European Commission

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Mr Hans Muilerman
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Brussels, 23. 09. 2019
ARES(2019)

Dear Mr Muilerman,

Thank you for your letter of 9 August 2019, in which you enquire about the implementation of the new scientific criteria for endocrine disruptors as regards the approval decisions taken by the Commission for active substances used in pesticides. I am pleased to inform you about the progress made in the EU on this important topic for the protection of human health and the environment.

The criteria were adopted after an in-depth discussion with all parties, including stakeholders like PAN. It is my sincere belief that these criteria, which are based on the widely agreed World Health Organisation's definition of an endocrine disruptor, are protective of human health and of the environment. They make best use of available science, stating that all relevant data including literature data should be considered in the assessment and they do not consider potency for hazard identification. As plant protection products dossiers are known to contain more data than other regulatory dossiers, and all available studies are considered in the assessment as requested by the criteria, I am confident that EU regulatory decisions are robust and based on sound scientific evidence.

Further, a guidance document prepared by two European Agencies together with the Joint Research Centre was available when the criteria became applicable (PAN was consulted on this document). This guidance document builds on the OECD framework laying down a tiered approach, and stating that OECD level 2/3 tests should be performed only in the case that level 1

assessment (evaluation of all relevant published literature) is not considered enough to derive a conclusion. This implies that an updated assessment of the available scientific data is necessary as a first step and, as defined in the guidance document, additional testing may be needed only in some cases. Using level 2/3 tests by default for all assessments would clearly not be in line with the OECD framework and would imply unnecessary animal testing, which would be in contradiction with the legal requirement in the Plant Protection Products Regulation to minimise animal testing.

Since 10 November 2018, the new scientific criteria have been applied strictly and without delay to all substances for which the evaluation and decision-making process was on-going, including dossiers submitted long before 10 November 2018. Such an immediate application of modified criteria to ongoing evaluations is not usual practice – the Commission has however chosen this approach in order to speed up the implementation of the new criteria, thus ensuring the best protection of human health and the environment. Regulation (EU) No 844/2012 was therefore amended[1] to make sure that applicants shall be requested to conduct additional studies for already submitted dossiers, where the information available is not sufficient to conclude the assessment on whether the approval criteria for endocrine disruption are met. With such an approach, there was no need to launch additional regulatory measures, as these would have not led to faster regulatory decisions than those triggered by the already planned or on-going regulatory procedures.

Having carefully studied your analysis, I would like to clarify what I perceive as apparent misunderstandings.

Firstly, the new scientific criteria cannot be applied retroactively to decisions taken before 10 November 2018, which is the case for the vast majority of the substances in your analysis. For these active substances, the new criteria will only apply at the stage of the renewal of approval. Nevertheless, the existing procedures (including the submission of confirmatory information) provide the Commission with the necessary tools to require additional data where needed and with the best possible timing.

[1] Commission Implementing Regulation (EU) 2018/1659 of 7 November 2018 amending Implementing Regulation (EU) No 844/2012 in view of the scientific criteria for the determination of endocrine disrupting properties introduced by Regulation (EU) 2018/605. OJ L 278, 08.11.2018, p.3. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R1659

Furthermore, you refer to the study[2] carried out by the Benaki Institute on our request for the purpose of the impact assessment that accompanied the Commission's proposal for the scientific criteria. I would like to recall the disclaimer on this study[3], which clearly states that the outcomes cannot be used for regulatory purposes as the information and the depth of the analysis cannot be compared to those in the regulatory context of the Plant Protection Products Regulation. It should therefore not come as a surprise that the results of this study are not always confirmed in the outcome of the regulatory assessment.

I concur with your view that during the assessment of dossiers submitted for the renewal of approval of active substances, Member States should first establish whether one of the cut-off criteria – including for endocrine disruption – is met, as foreseen in Article 11(4) of Regulation 844/2012. The analysis conducted by the Commission services for the REFIT evaluation of the pesticides legislation has revealed that Member States are instead systematically conducting a full assessment of the dossiers. This is an area where effective implementation of the legislation needs to be improved.

In conclusion, I am convinced that the EU has made a major step forward with the implementation of the new criteria to identify endocrine disruptors in plant protection products, thus ensuring a better protection of human health and the environment.

Yours sincerely,

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[2] https://ec.europa.eu/health/sites/health/files/endocrine_disruptors/docs/2016_impact_assessment_study_en.pdf

[3] The contents of this publication are the sole responsibility of the contractor and can in no way be taken to reflect the views of the European Commission. The present screening was carried out in the context of an impact assessment to evaluate the impacts associated to options for criteria to identify endocrine disruptors under the regulations on plant protection products and biocidal products. The screening was based on available evidence (no additional testing) and needed to be carried out in a limited time. The screening methodology was developed for the purpose of the screening exercise. The results of the screening therefore do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [in particular, Regulation (EC) No 1107/2009 on plant protection products, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1907/2006 REACH, Regulation (EC) No 1223/2009 on cosmetic products and the Water Framework Directive (EC) No 2000/60] and in no way prejudge future decisions on active substances to be taken pursuant to these pieces of the EU legislation. It would thus be erroneous to consider that the substances listed in the results of this study (SANTE/2015/E3/SI2.706218) are considered as endocrine disruptors within the meaning of the EU legislation.