EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Food and feed safety, innovation
**Pesticides and biocides**

Brussels,
SANTE/E4

Dear

**Subject:** **Your letter dated 7 September 2017 regarding the substance D4 and the results of the screening study performed in the context of an impact assessment for criteria to identify endocrine disruptors**

Thank you for your letter dated 7 September 2017, in which you provide us with an analysis of the assessment of the substance Octomethylcyclotetrasiloxane (also known as 'D4), as performed in the screening study[1] carried out in the context of an impact assessment[2]. We take note of your analysis and of your remarks.

In your letter, you often refer to the screening study as the "JRC assessment" or the "JRC report". We would like to highlight that, while the Joint Research Centre developed the screening methodology[3], the study itself was carried out by an external contractor (Benaki Phytopathological Institute) engaged by DG SANTE, who applied the methodology developed by the JRC.

As indicated on the first page of the study report (and shortly also on each page thereafter), "*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*

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

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

[3] http://publications.jrc.ec.europa.eu/repository/bitstream/JRC101950/jrc%20screening%20methodology%20for%20ed%20impact%20assessment%20(online).pdf

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*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".*

Considering that about 600 chemicals were screened in a limited time, we are aware that some miscalculation might have occurred with possible incorrect categorizations of one or more substances under certain options. This was part of the uncertainties acknowledged in the disclaimer reported on each page of the study report.

In the case of D4, the screening report concludes that this substance is an ED under all options, including option 4, which considers potency. In your letter, you indicate that there was a miscalculation and D4 should actually not have been categorized as ED under option 4. This happened because STOT-RE value for gas inhalation (50 ppm) was mistakenly used instead of STOT-RE value for vapour inhalation (0.2mg/l). Normalized cut-off value for 3 days should therefore not have been 1500 ppm, but 6 mg/L. The effect dose which was used for categorization under Option 4 is 700 ppm corresponding to 8.492 mg/L (8492 mg/m3 = 8.492 mg/L), which exceeds the normalized cut-off value 6 mg/L. Therefore, D4 should not have been categorized as ED under option 4. However, the normalized trigger was not exceeded by a factor > 1000, as mentioned in your letter, but only by a factor 1.4.

The screening study was conducted for the purpose of an impact assessment for which a report was published in 2016. No amendments to the screening study report are therefore considered at this stage. The Commission reiterates what is stated in the disclaimer present on each page of the screening study report. Thank you for your understanding.

Yours sincerely,