EUROPEAN COMMISSION

HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

EXTRACT OF THE SUMMARY REPORT OF THE STANDING COMMITTEE ON PLANTS, ANIMALS, FOOD AND FEED HELD IN BRUSSELS ON 12 DECEMBER 2017 – 13 DECEMBER 2017

Section *Phytopharmaceuticals - Plant Protection Products - Legislation*

The Complete Summary Report is available at the CIRCABC Link:

https://circabc.europa.eu/w/browse/dc726a32-02ef-4a22-8050-d228c60601a3

A.17 Endocrine Disruptors – state of play

The Commission informed that the public consultation[1] on the draft guidance to identify endocrine disruptors (ED), developed by EFSA and ECHA with support of JRC, is open until 31 January 2018. The final guidance will be applicable to both biocides and pesticides, provided that the criteria that will in the end be adopted for pesticides will not substantially differ from those adopted for biocides.

The Commission will organise a workshop on 1-2 February 2018 to test the applicability of the draft guidance on the basis of case studies using active substances currently under assessment in the context of the pesticides and biocides Regulations. Member States were invited to notify by 20 December 2017 on which active substance(s) they will submit case studies (a letter had been sent on 4 December, also uploaded on CIRCABC). The full case studies shall be submitted to the agencies and the Commission by 29 January 2018. Member States were invited to consider in particular substances currently under assessment and to cover human health and the environment. Two experts per Member State (one for biocides, one for pesticides) plus the speakers presenting selected case studies will be reimbursed. Stakeholders will also be invited.

The Commission will soon make available in CIRCABC for the Member States Competent Authorities for pesticides and biocides about 600 Excel files (one file per substance) containing the data and evaluations used in the screening[2] for the impact assessment that had been prepared to accompany the Commission's proposals for the criteria to identify endocrine disruptors. The data contained in these Excel files may contain confidential information and therefore shall not be distributed publicly. The data can be useful as a basis for evaluating endocrine disrupting properties of individual substances and for preparing case studies in view of the workshop mentioned above. However, the Commission strongly emphasised that the data and conclusions contained in these Excel files were only estimates performed for the

[1] https://echa.europa.eu/-/give-comments-on-the-draft-guidance-for-identifying-endocrine-disruptors
[2] https://ec.europa.eu/health/sites/health/files/endocrine_disruptors/docs/2016_impact_assessment_study_en.pdf

aim of an impact assessment. Therefore, these data and conclusions do not constitute evaluations of substances to be carried out under the respective chemical legislations and shall in no way prejudge future decisions on substances to be taken pursuant to the respective chemical legislations.

B.14 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Annex II to Regulation (EC) 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties.

The Commission explained that the revised draft Regulation is identical to the text voted in July, except for the deletion of the last paragraph with the provision on the growth regulators and the corresponding Recital. The revised draft Regulation thus followed exactly the request of the European Parliament (EP), which had objected on legal grounds to the draft Regulation voted in July by the Committee.

One Member State indicated it had no position so far and expressed concerns about the deletion of the growth regulators provision because the active substances concerned by that provision are important from the perspective of a more sustainable use of pesticides. Another Member State also expressed dissatisfaction about the deletion of the growth regulators provision and therefore could not support the draft Regulation.

One Member State recalled that it had already had misgivings about the earlier removal of the amendment to the derogation possibilities (changes to point 3.6.5 and 3.8.2. of Annex II to Regulation 1107/2009) that had been part of the Commission's first proposal in June 2016. Furthermore, it criticised that the Commission only followed the views of the European Parliament but was not considering in an equal manner the views of the Member States and the Council. In its view, the growth regulator provision was important provision which merely reflected the current arrangement of the plant protection product legislation which accepts and recognises the intended endocrine mode of action of growth regulators. The European Parliament had agreed in 2009 and 2013 to the plant protection product legislation and thus this Member State did not believe that the Parliament's position had been based on an in-depth analysis. The Member State further announced that it would abstain in a vote on the draft Regulation.

Another Member State agreed with the previous one speaking and stressed that the provision on growth regulators was important, but wondered if it could be considered in a separate legal document. It stressed that the adoption of the criteria should be done quickly and indicated it would support the draft presented.

The Commission reminded the Member States of its commitment made in July 2017 to table the 2nd text with the amendment to the derogation possibilities (changes to points 3.6.5 and 3.8.2 of Annex II to Regulation 1107/2009) once the criteria will be adopted. The Commission also explained that, in case of no opinion of the Committee, according to the Comitology procedures the Commission will prepare a draft Council Regulation and submit it to the Council and inform the European Parliament. The Council may then try to amend this draft Regulation within 2 months, and, if a qualified majority would support such a modified version, the European Parliament can object in the 2 subsequent months.

A Member State expressed its support for the draft Regulation, but indicated that the Commission should have asked the Court of Justice to annul the European Parliament objection, also to avoid setting a precedent, because the Commission had not exceeded the mandate given by Article 78 of Regulation (EC) No 1107/2009.

Another Member State indicated it cannot support the draft Regulation as both, the growth regulator provision and the amendment to the derogation possibilities were absent. It wondered whether the Commission had conducted an impact assessment concerning the growth regulators. The Commission indicated that the impact assessment performed in the context of this work only focused on the EATS modalities and that the growth regulators had therefor not been specifically considered. However, about 15 active substances are listed as insect growth regulators under Regulation (EC) No 1185/2009 concerning statistics of pesticides. As regards plant growth regulators the number is significantly higher, but not all substances listed are plant hormones. The Commission indicated also that the potential impact cannot only be measured in terms of number of active substances, because other agronomical factors need to be considered like for instance the need of alternative modes of action of the active substance to avoid resistance.

One Member States indicated that it did not support the draft Regulation. In its view, consistency is needed between the criteria for biocides and pesticides, and the European Parliament did not object to the criteria for biocides, although these contained the growth regulators provision. This was supported by another Member State, which indicated that it would be illogic if the same active substance will be identified as ED for pesticides and not for biocides. The Commission explained that the regulatory consequences for growth regulators in the biocides Regulation as regards their use by general public are the same for substances with endocrine disrupting properties on target organisms and non-target organisms, whereas a clear distinction as regards target and non-target organisms exists in the pesticides Regulation.

One Member State indicated that it does not support the text because the burden of proof needed to fulfil the criteria is too high. This was echoed by a second Member State.

One Member State suggested amending the proposed text. It had considered several possible alternatives and suggested it's preferred proposal, which is to amend the provisions under paragraph (2) sub (2)b of point 3.8.2 as follows: " *the relevance of the study design for the assessment of the adverse effects and its relevance at the (sub)population level, for the taxonomic groups mentioned in (2) (a), and for the assessment of the endocrine mode of action"*. This Member State asked the Commission if it would consider this or any other amendment. The Commission explained that the proposed modification was incoherent as the list of taxonomic groups to which it refers is an open list and thus the amendment has no effect.

One Member State did not support the draft Regulation as it insisted on the need for an amendment to the derogation possibilities in point 3.6.5 and 3.8.2 of Annex II to Regulation 1107/2009.

Another Member State supported the draft Regulation and stressed that a quick decision is needed on this topic.

The Commission put the draft Regulation to a vote. The Committee gave a favourable opinion with qualified majority (18 Member States in favour, representing 65,79 % of the EU population), 3 Member States against (5%) and 7 Member States abstaining (29,21%).

The Commission welcomed this outcome and indicated that the draft Regulation would now be sent to the Council and the European Parliament for scrutiny according to the regulatory procedure with scrutiny. They will have three months to examine it before final adoption by the Commission. The Regulation will enter into force 20 days after its publication in the Official Journal and be applicable six months after this.