



# CROPLIFE EUROPE ANNUAL CONFERENCE 2023

BREAKOUT 5: **SCIENTIFIC GUIDANCE DOCUMENTS AND  
THEIR EFFECT ON INNOVATION**

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# INTRODUCTION |

- **Where are we**
- **Areas of work**
- **Issues at stake**
- **Way forward**



# WHERE WE ARE

## Guidance and other assessment methodology documents

A comprehensive body of EFSA scientific assessment practices guides and supports our experts in ensuring reports respect the highest scientific standards.

This body of best practice covers both the scientific and procedural aspects of EFSA's scientific assessment, scientific rationale for evaluations and important scientific considerations such as data needs and formats, standards and reporting standards.

- **Cross-cutting guidance**  – guidance of the Scientific Committee/EFSA on broad assessment principles (e.g. uncertainty analysis, statistical reporting, structure of outputs) that apply to all or most of EFSA's scientific areas.
- **Sector-specific guidance documents** – guidance of the Scientific Panels or EFSA units used by EFSA scientists, other scientific bodies and our stakeholders, particularly applicants who submit dossiers for scientific evaluation.
- **Other assessment methodologies** – produced by EFSA scientific staff and peer-reviewed by independent experts, these can include methodological approaches and procedures, "state-of-the-science" reviews of international assessment best practices, as well as reviews of new and developing assessment tools.

- **Guidance on aneugenicity assessment**
- **Guidance on nanoparticles**
- **Guidance on the use of the Threshold of Toxicological Concern approach in food safety assessment**
- **Guidance on harmonised methodologies for human health, animal health and ecological risk assessment of combined exposure to multiple chemicals**
- **Guidance on Uncertainty Analysis in Scientific Assessments**



# WHERE WE ARE: SPECIFIC TO PPP

<https://www.efsa.europa.eu/en/applications/pesticides/regulationsandguidance>

## Scientific guidance

Applicable to all applications (submitted before or after 27 March 2021)

- [EC guidance documents on Active substances](#)  (European Commission's Standing Committee on Plants, Animals, Food and Feed – phytopharmaceuticals)
- [Guidance for the identification of endocrine disruptors in the context of Regulations EU 528/2012 and EC 1107/2009](#)
- [Submission of scientific peer-reviewed open literature for the approval of pesticide active substances](#)
- [Assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products](#)
- [Risk assessment of plant protection products on bees \(Apis mellifera, Bombus spp. and solitary bees\)](#)
- [Default Q10 value to describe the temperature effect on transformation rates of pesticides in soil](#)
- [EC working document on the procedure for application of basic substances to be approved in compliance with Article 23 of Regulation EC 1107/2009](#)  (Application template available from Annex II)



# AND ALSO

## Additional resources

- [Outcome of the pesticides peer review meeting on general recurring issues in physical and analytical methods](#) (2017)
- [Outcome of the pesticides peer review meeting on general recurring issues in physical and analytical methods](#) (2019)
- [Outcome of the pesticides peer review meeting on general recurring issues in physical and analytical methods](#) (2016)
- [Outcome of the pesticides peer review meeting on general recurring issues in physical and analytical methods](#) (2018)
- [Outcome of the pesticides peer review meeting on general recurring issues in physical and analytical methods](#) (2015)
- [Outcome of the pesticides peer review meeting on general recurring issues in physical and analytical methods](#) (2018)
- [Recommendations on the use of pesticides](#) (2017)
- [JRC FOCUS \(the FORum for the COordination of the Use of Pesticide Residues\)](#) (2018)
- [JRC FOCUS \(the FORum for the COordination of the Use of Pesticide Residues\) webpage](#) 

**Not GD, still providing insights on interpretation and general agreement**



## Administrative guidance

**Applicable to applications submitted as of 27 March 2021**

- [Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances and on the maximum residue level \(MRL\) application procedure](#)
- [EFSA's Catalogue of support initiatives during the life-cycle of applications for regulated products](#) (update 19 December 2022)

**Applicable to applications submitted until 26 March 2021**

- [Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances](#)
- [EFSA's Catalogue of support initiatives during the life-cycle of applications for regulated products](#)



## MOST RECENT

- <https://www.efsa.europa.eu/en/efsajournal/pub/7790>

### Risk assessment for Birds and Mammals

Published: 6 February 2023    Adopted: 15 December 2022



### Scientific guidance on soil phototransformation products in groundwater – consideration, parameterisation and simulation in the exposure assessment of plant protection products

Published: 15 March 2022    Adopted: 6 January 2022



### Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment of plant protection products

Published: 18 January 2022    Adopted: 30 November 2021



## ONGOING

- **Scientific and technical assistance on the assessment of studies concerning residues in rotational crops**
- **EFSA and ECHA scientific and technical assistance to develop a Guidance Document on the impact of water treatment processes on residues of active substances or their metabolites in water abstracted for the production of drinking water**
- **Revision of the guidance on the risk assessment of plant protection products on bees (Apis mellifera, Bombus spp. and solitary bees)**
- *Statement of the Scientific Panel on Plant Protection Products and their Residues (PPR Panel) on the design and conduct of groundwater monitoring studies supporting groundwater exposure assessments of pesticides*
- *Scientific Opinion on the collection, use and reporting of HCD for regulatory studies*



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## Highlights

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| <b>Screening of existing regulatory framework in view of new farming techniques/new pesticide application technologies</b> |
| <b>Negligible exposure: draft technical guidance SANCO-2014-12096</b>  |
| <b>Assessment of the relevance of metabolites in groundwater - SANCO/221/2000 rev.10 - February 2003</b>                   |
| <b>Non-target arthropods (Terrestrial Ecotoxicology - SANCO/10329/2002 rev 2 final - October 2002)</b>                     |
| <b>Amphibians &amp; Reptiles</b>   |
| <b>Non-target terrestrial plants (Terrestrial Ecotoxicology - SANCO/10329/2002 rev 2 final - October 2002)</b>             |
| <b>Guidance document for the Authorisation of Plant Protection Products for Seed Treatment (draft available)</b>           |
| <b>Guidance on risk assessment of microorganisms</b>   |



Close collaboration EC, MSs and EFSA



## ISSUES AT STAKE

- **GD up to date**
- **Evolving science**
- **Need of stability for risk assessors and applicants**
  
- **HOW TO RECONCILE THESE ASPECTS?**
- **ARE GD always behind?**



## ISSUES AT STAKE

- **Role of MSs (leading/supporting)**
- **Basic criteria to be followed (e.g. cross cutting GD)**
- **Simplification (is it possible)**
- **Engagement (of all actors!!!)**





# THANK YOU!

## Questions?

