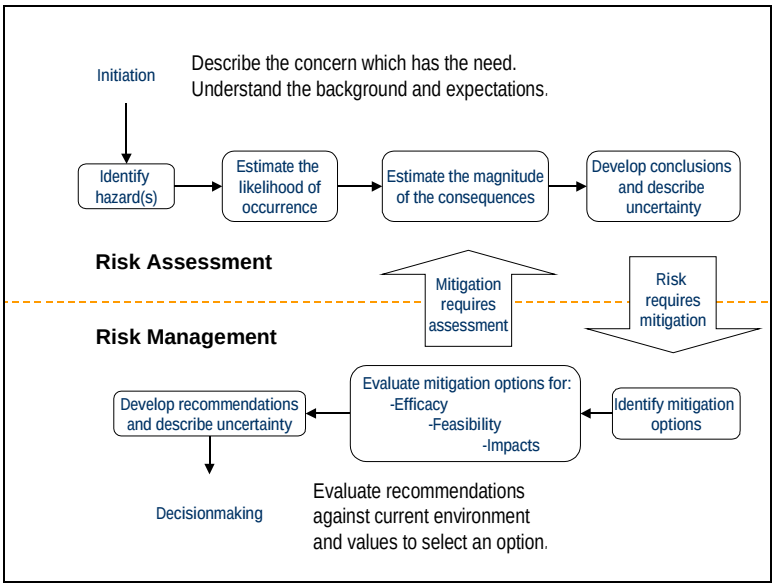


[4] Mr. Bob Griffin, Coordinator, IPPC Secretariat, FAO. The slides used for his presentation, as well as those used for most of the other presentations, are available at the WTO internet homepage (www.wto.org)

14. The risk analysis process could be initiated by a request for importation, after which a hazard identification followed. At the risk assessment stage, the probability, consequences and uncertainty were examined. Risk assessment posed the questions: what information is available? what is the quantity and quality of this information? what is the uncertainty and gaps in the information? After this, there would come a point in the risk analysis process where the analytical work was completed and a judgement had to be made about whether the risk was acceptable or not. This was the starting-point for risk management and where the SPS Agreement's concept of the appropriate level of protection was relevant.[5] Mr. Griffin noted that if the risk was not acceptable, then the next question was: what could be done to eliminate or reduce the risk to an acceptable level? Risk management, Mr. Griffin stressed, necessarily required risk assessment in order to evaluate the efficacy of the different options so as to determine how much the risk was changed and whether, as a result, it had become acceptable. The process was repeated until the risk was deemed acceptable (Figure 2).

15. In short, risk assessment focussed on probability, consequences and uncertainty, and resulted in conclusions about the risk. Risk management identified and evaluated options for mitigating the risk (efficacy), and considered the feasibility and impacts of using one management option or another. Mr. Griffin emphasized that the risk analysis resulted in recommendations, not decisions.

Figure 2



16. As risk analysis was the basis for applying SPS measures, it created important linkages between government institutions and the public. If a certain measure was challenged and there was no risk analysis in place as the basis for the measure, then there was no starting-point for a technical dialogue on the issue. This relationship had led to an increased awareness of the linkages between regulators, researchers and policy-makers. In particular, scientists were realizing that their input into policy-making was more important as a result of the SPS Agreement. Regulators had to rely on scientists, or the research community, to provide the scientific basis for their decisions; policy makers, in turn, relied on the regulators for the risk analysis output that provided the basis for their decisions.

17. Mr. Griffin stressed that a key component of any risk analysis was identifying uncertainty. A well-done risk analysis considered uncertainty as part of the scientific evidence. In this sense, the role of precaution lay in the judgement of the scientific evidence, *including* uncertainty. The

[5] This is also referred to as "acceptable level of protection". It is defined in Annex A, paragraph 5 of the SPS Agreement.

consideration of uncertainty was also key to decision-making. Here the distinction between uncertainty and variability was important. Variability would not be reduced with more information, it was normal and had to be accepted. Uncertainty was different because it dealt with, *inter alia*, errors, information gaps, out-of-date information or incorrect assumptions. The difference was that something could be done about uncertainty; in some cases it could be corrected and in an analytical context it could be measured.

18. It was noted that a risk analysis could not fail as a result of insufficient information. Risk analysis was used *because* of insufficient information. Used properly, risk analysis was an extremely useful and powerful tool for determining where information was lacking, what information gaps existed, and the quantity and quality of information that would improve decision-making. Mr. Griffin suggested that it would be counter-productive to avoid a risk analysis, or avoid completing a risk analysis, because of insufficient information as had been suggested by some interpretations of the "precautionary approach". Risk analysis was as much a tool for determining the level uncertainty as it was a tool for determining the level of risk.

19. Ms Stanton drew participants' attention to the April 2000 meeting of Codex Committee on General Principles and the discussion there on how to deal with "the use of precaution" (in the context of the proposed draft Working Principles for Risk Analysis) when faced with uncertainty in the area of food safety. Possible criteria for using precaution in the food safety area, and under what conditions these were to be used, had been discussed and government comments on alternative texts were being solicited by the Codex Committee on General Principles.

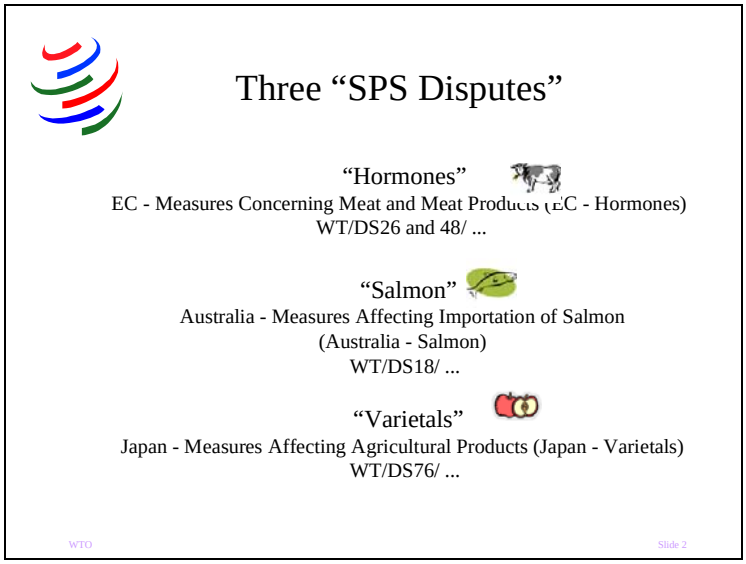
20. In response to questions regarding the sophistication of risk analysis techniques and the difficulties this posed to developing countries, Mr. Griffin stressed that while it was true that a risk assessment could be complex, this was neither necessary nor essential. What was essential was that an attempt be made; whether it resulted in a half-page report or a 200-page report was not important. All countries would normally have a basis for decisions that affected trade. If it was a risk basis, it was simply a matter of documenting this. No matter how preliminary, rudimentary or crude, such documentation provided a starting-point for technical dialogue. By far the large majority of decisions were based on very routine, cursory types of risk analysis, which in most cases were not controversial. It was important that developing countries not have the impression that risk analysis required overly-sophisticated systems and tremendous amounts of resources. Risk analysis could be done in the most limited circumstances; if information was limited then decisions would have to be based on limited information and if a trading partner contested the measure there would be a place to start the dialogue and exchange of additional information. It was pointed out that the SPS Agreement did not require any Member to *do* a risk assessment; it required the importing Member to *base* its measure on a risk assessment (see paragraph (b)). In other words, the risk assessment itself could be done by another Member, by a regional body or by an international organization.

21. Access to the internet was an important tool in risk analysis, particularly for developing countries, the reason being that the most difficult part of a risk analysis was gathering information. If the information was available, it was relatively easy to apply different methodologies and to do different kinds of evaluation and come up with conclusions. Much information was now readily available through the internet. Hence, in terms of technical assistance, internet access was a very important and efficient tool in the context of risk analysis.

SPS Agreement as it relates to scientific justification

22. Mr. Erik Wijkström[6] made a presentation on the disciplines of the SPS Agreement related to scientific justification. The objective of the presentation was to illustrate these provisions by using three disputes that had been brought to the WTO under the SPS Agreement. The full title of these disputes, including the abbreviations used in this report, are reflected in Figure 3.[7]

Figure 3



23. Mr. Wijkström noted that WTO Members had the basic right to ensure that imported food was safe for consumption. Likewise, they had the basic right to protect the life or health of their animals and plants from diseases or pests accompanying imported products. However, at the same time, Members had a basic *obligation* to ensure that SPS measures: (i) were applied only to the extent necessary to protect human, animal or plant life or health; (ii) were based on scientific principles; and (iii) were not maintained without sufficient scientific evidence *except* as provided for in Article 5.7.

24. The basic obligation to ensure that SPS measures were not maintained without sufficient scientific evidence was examined in detail in the *Japan – Varietals* Panel.[8] In that dispute, the Panel stated that for an SPS measure to be maintained without sufficient scientific evidence there needed to be a lack of an *objective relationship* between, on the one hand, the phytosanitary measure at issue (which was the varietal testing requirement) and, on the other hand, the scientific evidence submitted before the Panel. The Panel concluded that there was a lack of an objective relationship between the measure and the scientific evidence.[9] However, before finding a violation of Article 2.2, the Panel examined Japan's claim that its measure was a provisional measure in accordance with Article 5.7.[10]

25. The Panel found that four cumulative elements needed to be shown for a measure to be consistent with Article 5.7. A Member was allowed to provisionally adopt an SPS measure if: (i) the measure was imposed in respect of a situation where relevant scientific information was insufficient;

[6] Economic Affairs Officer, Agriculture and Commodities Division, WTO Secretariat.

[7] These panel and Appellate Body reports can be found on the WTO website (www.wto.org).

[8] The full titles and symbols of the Panel Reports are contained in Figure 3.

[9] *Japan-Varietals*, Panel Report, para. 8.42.

[10] On appeal, the Appellate Body described Article 5.7 as a "qualified exemption" from the obligation under Article 2.2 to maintain SPS measures based on scientific principles. *Japan-Varietals*, AB Report, para. 80.

and (ii) the measure was adopted on the basis of available pertinent information. Furthermore, there were additional obligations to: (iii) seek to obtain the additional information necessary for a more objective assessment of risk; and (iv) to review the phytosanitary measure accordingly within a reasonable period of time. The Panel only examined the third and fourth elements and found no evidence that Japan had sought to obtain information necessary for a more objective assessment of the risk and reviewed the measure accordingly within a reasonable period of time. It therefore found a violation of Article 5.7 and, consequently, Article 2.2. The Appellate Body upheld this ruling and confirmed that the four requirements were cumulative. It also noted that a "reasonable period of time" had to be established on a case-by-case basis.

26. In the *EC – Hormones* case, the European Communities did not invoke Article 5.7, it stated explicitly that the import prohibition was not a provisional measure. However, the European Communities invoked the "precautionary principle" as a general principle of law and argued that Articles 5.1 and 5.2 did not prevent Members from being cautious when setting health standards in the face of conflicting scientific evidence and uncertainty. In this regard, the Appellate Body did not take a position on the status of the precautionary principle in international law. It noted that the precautionary principle "found reflection in Article 5.7 of the SPS Agreement" and agreed with the Panel finding that the precautionary principle - to the extent it was not explicitly incorporated in Article 5.7 - did not override the provisions of Article 5.1 and 5.2 of the SPS Agreement.

27. Mr. Wijkström then turned to the provisions relating to risk assessment (Article 5) under the SPS Agreement. He noted that there was a link between the basic obligation to base SPS measures on science, contained in Article 2.2, and the more specific obligation contained in Article 5 of the SPS Agreement.[11] The first paragraph of Article 5 set out the obligation to base SPS measures on an assessment of risk.[12] In this regard, the *EC – Hormones* Panel, provided the first panel findings in the food safety area.

28. The *EC – Hormones* Panel noted that for food safety, the relevant part of the definition of a risk assessment was Annex A, paragraph 4 of the SPS Agreement: "the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs". Thus the Panel approached the issue by stating that the EC risk assessment needed to:

(a) "identify the adverse effects on human health (if any) arising from the presence of the hormones at issue when used as growth promoters in meat or meat products", and

(b) "if any such adverse effect exists, evaluate the potential or probability of occurrence of these effects."[13]

29. The Panel first addressed the issues of whether a risk assessment *existed*. The European Communities had invoked several scientific reports that the experts advising the Panel considered to be risk assessments. Hence, for five of the hormones, the Panel assumed that the European Communities had demonstrated the existence of a risk assessment. It next considered whether the EC measure was *based on* the scientific evidence submitted and came to the conclusion that it was not.[14] This was similar to the approach taken by the *Japan-Varietals* Panel a few years later: it compared the scientific conclusions reached in each of the studies to the scientific conclusion reflected in the measure, and came to the conclusion that there was a mismatch. The Appellate Body in *EC-*

[11] This link was emphasized by the Appellate Body when it stated that Article 2.2 and 5.1 should "constantly be read together" (*EC-Hormones*, AB Report, para. 180).

[12] In *Japan-Varietals*, the Panel focussed on the basic obligation contained in Article 2 as it found no risk assessment directly relevant to the varietal testing measures *per se* (in other words, the focus was on Article 2 and not Article 5). The Appellate Body approached this issues in the same way (*Japan – Varietals*, AB Report, paras 109-114).

[13] *EC-Hormones*, Panel Report, para. 8.98.

[14] *EC-Hormones*, Panel Report, para. 8.137.

Hormones upheld the Panel's finding and found that there was a lack of an "objective relationship" between the measure and the science. In the *EC-Hormones* case, the Appellate Body also made the point that the SPS Agreement was not prescriptive with respect to *who* did the risk assessment. The obligation was to *base* an SPS measure on a risk assessment. This meant that risk assessments made by others could be used (international standard-setting organisations or those done by other countries, if appropriate).

30. In the *Australia-Salmon* dispute, the risk assessment provisions of the SPS Agreement were also at issue. In this case, the concern was not one of food safety, but one of fish diseases associated with imports of Canadian adult, wild, ocean-caught Pacific salmon. The relevant definition of a risk assessment under the SPS Agreement was that contained in the first sentence of definition: "the evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measure which might be applied, and of the associated potential biological and economic consequences". With this in mind, the *Australia-Salmon* Panel set out a three-pronged approach to determine what a risk assessment should do in the animal health area:

(a) "identify the disease(s) whose entry, establishment or spread within its territory it wants to prevent as well as the associated potential biological and economic consequences

(b) "evaluate the likelihood of entry, establishment or spread of these diseases, as well as the associated potential biological and economic consequences; and,

(c) "evaluate the likelihood of entry, establishment and spread of these diseases according to the SPS measure which might be applied".

31. In examining the Australian risk assessment the Panel found that Australia had identified up to 20 diseases whose establishment or spread Australia wanted to prevent. Furthermore, according to the Panel, Australia had evaluated *some* elements of possibility and probability with respect to the likelihood of entry and considered a series of risk reduction factors to mitigate these risks (quarantine options). So although the Panel questioned why Australia had not used a previous risk assessment, which contained a fuller evaluation of the likelihood of entry, establishment and spread, the Panel *assumed* that Australia had fulfilled the requirements of the three-pronged test.[15]

32. The Appellate Body agreed that Australia had identified the diseases which posed a risk (the first requirement of the three-pronged test), however it reversed the Panel's findings on the other two elements. The Appellate Body was of the opinion that "some" evaluation of likelihood was not enough; it referred to the experts' opinions that an evaluation and expression of probability or likelihood, either quantitative or qualitative was *crucial* to a risk assessment. It concluded that the 1996 Final Report was not a proper risk assessment within the meaning of Article 5.1 and the first definition in paragraph 4 of Annex 1. Therefore, there was a violation of Article 5.1, and, consequently, a violation of the more basic obligation to base the measure on scientific principles as set out in Article 2.2.

33. Summarizing the provisions relating to risk assessment, Mr. Wijkström noted that with respect to both the basic obligation to base SPS measures on science, contained in Article 2.2, and the more specific provisions contained in Article 5.1-5.2, panels and the Appellate Body had compared the scientific evidence with the measure allegedly based on it. In doing this they had looked for a "rational or objective relationship" between the science and the measure.

[15] *Australia – Salmon*, Panel Report, para. 8.83 and 8.91.

34. The next main issue considered under Article 5 of the SPS Agreement was relevant to the notion of the "appropriate level of protection", defined in the SPS Agreement as follows:

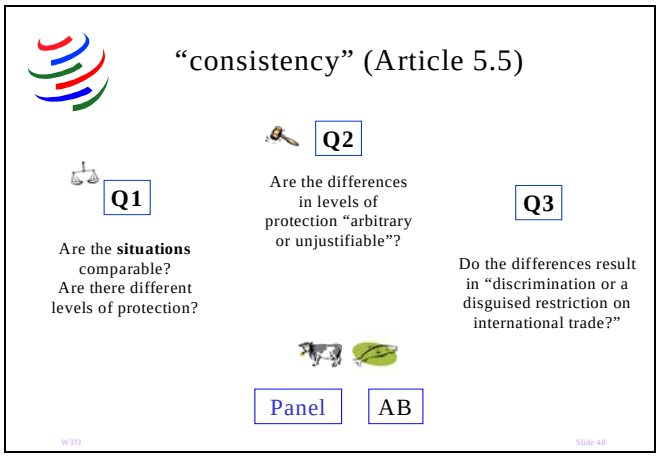
> "5. *Appropriate level of sanitary or phytosanitary protection* - The level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory.
>
> NOTE: Many Members otherwise refer to this concept as the "acceptable level of risk". [SPS Agreement, Annex A, paragraph 5, italics and note in original]

Mr. Wijkström noted that Article 5.5 disciplined the practical application of this concept:[16]

> "With the objective of achieving consistency in the application of the concept of appropriate level of sanitary or phytosanitary protection against risks to human life or health, or to animal and plant life or health, each Member shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade."

35. With respect to the three disputes at issue, Article 5.5 (often referred to as the "consistency" requirement) was looked at in both the *EC-Hormones* and the *Australia-Salmon* case. In the *Japan-Varietals* case it was not an issue. In both the former cases, the Panels and Appellate Body used the same three elements to show a violation in Article 5.5. These three elements were found to be cumulative in nature, i.e., all three elements had to be present for a violation to be found. These are summarised as three questions in Figure 4 below.

Figure 4



36. Mr. Wijkström noted that the examination of Article 5.5 was based on comparing "situations". The *EC-Hormones* Panel first examined the different treatment for administered natural hormones for growth promotion compared to those occurring endogenously in meat and other foods (first "situation"). The first question in Figure 4 had two parts: are the situations comparable, and do they reflect different levels of protection? The Panel found that the situations were comparable as the adverse health effect which was at issue in both cases was the same (carcinogenicity). Also, the Panel found that the levels of protection were different. In one case "no residue" level was allowed (ban on

[16] At its meeting of 21-22 June 2000, the Committee adopted "Guidelines to Further the Practical Implementation of Article 5.5" (G/SPS/15, dated 18 July 2000).

hormone-treated meat) and, in the other case, there was an unlimited residue level allowed (the same hormones occurring naturally).

37. The second main question was whether these differences in levels of protection were "arbitrary or unjustifiable". Here the Panel noted a number of factors: (i) the potential for adverse effects were the same (either for administered or endogenous hormones); (ii) the total residue level of natural hormones in meat from treated animals fell within the physiological range of levels found in meat from untreated animals, which varied according to sex and age of the animal; (iii) the residue level of natural hormones in many natural products (such as eggs and soya oil) was much higher than the level of residues of these hormones administered for growth promotion - as well as the total residue level of these hormones - in treated meat; and (iv) the significant difference in levels of protection between the two situations being compared. Considering all these factors, the Panel concluded that the difference in the levels of protection were "arbitrary and unjustifiable".[17] The Appellate Body disagreed. It stated that there was "a fundamental distinction between added hormones (whether natural or synthetic) and naturally-occurring hormones in meat and other foods".[18] It therefore reversed the Panel's finding on this first comparison.

38. The Panel also compared the ban on hormones for growth-promoting purposes with the allowed use of some of the same hormones for therapeutic and herd management purposes. A third comparison made by the Panel was a comparison of the different treatment for hormones used in beef production as compared to the use of carbadox as a feed additive in swine production (carbadox is an anti-microbial growth-promoter and also a carcinogen[19]). In both cases the Panel found a violation of Article 5.5 and the Appellate Body, in turn, reversed this finding. In this last comparison, however, the Appellate Body agreed that that European Communities' distinctions were arbitrary or unjustified, but, it did not agree that these differences resulted in "discrimination or a disguised restriction on international trade". It stated that it was:

> "unable to share the inference that the Panel apparently draws that the import ban on treated meat and the Community-wide prohibition of the use of the hormones here in dispute for growth promotion purposes in the beef sector were not really designed to protect its population from the risk of cancer, but rather to keep out US and Canadian hormone-treated beef and thereby to protect the domestic beef producers in the European Communities."[20]

39. In the *Australia-Salmon* case, Article 5.5 was also an issue. The same three-pronged approach was used (Figure 4). In this case, the Panel found that the there were different levels of protection (second part of the first question in Figure 4) between Canadian adult, wild ocean-caught salmon for human consumption ("Canadian salmon") and whole frozen herring for use as bait, and live ornamental finfish. The entry of Canadian salmon was restricted while the herring and ornamental fish were allowed access, despite the fact that in both situations there was at least one disease of common concern to Australia. The situations were considered comparable, or similar, in that the consequences of the adverse effect happening were similar. That is to say, if the disease entered via salmon or herring, the consequences could be presumed to be at least similar.

40. Next the Panel considered whether the different levels could be considered "arbitrary or unjustifiable". The Panel noted that since the level of protection for salmon was higher, one would expect a higher risk for salmon than for the other fish. Yet the evidence was to the contrary. The Panel stated:

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[17] *EC-Hormones*, Panel Report, para. 8.197.

[18] EC-Hormones, AB Report, para. 221.

[19] *EC-Hormones*, Panel Report, para. 8.231.

[20] *EC-Hormones*, AB Report, para. 245.

> "The evidence outlined above points in the direction of a *higher* risk of disease introduction associated with imports of bait fish and live ornamental fish than the risk posed by imports of salmon products for human consumption. Nevertheless, Australia imposes far stricter sanitary measures for the latter category than it does for the former."[21] [emphasis added]

41. The Panel found that Canada had raised a presumption that bait and ornamental fish posed a higher risk and that Australia had not rebutted this. Consequently the Panel found that the distinctions in the levels of protection were "arbitrary and unjustifiable" in the sense of the second element of Article 5.5 (Question 2 in Figure 4). This finding was upheld by the Appellate Body.

42. Finally, the Panel posed the question whether these differences resulted in "discrimination or a disguised restriction on international trade". It listed a number of considerations which, taken together, led the Panel to conclude that the measure was a disguised restriction on international trade. This conclusion was also supported by the Appellate Body. *Inter alia*, the Panel considered the arbitrary character in the differences in the levels of protection (bait/ornamental finfish could be presumed to represent a higher risk) and the substantial differences in the levels of protection. It also noted that the measure was not based on a risk assessment. Here the Appellate Body concurred stating that the non-existence of a risk assessment was a strong indication that the measure was not really concerned with the protection of health. Hence, the Appellate Body upheld the original Panel's finding that Australia's measure was in violation of Article 5.5 of the SPS Agreement.

43. Mr. Wijkström noted that with respect to "consistency", the Panels and Appellate Body had used a three-pronged approach to determine an inconsistency with Article 5.5 of the SPS Agreement (Figure 4). It was notable that even though a measure could be found to be arbitrary or unjustifiable in the sense of the second element, Article 5.5 would only be violated if these differences in the levels of protection *resulted in* "discrimination or a disguised restriction in international trade". The *Australia-Salmon* case was the only dispute where such a violation had been found.

The work of the three relevant standard-setting organizations

(i) *FAO Codex Alimentarius Commission (Codex)*

44. Mr. David Byron[22] reviewed recent decisions of the Codex related to risk analysis. In particular, he drew participants' attention to the work of the Codex Committee on General Principles which was elaborating general principles on risk analysis applicable to the work of all Codex Committees. Of importance in this regard was the adopted Codex "Statement of Principles Concerning the Role of Science in the Codex Decision Making Process and the Extent to Which Other Factors Are Taken Into Account." The statement of principles had four elements; it is quoted in full below. With regard to the second element, Mr. Byron noted that the concept of "other legitimate factors" still remained to be defined.

[21] Australia-Salmon, Panel Report, para. 8.137.

[22] Food Standards Officer, Joint FAO/WHO Food Standards Programme, Food and Nutrition Division, FAO. Codex Internet address: http://www.codexalimentarius.net.

STATEMENT OF PRINCIPLE CONCERNING THE ROLE OF SCIENCE IN THE CODEX DECISION-MAKING PROCESS AND THE EXTENT TO WHICH OTHER FACTORS ARE TAKEN INTO ACCOUNT[21]

1. The food standards, guidelines and other recommendations of Codex Alimentarius shall be based on the principle of sound scientific analysis and evidence, involving a thorough review of all relevant information, in order that the standards assure the quality and safety of the food supply.

2. When elaborating and deciding upon food standards the Codex will have regard, where appropriate, to other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade.

3. In this regard it is noted that food labelling plays an important role in furthering both of these objectives.

4. When the situation arises that members of Codex agree on the necessary level of protection of public health but hold differing views about other considerations, members may abstain from acceptance of the relevant standard without necessarily preventing the decision by Codex.

[21] Decision of the 21st Session of the Commission, 1995.

45. The Codex furthermore had adopted "Statements of Principle Relating to the Role of Food Safety Risk Assessment" and "Definitions of Risk Analysis Terms Related to Food Safety". Risk analysis itself was defined as: "A process consisting of three components: risk assessment, risk management and risk communication:

(a) Risk Assessment: A scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization;

(b) Risk Management: The process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options;

(c) Risk Communication: The interactive exchange of information and opinions throughout the risk analysis process concerning hazards and risks, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions".

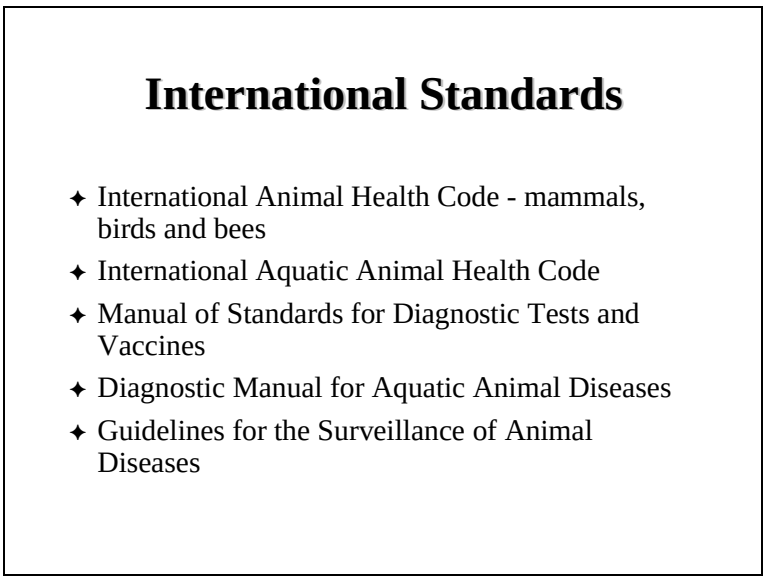
46. In response to a question regarding the Codex position on labelling of genetically modified organisms (GMOs), Mr. Byron noted that an *ad hoc* Codex Task Force on Biotechnology was currently looking at three issues: the issue of foods produced with biotechnology in general, nutritional aspects, and labelling. The Codex had not taken any decision to date.

(ii) *Office internationale des épizooties (OIE)*

47. Dr. Thierry Chillaud[23] began by noting that the majority of OIE members were developing countries. The OIE had three missions directly related to risk analysis: (i) increasing transparency in the animal health situation, (ii) safeguarding health in world trade, and (iii) providing animal health expertise.

48. Dr. Chillaud stressed the importance of standards and noted that animal health standards developed by the OIE constituted a key element in safeguarding the life and health of humans as well as animals. To develop these standards the OIE had four specialized commissions: (i) the International Animal Health Code Commission, (ii) the Standards Commission, (iii) the Foot and Mouth Disease and other Epizootics Commission, and (iv) the Fish Diseases Commission. The standards of the OIE are listed in Figure 5.

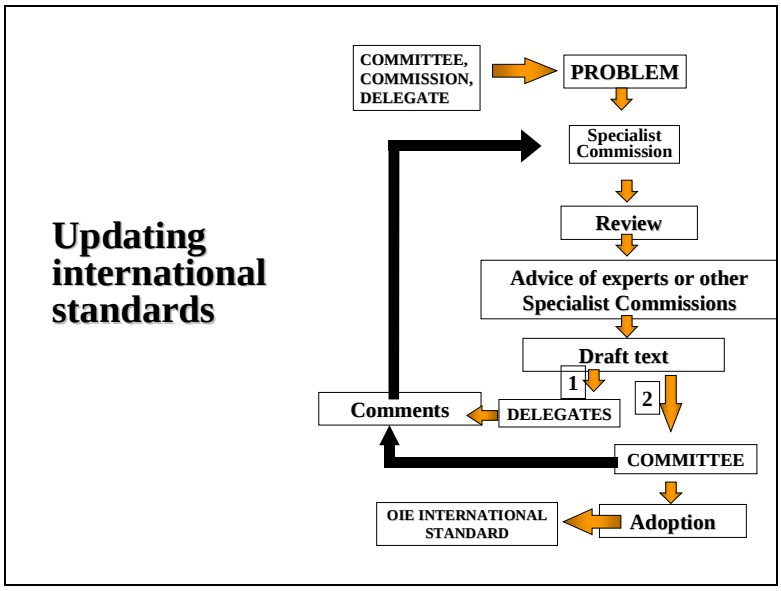
Figure 5



49. The standards were based on a risk assessment and developed according to the scheme presented in Figure 6. Dr. Chillaud noted that when an importing country carried out a risk assessment, it had to take into account the components of risk assessment specified in the International Animal Health Code chapter on the relevant disease applicable to the exporting country. This consisted of the evaluation of zoning and regionalization, as well as the evaluation of surveillance and monitoring of animal health. The concept of zoning (directly relevant to Dr. Stärk's presentation page 20), was strongly linked to the disease at issue, and the purpose behind the zoning. For example, with respect to African Horse Sickness, zoning was in place in order to enable South African race horses to participate in international competition. It was not, in that sense, a commercial issue. An example of a commercial aim of zoning was the Mexican programme of eradication of Classical Swine Fever with the objective of obtaining international recognition of disease-free zones. Another example was Uganda, which had decided to stop vaccination for Rinderpest in its territory south of the Nile, but was still vaccinating in the area north of the Nile because of risks from neighbouring countries.

[23] Head, Information and International Trade Department, *Office international des épizooties* (OIE). OIE Internet address: http://www.oie.int.

Figure 6

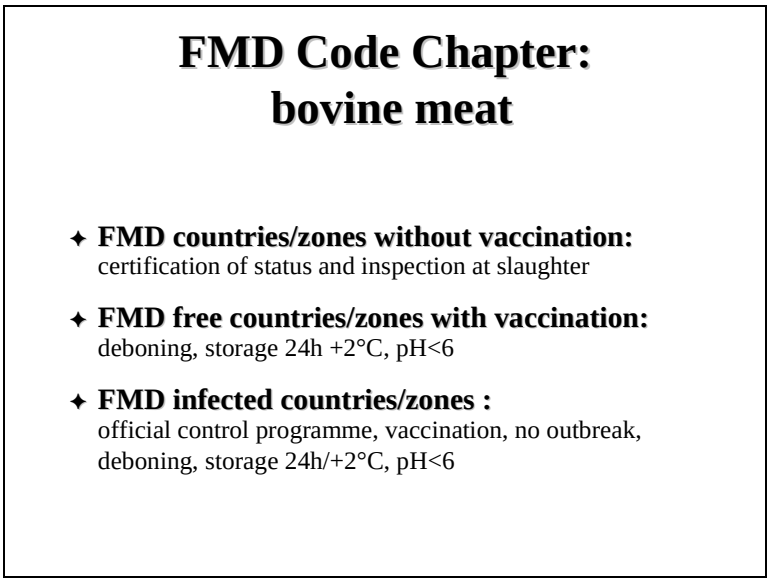


50. Dr. Chillaud used the OIE Chapter on Foot and Mouth Disease (FMD) to illustrate how the OIE Code was based on a risk analysis. He recalled that work had started with a request from the Uruguay Round Negotiating Group on Agriculture. During the negotiations of the SPS Agreement, the OIE had been asked to update its Chapter on FMD. After the request, the OIE created an *ad hoc* group and produced a "supporting document" that gave the scientific basis upon which a revised Chapter on FMD was developed. This resulted in a procedure for international recognition of the status of member countries vis-à-vis FMD.

51. Under the Code, a different status was attributed to a country, or zones within a country, in function of the disease control programme. For FMD this was a description of a country, or zone, free of FMD *without* vaccination, or *with* vaccination. The Chapter also indicated which products constituted a risk for international trade (for FMD: live ruminants and pigs – domesticated or wild – and their semen, embryos, meat, milk and derived products, etc). The Chapter included, product by product, and depending on the status of the country, the recommendations of the Code. Figure 7 illustrates the recommendations of the Code with respect to bovine meat and FMD.

52. Dr. Chillaud concluded his presentation with a summary of the work already completed or in progress at the OIE aimed at developing risk analysis in the animal health area. This included work undertaken in the OIE Scientific and Technical Review, the preparation of a booklet on risk analysis, and the development of provisions specific to aquatic animal diseases.

Figure 7



(iii) *International Plant Protection Convention (IPPC)*

53. Mr. Robert Griffin spoke about risk analysis in respect of plant health in the IPPC.[24] He noted that in contrast to information available on risk analysis in general, there was not a wealth of expertise and information on plant health in particular. The primary sources of information on risk analysis in the plant health area was the IPPC itself and national organizations that had devoted significant resources to it. Nevertheless, there had been a very significant evolution in the plant health area in the last ten years.

54. In IPPC terms, risk analysis was referred to as Pest Risk Analysis, or simply "PRA". The scope of IPPC work was limited to pests, and "pests" constituted a broad definition which included fungi, bacteria, viruses, nematodes, as well as insects and weeds. Since the IPPC did not have a long history of setting specific standards, in nearly all cases, phytosanitary measures put into place by governments would need to be based on risk analysis. A PRA was used to (i) justify protection measures affecting trade, (ii) evaluate or challenge other countries' measures, (iii) encourage technical dialogue and information sharing, and (iv) prioritize risk management and research.

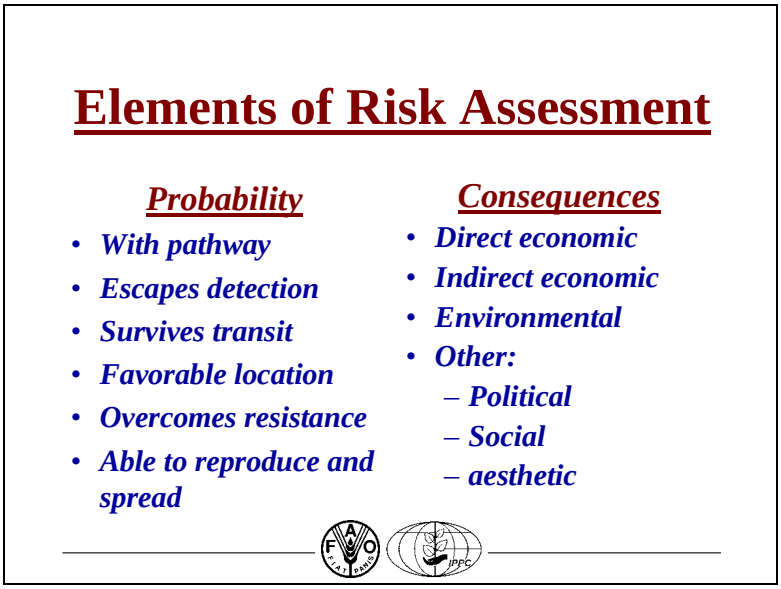
55. The IPPC began with the International Standard for Phytosanitary Measures (ISPM) No. 2, Guidelines for PRA. This was developed early in the 1990s, agreed in 1993 and adopted 1994. Mr. Griffin noted that the ISPM No. 2 was still in force, but there was agreement to revise and update the guideline. Following the adoption of ISPM No. 2, work was initiated on supplementary standards in four areas: pest categorization, probability of introduction, economic impact, and risk management. In the process of discussing amendments to the IPPC itself, it had been decided that a different family of standards would be developed. The IPPC would combine the four supplementary standards that were under development to create one standard on pest risk analysis for quarantine pests and another standard on pest risk analysis for regulated non-quarantine pests.

56. In plant health risk assessment, there were two primary elements: probability and consequence (Figure 8). Probability could be broken down into a number of independent events. These constituted a progression of events, or pathways, where if any of these events did not occur

[24] Internet: http://www.fao.org/WAICENT/FaoInfo/Agricult/AGP/AGPP/PQ/default.htm.

there was no probability. In other words, if any of the events was 0, the probability was 0; it was a multiplicative relationship. However, on the consequences side the relationship was additive. These elements of risk assessment as they related to probability and consequence were basic also to the risk assessments of the Codex and the OIE.

Figure 8



57. In conclusion, Mr. Griffin stressed the strong linkages that had developed between the regulatory community and the scientific community. Scientists were increasingly realizing their role in risk analysis and were becoming more active in their support for the policies that were applied in trade. An important part of risk analysis was the setting of priorities for research. Mr. Griffin stressed that scientists were realizing that by being more actively involved in risk analysis they were able to identify areas where research was needed and link that to trade concerns. In many cases this brought needed resources to the scientific community.

Case Studies

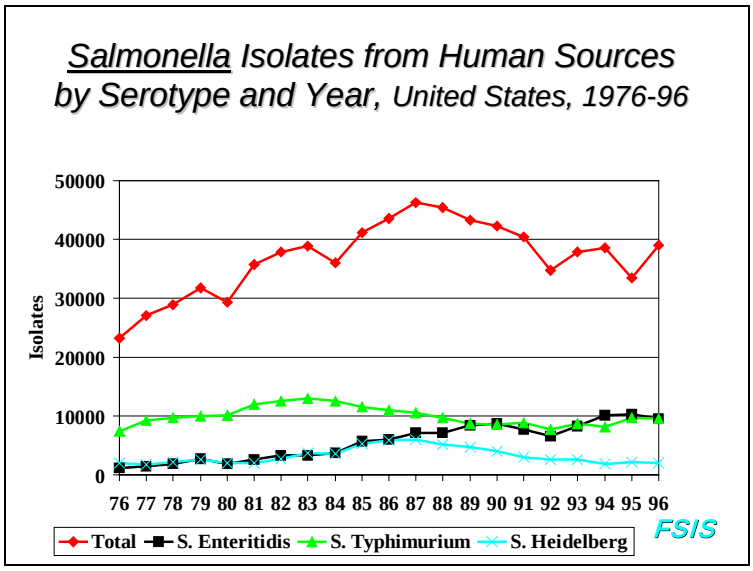
(i) *Characterization of BSE risk for certain countries in the central American region*

58. Dr. Eduardo Serrano[25] emphasized that he was presenting risk characterization, rather than a risk assessment. The origin of the study was a concern from Ministers in the central American region about the possibility of having imported BSE. Ministers wanted to know the probability of having already imported, or of importing in the future, this disease into the region. The conclusion of the study was that on the basis of information obtained by the OIRSA, the risk for the occurrence of BSE was minimal in the central American region. The prohibition of the importation from affected countries, as well as the scant use of meat-and-bone-meal were the factors that contributed to this finding. Even so, one of the recommendations was that the countries should enhance surveillance for any disease symptoms that could be related to BSE. Dr. Serrano stressed the fundamental importance of a solid base in epidemiology as a basis for risk analysis work in the animal health area.

[25] Secretariat of the Regional International Agricultural Health Organization, OIRSA.

(ii) *Salmonella Enteritidis in Eggs*

59. Dr. Noreen A. Hynes[26] presented a case-study on Salmonella *enteritidis* (hereafter "SE") in eggs and egg products. The objective of her presentation was to give an idea of how a risk assessment could help inform policy regarding the control of SE in eggs and egg products. She noted that WHO had estimated the number of diarrhoea diseases related to salmonella world wide at over 1,500 million each year, with the majority of the burden being carried by children under 5-year old (3 million deaths). 70 per cent of these illnesses were believed to be food-borne in nature. In the United States, the salmonella species were second only to campylobacter in the estimated total burden of bacterial food borne illnesses.



60. The objective of the risk assessment was to develop a scientific basis for a policy aimed at reducing human illness and death; it had several components: (i) the development of a farm-to-table model; (ii) the calculation of a baseline occurrence of human illness; (iii) the identification of target areas for risk reduction; (iv) the evaluation of effects of interventions, and (v) the identification of data gaps. An important conclusion was that one mitigation was good (for example chilling the egg directly after it had been laid and holding it at that cold temperature), but the combined impact of several mitigation measures was even better.

61. At the next step, risk management, the question was what could be done with the output from the risk assessment that would affect an improvement in public health through policy decisions. An "Egg Safety Action Plan" was developed. The overarching goal was to eliminate SE illnesses associated with egg consumption; an interim goal was to reduce the number of egg-associated SE illnesses by 50 per cent by 2005.[27] Eight different objectives were developed together with associated performance measures and timelines. One of these objectives was to "reduce the number of SE-containing eggs marketed to the consumer". The performance measure for this objective was a declining number of production sites testing positive for SE annually. The activities that were required to achieve this objective were: (i) consistent, nationwide SE reduction programmes for egg production; (ii) HACCP-based systems for shell egg processing and prerequisite programs; (iii) HACCP-based system for egg products processing and prerequisite programs; and (iv) refrigeration and labelling regulations for eggs from processor to consumer.

[26] Epidemiology and Risk Assessment Division, Food Safety and Inspection Service (FSIS), United States Department of Agriculture (USDA).

[27] The entire Egg Safety Action Plan is available on the Internet: www.foodsafety.gov/~fsg/ceggs.html. The SE Risk Assessment itself if available at www.fsis.usda.gov.

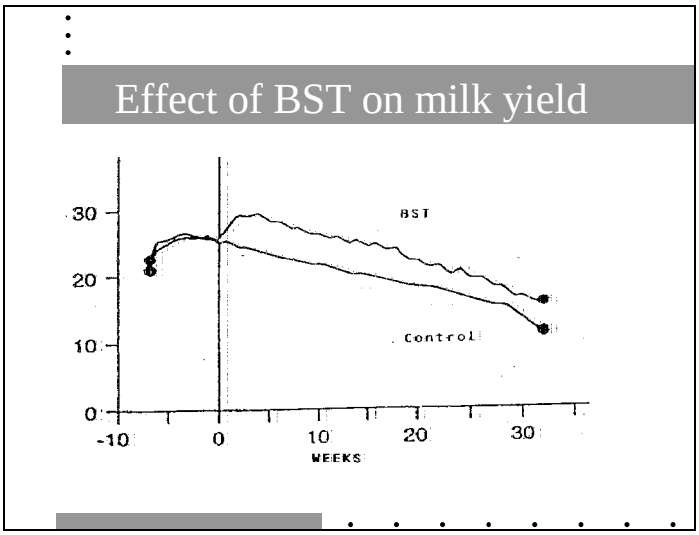
62. Dr. Hynes noted that the government had many different roles in implementing the Egg Action Plan. The States were responsible for inspection and enforcement. The Food and Drug Administration (FDA) developed producer standards and was responsible for surveillance and monitoring of the food supply. The FSIS developed standards for packers and processors and was also responsible for inspection and enforcement. The Centre for Disease Control (CDC) was responsible for the surveillance of human health outcomes. The example of the SE risk assessment showed how a risk assessment could be used as a public health tool to inform policy and regulation.

(iii) *Bovine Somatotrophin (BST)*

63. Mr. Moynagh[28] indicated that the main advisory body on animal health matters to the EC Commission was the Scientific Committee for Animal Health and Welfare. He stressed that the scientific committees were independent of the Commission and that consequently the risk analysis was not carried out by the Commission itself, but rather by an independent committee of scientists that *advised* the Commission. The reports of the scientific committees were available on the EC web site.[29] Mr. Moynagh described a study made in 1999 on the use of BST.

64. Mr. Moynagh began by noting that BST was a protein growth hormone produced naturally in bovine as well as in other animals. Commercial variations of BST (produced by pharmaceutical companies) were essentially the same as the natural products, although they had small amino-acid variations. BST was administered to dairy cows by injection normally every 14 days, with the main purpose of increasing milk yield; it had no therapeutic value. The effects on the milk yield are illustrated in Figure 9. The response varied between cows; some cows did not respond at all (no increase in milk supply) while others produce up to 25 per cent more milk. A typical response was about a 12 per cent increase in milk production. There were some changes in the composition of milk (fat, protein), but these remained within the normal variation level over the lactation period.

Figure 9



65. The EC risk assessment had considered two distinct issues: the effect on animal health and the effect on human health from drinking milk of treated animals. The scope of the risk assessment was broad, it was a general examination of BST and not an examination of a specific product dossier from a particular company. It was qualitative and involved a wide-scale literature review of published material on BST. In examining the data, the Scientific Committee confined itself to published papers

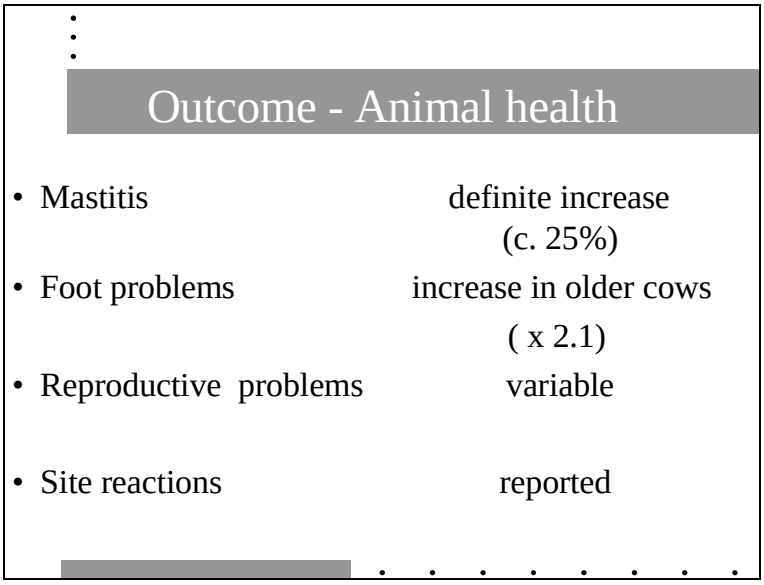
[28] Secretary of the Scientific Committee for Animal Health and Welfare, European Commission's Health and Consumer Directorate.

[29] Internet address: http://europa.eu.int/comm/dg24/index.html

and peer-reviewed journals as well as material from company submissions. The Committee was cautious about using non-peer reviewed papers or personal communications. In assessing the material the Committee considered (i) whether the experiment had been statistically robust enough to detect an effect (i.e., that the number of animals involved in the experiment was sufficient to detect an effect), and (ii) whether the effect reported was researched in detail.

66. With respect to *animal health*, the issues were, *inter alia*, (i) whether the use of BST resulted in an increase of mastitis; (ii) whether it resulted in increased foot problems in cows or lameness; (iii) whether it caused any fertility or reproduction problems; and (iv) whether there were any injection site reactions. The Committee determined that, while the various studies varied in their results, all indicated an increased level of mastitis. The increase in mastitis was probably around 25 per cent. Similarly, the Committee also determined that there was an increase in foot problems in cows; it set this increased risk at about 70 per cent compared to non-treated cows. The Committee determined that there was some reproductive effect, but that these effects were quite variable. Treated animals had a lower pregnancy rate and a shorter gestation length. Figure 10 summarizes the outcome of the animal health risk assessment.

Figure 10



67. With respect to *public health*, the issues identified for examination were (i) whether there was any effect on public health as a result of increased levels of BST in milk for consumption; (ii) whether there was an increase of mastitis in cows that resulted in an increased use of antibiotics, with related problems such as allergies or resistance developing to antibiotics; (iii) whether there were any changes in milk protein which could result in allergies; and, (iv) whether the increased levels of insulin growth-factors IGF-1 in milk from treated cows had any potential health effects.

68. With respect to the direct effect of BST in milk, Mr. Moynagh noted that BST and its metabolites were rapidly broken down in the gastric-intestinal tract. Pasteurization had the same effect. Furthermore, there was no interaction between bovine BST and the human growth-hormone receptors; it was a different molecule than the human molecule. There was no evidence of any direct biological effect in humans following oral ingestion. Hence, with respect to BST in milk, there did not seem to be any particular risk for any effects in humans from drinking such milk.

69. However, Mr. Moynagh noted that with respect to the insulin growth factors (IGF-1), a substance which was increased by the injection of BST, the situation was different. The growth factors at issue were involved in many physiological and biological processes which included cellular

growth-rate regulation and tumour promotion. IGF-1 from cattle was identical to human IGF-1. Since IGF-1 was also present in normal milk, it was quite difficult to determine to what extent it was increased by BST administration. There were considerable differences in the analyses of this substance. It appeared to range from a 25 per cent increase in some experiments to a five-fold increase in others. Furthermore, IGF-1 was not denatured by pasteurization. It survived digestion in combination with casein, which was an important constituent of normal milk. In this regard Mr. Moynagh noted that some of the initial experiments on the effects of IGF-1 on people were carried out with IGF-1 in isolation, without casein, and the conclusion was reached that it was denatured in the stomach. Yet in combination with casein it could pass through the gastrointestinal tract. On the other hand, it was also true that there was natural secretion of IGF in the human intestine and the intake with milk was much lower than that. So it did result in a small increase, but this was nothing new in terms of what went into the gastrointestinal tract. In conclusion, there were a number of "worrying points". When IGF levels had been measured in human blood, the 25 per cent of people with highest IGF-levels were more likely to develop cancer than the bottom 25 per cent. This related specifically to breast and prostate cancer. There was also a positive relation between dairy product consumption and breast-cancer. In light of this, the Scientific Committee decided that there was a need to know to what extent IGF-1 in the diet induced any adverse effects on the gastrointestinal tract as a consequence of *long-term* exposure, possibly over a life-time.

70. A question was posed regarding whether the *increase* in milk production *per se* was the mechanism that gave rise to the adverse effects, and not BST. In other words, if milk production were increased by other means, such as better feed, would the same effects arise? Mr. Moynagh explained that BST put animals into a negative energy balance a second time (following calving) which did not occur with normal milk production methods. Furthermore, if the dose of BST was increased beyond the level where milk increased, further side effects occurred. Taken together, these facts seemed to indicate that it was not simply the increase in milk supply that caused the adverse problems.

71. On the secondary risks, the Scientific Committee recognized that the use of BST could in some cases result in a longer clearance-time for drugs, which could result in undesirable drug residues. Also, more mastitis problems would lead to more use of antibiotics which ran counter the EC policy of reducing unnecessary use of antibiotics in farm animals.

72. In sum, the animal health findings were that BST administration did result in an increased risk of adverse health effects in the treated animal (mastitis and feet problems in particular). With respect to public health, there were no concerns about BST and its metabolites in milk (with increased use of antibiotics considered as an indirect issue). But there were concerns with IGF-1 in milk, and these related to the long-term increase of IGF-1 levels in the gut.

73. The action that the policy makers took on the basis of this risk analysis was, with respect to animal health, to continue the prohibition on the use of BST in the European Union. With respect to public health, no measures had been taken but the Commission was constantly reviewing the scientific evidence on this issue.

(iv) *Pork, African Swine Fever and Madagascar*

74. Dr. Katharina Stärk[30] explained how Madagascar could, hypothetically, use a risk assessment as a tool for resuming international trade after an outbreak of African Swine Fever (ASF) in 1998. Dr. Stärk noted that ASF was a viral disease that affected pigs, both domestic and wild, but had no human health implications. It was a notifiable disease included in the List A of the OIE (highly contagious and economically important). Countries not affected by the disease would have strong border measures in order to prevent introduction.

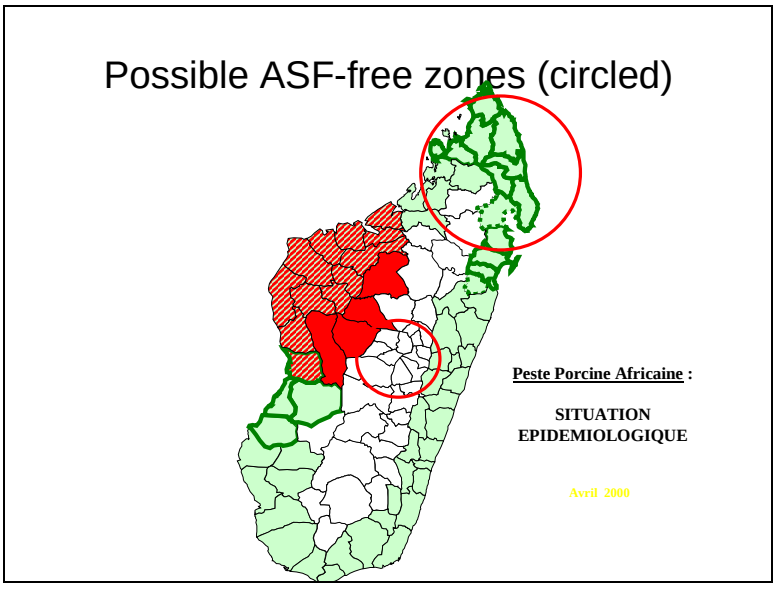
[30] Head of the monitoring and the Risk Analysis Group, Swiss Federal Veterinary Office, Bern.

75. Madagascar had been in the middle of a very positive development of pork production integrated with rice production when ASF was introduced on the island. The disease was diagnosed in 1998 and its origin remains unknown. Dr. Stärk noted that most of the island was affected, although there were some regions that appeared to be unaffected.

76. Exports of beef to the European Communities prior to 1995, and pork exports to La Reunion until 1998, had stopped due to a number of reasons, including the lack of surveillance and of good veterinary services within the country. According to the OIE's Animal Health Code, both surveillance and good veterinary services are essential for a risk assessment. The concept of zoning meant that the entire country did not have to have the same disease status.[31] Disease-free zones could be recognized by the OIE even though the disease was present at other places in the country. In Madagascar, there were areas where effective zones could be established, particularly because some areas could only be reached using one road – it would be relatively easy to control traffic. Surveillance would have to be established for domesticated pigs as well as for the movement of wild animals. With respect to which areas in Madagascar would be appropriate, Dr. Stärk noted that after the ASF epizootic most of the pigs on the island had either died, been sold or killed. Hence, a large area of the country did not have pigs (Figure 11). Animals from ASF-free herds outside of Madagascar could be imported and isolated in such areas. Among other factors, movements of wildlife and pigs, as well as people and feed, would have to be controlled.

77. After the zones had been put into place, Dr. Stärk suggested that it would not be a difficult matter to perform a risk assessment according to the OIE model and then provide the relevant information to trading partners.[32] It would be important for Madagascar, as an exporting country, to think about identifying weak areas and address these problems first. More specifically, it was essential to ensure that the ASF-free region remained ASF-free. The quality of surveillance and control would be crucial. Madagascar could also consider exporting processed products. Some processing procedures eliminated the virus from the product and therefore the risk of introducing the disease into the importing country. The status of the importing country was also important; in the south African region, only Tanzania and La Reunion were free from ASF, the other countries had (sporadic) reported ASF cases in 1998, or later.

Figure 11



[31] Article 6 of the SPS Agreement is relevant.

[32] For more details on the OIE and the concept of zoning see in paragraphs 47 to 52 above.

78. In concluding, Dr. Stärk emphasized that there could be no risk assessment without data. If a country planned to export it would have to be prepared to provide information requested by an importing country for conducting a risk assessment. If information was not given, trade was not likely to take place. In this regard, the risk analysis model set out by the OIE was rather flexible, particularly with respect to zoning. A qualitative assessment was sufficient. Dr. Stärk emphasized that it was a misconception to think that a risk assessment was a complicated numerical exercise. Risk assessment was a powerful tool also for exporting countries because it could avoid scientifically unjustifiable trade restrictions.

79. The Chairman noted that bilateral consultations were an important element in solving sanitary and phytosanitary concerns in order to facilitate trade. It was better to consult beforehand with a trading partner rather than finding at a later stage, after considerable resources had already been spent, that the importing country's sanitary or phytosanitary requirements were not met.

(v) *Aflatoxins*

80. Dr. John L. Herrman[33] presented a risk assessment on aflatoxins developed by the Joint FAO/WHO Expert Committee on Food Additives (JECFA).[34] He noted that risk assessment in general, was aimed at characterizing the risk on the basis of an evaluation of toxicological, epidemiological and related data and information on intake. When evaluating contaminants, JECFA established one or several end-points for assessment, depending upon the toxicological characteristics of the chemical and the available data. These included a tolerable intake expressed on a weekly basis (provisional tolerable weekly intake, PTWI), or, on rare occasions, an "irreducible level" (also known as ALARA), which was the concentration of a substance which could not be eliminated from a food without involving the discarding of that food altogether, severely compromising the ultimate availability of food supplies. A third end-point of a risk assessment was the determination of the relationship between intake of a contaminant and the probability of an adverse response in humans (quantitative risk assessment). The quantitative risk assessment was the most desirable end-point in the context of risk analysis because it facilitated decision-making in the context of risk management. However, it was often difficult to undertake a quantitative risk assessment because of lack of data.

81. Dr. Herrman used the risk assessment of aflatoxin B_1 as an example of a quantitative risk assessment. At its forty-ninth meeting in 1997, JECFA determined that aflatoxin B_1 caused primary liver cancer in most species that had been studied. Most of the epidemiological studies available found an association between the consumption of food contaminated with aflatoxin B_1 and liver cancer. It had also been determined that the carcinogenic potency of aflatoxins B_1 was enhanced in individuals with simultaneous hepatitis B infections. Hence, JECFA estimated the carcinogenic potency of aflatoxin B_1 in both the presence and the absence of hepatitis B and concluded that in the presence of hepatitis B virus infection, the potency was increased approximately 30-fold.[35] Next, JECFA used two examples to show how potencies could be used in determining the risks for populations. In one example, the level of contamination with aflatoxin B_1 was low and the proportion of the population carrying hepatitis B was small (1 per cent of the population). In the other example, the level of contamination with aflatoxin B_1 was higher and the proportion of the population carrying hepatitis B virus was 25 per cent. In both cases the impact of use of two hypothetical standards, 10 and 20 µg/kg, on relevant food commodities (groundnuts, cereals and maize) was considered.

[33] WHO Joint Secretary of the Joint FAO/WHO Expert Committee on Food Additives (JECFA), International Programme on Chemical Safety (IPCS), World Health Organization, Geneva.

[34] JECFA advises the Codex Committee on Food Additives and Contaminants and FAO and WHO Member States

[35] Potency is an expression of the number of cases per year per unit of aflatoxin B_1. For persons negative for hepatitis B virus, the Committee determined that there would be 0.01 case per year/100 000 people per ng (nanogram) of aflatoxin B_1/kg body weight per day (range 0.002-0.03). For persons positive for hepatitis B virus, the potency was established at 0.3 case per year/100 000 people per ng of aflatoxin B_1/kg body weight per day (range 0.05-0.5).

(a) Low-risk group (1 per cent of the population carries hepatitis B virus):

- Population risk for the 20 µg/kg standard was calculated at **0.0041 cancers per year per 100 000 people** (range 0.0006 - 0.01).

- For the 10 µg/kg standard, the risk was calculated at **0.0039 cancers per year per 100 000 people** (range 0.0006 - 0.01).

- Conclusion: reducing the hypothetical standard from 20 to 10 µg/kg yielded a reduction in estimated population risk by 2 cancers per year per billion people.

(b) In the higher-risk group (25 per cent of the population carries the hepatitis B virus):

- For the 20 µg/kg standard, the estimated population risk was **0.17 cancers per year per 100 000 people** (range 0.03 - 0.3)

- For the 10 µg/kg standard, the estimated population risk was **0.14 cancers per year per 100 000 people** (range 0.02 - 0.3).

- Conclusion: reducing the hypothetical standard from 20 to 10 µg/kg yields a reduction in estimated population risk by 300 cancers per year per billion people, considerably more than in the first example.

82. In light of the above, JEFCA made a number of conclusions in respect of how one might manage risk. First, vaccination against hepatitis B would reduce the potency of aflatoxins to vaccinated populations and thus the risk of liver cancer. It was noted that probably the vast majority of liver cancers was due to hepatitis, rather than the consumption of contaminated food with aflatoxins. Second, detectable differences in population risks were unlikely to be exhibited in going from a hypothetical standard of 20 to 10 µg/kg in populations with a low prevalence of hepatitis B in which the mean intake of aflatoxins was low. Populations in which both the prevalence of hepatitis B infection and the intake of aflatoxins were high would benefit from reductions in aflatoxin intake. It was also recognized that carriers of hepatitis C were probably also at increased risk from consumption of products containing aflatoxin, but quantitative estimates could not be made (no data). Most governments would probably find it more useful to estimate the risk of vulnerable groups than of the overall population. In doing that, the appropriate approach would be to base the risk assessment on the potency for those people who were carriers of hepatitis B virus.

83. Dr. Herrman made two separate general points. First, he noted that it was sometimes difficult to separate risk assessment from risk management, because the scientists who were doing the risk assessment knew that if the tolerable level was set too low, the impact on food supplies could be substantial. An example of this was methyl-mercury, which was present in certain fish. If a too stringent standard was established and actually applied, certain population groups could end up with a very important source of protein removed from their food supply to counterbalance a risk which probably would be smaller from the ingestion of methyl mercury. Second, Dr. Herrman pointed out that potency calculations could be used world-wide because toxicity was an inherent property of the substance.

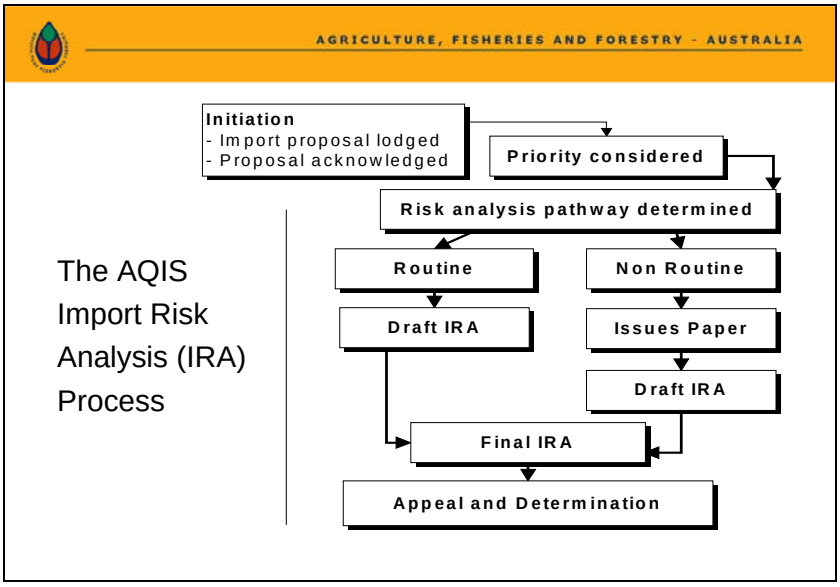
84. Dr. Herrman noted that further information on the basis for the evaluation of aflatoxins by JECFA and how it can be used could be found in the published report of the forty-ninth meeting of JECFA – WHO Technical Report Series No. 884, 1999. More details of the evaluation were included in the toxicological and intake monograph on aflatoxins – WHO Food Additives Series No.40, 1998. These documents were available from WHO Marketing and Dissemination (http://www.who.int/dsa/). Furthermore, information on estimating intake of food contaminants could be obtained at

http://www.who.int/fsf/. Dr. Herrman noted that JECFA had evaluated a large number of chemicals (in the order of 1,300 – 1,400 chemicals) which included food additives, contaminants and veterinary drugs. A summary was available in a searchable format at the address http://www.who.int/pcs/. The summary was updated approximately every two years.

(vi) *Ya Pear from the Hebei Province of the People's Republic of China*

85. Mr. Digby Gascoine[36] outlined the process followed by the Australian Quarantine and Inspection Service (AQIS) when conducting an import risk analysis (Figure 12). He noted that the AQIS Import Risk Analysis Process Handbook described the process in detail and that this was available on the internet.[37]

Figure 12



86. The process was initiated by a request for setting import conditions for a particular commodity. Alternatively, the process could be initiated by AQIS in circumstances where a decision was made to review existing conditions. Mr. Gascoine noted that there were more proposals than there was physical or financial capacity at any one time to handle the requests.[38] Thus setting priorities was particularly important. Once the priority was set, the next determination was whether the risk analysis would be a complex or a simple one. In the latter case, it would go down the left hand path (routine) in Figure 12. More technically complex risk analyses followed the non-routine path. There were two important differences in this regard. A non-routine risk analysis would first have to establish an import risk analysis panel. That panel was led by AQIS staff but it included independent scientific experts. An independent panel was not set up for routine risk analyses. Second, a non-routine risk analysis published an initial issues paper. This was done in order to get contributions and comments from stake holders, including trading partners, before a draft risk analysis was published. The draft risk analysis, which was always prepared for both routine and non-routine risk analyses, was released to stake holders for a 60-day comment period. The final import risk analysis was released for a 30 day period, giving stake holders the opportunity to make an appeal to an appeals panel which would

[36] Director of the Policy and International Division of the Australian Quarantine and Inspection Service (AQIS) and Chairman of the Codex Committee on Import and Export Certification and Inspection Systems.

[37] Available in PDF format at the AQIS internet address: http://www.aqis.gov.au/pubs/index.htm

[38] There were currently about 100 proposals lodged and about 51 import risk analysis under way. This engaged a staff of around 40 professional experts (veterinarians, plant pathologists, botanists etc.).

determine whether or not AQIS had followed the process correctly. Mr. Gascoine stressed that the appeal could not concern AQIS handling of the scientific information.

87. In relation to plant import-risk analysis, AQIS followed ISPM[39] which had three basic steps: (i) initiation, (ii) pest risk assessment, and (iii) determination of pest risk management measures. At the heart of the process was an attempt to determine what was the quarantine status of each pest or disease which could be in the pathway. It was an evaluation of information about distribution, biology, and the economic importance of each pest. It applied expert judgement to assess the possibilities of establishment, spread and damage that could occur. Having determined that there was a possibility, AQIS would then evaluate what the probability was. It was not sufficient to identify that something might go wrong, there was a need to focus on how *likely* this was. After this was done, the next issue was that of pest risk management, which was about choosing the measures which needed to be applied in order to reduce the risk to Australia's appropriate level of protection. The measure would furthermore have to be proportional to the risk identified in the pest risk assessment, as well as the least trade-restrictive measure required to achieve that appropriate level of protection.

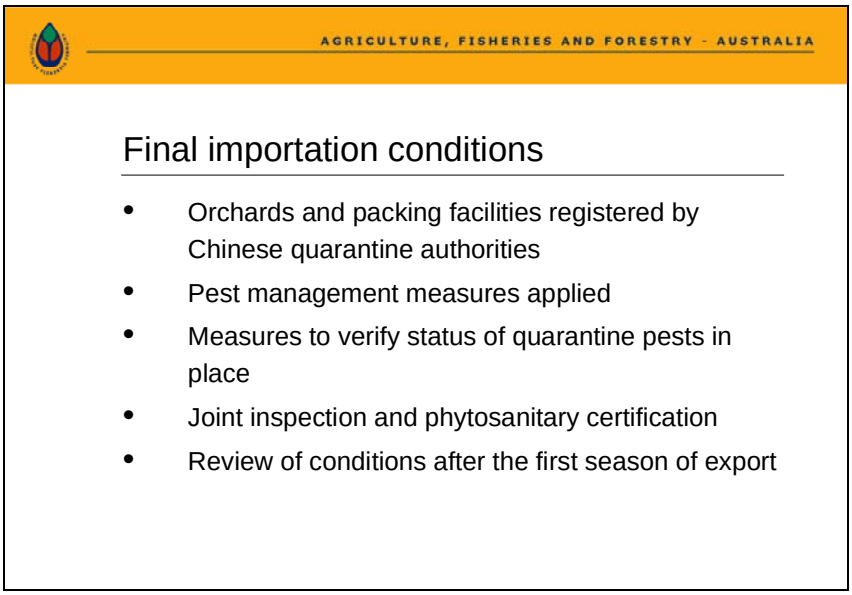
88. Mr. Gascoine used the example of the importation of Ya Pear from the Hebei Province of the People's Republic of China. In April 1991, China had applied to AQIS to set conditions for the import of fresh Ya Pear fruit from two designated export areas within the province of Hebei.

89. The import pathway was defined as fresh Ya Pear fruit from defined areas of China. First, a list was established of the pests which might be found in that pathway. After a process of interaction with the Chinese authorities that spanned over a period of years, 120 pests were identified. The next step was a process of analyzing which pests were of quarantine concern to Australia. After extensive bilateral talks between authorities on both sides, 18 pests were identified and the pest risk analysis could begin. Then followed the consideration of risk management measures which might be applied. For example, China had oriental fruit fly and one option was a trapping programme to detect seasonal incursions. Other management options were considered for, *inter alia*, brown rot – *Monilinia fructigena* (orchard freedom by survey plus petal testing), Japanese pear rust – *Gymnosporangium asiaticum* (host removal to 2 km radius or chemical control and bagging of fruit).

90. The last step was to set final import conditions, illustrated in Figure 13. The Chinese authorities were asked to register the orchards and the packing facilities from which they would source Ya Pear for Australia. They were asked to apply pest-management measures which included field sanitation and other pest-control measures (bags in one case, boxes, cartons, etc.). They were asked to establish measures to verify the status of quarantine pests (including a visit by an Australian plant pathologist to the export areas in China within the first year of trade to survey for pests and audit the Chinese authorities annual disease survey data). AQIS also required the Chinese authority (the State Administration for Commodity Inspection and Quarantine) to survey and to support their claims on pest-free areas. There was a requirement of joint inspection and certification (the signing of a scientific certificate by the AQIS pre-clearance officer) and AQIS reserved the right to examine certification and seals on the arrival of the commodity in Australia. Finally, and particularly important, the conditions were to be reviewed to ensure that they were the right conditions to regulate pest risk in this trade. The purpose of this was also to ensure that the conditions were not excessively strict.

[39] See paragraph 55 of Mr. Griffin's presentation on the IPPC.

Figure 13



91. The final conditions were set between the end of 1999 and early 2000. Since then, 78 containers of fruit – approximately 1700 tons – entered Australia and none were rejected as a result of pests associated with the imported fruit.

92. In conclusion, Mr. Gascoine noted that the process followed by AQIS had a number of important characteristics. First, and most important, it was consistent with the SPS Agreement's requirements. Second, it followed the relevant international guidelines. Third, it was thorough and highly transparent. The procedure was versatile, in the sense that the approach was modified according to whether the issue under consideration was a complex one or a less complex one. The procedure could be followed on a qualitative, quantitative or semi-quantitative basis. All risk analyses so far had been qualitative, as AQIS did not feel there was enough reliable data to enable the preparation of quantitative risk assessment. Because the same process and the same guidelines were followed for each case, it facilitated consistent risk assessment and it facilitated – although it did not ensure – consistency in risk management. Finally, the procedure was evolving. One draw-back was that it used a lot of resources, and it took time. Most of the time was taken by the analytical process conducted by professional experts, as well as for the public comment periods.

93. In response to a question on the notion of shared risk assessments and their availability to the public, Mr. Gascoine noted that the risk assessment could be useful to other countries, at least in part and to the extent that other countries had similar disease profiles. Responding to questions on the long time it took for import requests to be addressed, Mr. Gascoine stressed that the main reason for the long list of applications which were not being processed at the present time was not always the lack of resources within Australia, it was that for very many applications the data did not exist to allow a proper risk analysis to be commenced.

Conclusions

94. The following points are highlights from the various presentations made at the workshop:

- The requirement that sanitary and phytosanitary measures be based on science, and that the work of the standard-setting organizations be taken into account arose early in the negotiations of the Uruguay Round.

- Risk analysis does not provide a decision. It results in a *recommendation* on which a decision or a position – often at a political level – can be based.

- Risk analysis creates important linkages between government institutions, the scientific community and the public.

- Risk analysis does not necessarily fail as a result of insufficient information. A key objective of risk analysis is to identify uncertainty, which is part of the scientific evidence and the basis for decisions.

- A risk analysis does not have to be complex. It is above all essential that an attempt be made to conduct a risk assessment, even on the basis of very limited information. Sophisticated tools are less important than the use of rational arguments. Even a rudimentary risk analysis can provide the starting-point for dialogue between trading partners.

- Under the SPS Agreement there have been three disputes referred to dispute settlement panels. The question of scientific justification and the use of risk assessment were important issues in all of these disputes. The panel and Appellate Body reports are available to the public on the WTO internet home page. These provide insight into the practical application of the SPS Agreement's disciplines, particularly with respect to Article 5.

- In looking at risk analysis and the work of the three sister organizations, as well as the WTO, it is important that Members coordinate their activities and positions in capitals and across the different fora.

- In the context of technical assistance in the area of risk analysis, internet access is a useful tool as it facilitates the gathering of data and information, which is one of the most time-consuming aspects of risk analysis.

WTO SPS RISK ANALYSIS WORKSHOP
19-20 JUNE 2000

Programme

Monday, 19 June 2000 – Session 1

A	**Opening statement** · Frank Wolter (Director, Agriculture and Commodities Division)	**15:00**
B	**The link between the SPS Agreement and risk analysis** · Gretchen H. Stanton (Secretary of the SPS Committee, WTO Secretariat)	15:15
C	**Fundamentals of Risk Analysis and its practical application** · Robert Griffin (IPPC Secretariat)	15:45
D	**Examples from Members / Observers** · Eduardo Serrano (OIRSA) on the characterization of BSE risk for certain Central American countries · Noreen A. Hynes (United States) – on *Salmonella Enteritidis* in Eggs	16:30

Tuesday, 20 June 2000 – Session 2

E	**The SPS Agreement as it relates to scientific justification** · Erik Wijkström (WTO Secretariat)	**09:30**
F	**Examples from Members / Observers** *Continuation of Programme Item D* · James Moynagh (European Communities) – on BST · Katharina Stärk (Switzerland) – on Pork, African Swine Fever and Madagascar	10:30
G	**The Codex, OIE and IPPC – their work relating to Risk Analysis** · David Byron (Codex Secretariat) · Thierry Chillaud (OIE Secretariat) · Robert Griffin (IPPC Secretariat) · Discussion	11:30

Lunch break: 12:30 to 14:30 – Session 3

H	**Examples from Members / Observers** *Continuation of Programme Item D* · John Herrman (WHO Secretariat) – on Aflatoxins · Digby Gascoine (Australia) - Implementation of science-based risk analysis for application of SPS measures in Australia (Case-study on Ya Pear from Hebei Province of the People's Republic of China)	14:30
I	**Concluding Remarks** · Gretchen H. Stanton (WTO Secretariat)	17:00