

Current Risk Assessment of Non-Target Terrestrial Plants Under the Regulation (EU) 1107/2009

Deficit Analysis and Recommendations for the Revision of the Terrestrial Guidance Document

Byers Harry¹⁾, Solé Magali¹⁾, Baudson Caroline²⁾, Mathieu Laura²⁾, Kubátová-Hiršová Hana³⁾, Ghani Sweba¹⁾, Brendel Stephan¹⁾, Périllon Cécile¹⁾ and Matezki Steffen¹⁾

¹⁾German Environment Agency (UBA), Germany; ²⁾FPS Health Food Chain Safety Environment, Belgium; ³⁾Central Institute For Supervising and Testing in Agriculture, Czech Republic

Introduction







The current Terrestrial Guidance Document (TGD), SANCO/10329/2002, adopted over two decades ago, no longer reflects the latest scientific developments nor adequately incorporates the provisions of Regulation (EC) No. 1107/2009. In its 2014 Scientific Opinion (SciOp), the European Food Safety Agency (EFSA) has acknowledged various shortcomings in its review of the existing guidance, based on the state of scientific knowledge at that time, for the risk assessment of Non-Target Terrestrial Plants (NTTP) exposed to Plant Protection Products (PPP). This study aims to identify recent scientific advancements since the publication of the EFSA SciOp in 2014 through a comprehensive literature review.

Deficit Analysis

The work conducted updated the definition of the deficits presented in EFSA 2014 and found new deficits:

- ▶ 27 deficits were identified, which were already presented in the conclusions and recommendations of EFSA SciOp 2014.
- ▶ 5 additional deficits were identified following recent scientific papers or new agricultural practices (e.g. precision farming, RNAi Mode of Action...).
- ▶ Deficits were evaluated according to their Uncertainty, Relevance and Effort needed to resolve them.
- ▶ Deficits were grouped according to six topics such as Effect or Exposure (see figure below with two examples of deficits for each Topic).
- ▶ Key words were derived from the 32 deficits and were used to perform a literature review.

Overview of deficit groups and examples

 Data Requisite <ul style="list-style-type: none">• Species choice: crop vs wild species• Growth stage tested	 Effect <ul style="list-style-type: none">• Limitation of the OECD 208 & 227• Visual phytotoxicity
 Exposure <ul style="list-style-type: none">• Exposure pathway used• Multiple Application Factor	 Calibration <ul style="list-style-type: none">• Absence of a reference tier for NTTPs• Protectiveness of the tiered approach
 Higher Tier <ul style="list-style-type: none">• SSD refinement option• Population modelling	 In/Direct effects <ul style="list-style-type: none">• Indirect effects• In-field

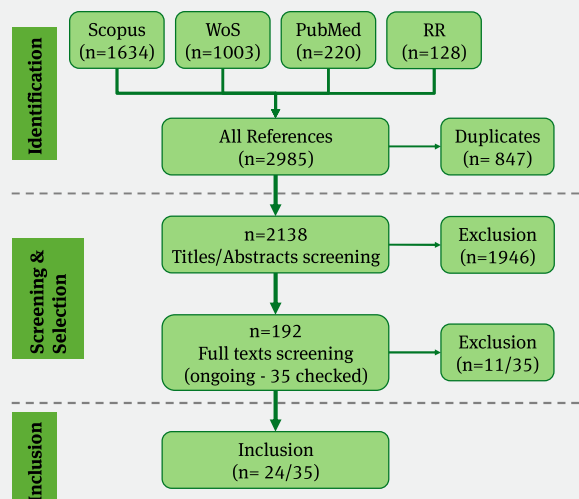
Literature review

A systematic literature review was conducted to identify new scientific knowledge, following the EFSA Journal 2011; 9(2):2092 methodology.

- ▶ The review focused on main topics: Chemicals (A), Species (B), Risk Assessment (C) and Deficits (D). For each topic, several keywords (kw) were combined using OR, and the different topics were combined using AND, resulting in a Boolean structure such as: $(kw-A \vee kw-B) \wedge (kw-C \vee kw-D)$
- ▶ In addition to the classical search, a Snowball search was performed through the ReasearchRabbit portal (RR), by using the EFSA 2014 SciOp as a starting point.
- ▶ A total of 2138 papers were identified, with 192 considered potentially relevant based on title and abstract.
- ▶ The full texts of these studies will be assessed based on their reliability and relevance.

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Literature review Prisma chart



Conclusion and Take home message

- The EFSA 2014 SciOp already prepared the ground for a future TGD for NTTP. Our work confirmed that the majority of the deficits identified remains relevant today.
- While several deficits still lack sufficient understanding (e.g. Calibration), others appear to be better characterized (e.g. effect-MAF).
- New deficits have also emerged as result of evolving agricultural practices and technological developments.
- About 200 scientific papers were identified through the literature review as potentially relevant for NTTP risk assessment knowledge.
- Most of these papers concern deficits from the Data Requisite and Effect topics. These papers are used to refine and better characterize the most relevant deficits, supporting the revision of the TGD.

While certain knowledge deficits still require fundamental research (e.g. reference tier, serial applications) the current state of scientific understanding already allows for significant improvements over the SANCO (2002) guidance. An updated TGD could incorporate surrogate methods and account for uncertainties based on best available knowledge where precise quantification of effects is not yet feasible. The current NTTP risk assessment framework is no longer fully aligned with the protection goals outlined in Regulation (EC) No. 1107/2009, thus a timely update of the TGD is urgently needed. Improvements must be implemented now using the knowledge already available.

Supplementary information:

For a detailed list of deficits and relevant articles, please access the supplementary document on Zenodo by scanning the QR code.

Contact:

Umweltbundesamt, Postfach 14 06, 06813 Dessau-Roßlau
NTTPproject@uba.de

Harry Byers
Pesticides Department
Telefon: +49 (0)340 2103-0

Stand: 6.07.P-Tu473

Supplementary
Information link:



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