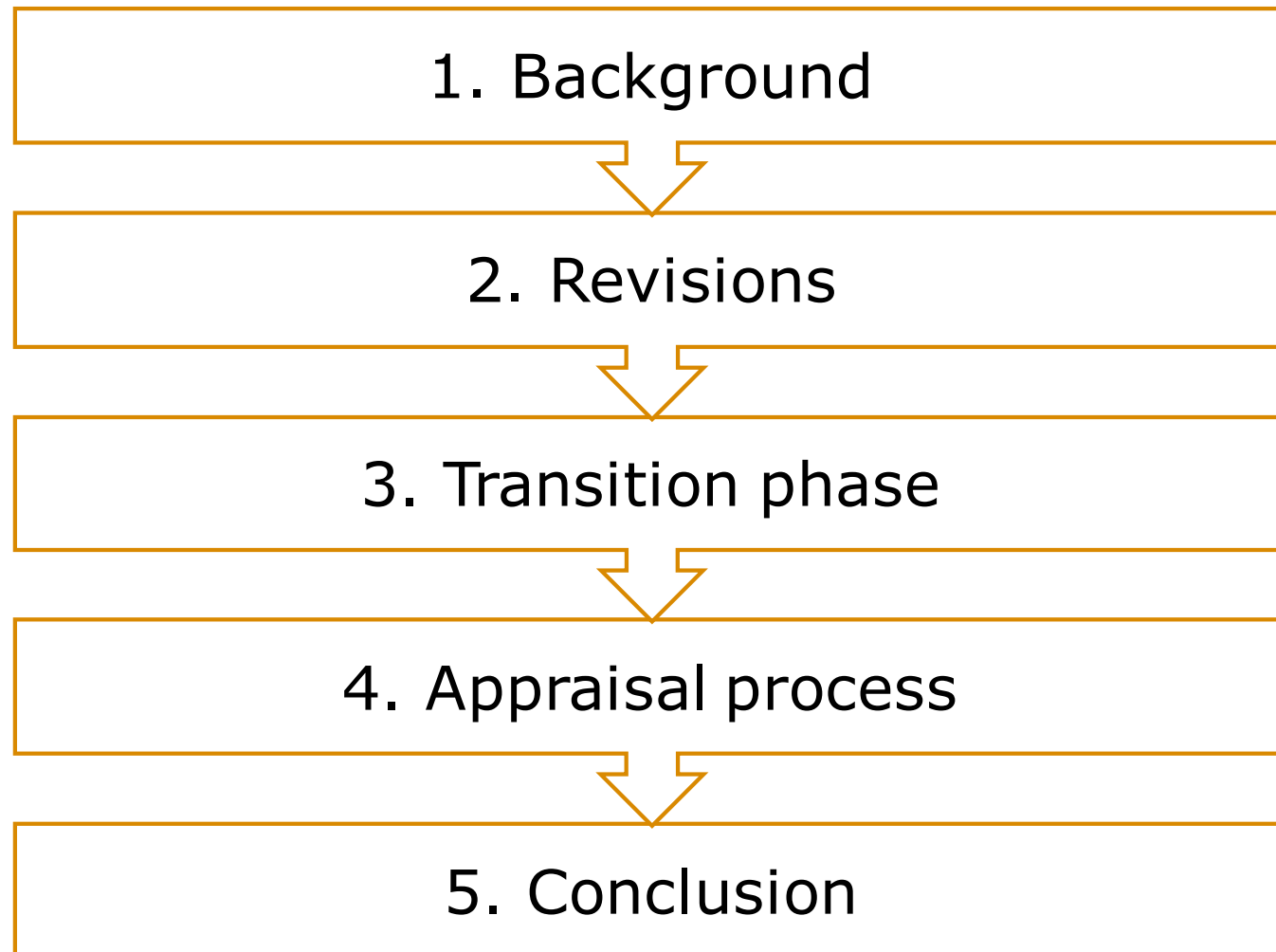


*Ad hoc meeting with applicants
(Parma; 13/6/2019)*



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



- 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



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

- 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

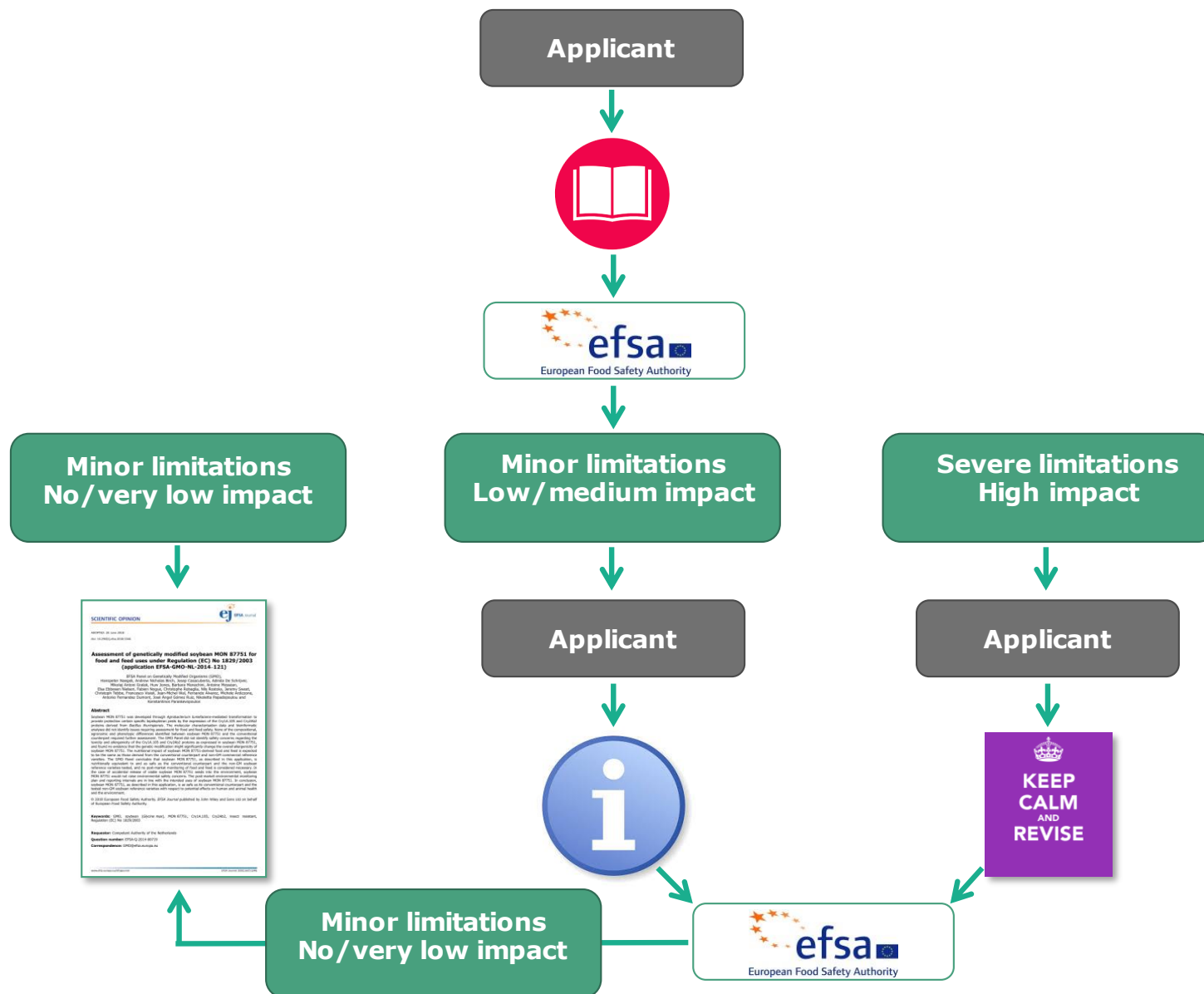
- Raw data
 - The list of relevant publications should be compiled in a reference management software and provided to EFSA in **.RIS format**

- 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

- 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 GMO 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



4. Appraisal process

	Past	Present
Who?	Methodology ↓	
	COMP/ERA WG (<i>ad hoc</i> information specialist + EFSA staff)	External contractor + EFSA staff
	Relevant publications ↓	
	GMO Panel/relevant expert WGs + EFSA staff	
How?	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

- Experience gained in the application of the former note on literature searching
- Mandatory systematic review is scientifically not sound; SR review 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



Subscribe to

www.efsa.europa.eu/en/news/newsletters
www.efsa.europa.eu/en/rss



Engage with careers



Follow us on Twitter

@efsa_eu
@plants_efsa
@methods_efsa