European Crop Protection

Import tolerances in the European Union

Can Import Tolerances be set for active substances impacted by the EU hazard-based criteria?

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Abstract

The aim of this paper is to provide further information and clarification on the European Union's (EU) system for setting import tolerances. In order to do so, this paper provides an overview of the EU's regulatory framework for plant protection products and for the setting of MRLs. It also explains the process for the evaluation of applications to set import tolerances in the EU.

The paper argues that, while legislative changes have introduced hazard based criteria into the authorisation of active substances at the EU level, such criteria are not included in the legislation on the setting of Maximum Residue Levels (MRLs) and should therefore not influence the process for setting MRLs and residue 'Import Tolerances' that are set to support international trade.

The paper examines in detail the EU's hazard based approval criteria, including the specific criteria on endocrine disruption that are currently being developed by European policy makers.

The paper sets out the arguments that using a hazard-based approach to setting import tolerances would be contrary to principles set out in the WTO Sanitary and Phyto-Sanitary (SPS) agreement and could have a substantial impact on international trade. The WTO requires that decisions are based on the assessment of risk and it is imperative that the EU continues to comply with the WTO SPS principles when deciding on the setting of Import Tolerance to support international trade.

It also concludes that any hazard based restrictions on the setting of Import Tolerances would be contrary to the EU's own legislation on the setting of maximum residue levels, as the hazard based cut-off criteria do not apply in the process for the setting of import tolerances in the EU.

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Introduction

With the introduction of hazard based criteria in the EU's legislation for plant protection products (PPPs), this paper aims to explain the potential challenges in the setting of residue import tolerances for third country trade with the EU. The paper provides further information on the general legislative frameworks, details of the requirements to set import tolerances, and also describes the potential challenge in setting and maintaining import tolerances for substances that may be removed from the EU market in the coming years.

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Legislative framework for pesticides evaluation in the European Union

There are two key Regulations in the EU that set out the EU's legislative framework for plant protection products and their residues.

Regulation 1107/2009[5] sets out the framework for placing active substances and PPPs on the EU market. This Regulation sets out that a PPP cannot be authorised in any of the 28 Member States unless the active substance(s) it contains has been approved at EU level and unless MRLs are set for the relevant crops. This regulation also sets out the criteria for the approval of active substances. While the initial EU legislation on the authorisation of PPPs was based on a risk assessment, Regulation 1107/2009 introduces hazard based criteria, whereby active substances can only be approved if they comply with both the hazard criteria as well as the risk assessment criteria.

Regulation 396/2005[6] sets out the framework for setting Maximum Residues Levels (MRLs) in food and feed. The key aim of this Regulation was to support intracommunity trade in the common market by establish EU-harmonized MRLs and repealing member state MRLs. The Regulation sets out the detailed process for setting MRLs, with consumer safety being a key evaluation area[7].

Regulation 396/2005 and the setting of import tolerances[8]

What is an Import Tolerance?

Article 3.2(g) of Regulation 396/2005 defines an import tolerance as being '*an MRL set for imported products to meet the needs of international trade where:*

- *The use of the active substance in a plant protection product on a given product is not authorised in the Community for reasons other than public health reasons for the specific product and specific use; or*
- *A different level is appropriate because the existing Community MRL was set for reasons other than public health reasons for the specific product and specific use*'

When do you need an import tolerance?

According to the definition provided above, an import tolerance is required when food or feed commodities imported in the EU contain residues of an active substance for which an MRL has not been set or is not set at the right level. This may be the case when:

- The imported commodity comes from a crop not grown in the EU
- An existing MRL for the active substance does not reflect importation needs (e.g. it is too low for the specific crop use)
- The crop is grown in the EU but the active substance is not authorised for use on it
- The active substance is not approved in the EU, i.e. has never been approved or has been withdrawn

[5] Regulation (EC) No 1107/2009 of the European Parliament and the Council, concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

[6] Regulation (EC) No 396/2005 of the European Parliament and of the Council, on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC

[7] Preamble 19 of the Regulation which states that *"The determination of MRLs for pesticides requires lengthy technical consideration and includes an assessment of potential risks to consumers".* See also Article 10.1: *'The [EFSA] shall assess […] the risks to the consumer [and] the risks of the acceptable daily intake or the acute reference dose being exceeded […]'.*

[8] Further details on the process and requirements of setting import tolerances are set out in annex 1.

When is an import tolerance not necessary?

The EU applies a default MRL of 0.01 mg/kg for any active substance/commodity combination for which an alternative MRL is not specifically established. Where a specific MRL value is not set, the default MRL applies whether or not an active substance is used on the crop concerned. The default value also applies to those active substances and to specific crop uses that are not directly authorised in the EU. It is therefore not necessary to seek and obtain an import tolerance on imported food/feed which is not expected to contain residues exceeding 0.01 mg/kg.

The withdrawal of EU MRLs

The European Commission interprets Article 17 of Regulation 396/2005 as an obligation to withdraw MRLs of active substances that have lost an authorisation in all Member States. This is typically the case for active substances that lose their community approval and, subsequently, lose all authorisations in the Member States. In these cases, the Commission will replace existing MRLs and Import Tolerances by the default 0.01 mg/kg MRL (or an alternative default value that may be set for some active substances[9]). This is unless it receives and successfully processes an application for import tolerances that are necessary to support continued trade. Where a withdrawal of MRLs or import tolerances is proposed following an EFSA evaluation, the European Commission is required to notify the WTO, providing an opportunity for third countries to comment[10].

Which information is necessary to apply for and set import tolerances?

The data requirements to set import tolerances are the same as for setting MRLs supporting uses in the EU. In meeting these requirements, there is however a key difference - in that residue data are generated outside the EU and reflect the commercial use of the active substance in exporting countries. In addition, EFSA also requires proof that the active substance has been approved and MRLs have been set in exporting countries, although this is not explicitly required in Regulation 396/2005.

Regulation 1107/2009: Criteria and process for approving active substances

EU decisions on the non-approval of active substances

Within the framework of Regulation 1107/2009 on the approval of plant protection products, there is a requirement for the regular review of active substance approvals. While many active substances were initially approved under the previous legislation (Directive 91/414), numerous changes have now been introduced into the criteria for active substance approval. In particular, it should be highlighted that 'hazard-based' criteria have now been introduced in addition to the risk based criteria that were already in place.

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[9] Recital22of Regulation 396/2005 states that:

> *"Where uses of pesticides are not authorised at Community level, MRLs should be set at an appropriately low level to protect the consumer from the intake of unauthorised or excessive levels of pesticides residues. In order to facilitate control of residues of pesticides, a default value is to be set for pesticide residues present in products or groups of products […]. It is appropriate to set the default value at 0,01 mg/kg and to provide for the possibility of setting it at a different level for active substances covered by Annex V, taking into account the routine analytical methods available and/or consumer protection".*

[10] References to WTO SPS notifications: https://www.wto.org/english/tratop_e/sps_e/sps_e.htm#notifications

What are the hazard based criteria for active substance evaluations

Hazard-based criteria are intrinsic properties of the active substance that, in principle, make them unsuitable for approval in the EU. It is important to note that classification decisions are taken without any consideration of the actual exposure risk. There are three main groups of hazard based criteria that have been introduced into the legislation:

- **C-M-R**: Substances classified as Category 1 (1-A and 1-B) under the Globally Harmonised System of Classification and Labelling of chemicals (GHS) for ***C***arcinogenicity, ***M***utagenicity, or ***R***eprotoxicity.
- **Endocrine disruptors**: Substances considered to have endocrine properties that may cause adverse effects in humans or populations of non-target organisms. The detailed EU criteria are currently under discussion in the EU and a decision on a Commission proposed set of criteria is pending.
- **POPs**: Substances considered to be Persistent Organic Pollutants (POPs), or with properties that trigger related EU criteria (as PBT -***P***ersistent,***B***ioaccumulative,***T***oxic; or vPvB – ***v***ery***P***ersistent,***v***ery***B***ioaccumulative)

While the POPs provisions are considered as environmental criteria, the provisions for both CMR and endocrine disruption are considered as criteria relevant for human health. The introduction of these criteria in the approval legislation has raised questions about the potential impact on the future setting of Maximum Residue levels and Import Tolerances for substances that are impacted by these criteria.

Impact of the review and re-approval process for substances

As part of Regulation 1107/2009, the approval of an active substance is granted for a fixed period – varying between 7-15 years depending on the properties of the active substance. This therefore requires a regular re-evaluation process for active substances. With approximately 450 active substances currently approved for plant protection use in the EU, over 100 of those substances are currently going through the review process (where registration dossiers having been submitted and the evaluation and decision making process is on-going)[11].

The addition of the hazard based criteria to the EU legislation is expected to impact many currently approved active substances, as they are evaluated as part of the review programme. Together with changes in the risk assessment process being managed by the European Food Safety Authority (EFSA), further active substances will face non-approval and a rapid phase-out from the European market.

Looking in particular at the hazard based cut-off criteria, a number of the active substances have been identified as potentially trigger these criteria. For example, there are a number of substances that currently have 'CMR' classifications in Category 1A/1B, and as part of the on-going review, additional substances are likely to be classified within the EU framework.

In addition, the hazard based criteria for substances identified as endocrine disruptors will potentially lead to the non-approval of active substances. The final EU criteria for endocrine disruption are still under discussion and the final impact is difficult to project as they will depend on the wording of the final agreed criteria and the way they will be applied. The European Commission have carried out their own impact assessment which suggests that around 30 substances would be impacted by the criteria that are currently under discussion[12]. However, given the uncertainty with

[11] For further details of the EU review programme, please see the European Commission website: http://ec.europa.eu/food/plant/pesticides/approval_active_substances/approval_renewal_en

[12] ` The European Commission impact assessment is available at:

the final definition and the modalities of application, industry is concerned that the impact could be much higher.[13]

Finally, the approval of active substances may be denied or lost for reasons that are related to human health concerns identified during the risk assessment process but are not related to the hazard-based criteria.

Can Import Tolerances be set for active substances that are not or no longer approved in the EU because failing human health hazard-based criteria?

As noted in the above section, the question of whether import tolerances can be set for active substances whose approval has been denied or revoked may therefore concern large numbers of active substances. That question is relevant to all situations where reasons for non-approval are somehow related to human health. It is not limited to the application of regulatory criteria for endocrine disruptor or other human health hazard-based rejection criteria. The question, in principle, does not concern situations where the non-approval decision is not related to human health (e.g. where other concerns are identified relative to other issues such as environmental safety, insufficient efficacy or where there is no applicant for re-approval).

What does Regulation 1107/2009 say?

As stated above, Regulation 1107/2009 introduced several hazard-based rejection criteria ('cut-offs') that are related to human health and these are specified in Annex II of the Regulation. For substances that trigger some of these criteria (category 1 carcinogen or reprotoxicant; endocrine disruptor), an active substance may still be approved where it can be shown that "*…exposure of humans to that active substance [...] is negligible…*" and *"…where residues of the active substance […] do not exceed the default value…"*[14].

It should be stressed that this wording on '*negligible exposure'* is only included in the Regulation on the placing of plant protection products on the market. It explicitly applies to the approval of active substances, not the setting of its MRLs or import tolerances.

What does Regulation 396/2005 say?

Import tolerances are applied for and set according to Regulation 396/2005. The Regulation defines an import tolerance as an MRL set to meet importation needs where '*the use of the active substance in a plant protection product on a given product is not authorised in the Community for reasons other than public health reasons for the specific product and specific use*'.

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https://ec.europa.eu/health/endocrine_disruptors/impact_assessment_en

[13] While there is an overlap between the two policy discussions on import tolerance setting and endocrine disruptors, it should be highlighted that these are two separate issues that will require very different solutions to minimise the potential impact on international trade. Any hazard based EU restrictions on the setting of import tolerances would be expected to have a much greater impact on WTO trading partners, their growers and traders.

[14] See Annex II points 3.6.3; 3.6.4 & 3.6.5. which states that cut-off substances shall not be approved *"…unless the exposure of humans to that active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with point (b) of Article 18(1) of Regulation (EC) No 396/2005."*

As import tolerances regulate concentrations of residues in food and possibly feed items the term '*Public health reasons*' applies to consumer safety concerns. It is therefore concluded that, according to this provision, import tolerances can always be set - unless consumer safety would be compromised by the residue levels in imported commodities.

EU legislation: The disconnect between risk and hazard in the EU legislation

While Regulation 1107/2009 introduces hazard based cut-off criteria and in parallel makes reference to default residue levels for substances that trigger these criteria, it should be highlighted that Regulation 396/2005 maintains an assessment process that is based on risk assessment. It is well established that acceptable risk can be demonstrated for (active) substances with properties representing hazard-based cut-offs in Regulation 1107/2009.

There is clearly a disconnect between the two pieces of legislation, with the hazard based concepts in Regulation 1107/2009 being incompatible with the risk based provisions of Regulation 396/2005. However:

- **In the setting of import tolerances for international trade, it should be highlighted that it is only the provisions of the Residues Regulation that apply**.
- Regulation 1107/2009 is not relevant for the setting of import tolerances, and the provisions in that Regulation (including the specific cut-off criteria provisions) should not prevent the legal decision making process to set import tolerances in the EU.

The SPS agreement - What are the requirements to ensure WTO compliance?

The European Union as a member of the WTO is a party to the WTO Sanitary and Phytosanitary (SPS) Agreement[15]. The SPS agreement explicitly requires that any SPS measure (such as the setting of an import tolerance) is '*based on an assessment […] of the **risks** to human […] health, taking into account **risk assessment techniques** developed by the relevant international organizations*[16]'. The SPS agreement therefore makes specific references to risk assessment – but there is no such reference to hazard-based criteria as reasons sufficient to take SPS measures. It is therefore concluded that applying a default import tolerance for the sole reason that an active substance meets one or more of the human health hazard criteria would be incompatible with the EU's obligations under the WTO rules.

Denying the setting of import tolerances (above the default level) can only be justified where a risk for European consumers has been identified during the evaluation process, irrespective of whether the active substance meets a hazard-based rejection criterion. A violation of the agreement by the introduction of arbitrary chosen criteria by one WTO member creates a very dangerous precedent for the future of the SPS agreement and opens the door for other members to apply their own criteria.

The WTO requires that decisions are based on the assessment of risk and it is imperative that the EU continues to comply with the WTO SPS principles when deciding on the setting of Import Tolerance to support international trade.

[15] Further information and references to the SPS agreement are provided in Annexes 2 & 3 of this document

[16] See Article 5.2 of the Article SPS (quoted in full in Annex 3)

Industry's position

A combined reading and interpretation of the provisions of Regulations 1107/2009 and 396/2005 and of the SPS agreement leads to the conclusion that the European Commission can and must set import tolerances when all of the following conditions are met:

- They are necessary to meet international trade needs
- They are applied for under Regulation 396/2005 and supported by the appropriate information
- It is established under Regulation 396/2005 that they are safe for EU consumers

Denying import tolerances, (i.e. setting them at a default value) for the sole reason that the active substance meets hazard-based rejection criteria under Regulation 1107/2009, violates the provisions of the SPS agreement and introduces arbitrary non-tariff barriers to trade.

Conclusion

- ***Regulation 1107/2009 introduces hazard based cut-off criteria as part of the process of approval and re-approval of active substances.***

- ***While questions have been raised about the potential impact on the setting of import tolerances for substances that will no longer be approved in Europe, it is concluded that any hazard based restrictions on the setting of import tolerances would be contrary to the EU's own legislation on the setting of maximum residue levels.***

- ***In the setting of import tolerances for international trade, it is only the provisions of the Regulation 396/2005 (the Residues Regulation) that apply. Regulation 1107/2009 is not relevant for the setting of import tolerances, and the provisions in that Regulation (including the specific cut-off criteria provisions) should not prevent the legal decision making process in setting import tolerances in the EU.***

- ***Hazard based restrictions on setting import tolerances would also be contrary to principles set out in the WTO SPS agreement and would have a substantial impact on international trade.***

- ***<u>The WTO requires that decisions are based on the assessment of risk and it is imperative that the EU continues to comply with the WTO SPS principles when deciding on the setting of Import Tolerance to support international trade.</u>***

- ***A violation of the agreement by the EU could encourage other WTO members to use their own criteria and presents a significant threat to the future use of the SPS agreement itself.***

ANNEX 1 - Regulation 396/2005 and the setting of import tolerances

Note: This section aims to provide some general additional information on the EU process for setting import tolerances.

When do you need an import tolerance?

Import tolerances are required when EU MRLs have not been set for the use of an active substance in a particular crop. As is the case in most global jurisdictions, when a full MRL is in place at the EU level, this will also be applied to third country trade and a separate IT is not necessary.

Article 3.2 of Regulation 396/2005 sets out the two cases where import tolerances are required to meet the needs of international trade[17]:

- the use of the active substance in a plant protection product on a given product is not authorised in the Community. This could be the case when the active substance is not approved in the EU; or where the substance is approved but the specific crop use is not approved
- a different residue level is appropriate for the specific product and specific use;

Where a particular active substance (AS) is not approved in the EU, there are two situations that are particularly relevant when considering the setting of import tolerances:

- **AS that has never been approved in Europe**: This may in particular be the case for new substances that are developed for markets that are not relevant in Europe, as the products are used on crops or to control specific pests that are not prevalent in the EU.
- **AS previously approved in Europe:** With a regular review of active substances in the European Union, many substances have been removed from the market in the past 20 years. While many substances have been removed for economic reasons (e.g. the small market size make it unviable to support an expensive re-authorisation process), in other situations, active substances have been 'non-approved' as the safety of the substance could not be demonstrated during the risk assessment process carried out experts in EU Member States and in EFSA *(more information on the impact of the EU active substance review is given below)*. Looking into the future, active substances will be removed from the European market when they trigger hazard based criteria put in place in the EU. The potential impact on the setting of import tolerances is discussed later in this paper.

What data will need to be provided to support an import tolerance

The European Commission and Member States provide detailed information on the data and submission requirements for import tolerance applications[18]. To be able to set new import tolerances for specific uses that are not authorised in the EU, the assessment would focus on the evaluation of data for the specific use, in particular looking at the residue data relevant for the GAP (Good Agricultural Practice) of that specific use. The evaluation will also look to ensure that the additional uses are within an acceptable 'risk basket' for that active substance.

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[17] The relevant text is set out in the definitions of Regulation 396/2005; Article 3.2.(g):

(g) 'import tolerance' means an MRL set for imported products to meet the needs of international trade where:

- *the use of the active substance in a plant protection product on a given product is not authorised in the Community for reasons other than public health reasons for the specific product and specific use; or*
- *a different level is appropriate because the existing Community MRL was set for reasons other than public health reasons for the specific product and specific use;*

[18] See EU Guidance document on the MRL setting procedure; SANTE/2015/10595 Rev. 4 (http://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_mrl_guidelines_mrl-setting-proc.pdf). Further information on the actual process of application is also available from Member State authorities. For example, the UK's Chemical Safety Directorate website: http://www.hse.gov.uk/pesticides/topics/pesticide-approvals/pesticides-registration/applicant-guide/maximum-residue-levels.htm

In addition, the submission and evaluation of active substance data may also be required. While this will be decided on a case-by-case basis, it will depend on the authorisation status of the active substance:

- **Active substance is approved in Europe**: In such cases, the relevant health end-points for the active substance have already been evaluated at the EU level and additional data on the active substance would in most not be required.
- **Active substance has never been approved in Europe**: In cases where the active substance has never been notified, evaluated or authorised in the EU, a complete dataset on toxicology, methods of analysis and residue behaviour may be required. In cases of uncertainty about the data that is required, it is recommended that the rapporteur MS should be consulted by the notifier.
- **Active substance previously approved in Europe:** As the active substance will have been evaluated in the EU, the dataset available will provide much of the information needed. However, some additional data may be required to update the dataset to be able to set the relevant endpoints for the active substance.

ANNEX 2 – Legal Analysis: Import Tolerance setting and the WTO obligations

1.1 The Commission's refusal to set ITs for products treated with PPPs containing "*cut off substances*" will have a significant impact on international trade. In the absence of an IT, the default value of 0.01 mg/kg[19] applies allowing imports only if pesticide residues remain below this limit of detection. This will in most cases amount to an import ban.

1.2 The WTO Agreement on Sanitary and Phytosanitary Measures (SPS Agreement)[20] confirms that Members, such as the EU, are entitled to adopt measures which they consider necessary for the protection of human health, animal health or the environment[21]. To the extent however that these measures[22] are capable of restricting international trade, they need to comply with certain requirements set out in the SPS Agreement and have to be notified under the SPS notification system[23]. This allows other Members to comment on the SPS measure, and if necessary, escalate the issue and make use of the WTO Dispute Settlement system.

1.3 In particular, Article 2.2 states that WTO Members are required to "*ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence…]*"[24].

1.4 Additionally, Article 5 of the SPS Agreement requires Members to "*ensure that their sanitary or phytosanitary measures are based on an assessment […] of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations*". In particular, Members should aim to minimise negative effects on trade and ensure that the least trade-restrictive measure is chosen (proportionality principle).

1.5 An SPS measure should be based on "*sufficient scientific evidence*" in the form of a risk assessment. The latter is described as an "*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*"[25].

Conclusion: A preliminary analysis of the WTO regime on SPS measures, and in particular the need for such measures to be science-based and proportionate, seems to suggest that a purely hazard-based measure – such as the principal refusal to set ITs for cut-off substances – would raise serious concerns under the SPS Agreement.

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[19] A default value of 0.01 mg/kg is set unless a specific default value is set after evaluation of relevant data.

[20] http://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm.

[21] Article 2(1) SPS Agreement: "*Members have the right to take sanitary and phytosanitary measures necessary for the protection of human, animal or plant life or health, provided that such measures are not inconsistent with the provisions of this Agreement*".

[22] SPS measures caught by the SPS Agreement are defined in Annex A, point 1, of the SPS Agreement. These include measures applied "*to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs*". It is further specified that SPS measures "*include all relevant laws, decrees, regulations, requirements and procedures including, inter alia, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labelling requirements directly related to food safety*".

[23] Article 7 SPS Agreement.

[24] Article 2(2) SPS Agreement.

[25] Annex A, point 4, SPS Agreement.

Annex 3 – WTO SPS Agreement (Key reference articles)

Article 2 - Basic Rights and Obligations

1. Members have the right to take sanitary and phytosanitary measures necessary for the protection of human, animal or plant life or health, provided that such measures are not inconsistent with the provisions of this Agreement.
2. *Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence*, except as provided for in paragraph 7 of Article 5.
3. Members shall ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members. Sanitary and phytosanitary measures shall not be applied in a manner which would constitute a disguised restriction on international trade.
4. Sanitary or phytosanitary measures which conform to the relevant provisions of this Agreement shall be presumed to be in accordance with the obligations of the Members under the provisions of GATT 1994 which relate to the use of sanitary or phytosanitary measures, in particular the provisions of Article XX(b).

Article 5 - Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection

1. *Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations.*
2. In the assessment of risks, Members shall take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest- or disease-free areas; relevant ecological and environmental conditions; and quarantine or other treatment.
3. In assessing the risk to animal or plant life or health and determining the measure to be applied for achieving the appropriate level of sanitary or phytosanitary protection from such risk, Members shall take into account as relevant economic factors: the potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or disease; the costs of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risks.
4. Members should, when determining the appropriate level of sanitary or phytosanitary protection, take into account the objective of minimizing negative trade effects.
5. 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. Members shall cooperate in the Committee, in accordance with paragraphs 1, 2 and 3 of Article 12, to develop guidelines to further the practical implementation of this provision. In developing the guidelines, the Committee shall take into account all relevant factors, including the exceptional character of human health risks to which people voluntarily expose themselves.
6. Without prejudice to paragraph 2 of Article 3, when establishing or maintaining sanitary or phytosanitary measures to achieve the appropriate level of sanitary or phytosanitary protection, Members shall ensure that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility.
7. In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.
8. When a Member has reason to believe that a specific sanitary or phytosanitary measure introduced or maintained by another Member is constraining, or has the potential to constrain, its exports and the measure is not based on the relevant international standards, guidelines or recommendations, or such standards, guidelines or recommendations do not exist, an explanation of the reasons for such sanitary or phytosanitary measure may be requested and shall be provided by the Member maintaining the measure.