EUROPEAN COMMISSION

HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

EXTRACT FROM THE SUMMARY REPORT OF THE STANDING COMMITTEE ON PLANTS, ANIMALS, FOOD AND FEED HELD IN BRUSSELS ON 4 JULY 2017

(Section Phytopharmaceuticals - Plant Protection Products - Legislation)

The Complete Summary Report is available at the CIRCABC Link:
https://circabc.europa.eu/w/browse/64ae079f-5ba2-44e9-95f5-74b8f6e1869a

B.01 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 opened the meeting and stressed that there was no intention to re-open technical discussions since all arguments and positions had been exhaustively discussed already in previous meetings of the Standing Committee on Plants, Animals, Food and Feed (SC PAFF). The Commission reminded Member States (MS) that the text had evolved substantially since June 2016. The text tabled for this meeting had already been tabled on 18 and 30 of May 2017.

The Commission reiterated its commitment to resume discussions on the text on the amendment to point 3.6.5 of Annex II to Regulation (EC) No 1107/2009 once the criteria are adopted, which is also stated in the published summary records of the SC PAFF held on 17-18 May and 30 of May, 2017.

Further and in order to address the request of some MS, the Commission committed to adopt the guidance document for the implementation of the hazard-based criteria, currently under development by EFSA and ECHA, according to Article 77 of Regulation (EC) No 1107/2009 (advisory procedure). This had already been indicated to MS via a note uploaded on CIRCA BC prior to the meeting.

The Commission indicated that it was aware that several delegations intended to make declarations for the minutes of the meeting and stressed the fact that these declarations would be published in annex to the summary report of the meeting. The Commission invited MS to indicate their desire to make such declarations when casting their vote and then send them in writing. The Commission asked whether there were any final comments prior to the vote.

One MS took the floor and thanked the Commission for the efforts made to accommodate its requests. This MS recalled that it had a national strategy on endocrine disruptors and that it was therefore following very closely the issue at EU level and especially the implementation of the criteria. This MS had requested some modifications in the text and some of its concerns had been addressed. Therefore, this MS was now ready to support the text, as tabled.

Another MS said it would support the text and indicated it would make a declaration for the minutes concerning the growth regulators' provision.

The Commission then invited MS to express their positions and to indicate the reasons in case they were voting against the draft Implementing Regulation or abstaining.

- 21 MS representing 72.35% of the population voted in favour of the text. From these : seven MS voting in favour thanked the Commission for its commitment to resume discussions on the text on the amendment to point 3.6.5 of Annex II to Regulation (EC) No 1107/2009 and urged to do so as soon as possible.

- Three MS voted against:
    - One MS because the text on the amendment to point 3.6.5 of Annex II to Regulation (EC) No 1107/2009 was not tabled for a vote at the same time
    - Two MS because they consider that the burden of proof required by the criteria is too high. These MS indicated they would send in writing their declaration, to be included in the minutes.

- Four MS abstained because the text on the amendment to point 3.6.5 of Annex II to Regulation (EC) No 1107/2009 was not tabled for a vote at the same time

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

Declaration by Denmark and Sweden

Denmark and Sweden have voted against the proposal.
We regret that the Commission has not listened to the major concern, voiced by Denmark, Sweden and others, that the criteria proposed requires an unprecedented high level of evidence to identify endocrine disruptors compared to other problematic substances, such as CMR-substances and do not properly reflect today's scientific knowledge on endocrine disruptors. The effect of the high level of evidence required is that the ban will not cover substances for which there are substantial data pointing towards endocrine disrupting properties. This is contrary to the actual wording of the Regulation and the clear intent of the legislators'. In total, the criteria fail to meet the level of protection foreseen by the co-legislators.

Declaration by Germany

The German delegation agrees to the European Commission's draft Regulation but point to the fact that the passage regarding the effects of the substances with intended mode of action in point 3.8.2 is to be understood exclusively for

the purposes of point 3.8.2 as is also mentioned in recital (7) of draft Regulation SANTE-2016-12020-REV 4:

> *„effects ..... shall not be considered for the identification of the substance as having endocrine disrupting properties "for the purposes of this section"."*

In addition to that, the German delegation emphasises that there are very strict limits to the exception for endocrine active substances. Active substances with specific endocrine modes of action on harmful organisms, e.g. moulting inhibitors, show no endocrine mode of action that is of relevance to humans. Additional adverse effects on humans are therefore not to be expected from these active substances as a matter of principle. On the contrary, the selectively acting substances reduce the exposure to far more unspecific insecticides and can be of advantage to human health and the ecosystem.

The German delegation demands, and explicitly insists, that the active substances covered by this exception have to undergo a complete risk assessment and may only be approved if they meet the requirements under Article 4 of Regulation (EC) No 1107/2009.