SANTE E4-Plant protection products

State of play on phytosanitary products:

a. Information on the legislation regarding neonicotinoids.

The Commission Implementing Regulations amending the conditions of approval of the active substances imidacloprid, clothianidin and thiamethoxam were published in the Official Journal of the European Union on 30 May 2018. These Regulations completely ban the outdoor uses of the three substances and only the use in permanent greenhouses remains possible. After withdrawal of support by the applicants for the renewal of approval for clothianidin and thiamethoxam, the approval of these substances expired on 31 January 2019 and 30 April 2019 respectively.

Background information, including links to the 2018 Implementing Regulations, can be found on the following website:
https://ec.europa.eu/food/plant/pesticides/approval_active_substances/approval_renewal/neonicotinoids_en

Article 53 of Regulation (EU) No 1107/2009 on pesticides provides for the possibility that Member States can grant authorisations for uses of substances not approved at EU level (the so-called "emergency authorisations"), provided that strict conditions are fulfilled, in particular that there is a danger to plant health that cannot be controlled by any other reasonable means (including non-chemical measures).

A few Member States repeatedly granted such emergency authorisations for the restricted neonicotinoids since the first restriction in 2013. The Commission therefore mandated the European Food Safety Authority (EFSA) in 2017 to assess whether the emergency authorisations granted repeatedly by some Member States for the uses restricted in 2013 were justified. EFSA found that for about one third of them, this was not the case. Based on that assessment, and in accordance with Article 53(3) of Regulation (EC) No 1107/2009, the Commission is in the process of preparing Decisions for 2 Member States (Romania and Lithuania) preventing them to repeat the granting of certain emergency authorisations for neonicotinoids.

Overall, the Commission intends to increase oversight about emergency authorisations granted by the Member States, given the high numbers and the severe criticism about them from the European Parliament, from NGOs and also from the farming sector in some Member States who feels disadvantaged compared to those in others. Member States also have the possibility to raise concerns about the emergency authorisations granted by others in the Standing Committee on Plants, Animals, Food and Feed – so far, this has never been done.

b. Information on the Bee Guidance Document

The Bee Guidance Document published by the European Food Safety Authority (EFSA) in 2013[1] establishes a methodology to assess the acute risk for additional exposure routes other than only spray applications (which is the case in the currently applicable guidance) and methods to assess the chronic risk. Furthermore it includes new requirements for field testing. Additionally it proposes a methodology to assess the risk for bumble bees and solitary bees besides honey bees.

Since its adoption in 2013, the EFSA Bee Guidance Document has been criticised by many Member States during the discussions for its endorsement at the Standing Committee of Plants, Animals, Food and Feed.

Over the last six years, endorsement for the Guidance has failed, because many Member States do not wish to implement the Guidance before a further review, in particular for the parts related to the assessment methodology for chronic risks.

The Commission has therefore recently proposed to make a step forward by implementing the parts on the Guidance Document where there is an agreement among Member States (such as the methodology related to acute risk to honeybees). In agreement with Member States, the Commission also mandated EFSA to review the Guidance Document with priority, taking into account that it is likely that new scientific evidence has become available since 2013. EFSA has also been asked to closely involve all relevant stakeholders into this process. EFSA therefore already published on their website[2] a call for nominating stakeholder experts to the ad hoc EFSA Bee Guidance Stakeholder Consultation Group. Deadline for nominations is 21 May 2019.

The Commission is not lowering the current level of protection with regard to chronic risks to bees. On the contrary, existing data requirements on chronic risk to bees already included in Commission Regulation (EU) No 283/2013 are maintained and relevant data should be available in the application dossiers and allow assessing the potential long-term risks to bees. Furthermore, through the implementation of the parts of the EFSA Guidance related to acute risks, including assessment of different exposure routes and new requirements for higher tier testing, that part of the risk assessment will be strengthened, while there will be no change for the chronic assessment until after the review mandated to EFSA.

[1] http://www.efsa.europa.eu/en/efsajournal/pub/3295
[2] http://www.efsa.europa.eu/en/press/news/190508