EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Director-General

Brussels,
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NOTE TO MR ARŪNAS VINČIŪNAS,
HEAD OF CABINET OF COMMISSIONER ANDRIUKAITIS

Subject: **Handling of requests for import tolerances for active substances falling under the cut-off criteria laid down in Regulation (EC) No 1107/2009**

This note is to inform you of the latest developments in the discussion on the impact of the human health related hazard-based approval criteria ("the cut-off criteria") laid down in Regulation (EC) No 1107/2009 on the handling of requests for import tolerances (ITs) for pesticide residues (maximum residue levels (MRLs) of pesticides for imported products), and to seek your approval on the way forward.

Following the last exchange on the subject[1], the Commission presented to the Standing Committee on Plants, Animals, Food and Feed (PAFF) – section Pesticide Residues on 26/27 September 2018 the revised approach for the handling of ITs for active substances falling under the cut-off criteria. As a reminder, this approach consists of:

1. The deletion of existing ITs for active substances falling under the cut-off criteria on the basis of Article 17 of Regulation (EC) No 396/2005 ("the MRL Regulation"), which allows for deletion of MRLs without seeking the opinion of EFSA for active substances present in plant protection products whose authorisations have been withdrawn. Member States have to withdraw authorisations following non-renewal or expiry of approval for active substances, regardless of their falling under the cut-off criteria or not.

2. For requests to set new ITs, risk assessment in line with the MRL Regulation, and risk management decisions taking into account the outcome of the risk assessment and other legitimate factors as well as the precautionary principle.

Based on the somewhat surprising Member States' comments received, including those at and after the PAFF meeting of 26/27 September 2018, only four Member States (BE, FR, IT, SI) clearly signalled their support for this approach. FR would be prepared to go even further, by rejecting import tolerance requests already at Member State level without proceeding with a risk assessment. On the other hand, several Member States supported an exclusively risk-based

[1] Your e-mail of 06/03/2018, Ares(2018)1242084, and further clarification in the e-mail of the Deputy Head of Cabinet of 12/03/2018, Ares(2018)1371711, both in answer to Note Ares(2018)834793, 13/02/2019; please also see earlier exchange on the subject: your e-mail of 24/03/2015, Ares(2015)1360917 in answer to Note Ares(2015)1012143, 06/03/2015.

approach to the deletion of old ITs and setting of new ITs (AT, DE, LT, NL, PL, PT, UK), with some of them additionally voicing concerns regarding the legal soundness of the deletion of all MRLs, including ITs and Codex MRLs (CXLs), on the basis of Article 17. The position of one Member State (ES) initially supportive of the stricter approach presented by DG SANTE is uncertain following more recent comments. According to those that raised concerns, existing ITs and CXLs should be maintained, as the risk assessment preceding their setting concluded there was no risk for human health. The UK also emphasised the lack of coherence for the handling of the ITs, as existing ones would be deleted on the basis of a hazard-based approach, while new ones would be evaluated following a risk-based approach.

Furthermore, in the numerous interventions on this topic in the WTO-SPS Committee and bilateral correspondence and meetings, practically all third countries have strongly criticised the deletion of all MRLs for cut-off substances as not being in line with the WTO-SPS Agreement[2], which requires a risk-based approach. This issue remains also a particularly difficult point in the EU-US relations.

We therefore seek your advice on the way forward, considering the two following options for MRL action following non-renewal or expiry of approval for active substances falling under the cut-off criteria. Please note that the options differ only in the first step (deletion of existing MRLs including ITs), while the second step (requests for new ITs) is identical:

Option 1: Continuing with the approach:

First step: after non-renewal or expiry of approval of the active substance, and the end of all grace periods for plant protection products containing it, all MRLs are deleted, i.e. MRLs that were set based on authorisations in EU Member States, MRLs that were set based on specific IT requests, and MRLs that were set based on CXLs.

Second step: if subsequently requests for new import tolerances are submitted, a Member State and thereafter EFSA carry out a full risk assessment. The Commission proposes a risk management decision on the import tolerance request that takes into account the outcome of the risk assessment, other legitimate factors, and the precautionary principle. It is expected, in the light of the hazards at stake for which safe exposure thresholds can only seldom be determined, that the outcome of the risk assessment would often lead to the rejection of import tolerance requests. However, for some requests the outcome might confirm the absence of risk so that the ITs can be granted.

Pros: this strict approach would correspond to a large extent to the wishes of the European Parliament (as voiced among others in the report from the PEST Committee) and the EU farming community, to treat imported commodities equally strict as those produced in the EU.

Cons: this approach carries the risk of insufficient support from Member States (e.g. when voting in the PAFF Committee on draft Regulations lowering all MRLs including ITs and CXLs for cut-off substances). Moreover, third countries will continue to forcefully oppose this approach, with a strong risk of formal WTO disputes. This may also impact the EU-US dialogue.

Option 2: Changing the approach:

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[2] The WTO Agreement on the Application of Sanitary and Phytosanitary Measures.

First step: substances falling under the cut-off criteria would be treated in the same way as any other non-approved substance, i.e. after non-renewal or expiry of approval of the active substance, and the end of all grace periods for plant protection products containing it, only those MRLs that were set based on authorisations in EU Member States will be proposed for deletion, whereas those MRLs that were set based on specific IT requests or MRLs that were set based on CXLs would be maintained – except for cases where EFSA identified potential risks during the preceding assessment[3], and provided that the assessment took account of the hazard that led to the conclusion that the substance meets the cut-off criteria. Moreover, following specific requests from interested parties and firm commitments to generate necessary data and submit import tolerance requests, MRLs that were set based on EU uses would be maintained for a limited period until a decision on that import tolerance request is taken. Furthermore, CXLs can replace MRLs that were set based on EU uses. Both measures (temporary maintenance of MRLs following request, and setting of MRLs based on CXLs) likewise require that EFSA did not identify potential risks during the preceding assessment, and provided that the assessment took account of the hazard that led to the conclusion that the substance meets the cut-off criteria. Both measures are in line with current practice and help addressing the concerns of trading partners, as for their exports to the EU they often rely on MRLs that were set based on EU uses and that would otherwise not be maintained after non-renewal or expiry of approval of active substances (falling under the cut-off criteria or not).

Second step: if subsequently requests for new import tolerances are submitted, a Member State and thereafter EFSA carry out a full risk assessment. The Commission proposes a risk management decision on the import tolerance request that takes into account the outcome of the risk assessment, other legitimate factors, and the precautionary principle. It is expected, in the light of the hazards at stake for which safe exposure thresholds can only seldom be determined, that the outcome of the risk assessment would often lead to the rejection of import tolerance requests. However, for some requests the outcome might confirm the absence of risk so that the ITs can be granted.

Pros: this approach enjoys more backing than option 1, based on views expressed by Member States so far, although it does also not guarantee sufficient support from Member States, when the Commission presents proposals to amend MRLs in the PAFF. Moreover, it addresses the concerns of third countries who insist that ITs should be established on the basis of a risk assessment, thus reducing the likelihood of formal WTO disputes.

Cons: this approach would correspond less to the wishes of the European Parliament (as voiced among others in the report from the PEST Committee) and the EU farming community, to treat imported commodities equally strict as those produced in the EU.

Overall, it can be expected that many decisions on MRLs for substances falling under the cut-off criteria would in actual fact be identical for both options, due to an unfavourable or inconclusive risk assessment during the preceding evaluation.

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[3] For the recent case of linuron, the non-approval was based on the classification as toxic for reproduction category 1B and endocrine disrupting properties, but also other concerns identified and relevant for protection of consumers, including that the consumer risk assessment could not be finalised due to a number of serious deficiencies in the data package. Subsequently, all MRLs were deleted.

Likewise, for the recent case of iprodione, the non-approval was based on the proposed (by EFSA) classification as carcinogen category 1B and endocrine disrupting properties, but also other concerns identified and relevant for protection of consumers, including concerns on the genotoxic potential of a metabolite. Subsequently, all MRLs were deleted.

Conclusion: in the light of the rather negative feedback from a significant number of Member States on option 1 at the PAFF meeting in September 2018, and the need to obtain a qualified majority on draft acts amending MRLs, as well as taking into account the positions of practically all third countries, DG SANTE considers that the second option is the preferred one.

It is not clear how the other DGs who were involved in the discussion and agreed to the current approach would position themselves with regard to the second option. It can be expected that DG TRADE will strongly support it, whereas it is less clear for the other DGs, especially for DG AGRI who might raise the issue of discrimination between EU and third country farmers. However, this would equally apply for substances not falling under the cut-off criteria, where DG AGRI has never opposed the approach so far.

Our position, when agreed internally in the Commission, should first be shared with Member States. If sufficient support is obtained in the PAFF Committee, the position should be carefully communicated to third countries and stakeholders, not least in view of earlier communication on this topic[4]. To this end, an information note could be distributed to trading partners through the WTO-SPS Committee, and to stakeholders through the Advisory Group on the Food Chain and Animal and Plant Health. Moreover, the procedural guidance published on the SANTE website should be updated accordingly.

I would appreciate to receive your agreement on the proposed approach in order to discuss it with the other services.

Anne Bucher

Cc: Ms N. Chaze, Cab Andriukaitis Cad (ve ju-ca-15.cad),
Mr M. Hudson,
Ms S. Jülicher,
(DG SANTE)

[4] Note of DG SANTE to other DGs, Ares(2017)3458667, 10/07/2017; letter of Commissioner Andriukaitis to ambassadors of third countries, Ares(2018)3670816, 10/07/2018; Note of DG SANTE to other DGs, Ares(2018)3984036, 27/07/2018