EuropaBio-EFSA meeting

Explanatory note on literature searching conducted in the context of GMO applications for (renewed) market authorisation and annual post-market environmental monitoring reports on GMOs authorised in the EU market – 2019 update

Parma, 13 June 2019

Objective of today's meeting

To reach a common understanding on EFSA's expectations for literature searches performed in the context of GMO applications

- What has changed with respect to the 2017 Explanatory Note

Appropriate search strategy

Updated *Explanatory Note* published by EFSA in April 2019

APPROVED: 26 March 2019

doi:10.2903/sp.efsa.2019.EN-1614

Explanatory note on literature searching conducted in the context of GMO applications for (renewed) market authorisation and annual post-market environmental monitoring reports on GMOs authorised in the EU market

European Food Safety Authority (EFSA),
Yann Devos, Irene Muñoz-Guajardo, Fernando Álvarez and Julie Glanville

Comparison Explanatory notes 2017 vs 2019

The **objective and scope** of the searches have not changed.

> *According to Article 6(1) of the Implementing Regulation (EU) No 503/2013, "the application shall include a systematic review of studies published in the scientific literature and studies performed by the applicant within the period of ten years prior to the date of submission of the dossier on the potential effects on human and animal health of the GM food and feed covered by the application".*

Wording on how to set up the searches is somewhat different:

- **2019 Explanatory Note** (section 3.2. Searching for/identifying relevant publications; page 13) - EFSA considers that the search strategy should be broader than the review topic.

Section 1.3. (page 7)
Transition period

"*The requirements outlined in this updated explanatory note are fully applicable to all (renewal) GMO applications and annual PMEM reports submitted at least three months after its publication date*".

EuropaBio considers that the *Explanatory Note* applicable to an application is the one that was in force at the time of submission of the application. Therefore it is our understanding that the 2017 *Explanatory Note* remains applicable to all GMO applications that are currently in the system.

Section 3.2.2.2. (page 18)
Search terms

"Applicants should systematically identify appropriate indexing terms for the desired key elements of the review questions by searching the thesauri of electronic bibliographic databases for matching indexing terms (if available), or by searching for obvious relevant publications and noting the indexing terms which have been added to those records by the database indexers (EFSA, 2010a)."

EuropaBio is seeking clarification/examples regarding the use of **controlled vocabulary**, since the applicable controlled vocabulary (GMO, plant name, intended trait…) would not identify additional relevant publications compared to appropriate free-text searches.

Section 3.6.2. (page 34)
Entry date

"When updating a search for a scoping review, applicants should not simply rerun the search for the time period elapsed subsequent to the end of the initial search, and thus search for publications with a more recent publication year than the initial search. Publications for earlier years may still be being added to an electronic bibliographic database. Consequently, EFSA recommends that searches are run with the publication dates for all the previous search periods

EuropaBio seeks clarification on practicality of this recommendation as it is unlikely to identify additional publications, since the approaches currently used to prevent missing these publications are equally efficient.

Section 3.6.2. (page 34)
Entry date (cont)

Approaches used currently to prevent missing publications that may be added later to a database are equally effective:

- Use a search strategy that encompasses multiple sources and therefore has redundancy. A relevant paper that would enter one database late would most likely have been captured by another source; or

- Limit search results not by **PD** (publication date) or **ED** (entry date), but by **UP** (update date), if the database allows

Concluding remarks

The search strategies currently implemented by the applicants are broad enough and redundant enough to ensure that the relevant publications are retrieved