Module 2: Risk Assessment

Next

The objectives of the module are:

- Introduce the SPS Agreement's obligations regarding risk assessment (Article 5, paragraphs 1 to 3). You will learn how the SPS Agreement defines risk assessments in different situations (pest/disease risk vs. food/feed safety risk) and what Members need to consider in their risk assessments.
- Illustrate the topic through interpretations by WTO dispute settlement panels and the Appellate Body, and other practical examples.
- Explore relevant SPS Committee discussions.

Codex

OIE

IPPC

A key obligation of the SPS Agreement is that measures be based on scientific principles and not maintained without sufficient scientific evidence (Article 2.2). One 'avenue' to comply with this requirement is by adhering to relevant international standards – those of Codex, IPPC and OIE – in domestic rule-making.

However, Members do not always base their measures on internationally-agreed standards for different reasons. First, the "Three Sisters" have not elaborated international standards for every aspect of food safety, animal and plant health. Second, Members may – and indeed, have the right to – adopt SPS measures that achieve a higher level of health protection than that reflected in the relevant international standards, if they present scientific evidence in accordance with the relevant provisions of Article 5 of the SPS Agreement.

Such scientific evidence must take the form of a risk assessment, which is addressed in Article 5, paragraphs 1-3 of the SPS Agreement, and will be the subject of this Module.

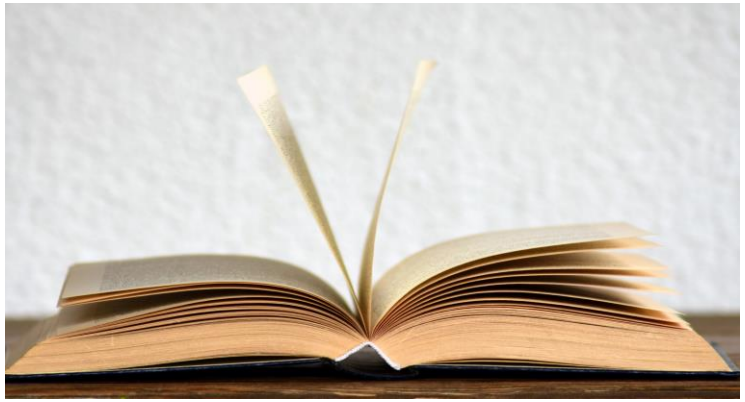
Paras 1 to 3 of Art. 5 discipline the assessment of risk and determination of the measure to be applied for achieving the appropriate level of sanitary or phytosanitary protection.

The questions we look at when thinking about risk assessment include: “is there a risk assessment consistent with the SPS Agreement?”, and “is the SPS measure based on it?”

You will probably recognise a similarity to the wording used regarding the concept of harmonization, included in Article 3, whether there is a relevant international standard, and whether the measure is based on it.

Article 5.1

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.

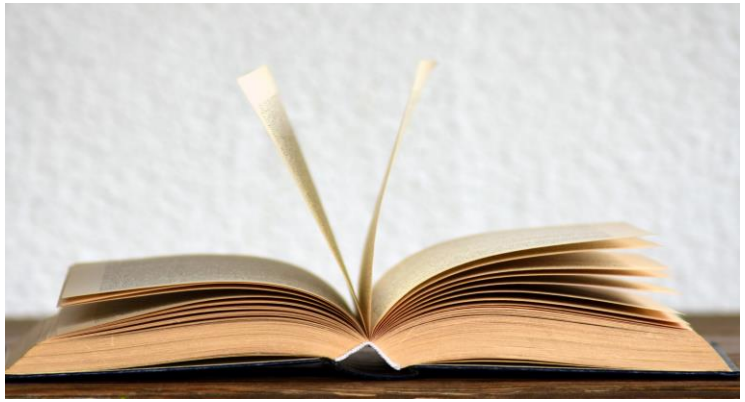


Article 5.2

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.

Article 5.3

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.



Two types of risk assessment

The SPS Agreement foresees two types of risk assessments:

1. Ones evaluating the potential for adverse effects arising from additives, contaminants and other hazardous substances in food or feed, on the one hand.

2. Ones evaluating the likelihood of the entry, establishment or spread of pests/diseases and the associated biological and economic consequences, on the other.

It is important to determine which type of risk assessment is applicable in a particular situation, as they differ.

First, you can see that a pest/disease risk analysis involves an evaluation of the "associated biological and economic consequences" from the entry, establishment or spread of pests or diseases. Notably, reference to considering any such economic consequences is absent from the definition of a food safety-related risk analysis. As some would say, "one cannot put a price tag on human health".

Second, a pest/disease risk analysis involves an evaluation of the likelihood of the risk materialising, while an assessment of food-borne must evaluate the "potential" for adverse effects occurring – something which has been understood to imply a less demanding test than that used in a pest/disease context.

Third, a pest/disease risk assessment must evaluate likelihood "according to the measures which might be applied", which may require also an evaluation of other alternative measures, in addition to those already in place.

Annex A.4

Risk assessment — 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 measures which might be applied, and of the associated potential biological and economic consequences;

or 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.

For more details see Van den Bossche: The Law and Policy of the World Trade Organization, 2017. See also the Appellate Body reports in Australia – Salmon, para. 123, EC – Hormones, para. 184, and US/Canada – Continued Suspension, para. 569

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Assessment of risks from pests and diseases

Example: *Australia – Salmon* (1998)

An assessment of pest or disease-risk involves an analysis of the likelihood of a pest or disease entering, establishing, and spreading; and of the associated potential biological and economic consequences.

In the dispute *Australia – Salmon* (1998), the measure at issue was Australia's ban on the importation of fresh, chilled or frozen salmon, allegedly to protect the domestic salmon population from a number of diseases. Canada, the complainant, claimed that salmon imported for human consumption was unlikely to lead to the introduction of any such diseases.

The Appellate Body reiterated that an assessment of risks arising from pests and diseases must:

- Identify the pests or diseases whose entry, establishment or spread, the Member wants to prevent within its territory, as well as the potential biological and economic consequences associated with the entry, establishment or spread of these pests or diseases;
- Evaluate the likelihood of the entry, establishment or spread of these pests or diseases, as well as the associated potential biological and economic consequences; and
- Evaluate the likelihood of entry, establishment or spread of these diseases according to the SPS measures which might be applied.

For more practical examples and explanations of the relevant concepts, please consult the materials of the SPS Committee's Workshop on Risk Analysis (October 2014)

Assessment of food-borne risks

Example: *EC – Hormones* (1998)

In the dispute *EC – Hormones* (1998) the United States and Canada questioned the ban imposed by the European Communities on imports of beef from hormone-treated cattle, for food safety reasons.

In this case, the Appellate Body applied a two-step test for the assessment of food-borne risk:

- An identification of the adverse effects on human (or animal, as the case may be) health arising from the presence of additives, contaminants, toxins, etc.; and
- If such adverse effects exists, evaluation of the potential occurrence of these effects.

The Appellate Body recognised that there must be an "identifiable risk" and that this risk need not be quantified but can also be expressed qualitatively.

To guide Members in the assessment of risk, Article 5.1 urges them to take into account the techniques developed by relevant international organizations. These, as you remember, are the "Three Sisters" Codex, IPPC and OIE.

The Three Sisters have developed guidelines, in their respective fields of action, on risk analysis, which is a three-step process that includes risk assessment, risk management and risk communication.

Codex

IPPC

OIE

The Three Sisters have indeed developed guidelines, in their respective fields, on risk analysis: three-step process that includes risk assessment, risk management and risk communication.

Note that Article 5.1 requires Members to "take into account" techniques developed by Codex, IPPC and OIE. It does not require Members to conform to such techniques in their risk assessments, nor, considering that Members' conditions differ, that compliance with such techniques alone shows that the measure is consistent with Article 5. Rather, in the words of the Appellate Body in dispute *Japan – Apples* (2003), reference to such techniques "is useful … should a dispute arise in relation to the risk assessment".

The "Three Sisters" presented on their approaches to risk analysis at the SPS Committee's Workshop on Risk Analysis (2014).
Please consult the websites of the Three Sisters for up-to-date information.

Risk assessment – factors to be taken into account

SPS Agreement Article 5 paragraphs 2 and 3

While the SPS Agreement does not lay down a particular risk assessment methodology, its Article 5.2 lists certain factors that Members must take into account. These include consideration of:

- 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 and other treatment.

As the Appellate Body has put it, Article 5.2 shows that a risk assessed under Article 5.1 "is not only risk ascertainable in a science laboratory operating under strictly controlled conditions, but also risk in human societies as they actually exist, in other words, the actual potential for adverse effects on human health in the real world where people live and work and die" (Appellate Body in *EC – Hormones*).

The Appellate Body further clarified (and confirmed in dispute *US/Canada – Continued Suspension*) that the list in Article 5.2 is not a closed one, and that risks related to detection and control of compliance with certain requirements (such as the failure to observe good veterinary practice) may also be taken into account as part of the risk assessment.

Finally, Article 5.3 requires Members to take into account the following relevant economic factors in assessing risks to animal or plant life or health:

- The potential damage in terms of loss of production or sales;
- The costs of control or eradication; and
- The relative cost-effectiveness of alternative approaches.

There is no requirement to take economic factors into account in risk assessments concerning human life or health.

"Base measure on a risk assessment"

The Appellate Body in *EC – Hormones* (1998) interpreted the obligation to base an SPS measure on a risk assessment as a substantive requirement that refers to a certain objective or rational relationship between the SPS measure and the risk assessment. Article 5.1 read together with Article 2.2 requires the results of the risk assessment to "sufficiently warrant", or "reasonably support" the relevant SPS measure.

The Article 5.1 requirement that SPS measures be based on a risk assessment is qualified by the sentence "as appropriate to the circumstances", which provides for a certain degree of flexibility regarding the way in which the risk assessment has to be carried out. As stated by the Panel in *Australia – Salmon* (1998), a risk assessment may vary according to the source and subject of the risk, product involved, origin and destination, including country-specific situations. This country/situation-specific flexibility does not, however, remove the obligation to base an SPS measure on a risk assessment.

- Objective or rational relationship
- Sufficiently warrant, reasonably support…
- Qualification "as appropriate to the circumstances" – certain degree of flexibility

Before we continue with the module, let's recall some general observations that the Appellate Body has made regarding the requirement to base SPS measures on a risk assessment:

1. Members are not required to base a measure on a quantitative risk assessment, but may instead rely on a qualitative assessment of potential risks. In other words, the risk assessment does not have to arrive at a numerically expressed or quantitative result. (*EC - Hormones*)

2. The risks addressed should, nevertheless, be ascertainable – actual risks that may materialize. Theoretical uncertainty is not the kind of risk which is envisaged in Article 5.1. (*EC – Hormones*)

3. The risks covered should be specific to the situation/risk at hand. It is not sufficient for a risk assessment to identify a general risk of harm, or address the overall risk related to the combination of all diseases of concern, for example. (*Japan – Apples*)

Risk assessment

- Do not need to be quantitative
- Ascertainable, actual risks
- Specific
- Analysis of risks in the "real world", beyond laboratory conditions
- No requirement to carry out own assessment
- Can also reflect divergent or minority views from a qualified source
- Dynamic element – need to revisit if science evolves

4 As already mentioned, risk assessments may go beyond controlled laboratory conditions and consider the probability of risks materializing – in the words of the Appellate Body – in the "real world where people live and work and die". (*EC – Hormones*)

5 Members do not have to carry out their own risk assessments – they may rely on assessments made by other Members, or international organizations. This point is of specific relevance to developing countries facing resource constraints. (*EC – Hormones*)

6 Risk assessments do not need to reflect the mainstream scientific opinion, but may also be based on divergent or minority views from a qualified and respected source. (*EC – Hormones*)

7 Article 5.1 should be read together with Article 2.2, which requires that SPS measures not be maintained without sufficient scientific evidence. Accordingly, the evolution of relevant scientific evidence since the completion of a risk assessment may also be considered as "an indication that the risk assessment should be reviewed or a new assessment undertaken" (*EC – Hormones*, *Japan – Apples* (Panel), *EC – Biotech* (Panel)).

Practical example

What should Country A's regulatory bodies keep in mind in terms of the risk assessment obligations contained in the SPS Agreement?

Country A, a WTO Member, through one of its governmental agencies, decides to address the safety of shell eggs and egg products, and specifically the possible contamination by *Salmonella enteritidis*, in order to protect human health against food-borne risks.

If Country A decides to conduct its own risk assessment, it has to identify the adverse effects that the presence of *Salmonella enteritidis* in eggs causes to human health. Once the adverse effects are established, it should evaluate the potential occurrence of these effects, in order to establish the risk.

Remember that, in the assessment of risks, it should take various factors into account, among others available scientific evidence; relevant processes and production methods; and relevant inspection, sampling and testing methods (Article 5.2).

A group of experts in Country A sets the objectives of this risk assessment, namely:

1. Establish the unmitigated risk of food-borne salmonellosis (e.g. the risk of taking no measure);
2. Identify and consider the efficacy of some risk management interventions for addressing the problems associated with salmonella in eggs and egg products; and
3. Identify data needs, and prioritize future data collection efforts.

Its final risk assessment model consists of six modules:

1. Introduction and Methodology;
2. Hazard Identification;
3. Hazard Characterization of *Salmonella enteritidis*;
4. Exposure Assessment of *Salmonella enteritidis* in Eggs and Egg Products;
5. Risk Characterization of *Salmonella enteritidis* in Eggs and Egg Products; and
6. Evaluation of Risk Mitigation measures for *Salmonella enteritidis*.

Its risk assessment determines that 5% of its shell eggs are usually infected with *Salmonella enteritidis*. The data also showed that of about 250,000 cases of illnesses registered every year, about 25,000 are cases of human illness likely related to *Salmonella enteritidis* ritidis in eggs.

Finally, the risk assessment identified various alternative measures which could be imposed, such as: requiring that table eggs come only from poultry flocks tested to be free of *Salmonella enteritidis*, or that eggs from flocks of *Salmonella enteritidis* be subject to precooking, or educating the public about the need to thoroughly cook any foods containing eggs, etc., and the extent to which each of those measures might reduce the risk of human illness.

True or False

Developing country A raises concerns about a possible entry of a pest that may considerably damage its crops. However, the country does not have the technical or institutional means to carry out a risk assessment within the meaning of Article 5.1 of the SPS Agreement. Neighbouring country B has scientifically evaluated the risks of the entry of the pest to the same crops. Country A can rely, as is relevant in its circumstances, on the findings of this risks assessment as the SPS Agreement does not establish an obligation on countries to carry out their own risk assessments.

- ◯ True
- ◯ False

Solution

TRUE

Countries do not have to carry out their own risk assessments, they can also rely on risk assessments carried out for instance by other Members, regional bodies, or international organizations. The risk assessments do have to be "appropriate to the circumstances", so the two countries would have to have similar phytosanitary conditions, for example. Risk assessments are indeed resource-intensive, so this is of importance particularly to developing countries which may have limited means to scientifically evaluate SPS risks.

True or False

The negotiators of the SPS Agreement decided to make a distinction in the requirements placed on assessments of pest or disease risks, on the one hand, and food-borne risks, on the other. This distinction is reflected in Annex A.4 of the SPS Agreement, which stipulates that economic consequences are to be considered only in risk assessments that concern food safety issues.

- ○ True
- ○ False

Solution

FALSE

There is indeed a distinction between the requirements set on pest or disease-related risk assessments, on the one hand, and on food- or feed-related risk assessments, on the other. However, economic consequences are explicitly mentioned in the context of an analysis of pest or disease risks. There are also other differences between the two types of risk assessments – these differences have been taken to indicate, together, less "strict" requirements on an assessment of food-borne risks.

True or False

A risk assessment valid under Article 5 does not need to represent the 'mainstream', or majority, scientific opinion – it may also reflect the views of scientists taking a divergent view.

- ○ True
- ○ False

Solution

TRUE

Article 5.1 does not require a risk assessment to embody only the view of a majority of the relevant scientific community. In some cases, the very existence of divergent views presented by qualified scientists who have investigated the particular issue at hand may indicate a state of scientific uncertainty.

The Appellate Body found that:
"In most cases, responsible and representative governments tend to base their legislative and administrative measures on 'mainstream' scientific opinion. In other cases, equally responsible and representative governments may act in good faith on the basis of what, at a given time, may be a divergent opinion coming from qualified and respected sources. By itself, this does not necessarily signal the absence of a reasonable relationship between the SPS measure and the risk assessment, especially where the risk involved is life-threatening in character and is perceived to constitute a clear and imminent threat to public health and safety." (EC – Hormones, paragraph 194).

Takeaway Messages

1. Members may comply with the obligation to base SPS measures on science by basing them on a risk assessment that fulfils the requirements of Article 5.1 – 5.3 of the SPS Agreement.

2. Article 5 does not prescribe a specific risk assessment methodology, but directs Members to risk assessment techniques developed by Codex, IPPC and OIE. It also lists other factors – such as available scientific evidence and relevant ecological and environmental conditions – that should be considered.

3. The Appellate Body has made, among others, the following general comments regarding the obligation to base SPS measures on a risk assessment:

   - Risk assessments should be specific (i.e. demonstrate more than a general risk of harm).
   - They may also be qualitative (not arrive at a numerical result).
   - Members do not have to carry out their own risk assessments – they can also resort to ones completed by other Members, or regional organizations, for example.
   - Risk assessments can also reflect minority or divergent views, as long as these are from a qualified and respected source.


Well done you have finished module 2!
You can know take the post-test and
then start module 3.

Next