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DEVELOPMENT AND APPLICATION OF RESIDUE LIMITS TO FOODS IN TRADE UNDER WTO SPS PRINCIPLES

Submission by Australia to the meeting of 15-16 November 1995

The following paper has been received from the delegation of Australia with the request that it be circulated to all Committee Members and considered under the proposed agenda item relating to generic SPS trade issues (Item I).

Summary

Maximum residue limits are applied by many countries as a means of ensuring the health status of food supplies. Such limits are sanitary measures within the scope of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures, and must be formulated and/or applied by WTO Members in accordance with the principles set out in the Agreement. National approval procedures for establishing residue limits may be slow, expensive and potentially discriminatory in their operation.

In some instances trade into a national market may be restricted because appropriate residue limits have not been established. A large number of maximum residue limits have been established as international standards by the Codex Alimentarius Commission, and can be used as a basis for the harmonization of Members' measures.

MRLs which have been established at the national level should be interpreted and applied in accordance with SPS principles.

Background

1. The conventional approach to limiting hazards to health which may be caused by the presence of chemical residues in foodstuffs is the application of maximum residue limits (MRLs). Where testing of foods shows residue levels exceeding the MRL the relevant lot, batch or consignment is normally excluded from the market place.

2. The process of establishing an MRL usually commences with an evaluation of the toxicity to humans of the chemical substance concerned, based on scientific data about the chemical including results of trials on laboratory animals and tests to establish the propensity of the substance to accumulate in the body. An acceptable daily intake level (ADI) is estimated as the safe level of exposure over a human lifetime by applying safety factors to the no-observable-effect-level (NOEL) determined in the chemical risk assessment. The amount of a chemical contaminant which is permissible in an individual food logically depends upon the total amount of the chemical to which an individual may be exposed from all dietary sources; hence it is necessary to calculate a theoretical maximum daily

intake (TMDI) and consider the relationship of the TMDI to the ADI of the chemical in estimating the maximum permissible concentration of the substance in any individual food. The MRL is then set as far below this level as is achievable if producers use the chemical in accordance with good agricultural practice (GAP). The MRL may be much lower than the theoretical safe level.

Interpretation of MRLs

3. It follows from this procedure that an MRL is not of itself a safety limit; instead it is a limit which defines whether GAP has been followed in the use of the relevant chemical. Food in which the concentration of a chemical exceeds the MRL may or may not present a health risk according to whether the actual level is high enough to exceed the acceptable daily intake.

4. However the presence of chemical residues at a level exceeding the MRL is evidence that good agricultural practice has not been followed, and accordingly that there is heightened risk that food safety practices and controls may not be adequate.

National Approval Procedures

5. Many countries have statutory or administrative procedures for determining limits on chemical contaminants in food. These procedures are usually brought into operation by the making of an application by an individual or company. The application may be for the registration for use of a chemical and the setting of a suitable MRL relevant to the proposed use, or the application may be only for establishment of an MRL.

6. To allow adequate assessment of risk, it is necessary for the applicant to supply certain specified information principally relating to the properties of the chemical. There may be a published protocol defining this information dossier. The cost of compiling the dossier may be very high (for example, some millions of dollars for a new pesticide), and there may also be significant costs for applicants in shepherding their proposals through the approval procedures. Where intellectual property rights are not fully protected, the inventor of a chemical may be unwilling to submit it to the registration process for fear of losing control of commercially valuable information. The national approval process may extend over a considerable period of time.

7. It is normal practice in some countries for relevant international (i.e. Codex) standards to be taken into consideration in the setting of a national MRL, and in other countries the Codex MRL may be the only basis for the national MRL. Particular aspects of dietary composition at the national (or sub-national) level may be one of the objective factors taken into consideration by a country in deciding whether to follow an established Codex MRL.

8. Where national approval procedures have not been completed for a chemical, the relevant law may dictate that the limit applicable to the residue of the chemical in any food is zero. For practical purposes, a default level such as 0.1 parts per million or the limit of detection for the chemical residue concerned may be established.

Application of limits

9. MRLs serve as accept/reject criteria in decisions as to whether batches, lots or consignments of food should be permitted to enter the marketplace or be withdrawn from sale. According to the relevant law and circumstances, regulatory action could include:

- exclusion from sale of the offending item
- consequential residue testing of companion product

- exclusion from sale of the whole batch, lot or consignment
- intensified testing on other (including future) product from the same source eg. from the same factory or from the same exporting country, possibly accompanied by official suspension of production or trade pending investigation of the matter by testing or other means.

10. Importing countries may require certification by the authorities of exporting countries that food conforms with importing country standards and may choose to verify conformity by examination of the exporting country's control systems and/or by sample testing of product on arrival.

SPS provisions

11. The SPS Agreement requires that:

- measures are applied only to the extent necessary to protect life or health, are based on scientific principles, and are not maintained without sufficient evidence except on a provisional basis;

- measures do not arbitrarily or unjustifiably discriminate between Members of the WTO, nor constitute a disguised restriction on international trade;

- measures shall be based on relevant international standards; or, if they are more stringent, there must be a scientific justification based in risk assessment, risk must be managed consistently at the national level, and measures shall not be more trade restrictive than is necessary to achieve the appropriate level of protection;

- measures must be made, and maintained in a transparent way.

12. In Annex C to the SPS Agreement it is provided that "where an importing Member operates a system … for the establishment of tolerances for contaminants in food [or] beverages … which prohibits or restricts access to its domestic markets for products based on the absence of an approval, the importing Member shall consider the use of a relevant international standard as the basis for access until a final determination is made". Additionally, Annex C says that information requirements for the establishment of tolerances for contaminants shall be limited to what is necessary, and confidentiality shall be maintained in order to protect legitimate commercial interests (Annex C, paragraph 1(c) and (d)).

13. In relation to the application of standards such as MRLs, for example in taking of samples and testing them for residues, Annex C of the Agreement says that such procedures shall be undertaken and completed without undue delay and in a non-discriminatory way.

14. If national procedures for establishing and applying MRLs are to conform with SPS requirements, they must not only meet the specific provisions of Annex C referred to above but also the general provisions concerning risk assessment, consistency in risk management and so forth, as required by Article 8 of the Agreement.

Codex activities

15. The Codex Alimentarius Commission has established several thousand MRLs for particular chemicals, including pesticides and veterinary drugs, in particular foods. This work is continuing through the relevant Codex technical committees using input from the Joint Meeting on Pesticide Residues and the Joint Expert Committee on Food Additives.

Conformity with WTO/SPS requirements

16. The following are three examples of the way in which the development and application of residue limits to foods may not conform with WTO/SPS requirements.

Arbitrarily low limits

17. Many countries tend to arbitrarily apply very low or zero tolerances for residues of chemicals for which an assessment has not been carried out within the established national approval procedure. Such standards are not based on risk assessment and do not have a specific scientific justification. (The prohibition of food additives which are not included in a positive list presents a similar situation.) However, these countries may not be able to conduct a proper risk assessment because they do not have access to the necessary technical information; and even if they could create the requisite information through a testing programme and other means, it would be costly and wasteful to duplicate work which had already been done in other countries.

18. This situation may be inherently discriminatory against exporting countries. An importing country will tend to have registered for use, and residue tolerances set for, those pesticides or veterinary drugs which are used by its domestic agricultural industries. There is little incentive for a chemical company to submit its proprietary chemical for registration in any country in which there is not a significant market for the chemical . Importing countries have no incentive to make additional efforts to set tolerances for chemicals where the necessary dossier of technical information is not readily available.

19. On the other hand importing countries may not be aware of the need for appropriate tolerances to be set for chemicals used by exporters, unless (for example) import screening finds foods containing residue levels which violate the nil or default tolerance of the importing country.

Limits not more trade restrictive than required

20. Another problem arises where a country does set a pesticide residue tolerance which reflects technical need and good agricultural practice only in relation to the agricultural practices which are followed in that country. For example, tolerances for residues of a particular chemical may be established only for foods (crops or animal products) grown in that country, whereas other countries may justifiably use the same chemical on other crops or food producing animals. A standard set to accommodate good agricultural practice at the national level may be too stringent to accommodate good agricultural practice in other exporting countries. Such a standard may not be the least trade restrictive measure consistent with the achievement of the country's acceptable level of protection, taking into account technical and economic feasibility.

Response action proportional to risk

21. An action to seize and destroy a food consignment because it was shown to have marginally exceeded an established MRL or tolerance may, in reality, contribute little to the protection of public health. This is because the effect on health of residues of agricultural and veterinary chemicals are measurable only in terms of the time exposure at levels considerably in excess of established MRL's. Actions to trace and investigate occurrences and to cause modifications to ensure good agricultural practice are more likely to confer long term public health protection.

Issues for consideration

22. Having regard to the provisions of the SPS Agreement, the main elements of a national approach to *setting residue limits* could include:

- widest possible adoption at the national level of Codex MRL's
- determination of other MRLs to consider not only national needs but also the needs of trading partners in relation to good agricultural practice in the use of particular agricultural chemicals
    - accommodating both the range of crops on which a chemical is used and differences in the pattern or the intensity of use
- availability of a mechanism to set additional MRLs on a temporary or otherwise limited basis to accommodate immediate and significant trade needs
- systematic review of established nil or default tolerances to identify situations in which such standards are unjustifiably restrictive of trade.

23. In relation to measures applied by Members in the event of a detection of residue levels in violation of the Members' standard, it could be appropriate for Members to review established practices or protocols to ensure that action taken is proportional to the risk to human health. For example, mechanisms should allow for differential action between cases according to frequency and/or severity of violations.

24. Under Article 12.2 of the Agreement, the Committee on Sanitary and Phytosanitary Measures -

> " … shall encourage the use of international standards, guidelines and recommendations by all members and, in this regard, shall sponsor technical consultation and study with the objective of increasing coordination between international and national systems and approaches for approving the use of food additives or for establishing tolerances for contaminants in foods, beverages or foodstuffs."

The Committee could consider how such a procedure could be pursued, in conjunction with the Codex Alimentarius Commission, in relation to the matters covered in this paper.