Import tolerances

- Import tolerances can be requested to increase an MRL in order to allow for imports in the EU, for instance when there is no authorisation in the EU but an authorisation exists in a third country and the MRL is safe for consumers. It is also possible for active substances falling under the hazard-based cut-off criteria of the EU legislation.

- Such import tolerances will undergo systematically a risk assessment, as foreseen by the EU legislation on maximum residue levels, and in line with the WTO requirements.

- The granting of the import tolerances for such substances will then be considered on the basis of the risk assessment, on a case-by-case basis, taking into account all relevant factors.

BACKGROUND

Import tolerances

The EU legislation on pesticides include hazard-based cut-off criteria, which prohibits any substance having mutagenic, carcinogenic, reprotoxic and endocrine disrupting properties to be used in plant protection products.

The EU legislation also set maximum residue levels (MRLs) of pesticide that can be tolerated in food and feed, after a science–based risk assessment showing that such levels are safe. Import tolerances (ITs) can be requested by third countries applicants to increase a given MRL and allow imports in the EU. IT requests are granted only if the risk assessment show there are no health concern.

The question to grant or not ITs for active substances falling under the cut-off criteria was debated with Member States and led to concerns among third countries, including Canada, which recalled that under the SPS agreement, the identification of a risk, and not a hazard only, was necessary to justify any measure.
It is now agreed that IT requests for such substances, will undergo the procedures laid down in the EU legislation, including a risk assessment. The granting of the IT will then be considered in line with risk analysis principles on a case-by-case basis taking into account all relevant factors.

**SPEAKING POINTS/KEY MESSAGES**

**Endocrine disruptors**

- The criteria to identify endocrine disruptors in the context of the plant protection products legislation will start applying as of 10 November 2018, including to ongoing applications.

- The guidance document of EFSA and ECHA on the implementation of the adopted criteria was published on 7 June 2018 and is to be used by risk assessors in their evaluation of substances.

- The act including the technical amendment to the clause on negligible exposure for plant protection products was discussed at the July 2018 SC PAFF meeting.

- At this point in time there is only limited support for this act.

- The Commission will reflect on the next steps.

**BACKGROUND**

**Endocrine disruptors**

The scientific criteria to identify endocrine disruptors for biocides and pesticides are now in place. The new criteria are applicable from 7 June 2018 for biocides (Delegated Regulation (EU) 2017/2100) and will be applicable for pesticides from 10 of November 2018 (Regulation (EU) 2018/605). The criteria also apply to on-going processes for the approval or renewal of approval of active substances.

The criteria for pesticides and biocides are in practice the same and thus ensure a harmonised approach. They are based on the WHO definition of endocrine disruptors. They require consideration of all relevant scientific information (including scientific publications) and apply a weight of evidence approach.
The Guidance document for the implementation of the adopted criteria has been finalised by the European Food Safety Authority (EFSA) and the European Chemicals Agency (ECHA) and is published on the websites of EFSA and ECHA. A public consultation on the draft guidance was carried out in December 2017 and January 2018.

As regards the act including the technical amendment to the clause on negligible exposure for plant protection products, the Commission resumed discussions with EU Member States at the meeting of the Standing Committee meeting on Plants, Animals, Food and Feed on 19/20 July.

The outcome of an indicative 'tour de table' was that 11 Member States would be in favour, 5 Member States against, 12 Member States would abstain or had currently 'no position', with some indicating they would have voted in favour in 2016 but currently had no mandate. The Commission concluded that at this point in time there is only very limited support, and invited in particular those Member States which have not expressed their position to inform about their positions by 3 September.