EU OFFENSIVE ISSUES

Pesticides

As a follow-up of the EWG discussions on SPS in October 2018, the EU and the US agreed to hold an expert meeting to discuss the EU procedure on pesticide registration and renewal including the EU process for product reviews, required content of dossiers, EFSA policies on uncertainty and data gaps and identifying a mechanism for the EU to establish risk-based import tolerances for pesticides. The meeting is planned for 28-29 January 2019 in Brussels.

EU POSITION

Criteria to identify endocrine disruptors under the pesticides legislation have been adopted and became applicable as of 10 November 2018. An active substance falling under these criteria cannot be approved, unless it falls under one of the limited derogation possibilities. **Import tolerances for such substances can be requested by third countries and will systematically undergo risk assessment** (as foreseen by the EU legislation on maximum residue levels and in line with WTO rules). The granting of the import tolerances for such substances will be considered on a case-by-case basis based on the outcome of the risk assessment taking into account all relevant factors.

DEFENSIVES

- The EU has been very transparent towards its trade partners during the process of developing criteria to identify endocrine disruptors (WTO notification, information session on EDs in the margins of the SPS Committee in October 2016, information note to the WTO in December 2017)
- In the current political climate that is highly sensitised to pesticide-related issues it would be counterproductive to discuss this issue in bilateral negotiations with the US, as this will be interpreted as another attempt to undermine the high level of protection for health and environment in the EU.

BACKGROUND

The EU Pesticides Legislation (Regulation (EC) No 1107/2009) contains approval criteria for active substances that are partly based on the intrinsic properties of the substances (i.e. their hazards). Substances classified as carcinogenic, mutagenic, toxic to reproduction (Categories 1A or 1B), or substances that have endocrine disrupting properties are the so-called “cut-off criteria” substances.

The US considers this as a ‘hazard-based approach’ and to be incompatible with the rules of the WTO SPS Agreement, which requires measures to be taken on the basis of a risk assessment (on the basis of both the hazard and the exposure).
However, the intrinsic properties (hazards) specified in the cut-off criteria mentioned above are so severe that the EU legislators considered that any exposure of such substances leads to unacceptable risk.

Import tolerance requests for cut-off criteria substances will undergo the procedures laid down in the EU legislation, including a risk assessment. The granting of the import tolerance will then be considered in line with risk analysis principles on a case-by-case basis taking into account all relevant factors.
Import tolerances

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- Import tolerances can be requested to increase a maximum residue level (MRL) in order to facilitate imports into the EU, when there is an authorisation for a plant protection product in a third country but no authorisation in the EU (or the crop is not grown in the EU), and the MRL is safe for consumers.
- The setting of import tolerances is also possible for active substances falling under the hazard-based cut-off criteria of the EU legislation.
- Such import tolerance applications will systematically undergo a risk assessment, as provided for in the EU legislation on MRLs, and in line with 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.

Only if pressed:

- Following non-approval of a substance falling under the cut-off criteria, the approach of DG SANTE is that all existing MRLs will be proposed for deletion. Import tolerances should be requested well before the effective deletion of the MRLs, given the time necessary for their evaluation.

Issue/Background

The EU legislation on pesticide approvals/authorisations includes hazard-based cut-off criteria, which prohibit any substance having mutagenic, carcinogenic, reprotoxic or endocrine-disrupting properties to be used in plant protection products in the EU.

The EU legislation also sets maximum residue levels (MRLs) of pesticides that can be tolerated in food and feed, after a science-based risk assessment has shown that such levels are safe. Import tolerances can be requested by applicants to increase a given MRL based on the agricultural practices in a third country, to facilitate imports into the EU. Import tolerances are granted only if the risk assessment shows that there are no health concerns for European consumers.

The question to grant or not tolerances for substances falling under the cut-off criteria led to concerns among third countries and stakeholders, including ECPA, who recalled that the WTO-SPS agreement requires the identification of a risk, and not a hazard only, to justify a rejection of an import tolerance.

It is agreed that import tolerance requests for such substances will undergo the procedures laid down in the MRL legislation, including a risk assessment. The setting of import tolerances will then be considered on the basis of the risk assessment on a case-by-case basis, taking into account all relevant factors.

The approach currently favoured by DG SANTE includes the deletion of all existing MRLs following the non-approval of substances falling under the cut-off criteria, as a preceding step before new MRLs based on import tolerance requests can be set. However, recent discussions in the Standing Committee
showed that there is little support among Member States for this approach. More Member States favoured that MRLs are kept when they were set based on earlier import tolerance requests or on recent Codex MRLs. A note is in preparation to seek clarification on a possible modification of the line to take. It would be premature to communicate the matter to ECPA at this point in time.

**GFL proposal – PPP amendments**

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See briefing on GFL proposal – general part.

**Issues/ Background**

The proposal puts forward an amendment of the General Food Law (GFL) and specific changes to eight pieces of sectorial legislation among which the Plant Protection Products (PPP) Regulation. For the latter, the amendments proposed concern the making publically available of the full dossier including the study reports on toxicity and ecotoxicity tests. Only very limited parts that can be treated as confidential will not be made public. Confidentiality will be assessed by the European Food Safety Authority (EFSA).

The proposal aims to give citizens greater access to information submitted to EFSA on approvals in the agri-food chain, provides the possibility for additional studies to be requested by the Commission and will involve Member States' scientists more closely in approval procedures.

In line with these objectives, some provisions of the PPP Regulation have to be amended accordingly (i.e. until now, only the summary dossier is made public, while in the future the full study reports are to be made public).

The changes in the Articles on confidentiality in the PPP Regulation are only made to avoid duplication with the amended GFL provisions; there is no substantial difference among the previous framework and the new framework as amended by the proposal. The elements of a certain dossier that could be treated as confidential are not changed.

In addition, since the PPP Regulation is not *stricto sensu* Union food law, which is the scope of the GFL, it is proposed to make an explicit reference to the provision of the PPP Regulation to expand the application of the GFL provisions on transparency and confidentiality as well as personal data to the PPP Regulation.

As to future actions, the Commission will need to amend the Implementing Regulation 844/2012 on the renewal procedure for active substances in order to align the provisions set out in that Regulation with the amendments that will be introduced by the GFL proposal.
Future challenges / REFIT evaluation

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- Recall that the EU legislation on pesticides is designed to ensure a high level of protection of both human and animal health and the environment but also to improve agricultural production.

- Explain that the Commission is aware of the concerns of industry about the loss of active substances that currently form part of the toolbox of solutions, but stress that the strict criteria for approval of active substances in the EU pesticides legislation must be respected. Recall that the number of active substances available in the EU has actually increased since 2011.

- To mitigate the loss of older (and problematic) active substances, industry should work to develop new active substances that both meet the needs of farmers and meet the strict human health and environmental requirements. Industry needs to invest in innovative application methods, which would allow for more targeted use – reducing risks.

- The REFIT Evaluation is looking at these issues and a report to the Council and the Parliament will be presented during the first half of 2019.

Background

There is a perception that the number of active substances approved in the EU has declined since 2011 when the Plant Protection Products (PPP) Regulation started to apply. This is wrong as the number has actually increased (427 in 2011, 486 in 2018). However, in 2018, several active substances that have been used for many years on a broad range of crops and have been important tools for farmers have been withdrawn from the market due to safety concerns (e.g. iprodione, diquat, thiram, neonicotinoid substances). This has led to difficulties in certain sectors as finding replacements for these substances (which were highly efficacious and cheap) is challenging.

The Commission is close to finalising its REFIT Evaluation of the PPP and maximum residue levels (MRL) Regulations. The roadmap was published in November 2016. An external contractor has carried out a study to collect evidence and the final report was published on 18 October 2018. ECPA has been fully involved in all consultation steps.

The external study found that overall the two pieces of legislation are effective to achieve the objectives to ensure a high level of protection of health and environment and facilitate the functioning of the internal market. There is a clear EU added value of both Regulations. However, there is margin for improvement as regards efficiency, in particular by improving adherence to the legal timelines for the various processes set out in the legislation, such as for granting product authorisations. Also, Member States are not making sufficient use of the possibility to mutually recognise authorisations. The increasing number of emergency authorisations granted by Member States is a result of these problems.

Both Regulations also foresee that the Commission reports to the Council and the Parliament on their implementation. The report on the implementation will be presented to the Council and to the
European Parliament in the first half of 2019, accompanied by a Staff Working Document on the results of the REFIT evaluation. It is still too early to make assumptions or propose future actions.