Update on ECHA's current guidance activities

Safer Chemicals Conference

6 October 2021

European Chemicals Agency

Main ongoing projects

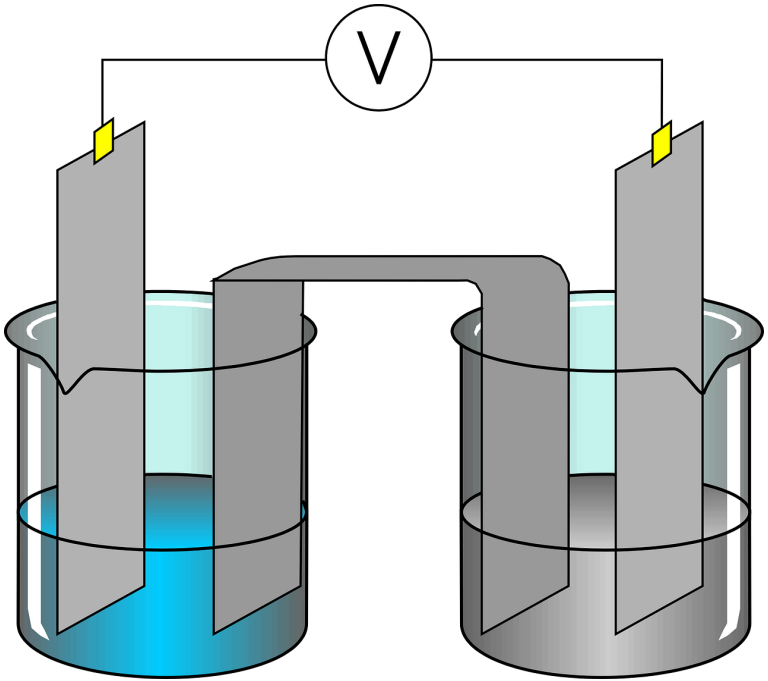
- ✓ Guidance to assess the risk to arthropod pollinators (including bees) from the use of biocides
- ✓ Recommendation of BPC Working Groups on "*In situ* generated active substances"
- ✓ Guidance on human health information requirements (Vol III Part A)
- ✓ Guidance on the impact of water treatment processes on residues of active substances or their metabolites in drinking water
- ✓ Guidance on efficacy (Vol. II, Parts B+C) – Revisions for PT19/Annex 4

Guidance to assess the risk to arthropod pollinators (including bees) from the use of biocides

- ✓ Currently limited guidance available, which is why EFSA and ECHA are working on this project
- ✓ Expert group composed of Member States, ECHA and EFSA in charge of drafting
- ✓ ECHA and EFSA agreed to harmonise their environmental protection goals
- ✓ Consultations expected in Q2 2022
- ✓ Publication planned in Q3-Q4 2022

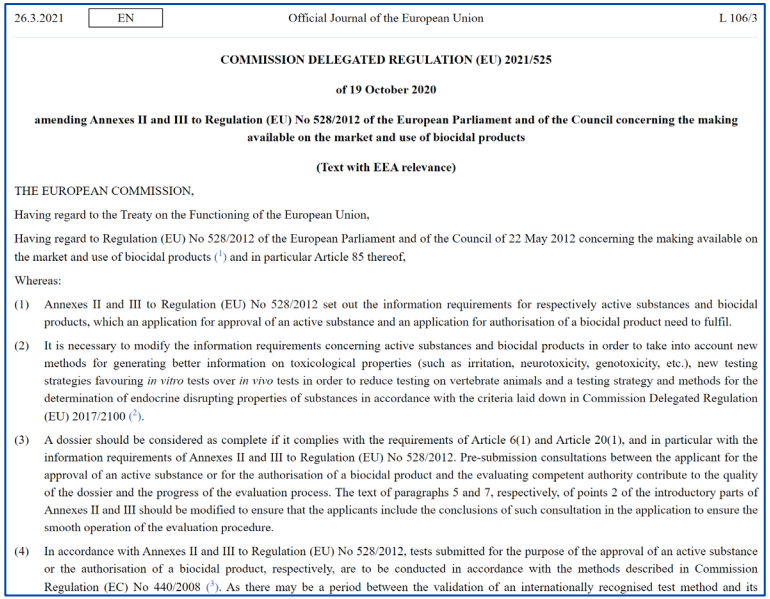
Recommendation of BPC Working Groups on "*In situ* generated active substances"

- ✓ Following agreements at the competent authority meeting, ECHA's recommendations for *in situ* generated substances need to be updated
- ✓ Drafting ongoing
- ✓ Publication currently expected in Q2 2022



Guidance on human health information requirements (Vol III Part A)

- ✓ Update needed as BPR annexes on information requirements revised
- ✓ Drafting finalised
- ✓ Consultation ongoing
  - ✓ Partner Expert Group (PEG) meeting in October 2021
  - ✓ Competent authority/European Commission consultation in Q1 2022
- ✓ Publication expected in Q1 2022



26.3.2021 EN Official Journal of the European Union L 106/3

COMMISSION DELEGATED REGULATION (EU) 2021/525

of 19 October 2020

amending Annexes II and III to Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products [1] and in particular Article 85 thereof,

Whereas:

(1) Annexes II and III to Regulation (EU) No 528/2012 set out the information requirements for respectively active substances and biocidal products, which an application for approval of an active substance and an application for authorisation of a biocidal product need to fulfil.

(2) It is necessary to modify the information requirements concerning active substances and biocidal products in order to take into account new methods for generating better information on toxicological properties (such as irritation, neurotoxicity, genotoxicity, etc.), new testing strategies favouring *in vitro* tests over *in vivo* tests in order to reduce testing on vertebrate animals and a testing strategy and methods for the determination of endocrine disrupting properties of substances in accordance with the criteria laid down in Commission Delegated Regulation (EU) 2017/2100 [2].

(3) A dossier should be considered as complete if it complies with the requirements of Article 6(1) and Article 20(1), and in particular with the information requirements of Annexes II and III to Regulation (EU) No 528/2012. Pre-submission consultations between the applicant for the approval of an active substance or for the authorisation of a biocidal product and the evaluating competent authority contribute to the quality of the dossier and the progress of the evaluation process. The text of paragraphs 5 and 7, respectively, of points 2 of the introductory parts of Annexes II and III should be modified to ensure that the applicants include the conclusions of such consultation in the application to ensure the smooth operation of the evaluation procedure.

(4) In accordance with Annexes II and III to Regulation (EU) No 528/2012, tests submitted for the purpose of the approval of an active substance or the authorisation of a biocidal product, respectively, are to be conducted in accordance with the methods described in Commission Regulation (EC) No 440/2008 [3]. As there may be a period between the validation of an internationally recognised test method and its

Commission Delegated Regulation 2021/525 – available at https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32021R0525

Guidance on the impact of water treatment processes on residues of active substances or their metabolites in drinking water

- ✓ Currently limited guidance available on the topic, which is why EFSA and ECHA are working on this project
- ✓ EFSA (in the lead)/ECHA collaboration
- ✓ Drafting started
- ✓ Consultation expected in Q3 2022
- ✓ Publication currently expected in Q3 2023

Guidance on efficacy (Vol. II, Parts B+C) – for product types 18/19

- ✓ Currently limited guidance available on the topic, especially related to repellents against mosquitoes
  - ✓ Drafting finalised
  - ✓ PEG consultation finalised
  - ✓ Publication currently expected in Q4 2021

Guidance on efficacy (Vol. II, Parts B+C) – Updates to Appendix 4 – for product types 1-5

- ✓ Discussion finalised at the WG level
- ✓ PEG consultation ongoing
- ✓ Publication currently expected in Q4 2022

Thank you!

Claudio.putzu@echa.europa.eu