# Topic 3–Deviations from International Standards

# Objective

- To identify practical, feasible and readily implementable solutions and good practices that could improve the quality, clarity, consistency and usefulness of information provided under Item 8 (Deviations from international standards) of the WTO SPS notification format.

# Challenges identified

The following challenges were identified through discussions in the TWG:

- Free-text descriptions of deviations make it difficult to categorize/monitor deviations;
- Free-text descriptions of deviations may result in inconsistencies across Members; and
- NNAs and NEPs need information from the regulators themselves to provide accurate descriptions of deviations from international standards.

- Difficulties in identifying relevant international standards and justifying deviations;
- The complexity of, and frequent updates to, Codex, WOAH and IPPC standards;
- Weak inter-agency coordination and fragmented information;

# Possible approaches

- Presenting possible examples of deviation, followed by an explanation;
- Providing examples of free-text description in the notification format;
- Seeking better domestic coordination and a better understanding of international standards; and
- Utilizing modern digital tools.

# Proposed solutions

**Develop practical guidance for drafting information on the existence of international standards, guidelines or recommendations in the notification format.**

The quality of information provided in Item 8 can be improved through revisions to the Practical Manual for SPS National Notification Authorities and SPS National Enquiry Points, without changing the notification format. Accessible and user-friendly guidance could:

a. Clarify that, under Article 3.3 of the SPS Agreement, a deviation should be explained on the basis of (i) scientific justification or (ii) the level of protection a Member determines to be appropriate in accordance with Article 5;

b. Present illustrative and voluntary categories of the nature/basis of deviation, which do not constitute additional notification requirements;

**Include a one-page-checklist/decision flow to identify the relevant Codex, WOAH or IPPC standard, the nature of the difference, and available supporting scientific information**

## A. Identification of the International Standard

| Check | Question | Action |
|---|---|---|
| ☐ 1 | Is the measure related to food safety, animal health or plant health? | Identify the relevant SPS area. |
| ☐ 2 | Is there a relevant international standard? | Search the applicable Codex, WOAH or IPPC source. |
| ☐ 3 | Which standard-setting body is relevant? | Record Codex / WOAH / IPPC. |
| ☐ 4 | What is the relevant standard/reference? | Record the standard/guideline/reference number and title. |
| ☐ 5 | Is the standard current version? | Check the latest available version/amendment. |
| ☐ 6 | Does the international standard cover the same product, hazard and measure? | Verify the scope and applicability. |
| ☐ 7 | Is there no relevant international standard? | Indicate that no relevant international standard exists, where applicable. |

## B. Identification of Deviation

| Check | Question | Action |
|---|---|---|
| ☐ 1 | Is the proposed measure different from the relevant international standard? | Compare the proposed requirement with the international standard. |
| ☐ 2 | What is the nature of the difference? | Identify the difference in level, scope, method, requirement or application, as applicable. |
| ☐ 3 | Is the measure more stringent/different in another way? | Briefly describe the difference without making assumptions about its justification. |

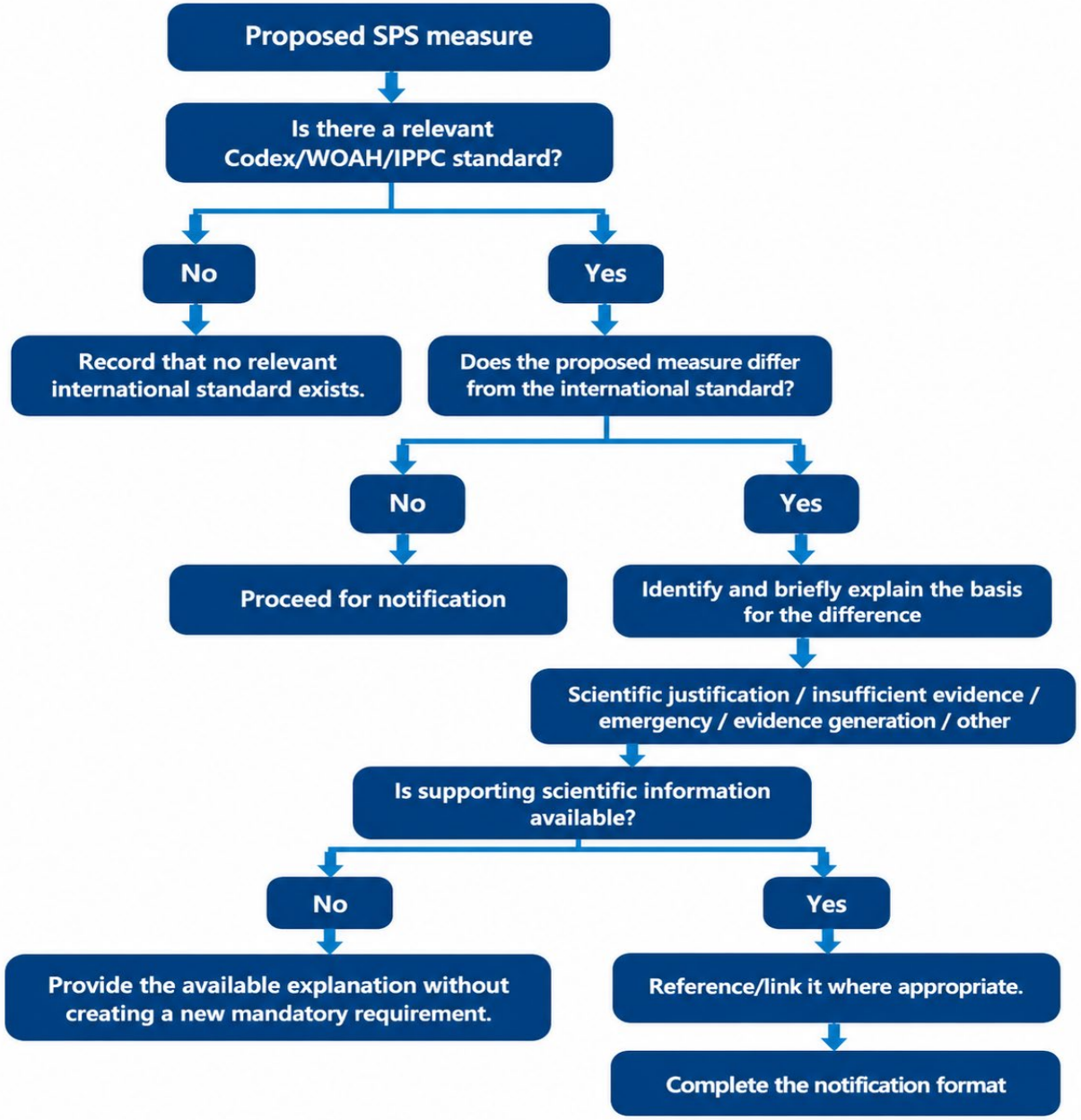
## C. Explanation of the Basis for Deviation

| Check | Possible category | Illustrative question |
|---|---|---|
| ☐ 1 | Scientific justification | Is the measure based on a risk assessment or other scientific analysis? |
| ☐ 2 | Insufficient scientific evidence | Is additional evidence needed to determine an appropriate level/measure? |
| ☐ 5 | Other basis | Is there another relevant basis that should be briefly explained? |

# D. Supporting Scientific Information

| Check | Question | Action |
|---|---|---|
| ☐ 1 | Is supporting scientific information available? | Identify relevant risk assessment, study, monitoring data or other evidence. |
| ☐ 2 | Is the information publicly accessible? | Where appropriate, provide a reference or link. |
| ☐ 3 | Is the reference sufficient to locate the evidence? | Provide title, organisation/author, year or other relevant identifying information. |
| ☐ 4 | Is the evidence directly relevant to the notified measure? | Confirm that the cited evidence supports the explanation provided. |

# Decision flow



# Develop examples and training materials

- The Practical Manual could include additional examples of how to complete Item 8, such as using examples of model (or actual) notifications indicating which parts describe "why" and "how" the measure deviates from the relevant international standard. The WTO could also develop a collection of good-practice notification examples, demonstrating appropriate use of references, links and supporting documents.

# Example

**Is there a relevant international standard? If so, identify the standard:**

**[X] Codex Alimentarius Commission** ***(e.g. title or serial number of Codex standard or related text)*****:** Pesticide Residues in Food and feed – Pesticide Index – *** – Pesticide X

**[ ] World Organization for Animal Health (OIE)** ***(e.g. Terrestrial or Aquatic Animal Health Code, chapter number)*****:**

**[ ] International Plant Protection Convention** ***(e.g. ISPM number)*****: [ ] None**

**Does this proposed regulation conform to the relevant international standard? [ ] Yes [X] No**

If no, describe, whenever possible, how and why it deviates from the international standard: Since the Codex Alimentarius Commission has set the MRLs for Pesticide X in these commodities, [competent authority of Y Country ] evaluated whether the determined MRLs are safe or, otherwise, whether any changes in the MRLs are necessary or appropriate. According to their assessment, aggregate exposure will exceed the limit of ADI if [competent authority] accepts the Codex MRLs for these commodities, making [competent authority] disregard the new MRLs. [①]. Instead, we have established the MRLs for the commodities using the maximum dietary burden of the respective animals from [a data source], the highest value among major countries. [②]. As a result, [competent authority] is able to make sure that an adequate margin of exposure exists for ADI and ARfD. Thus [competent authority] concludes that there is a reasonable certainty that no harm will be caused to our general population, or specifically to infants and children, from aggregate exposure to the residues of Pesticide X.

**① "why" it deviates from the international standard**
**② "how" it deviates from the international standard**

- Training programs for NNAs and NEPs could focus on international standards that are frequently cited in Item 8, including through case sharing and the SPS Mentoring system. Regional webinars and workshops on finding the relevant international standard and drafting clear justification could be organized.

- An e-learning module using actual notification examples could be developed. Where possible, recordings or training programs could be made available on the WTO website.

# Explore optional ePing drafting support

- Utilizing modern digital tools could assist NNAs in preparing Item 8, without changing the notification format. Functions such as help icons or pop-up prompts could display illustrative examples and highlight the elements to be described, such as the basis for deviation under Article 3.3 and the nature of the deviation.
- The prompts could also provide links to the relevant section of the Practical Manual and to illustrative examples. They would be for reference only and would not involve the selection of options or constitute additional notification requirements.
- To integrate the ePing platform with the databases of the three sister organizations - Codex, IPPC and WOAH - to facilitate the identification and retrieval of relevant international standards based on HS codes and product classifications.

# Explore setting an inter institutional-coordination working group

- Determining whether a notified SPS measure deviates from an international standard often requires specialized expertise. Where the NNA is not the competent authority responsible for developing the SPS measure, a domestic coordination process could be established whereby the competent authority provides the NNA with the necessary information to complete Item 8 when preparing a notification. Such process could include, for example, a national committee for discussing SPS issues for which the frequency is defined, taking into account Members' differing national circumstances and regulatory systems. The NNA and NEP should not independently create or interpret scientific justification. They should communicate the authoritative information provided by the competent authority.


Thank You