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HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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SUMMARY REPORT OF THE STANDING COMMITTEE ON PLANTS, ANIMALS, FOOD AND FEED HELD IN BRUSSELS ON 22 JUNE 2016

(Section Phytopharmaceuticals - Plant Protection Products - Legislation)

CIRCABC Link: *https://circabc.europa.eu/w/browse/bafb8685-0673-4508-9bef-ca42db9301a4*

A.01 Communication from the Commission to the European Parliament and the Council on endocrine disruptors and the draft Commission acts setting out scientific criteria for their determination in the context of the EU legislation on plant protection products and biocidal products.

Member States were informed that a Communication was published on 15 June 2016 which is based on the impact assessment report as accompanying document.

A.02 Commission Staff Working Document - Impact Assessment Report Defining criteria for identifying endocrine disruptors in the context of the implementation of plant protection products regulation and biocidal products regulation.

Member States were informed about the impact assessment, which is based on a screening study and additional evidence, analysed via a Multi Criteria Analysis. The Commission informed that the impact assessment does not conclude on any preferred option for the criteria to identify endocrine disruptors, and the decision on which option to choose to draft the criteria to identify endocrine disruptors has been taken on the basis of scientific considerations.

One Member State noted that the Commission refers to a "consensus in the scientific community" but this consensus refers to 20 scientists invited to BfR in April 2016. The Member State asked the Commission why it gave so much importance to this meeting with only a selected group of scientists. The Commission acknowledged it was a reduced group of scientists. However, the main players representing the two scientific views that have been present in the discussions during the last years were equally represented in the meeting. Furthermore, the meeting was organised with the purpose to find consensus on the agreements and disagreements.

One Member State asked the number of active substances falling under Categories II and III for Option 3. There are 84 Plant Protection Products (PPP) in Cat II and 46 in Cat III, as detailed in Annex 5 of the impact assessment report.

One Member State wanted clarification regarding the weighting for the Multi Criteria Analysis-criteria. If 38% of the weight was given to human health and environment in the most conservative scenario, was Option 4 still the best performing option?

The Commission clarified that there were 19 criteria across six areas in the impact assessment. For the most conservative scenario mentioned by the Member State, the attributed total weight for human health and environment was actually higher, but with regard to the sub-criteria related to hormone related diseases and environmental criteria related to endocrine disruptors the weight was 38%. Option 4 stayed the best performing option for this scenario.

C.01 Exchange of views of the Committee on a draft Commission Regulation (EU) …/…of XXX setting out scientific criteria for the determination of endocrine disrupting properties and amending Annex II to Regulation (EC) No 1107/2009.

Member States were informed that with the submission of this draft act the Commission has fulfilled its obligations under Regulation EC (No) 1107/2009. The Commission explained that the draft act for the Biocidal Products (BP) is different because the Commission is mandated to adopt the criteria. However the aim is to have the same criteria under both regulations. Therefore, the vote in the Standing Committee on Plants, Animals, Food and Feed (PAFF) is intended to be taken before adoption of the BP criteria. The Commission encourages delegations to coordinate their position (PPP and BP) at national level in order to achieve harmonised criteria for the Plant Protection Products Regulation (PPPR) and Biocidal Products Regulation (BPR). The intention is to adopt the criteria as soon as possible. The Commission asked for the support of national delegations.

The Commission reminded about the obligation to notify the WTO TBT and SPS committees. The notifications have been done. The corresponding commenting period takes 60 days and will be finished mid-August.

Through the feedback mechanism the public is consulted for 4 weeks, starting 30 June 2016. There is a meeting with more than 90 invited stakeholders planned on 30 June 2016. Comments made by stakeholders will be available on CIRCABC. The Commission will provide feedback from stakeholders meeting and the feedback mechanisms.

Member States were informed that the criteria are based on the WHO definition and are therefore based on the presence of an adverse effect, the mode of action and the causal link between these two. Letters have been sent to the European Chemicals Agency (ECHA) and the European Food Safety Authority (EFSA) to ask them to get ready for the work ahead. The next steps in the process were explained and the Commission informed that in the best case the criteria will be adopted at the end of 2016 or beginning of 2017.

Several Member States thanked the Commission for presenting the criteria.

Numerous Member States voiced concerns over getting too little time to scrutinise the criteria. The Commission is aware that the delegations have not had much time to

reflect on the presented criteria. Member States will examine the criteria carefully before taking position and give comments. The views expressed in this meeting are preliminary and Member States were asked to send written comments by 7 July 2016.

Several Member States raised concern over the wording in the criteria "known" and "presumed". Member States would like the Commission to clarify on what scientific grounds the proposal to identify only known and not also potential/presumed Endocrine Disruptors (ED) as this is not in line with Option 2 in the Roadmap. The Commission explained that the criteria are based on the WHO definition but the wording comes from the Classification, Labelling and Packaging (CLP) legislation and this may cause confusion. The WHO definition reads “alters function” and not “may alter function”, and in light of this the Commission does not believe it reduces the scope.

It is not the intention to reduce the scope of the regulation and the wording "known to cause" is mentioned only in the first part of the criteria (i.e. the three principles of the WHO definition). In the second part of the criteria, i.e. the implementation part of the criteria, a wider scope is evident as it is explained how to implement the criteria; e.g., under consideration of weight of evidence, biological plausibility, etc.

Several Member States wanted the Commission to explain how they should interpret the weight of evidence and why the identification is primarily based on international agreed study protocols. The Commission clarified that the criteria state that all relevant studies and evidence should be considered. However, the PPP data requirements in place, which are based on the international agreed study protocols, need to be acknowledged.

Two Member States were concerned that there is a lack of evidence to identify EDs, especially the Mode of Action (MoA). Other Member States were also concerned that the burden of proof seems too high. The Commission explained that there are studies available to establish the MoA and more studies are under development (in particular OECD validated methods). For adverse effect there are study protocols available. The Commission acknowledges there are gaps for MoA and the links but available tools will increase in the future. The Commission does not agree that the burden of proof is too high. Both in vitro and animal studies are asked for. In the PPPR there are concrete data requirements for ED properties as part of the new data requirements, including corresponding Communications, from 2013. If there is evidence that there is suspected ED this is already used for confirmatory data. The data requirements will also be updated when new tests become available.

One Member State wanted the Commission to include potency in the criteria. Another Member State stated that it is necessary to protect competition and take socio-economic aspects into consideration.

Two Member States expressed a wish that the criteria instead should go beyond the definition of a single class of hazard, which is insufficiently protective. They would prefer "Option 3+A" and favour a definition which also includes presumed or suspected endocrine disruptors, which will allow to anticipate and initiate preventive approaches before all the scientific confirmations are available. The Commission explained that it did not have a mandate to come up with classification as the CLP

(CLP has a different objective) but to identify ED in the context of approvals of active substances (AS) for PPP and BP. In the context of the approval of AS, a "yes or no" answer is needed. The Commission does not have the mandate to propose a prioritisation of active substances in particular under the regulatory system of PPPs and BPs, where there would be no regulatory consequences for categories.

One Member State stressed that not only reproduction and development is an issue on populations but also other mechanisms, e.g., metabolism on migrating birds might have effect on populations.

One EEA country wondered if the effect can be based on in vitro studies or if it must be shown in an intact organism. Several Member States had similar concerns, with regards the need of proven evidence from field studies. The Commission explained that epidemiological evidence of effects in animals in the field is not needed, but that the main body of evidence is expected to come from animal studies. It is clearly stated that tests from animal studies should be relevant for humans - unless there is evidence that the contrary is proved. Regarding in vivo studies, they will almost always be required as part of the standard data requirements but the Commission does not restrict to only in vivo studies. For the MoA in vitro test are available but for adverse effect rather in vivo test are needed.

One Member State wondered if there will be a need to perform additional animal studies as this would not be in line with the aim to reduce animal studies. The Commission clarified that it is not expected that more additional animal studies are required with the presented criteria, however, using categories may trigger additional animal testing. The screening exercise was possible based mainly on the data submitted under the normal data requirements. What is mostly missing is information on the MoA, but this information may be generated via in vitro studies.

Six Member States mentioned the change in the derogations under 3.6.5 from negligible exposure to negligible risk.

Some Member States wondered if the Commission has the mandate to propose this change. The Commission explained that the hazard based approach in the regulation is not changed and that for this there is no mandate. However, Article 78 of the PPPR gives the Commission the right to amend the Annex to take into account current technical and scientific knowledge and that is the reason for proposing an adjustment of the derogations.

Hazard based decision making is the basis in both PPPR and BPR and in both regulations there are derogations. In BPR it is possible to consider negligible risk and socio-economic considerations, while in PPPR there is only negligible exposure. Thus, in terms of impacts there will be differences in PPPR and BPR under the current system and that is why the options A,B, and C were included in the Roadmap.

While the hazard approach is kept the derogation in the PPP is proposed to be adjusted to current scientific knowledge, aligning it with the BP Regulation, which will result in better implementation, harmonised across both regulations. The criteria are based on science because key scientific papers state that ED should be assessed considering risk elements. In detail: there are clear indications from EFSA, Scientific

Committee on Consumer Safety and BfR consensus paper that potency is not part of the identification as ED, but that risk considerations should be taken into account when assessing the substances.

The decision making including the derogations imply that a substance identified as ED will be banned but in some cases derogations may be applicable. In case a substance would be approved under the derogations, it would be approved as a Candidate for Substitution (CfS), implying a shorter approval period and restrictions. Member States will need to perform comparative risk assessments before granting any authorisation.

The derogations cannot be compared with a normal risk assessment. The Commission explained that if only exposure is considered, there is a risk to approve substances that have low exposure but may still pose a risk because of their high hazard. With a risk based approach this could not happen, as both exposure and hazard would be considered.

One Member State asked what approach should apply to the non-threshold substances if the derogations are risk based. The Commission stated that it should be assessed on a case by case basis if an active substance identified as an ED has a threshold or not and this is what the risk assessment is doing. EFSA explained that scientifically it is possible to do a risk assessment for a non-threshold active substance.

One Member State asked if the Commission intends to implement criteria without a transition period. If that would be the case, would that mean that an application already submitted needs to include the new criteria. The Member State would also like to know what will happen to substances that are ED but fall under other legislations, e.g., caffeine and pulses. Is the intention to extend the scope beyond BPR and PPPR and go further and prevent exposure to any route? The Commission answered that the criteria are only for PPP and BP. No transitional periods are foreseen and the intention and political will is to implement the criteria as soon as possible. The Commission is in contact with ECHA and EFSA on how to implement the criteria and has invited both agencies to already take the necessary steps to make sure they are prepared when the criteria are adopted and entered into force. The intention is to have the criteria applied to all substances where no vote has already been taken. This may have implications for the review programs.

One Member State wondered if ECHA will harmonise the classification of an ED substance. As ECHA is not involved in PPP, this would only be possible for BP and REACH.