

Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties

Date: May 2018

The European Union is the first region and regulatory system worldwide to define scientific criteria for endocrine disruptors (EDs). Under EU's Biocidal Products and Plant Protection Products Regulations (EU No 528/2012 (BPR) and EC No 1107/2009 (PPPR)), an active substance, which is considered as having ED potential will not be approved unless the risk from exposure is negligible (BPR), unless exposure is negligible (PPPR), or there is evidence that it is essential to prevent or control serious pests or it is required on socioeconomic grounds (BPR).

The ED-criteria for plant protection products (EC No 1107/2009) have been under scrutiny of the European Council and the European Parliament (EP). The initial regulation was rejected by the EP in October 2017. The new proposal taking into consideration the claims of the EP (the criteria contain no more the specific provision for the so-called "growth regulators") was adopted by a narrow Qualified Majority during the Standing Committee on Plants, Animals, Food, and Feed (PAFF) meeting dated 12-13 December 2017. The final adoption by the Commission has been recently performed in April 2018.

The corresponding Regulation (EU) No 2018/605 dated 19 April 2018 defines the scientific criteria to determine ED properties of active substances, safeners and synergists and amends Annex II of Regulation (EC) No 1107/2009.

The criteria to identify adverse effect to humans and adverse effect on non-target organisms are very similar. An active substance, safener or synergist shall be considered as having endocrine disrupting properties if:

- (1) *it shows an adverse effect in /an intact organism or its progeny/non-target organisms,*
- (2) *it has an endocrine mode of action (altering the function(s) of the endocrine system)*
- (3) *the adverse effect is a consequence of the endocrine mode of action.*

In point 3.6.5/3.8.2 of Annex II to PPPR the corresponding paragraphs will be added after the fourth/sole paragraph regarding the ED criteria.

Identification of a substance as endocrine disruptor (ED)

The identification of an active substance, safener or synergist as having ED properties that may cause adverse effect in humans or in non-target organisms is based on a procedure using all available relevant scientific data. These data shall be assessed based on a weight-of-evidence (WoE) approach in order to consider if the criteria set out are fulfilled.

The WoE shall be used to investigate the putative link between the adverse effect(s) and an endocrine mode of action.

Of note, "*adverse effects that are non-specific secondary consequences of other toxic effects shall not be considered for the identification of the substance as endocrine disruptor.*" (Commission Regulation (EU) 2018/605).

Referring to the new Commission Regulation (EU) 2018/605, the European Commission is of the opinion that "*The criteria for the determination of endocrine disrupting properties reflect the current state of scientific and technical knowledge and allow identifying active substances having endocrine disrupting properties more*

*accurately. The new criteria should therefore apply as soon as possible, while taking into account the time necessary for Member States and the Authority to prepare for applying those criteria. Therefore, from **20 October 2018**, those criteria should apply except where the relevant Committee has voted on a draft Regulation by 20 October 2018. The Commission will consider the implications for each procedure pending under Regulation (EC) No 1107/2009 and, where necessary, take appropriate measures with due respect for the rights of the applicants. This may include a request for additional information from the applicant and/or for additional scientific input from the rapporteur Member State and the Authority.”**

Thus, the new criteria to identify ED will apply as of 20 October 2018* to all on-going and future evaluations of active substances used in plant protection products.

With regard to biocides, in a first step the new ED-criteria for biocidal products (EU No 528/2012) were approved in November 2017. These very similar ED-criteria will apply from 7th June, 2018, to all new and on-going applications for biocides.

Furthermore, a draft guidance document for identification of EDs in the context of BPR and PPPR was published for public consultation in 2017/2018. Meanwhile, ECHA and EFSA are in the process of finalizing this technical Guidance document to implement the identification of EDs in the context of the BPR and the PPPR which is planned to be published in June 2018.

Consequences for on-going and future evaluations of active substances from 20 October 2018* onwards

Based on the setting of these scientific criteria for substances used in plant protection, the causal link between an endocrine mode of action and adverse health effects is crucial for the reliable identification of endocrine disruptors. Since current methodology for the assessment of (eco)toxicological hazards is largely based on endpoints indicative for altered biological function, the distinct identification of an endocrine mode of action and of a causal link to adverse health effects is considered to represent a major new challenge in hazard identification.

Even with the enforced EU ED criteria and the ED guidance on hand, expert work and judgement will be needed to evaluate the putative ED properties of compounds in the forthcoming process, especially in cases where the scientific evidence is ambiguous or contradictory.

SCC has a wide spectrum of expertise in the assessment of potential endocrine disruption. This allows us to successfully anticipate regulatory challenges and confidently guide our clients through the difficulties in developing target-specific strategies. To keep up to date with every new requirement, we continuously monitor the current regulatory and scientific developments in this field, both in the EU and worldwide.

Our expertise covers the entire range of methods that can be used in the development of an appropriate assessment strategy, including mode of action (MoA) analyses and adverse outcome pathway (AOP) concepts as well as weight of evidence (WoE) approaches.

SCC will serve you as a dedicated and highly experienced partner when it comes to assembling the lines of evidence.

We will support you in gathering, evaluating and putting together all relevant information required for establishing whether the ED criteria are fulfilled.

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***Date has been changed to 10 November 2018**

Corrigendum to Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties [L 111/10, 2018, Document 32018R0605R(01)]