

**EQUIVALENCE -
ARTICLE 4 OF THE AGREEMENT ON THE APPLICATION OF
SANITARY AND PHYTOSANITARY MEASURES**

Communication from Argentina¹

INTRODUCTION

1. The obligation to base sanitary and phytosanitary measures on scientific evidence is a guarantee of objectivity. However, the appropriate level of protection imposed by each country in deciding whether or not to accept imports is a source of concern for the developing countries in relation to the implementation of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). Clearly, what is at stake here is the prospect for the developing countries of having access, in the near future, to international markets.

2. The central issue in these discussions is the equivalence of control systems in force at the national level based on the correct interpretation of three basic concepts: sanitary measures, appropriate level of protection and objective safety. Until now, when an exporting country has sought access to another market, it has had to comply with the demands of the importing country both as regards the actual requirements and verification of effective compliance of the product exported with those requirements. In other words, the exporting country has had to comply with the sanitary measures of the importing country.

3. Under the SPS Agreement, this has changed, with the incorporation of the concept of equivalence of measures. Indeed, Article 4 of the SPS Agreement stipulates that "Members shall accept the **sanitary or phytosanitary measures** of other Members as equivalent, even if these measures differ from their own", if the exporting Member achieves "the importing Member's **appropriate level of (...) protection.**" The concept of equivalence being linked to the appropriate level of protection, the Agreement defines this term as "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." This very general wording used in establishing the principle of **equivalence** of control systems at the multilateral level has inevitably given rise to a variety of interpretations.

4. Certain countries have argued that the determination of this appropriate level of protection was an unquestionable sovereign authority of the importing State, which had full discretion in determining whether or not an imported product complied. Other countries have maintained that this authority, while sovereign, was subject to compliance by the importing country itself with the appropriate level imposed, and that there could be no arbitrary or unjustifiable distinctions in the levels it considered appropriate in different (but comparable) situations, if such differences resulted in discrimination or a disguised restriction on international trade.

¹ The first part of this document was presented at the meeting of the Committee on Sanitary and Phytosanitary Measures in March 2001 (Job(01)/31) and the Annex was presented at the July 2001 meeting.

5. While the guidelines in Article 5.5 of the SPS Agreement recognize the authority of the importing country in fixing its appropriate level of protection, the issue of determining when a measure is equivalent to another and how that "judgement" relates to the adequate level of protection and objective safety are still open to discussion. These matters are being addressed at the international level in the SPS Committee and the Codex Alimentarius, and discussions are already taking shape in the framework of the International Plant Protection Convention (IPPC) and the Organisation Internationale des Epizooties (OIE).

6. The Codex has made progress on the issue of equivalence of control systems, producing several documents, of which two have already been approved and two are currently being prepared:

- CAC/GL 26/1997 "Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems";
- CAC/GL 34/1999 "Guidelines for the Development of Food Import and Export Inspection and Certification Systems";
- ALINORM 01/30 A Appendix III (CX/FICS 00/6) "Proposed Draft Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems";
- CX/FICS 00/7 "Proposed Draft Guidelines on the Judgement of Equivalence of Technical Regulations Associated with Food Inspection and Certification Systems".

7. In addition to being discussed at the multilateral level, the issue of equivalence of control systems is on the agenda of regional, bi-regional and hemispheric integration processes. In this connection, the States parties to MERCOSUR adopted Resolutions GMC 77/98, 50/99 and 60/99 in the Common Market Group establishing the criteria, principles and scope for determining the equivalence of control systems in MERCOSUR. The issue is currently being discussed in the FTAA. Alternative proposals have been submitted for analysis with a view to determining what will ultimately form part of the draft chapter on sanitary and phytosanitary measures. Nor has the issue of equivalence of control systems been neglected in the discussions aimed at establishing bi-regional cooperation between the EU and MERCOSUR.

8. The above considerations bring to light the relevance and direct relationship of this issue to market access in the negotiations in which countries have engaged at the regional, hemispheric and multilateral levels.

DIFFERENT VIEWPOINTS

9. The aspects of the determination of equivalence that are of most concern to the developing countries can be summarized as follows:

- Domestic sanitary measures in the different countries must be based on scientific principles, proportional to the risk, and sufficient to ensure an appropriate level of safety.
- While the sanitary measures of another country need not be identical to achieve the appropriate level of protection, this is where the concept of objective safety comes into play, and that concept is specific (MRL for a given food).
- The system of equivalence must offer the possibility of different measures to guarantee the appropriate level of protection.
- The burden of proof and the possibility for the importer to deny the existence of equivalence.

- The safety objective is not mentioned in the SPS Agreement, nor is there any indication of how that objective safety will be the element that facilitates comparison between sanitary measures.
- Link between objective safety as a target and as an element in helping to describe the measure to achieve the appropriate level of protection.

Essential criteria:

- Need for the importing country to identify the appropriate level of protection;
- objective demonstration by the exporting country;
- the response to the equivalence must be objective.

The key to the problem for the developed countries is to ensure that the exporting country demonstrates satisfactorily that the sanitary measures achieve their appropriate level of protection.

10. With respect to the doubts and concerns of the developing countries with respect to the effective facilitation of trade that the adoption of a procedure for the determination of equivalence would involve, the following points should be borne in mind:

- This is a key issue, both at the multilateral level and at the regional level, since market access for the developing countries will largely depend on what is agreed in this respect;
- the requirements for achieving equivalence must not turn into disguised restrictions on trade that block access to markets by the developing countries;
- the subject must be raised in other fora, essentially in conjunction with trade facilitation and market access;
- it must be a trade facilitation instrument and not a market protection mechanism.

Priority objectives:

- Trade facilitation;
- to eliminate duplication of controls;
- to ensure that implementation costs do not exceed profits in order to guarantee competitiveness of the products in foreign markets;
- transparency;
- to adopt WTO/SPS procedures;
- to ensure quality and confidence in the products negotiated;
- to achieve the appropriate level of protection at minimum cost to the offerer, avoiding the transfer of the cost to the price of the product;
- to guarantee a reasonable level of access.

The key to the problem is to ensure that the equivalence of control systems is a mechanism which guarantees market access and does not constitute an additional difficulty for the developing countries.

A NEW APPROACH

11. When it comes to the different concerns felt by the developed countries and developing countries with respect to the problem of equivalence of control systems, it should be stressed that while the former focus on the need to guarantee as fully as possible the technical and scientific precision of the determination of equivalence, the latter focus on the need to ensure that the determination guarantees market access rather than making such access even more difficult. *In this respect, and from the point of view of the developing countries, the problem of equivalence of control systems, presented as a matter of great technical and scientific complexity, should be kept within the confines of the reality of bilateral trade.*

12. *The problem can be illustrated, for example, by a practical exercise consisting in analysing the statistics for the exports of a developing country to a given market. The bulk of these exports will undoubtedly be seen to concentrate on very few products and to involve very few enterprises. The case-study below attempts to bring the theoretical, technical and scientific discussion within the context of the reality of developing country exports.*

Case-study:

13. Total exports for 1999 from Argentina to country XX under chapters 1 to 24 of the Tariff Nomenclature amount to a total of \$68,842,502. 75 per cent of that total is covered by six tariff headings, corresponding to the following products:

- Meat of bovine animals, boneless, frozen;
- shelled peanuts;
- chocolate and cocoa preparations;
- prepared or preserved meat;
- wine;
- grape juice (including must).

There is very little trade in other products – indeed they represent, in total, 25 per cent of the remaining exports.

This case shows that there is little diversification of Argentine exports to country XX, 75 per cent thereof being concentrated on six products.

14. Regarding exporting enterprises, only a handful account for 75 per cent of exports:

- Meat of bovine animals, boneless, frozen: 4 enterprises;
- shelled peanuts: diversified: 13 enterprises;
- chocolate and cocoa preparations: 1 enterprise;
- prepared or preserved meat: 1 enterprise;
- wine: 4 enterprises;
- grape juice (including must): 4 enterprises.

The analysis conducted reveals that the exporting companies are not diversified either, and that 75 per cent of exports of the product are concentrated in the hands of very few of them.

15. This concentration clearly facilitates the control of processing plants where necessary, and of the products authorized for exportation.

16. Consequently, the determination of equivalence of control systems in the two countries should boil down to the recognition by the importer of the certification which the national control body of the exporting country provides for the products that are effectively exported and/or approval of the establishments where required.

PROPOSAL

17. The international standard for the determination of equivalence should be based on the following criteria and content:

- The main guiding principles of the process of determining equivalence should be gradualness, reciprocity, non-discrimination and special consideration of historical trade;
- the equivalence analysis must be conducted on the product or products that are being exported without seeking general equivalencies covering the totality of the national control system;
- the importing country should analyse the sanitary and phytosanitary measures of the exporting country, comparing them with its own sanitary and phytosanitary measures in order to consider whether the appropriate level of protection is reached in the same way as at the national level;
- equivalence should be based on bilateral agreements, with a general part establishing overall principles, objectives and long-term targets, and specific annexes for the products traded;
- the national lists of products that could potentially be exported between the two countries involved should be analysed at the bilateral level, with special emphasis on historical trade and previous refusals;
- special consideration should be given to historical trade, ensuring that it is not interrupted during the negotiation of an equivalence agreement; a standstill clause should be included, if necessary, in order to guarantee the situation that prevailed at the time of initiation of the negotiations;
- there should be a fast-track procedure involving automatic recognition of historically traded products;
- distinctions should be drawn between the risk categories of products under analysis;
- low-risk products should be considered eligible for immediate equivalence;
- in the case of new products which are being exported for the first time, the procedure for determining equivalence should be applied in its totality, leaving open the possibility, where feasible, of using the information contained in the risk analyses carried out by the importing country or by any other country²;

² As recognized by the DSB in *European Communities - Measures Concerning Meat and Meat Products (Hormones)* (WT/DS26), Analysis of Article 5.1. The DSB reaffirmed this criterion in *Australia - Measures Affecting Importation of Salmon* (WT/DS/18). Section B.8, Article 5.1 of the SPS, footnote 10.

- the correct information should be supplied so that the exporting country can meet the requirement of demonstrating that its product is equivalent;
- the importing country should cooperate technically in the process of determining equivalence.

18. It should be made clear that equivalence does not prevent the importing country from conducting the necessary product control and sampling prior to marketing. Should problems arise or should there be an emergency health situation, existing import prohibitions or similar measures shall apply without prejudice to the existence of equivalence agreements.

CONCLUSION

Agreements on the equivalence of food control systems must act as an instrument for ensuring legal certainty of trade, guaranteeing market access, eliminating duplication of controls and contributing to the liberalization of international trade, to the legitimization of historical trade, to the facilitation of the entry into markets of new products and to the enhancement of mutual confidence between national control bodies.

ANNEX

EQUIVALENCE AGREEMENTS ON FOOD CONTROL SYSTEMS AND THEIR IMPACT ON MARKET ACCESS

The proposal presented in the first part of this document, "Equivalence agreements on food control systems and their impact on market access" is further developed hereunder as a contribution to the regulation of Article 4 of the SPS Agreement.

1. The main guiding principles of the process of determining equivalence should be gradualness, reciprocity, non-discrimination and special consideration of historical trade

Both the overall legal framework of which Article 4 forms part and the guiding principles of the SPS Agreement should be considered by member countries when determining equivalence.

It is suggested that the following principles and criteria should also be taken into consideration in that process.

Reciprocity:

It should be understood that, in order to ensure balanced trade, the equivalence determination process should take the interests of both parties into account.

Non-discrimination:

With respect to the "achievement" of the Appropriate Level of Protection, the sanitary measure of the exporting member shall be evaluated in accordance with the parameters and criteria used by the importing country to evaluate its own measures. In this sense, although Article 4 of the SPS Agreement states that sanitary and phytosanitary measures shall achieve the Appropriate Level of Protection of the importing country, it should be understood that this requirement is only applicable provided that the sanitary and phytosanitary measures of the importing country also achieve such a level.

Gradualness:

In this sense, the process should be considered to have a series of successive objectives and aim at the equivalence, not of sanitary measures and control systems as a whole, but of those applied to the particular product or group of products that the exporting member is able to export.

Historical trade:

Products which have already been traded between importing and exporting parties should not be treated in the same way as a new product being incorporated into bilateral trade.

This is due to the fact that the product has already been duly tested and inspected by the competent national authorities of the importing member (see the simplified mechanism in item 7).

2. The equivalence analysis must be conducted on the product or products that are being exported without seeking general equivalencies covering the totality of the national control system

The equivalence determination process should take the sanitary and phytosanitary measures and control and inspection systems governing the product to be exported into consideration.

There are four basic reasons for this:

- (a) The non-equivalence of the control system applied by the exporting country to a certain sector (e.g., dairy products) does not imply any risk for the importing country in relation to imports of products belonging to a different sector (e.g., citrus).
- (b) Developing country exports almost always comprise only a small range of products.
- (c) Evaluating entire control systems would involve lengthy equivalence determination processes. An exporting developing country would most likely be unable to demonstrate equivalence when the importing country is a developed one, even though equivalence could easily be demonstrated in the case of export products.
- (d) Developing countries would be unable to bear the costs of a global equivalence demonstration and, since they export very few products, this cost would be passed onto the products, thereby rendering them non-competitive.

3. The importing country should analyse the sanitary and phytosanitary measures of the exporting country, comparing them with its own sanitary and phytosanitary measures in order to consider whether the Appropriate Level of Protection is reached in the same way as at the national level

It is crucial that the importing country, when considering the objective demonstration of the equivalence of sanitary and phytosanitary measures regarding "achievement" of its Appropriate Level of Protection, should bear in mind that its own measures should also "achieve" such a level.

Care should be taken to ensure that the Appropriate Level of Protection, which constitutes a sovereign decision by the importing country, does not constitute a disguised trade restriction. In this sense, although a country may have very high, and lawfully established, sanitary goals, these may not be reflected in actual sanitary measures or control systems or, quite simply, may not be observed.

In this sense, the exporting country should not be required to comply with an Appropriate Level of Protection that the importing country itself cannot "achieve", even though it may be a perfectly legitimate goal.

In conclusion, the equivalence determination conducted by the importing country should establish the correspondence of the measure or system, not to theoretical and abstract regulations, but to the measure or system of its own which is actually enforced.

4. Equivalence should be based on bilateral agreements, with a general part establishing overall principles, objectives and long-term targets and with specific annexes for the products traded

It is very important for developing countries that equivalence agreements contain a general part establishing principles, criteria, objectives and goals and a specific part identifying the agreed products or groups of products coming under the agreement, measures determined to be equivalent,

procedures and, in particular, the controls actually eliminated or simplified on the basis of determination of equivalence.

In concrete terms, this involves an Annex listing the products concerned, existing controls on such products and, in particular, the controls to be eliminated or simplified so as to make the facilitation involved clear in the agreement itself. Enforcement of the agreement should not be left entirely to the discretion of the control authorities.

5. The national lists of products that could potentially be exported between the two countries involved should be analysed at the bilateral level, with special emphasis on historical trade and previous refusals

Developing countries' lists of products will no doubt include those which, in terms of quantity and quality, they are in a position to export and which are probably already being exported (see the simplified mechanism in item 7).

If any of the products that developing countries are able to export are subject to sanitary restrictions, special attention should be paid to this particular item, so that, if the importer is a developed country, it can find a way to cooperate with the developing country in order to achieve definitive equivalence.

This should be set out in detail in the Annex, together, if possible, with a timetable of the planned activities and deadlines.

6. Special consideration should be given to historical trade, ensuring that it is not interrupted during the negotiation of an equivalence agreement; a standstill clause should be included, if necessary, in order to guarantee the situation that prevailed at the time of initiation of the negotiations

Under no circumstances should trade which is already under way between parties, or in products involved in an equivalence determination process, be hindered or impaired as a result of new negotiations on an equivalence agreement. It should, in all cases, be understood that Article 4 of the SPS Agreement is an instrument designed to facilitate, not hinder, existing procedures.

7. There should be a fast-track procedure involving automatic recognition of historically traded products

The simplified equivalence determination mechanism should be agreed on the basis of the elimination of the steps which, while provided for in the general procedure for products which have not yet been traded between the parties, are considered to have been fulfilled and sufficiently demonstrated, based on the knowledge of the health authorities and the confidence they have acquired over time and on product health. In this sense, the absence of previous refusals, i.e., failure to comply with sanitary certificate requirements, will be an important indicator.

8. Distinctions should be drawn between the risk categories of products under analysis

The different degrees of health risk presented by the products should be considered, taking into account whether they are processed and packaged and whether they are really liable to transmitting disease.

9. Low-risk products should be considered eligible for immediate equivalence

Products with a low health risk may also benefit from simplified mechanisms. They may therefore be treated as a priority according to the exporting party's interest, in order to make progress and ensure the access of products which, given their low risk, may quickly be considered equivalent.

10. In the case of new products which are being exported for the first time, the procedure for determining equivalence should be applied in its totality, leaving open the possibility, where feasible, of using the information contained in the risk analyses carried out by the importing country or by any other country

In the case of products being exported to another member for the first time, the established procedure should be applied in full, in accordance with the risk involved.

Given the cost for developing countries of performing their own risk analysis and to avoid making them any more expensive in the interests of product competitiveness, the possibility (pursuant to Article 5.1 of the SPS Agreement) of using a risk analysis conducted by the importing or another member - technical circumstances permitting - should be considered.

This is crucial to the economies of developing countries because, when situations are comparable, the use of available international information could avoid tests, demonstrations and trials being totally or partially duplicated, thereby resulting in savings of both time and money.

11. The correct information should be supplied so that the exporting country can meet the requirement of demonstrating that its product is equivalent

It is vital that the importing country should provide all the information required for equivalence determination as quickly as possible, thus facilitating the task of the exporting country, especially when the latter is a developing country. Transparency and speed in conveying both information and requirements are essential conditions for an exporting country to successfully begin an objective demonstration.

If need be, the exporting country may also ask the importing country for reasonable access to its control system in order to facilitate the objective demonstration requested. Under no circumstances may this involve disclosure of confidential information which could hinder compliance with sanitary or phytosanitary legislation or damage the legitimate commercial interests of certain companies.

12. The importing country should provide technical cooperation in the process of determining equivalence

This is crucial when the exporter is a developing country. Needs and details regarding the product(s) concerned should be determined for each individual case and set out in the bilateral agreement under negotiation.
