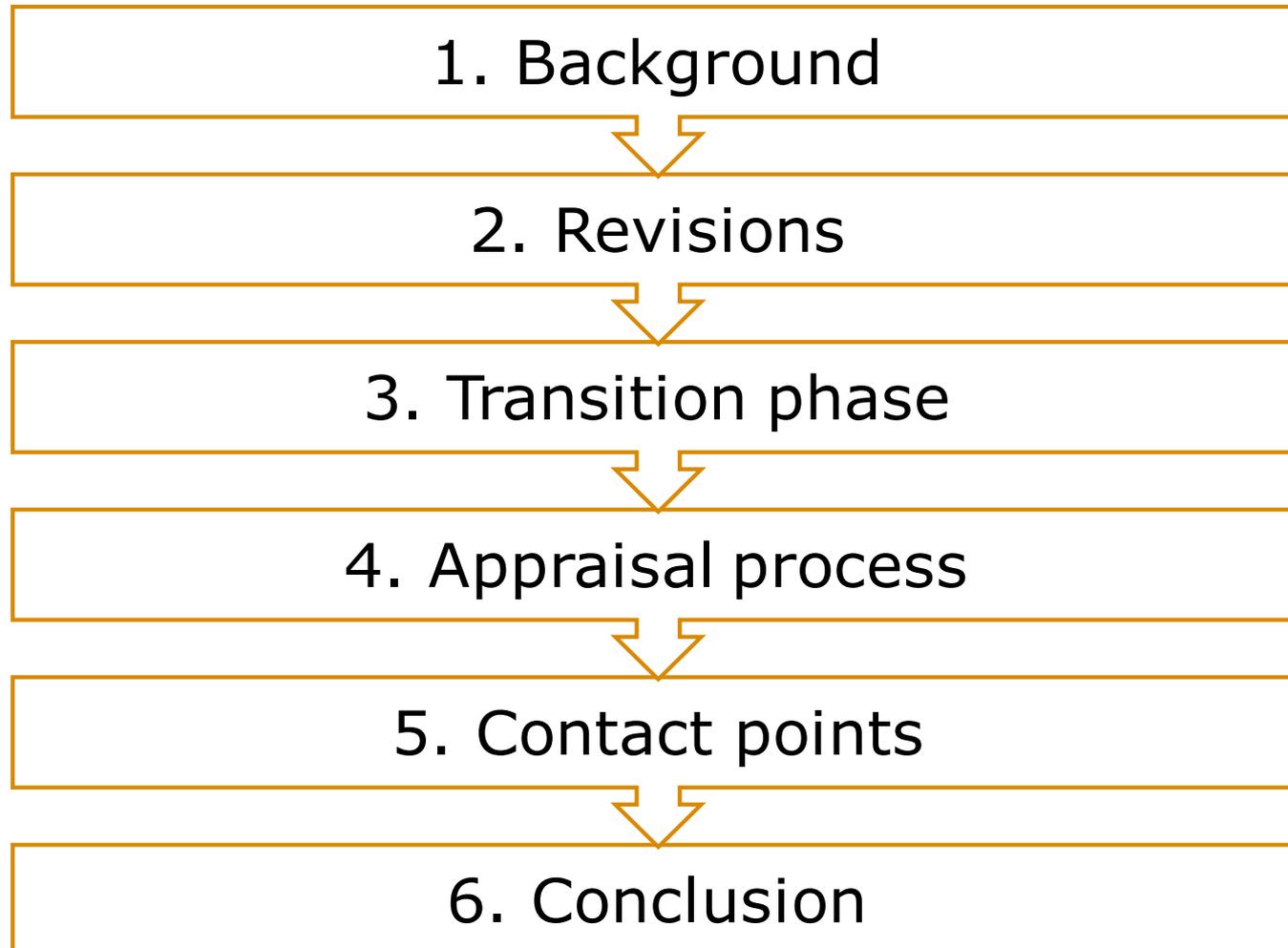


GMO Network meeting  
(18-19 June 2019; Parma)

# EFSA's updated explanatory note on literature searching: Revisions and appraisal process

**Yann Devos**

Senior Scientific Officer – Ecology



- Initial note published in April 2017
  - EFSA Supporting Publications



**TECHNICAL REPORT**

APPROVED: 5 April 2017  
doi:10.2903/sp.efsa.2017.EN-1207

**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 Munoz Guajardo Julie Glanville and Elisabeth Waigmann

## ■ Triggers

- Article 6(1) of Regulation (EU) No 503/2013
  - *“The application shall include a **systematic review of studies published in the scientific literature** [...] within the period of 10 years prior to the date of submission of the dossier on **the potential effects on human and animal health of the genetically modified food and feed** covered by the application”*
- Applicants have undertaken searches to various degrees of rigour

- General objectives
  - Clarify
    - Scope and methodology for literature searching
    - How to
      - Conduct and report systematic/extensive literature searches
      - Present the results of any scoping reviews
  - Promote transparency
  - Facilitate appraisal
  - Enable reproducibility

- Specific recommendations
  1. Formulating review questions
  2. Searching for relevant publications
    - Select information sources
    - Construct search strategy
  3. Selecting publications
  4. Extracting high level data from the relevant publications, where appropriate
  5. Summarising and reporting the data, and considering the implications of the findings

- Initial note
  - Subject to revision
    - In view of any amendments to Regulation (EU) No 503/2013
      - ...
    - When experience is gained in its application
      - Substantial experience gained since 2017
      - EuropaBio feedback on note

- Updated noted published in April 2019
  - EFSA Supporting Publications



**TECHNICAL REPORT**

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**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),  
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- Information sources
  - Electronic bibliographic databases
    - *At least* two multi-disciplinary databases
  - Internet searches
    - Relevant key organisations involved in GMO risk assessment
      - N/A if risk assessments on stacked events are not reported
  - Manual searches
    - Checking reference list from recent relevant publications

- Search strategy
  - EFSA does not recommend any specific approach for the search strategy
    - Applicants are encouraged to construct the most practical search strategy on a case-by-case basis
      - Applicants should describe clearly how they have constructed the search strategy, with justifications
  - Appendix
    - Informative and non-exhaustive examples of how to conceptualise search strategies

- Reference publications
  - Flexibility
    - EFSA acknowledges that, owing to the novelty of some GMO products, no or only a limited number of publications are published
      - Applicants are encouraged to explore alternative approaches for the selection of reference publications
    - If no suitable reference publications can be identified, this should be reported, along with the approaches used for their identification

- Reference publications
  - Examples of alternative approaches
    - For stacked events
      - Publications about the single(s) and/or subcombination(s)
    - For single events
      - Publications on proteins similar to the newly expressed one
  - Publications that do not necessarily contribute to the knowledge informing risk assessment of the GMO under consideration
    - Benefits, socio-economics, ethics, crop protection, detection methods, efficacy and public perception

- Relevance criteria: Molecular stacks
  - Exclude publications that address one or several of the newly expressed proteins in the molecular stack
    - Conditions:
      - That has/have been previously risk assessed by EFSA and/or its GMO Panel
      - +
      - For which the safe use has been determined by EFSA and/or its GMO Panel

- Relevance criteria: Previously assessed publications
  - Exclude publications that have been previously assessed by EFSA and/or its GMO Panel
    - Conditions:
      - Cited/referenced in an EFSA/GMO Panel output
      - In case a publication reports several studies/datasets, all studies/datasets relevant for the review question should have been previously assessed by EFSA and/or its GMO Panel

- Relevance criteria: Reporting format
  - Exclude publications that do not present original/primary data (i.e., editorials, position papers)
  - Include relevant risk assessments performed and reported by relevant key organisations

- Raw data
  - The list of relevant publications should be compiled in a reference management software and provided to EFSA in **.RIS format**

- Reporting of updated searches
  - Search strategy
    - Provide justification that strategy is still valid
  - Reference publications
    - No longer applicable
  - Reporting (“light”)
    - Limited to selecting publications, extracting high level data and summarising results and their risk assessment implications

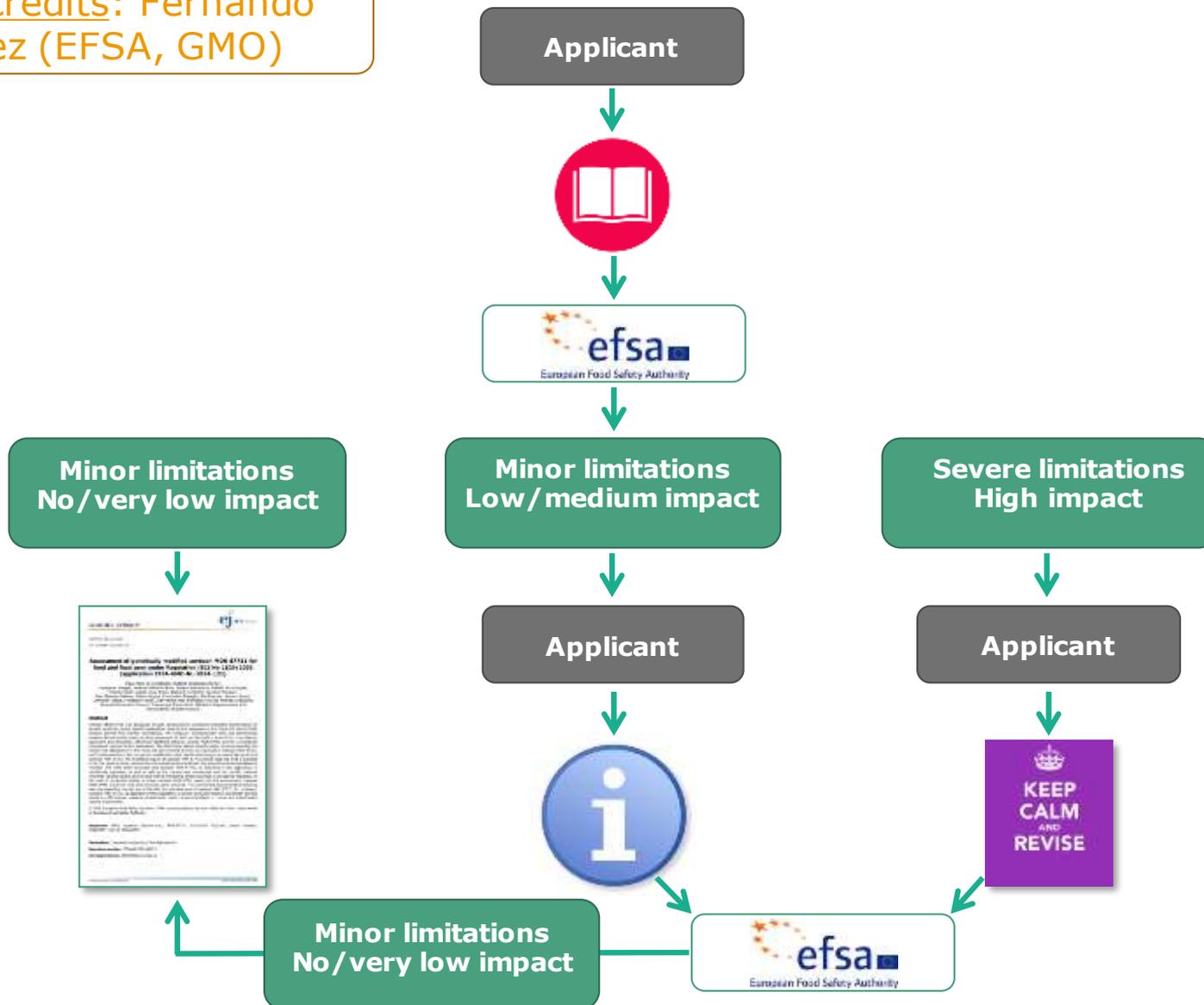
- Completeness checklist
  - Simplified and shortened substantially
  - Only applicable for initial searches/reviews

- 3-months after publication date (4 April)
  - The requirements outlined in the updated explanatory note will be fully applicable to
    - all (renewal) GMO applications
    - annual post-market environmental monitoring (PMEM) reports
  - submitted **on/after 4 July 2019**

- In the context of GMO applications → scoping reviews (SR)
  - In principle, two entry points:
    - Initial SR at the validation of the application
    - Updated SR at the end of the risk assessment
      - From 4 July onwards
        - “Light” reporting of updated SR
        - Appraisal focus on
          - Results
          - Confirmation that former methodology remains suitable

# 4. Appraisal process

Figure credits: Fernando Alvarez (EFSA, GMO)



# 4. Appraisal process

	Past	Present
<b>Who?</b>	Methodology ↓	
	COMP/ERA WG ( <i>ad hoc</i> information specialist + EFSA staff)	External contractor + EFSA staff
<b>How?</b>	Relevant publications ↓	
	GMO Panel/relevant expert WGs + EFSA staff	
<b>How?</b>	Critical appraisal tool	
	EFSA (2015)	<i>Before 4 July:</i> EFSA (2015)
		<i>From 4 July onwards:</i> Revised EFSA (2015) aligned to updated note

- Note to the guidance on literature searching
  - Project coordinator
    - Yann Devos (EFSA, GMO)
  - Project contributors
    - Irene Muñoz-Guajardo (EFSA, AMU)
    - Julie Glanville (YHEC, University of York)
    - Fernando Álvarez (EFSA, GMO)
- Appraisal of literature reviews/searches
  - Project coordinator
    - Fernando Álvarez (EFSA, GMO)
  - Project contributor
    - Irene Muñoz-Guajardo (EFSA, AMU)

- Experience gained in the application of the former note on literature searching
- Mandatory systematic review is scientifically not sound; SR approach followed instead
- Updated note applicable from 4 July 2019 onwards
  - Several revisions implemented
- Revised appraisal process for methodology
  - External contractor + EFSA staff

## Thank you for your attention



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