Ref. Ares(2023)2476057 - 05/04/2023

Update on implementation of the Transparency Regulation in the context of Regulation (EC) 1829/2003/EC

Trusted science for safe food

efsa
European Food Safety Authority

Transparency Regulation (TR) applicable as of 27th March 2021

efsa
European Food Safety Authority

4 pillars

Transparency

Better access to scientific studies

More reliable independent studies

EFSA will have more access to relevant scientific evidence in requests for authorisation

Better governance

Member States will contribute more to EFSA's governance and scientific Panels

Effective risk communication

Improve coordination between risk assessors and risk managers to ensure better communication to stakeholders and general public

Applicable For - New dossiers/applications submitted on or after 27th March 2021

Click here to access the Factsheet: "A Modern and Sustainable Food Law in the EU"

post-TR TOOLS available to Business Operators

Connect EFSA

- ✓ **Notification of Studies (NoS)**
- ✓ **Pre-submission Advice (PSA)**
- ✓ AskEFSA
- ✓ Public Access to Document
- ✓ Targeted MS consultation
- ✓ **Public consultation**

E-Submission Food Chain

- ✓ Dossier eSubmission
- ✓ Request for Information (RFI)
- ✓ Additional Data Request (ADR)
- ✓ Follow-up lifecycle

Open EFSA

- ✓ Monitoring of Risk Assessment workflow
- ✓ Dissemination portal
- ✓ Proactive disclosure of non-confidential information

https://www.efsa.europa.eu/en/applications/toolkit

Dossier Intake: Business Operator to National Competent Authority [NCA]

ESFC

Business Operator submits to **National Competent Authority (NCA)** the **Notification consisting of the Technical Dossier** and any **Confidentiality Requests** of specific sections of the dossier [e.g. studies, data]
EC is informed

ESFC

NCA submits to EC the Notification received from the Business Operator

ESFC

EC sends the **Mandate** to **EFSA** asking to assess the Dossier under Reg. 1829/2003/EC to carry out the Risk Assessment of the dossier notified to the Member State

GMFF Dossier Intake: EC to EFSA

ESFC

EC makes the Technical Dossier available to **EFSA** the **Dossier** received from **NCA [CI and nCI version]**

OpenEFSA

EFSA makes publicly available [OpenEFSA] the **nCI version of the dossier** received from **NCA**

ESFC

EFSA carries out the **Completeness Check** of the submitted dossier and the list of submitted vs **Notified Studies**

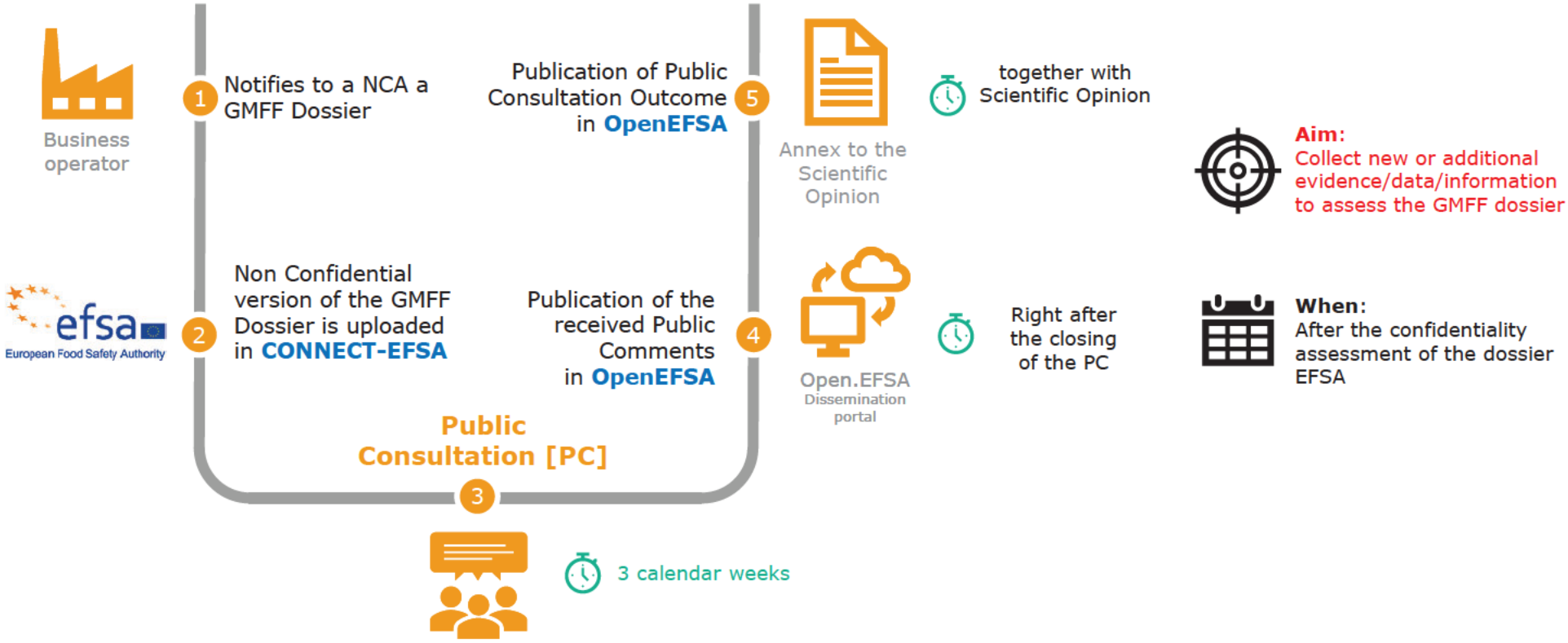
EFSA sends to the Business Operator Requests for Information [RFI]

Business Operator delivers to EFSA the requested Missing Information

The outcome of the CC phase is the VALID Dossier

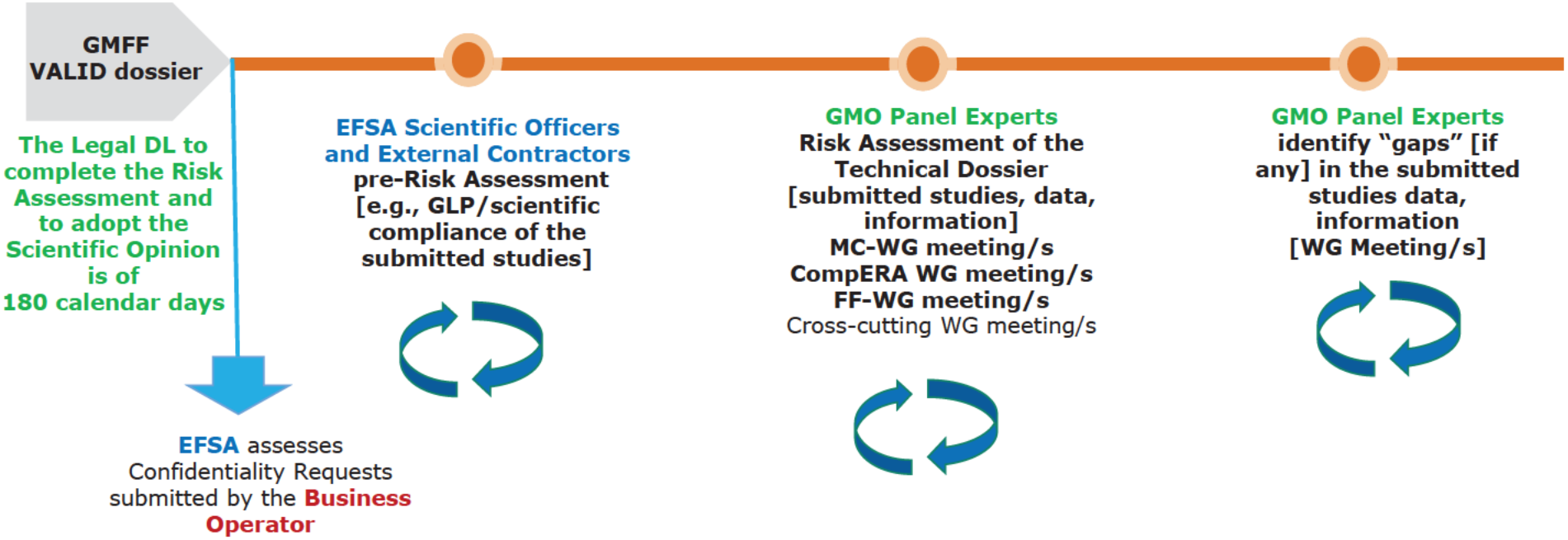
GMO Panel Experts execute the Risk Assessment of the **VALID Dossier**

Public Consultation [PC] of the nCI version of the Dossier



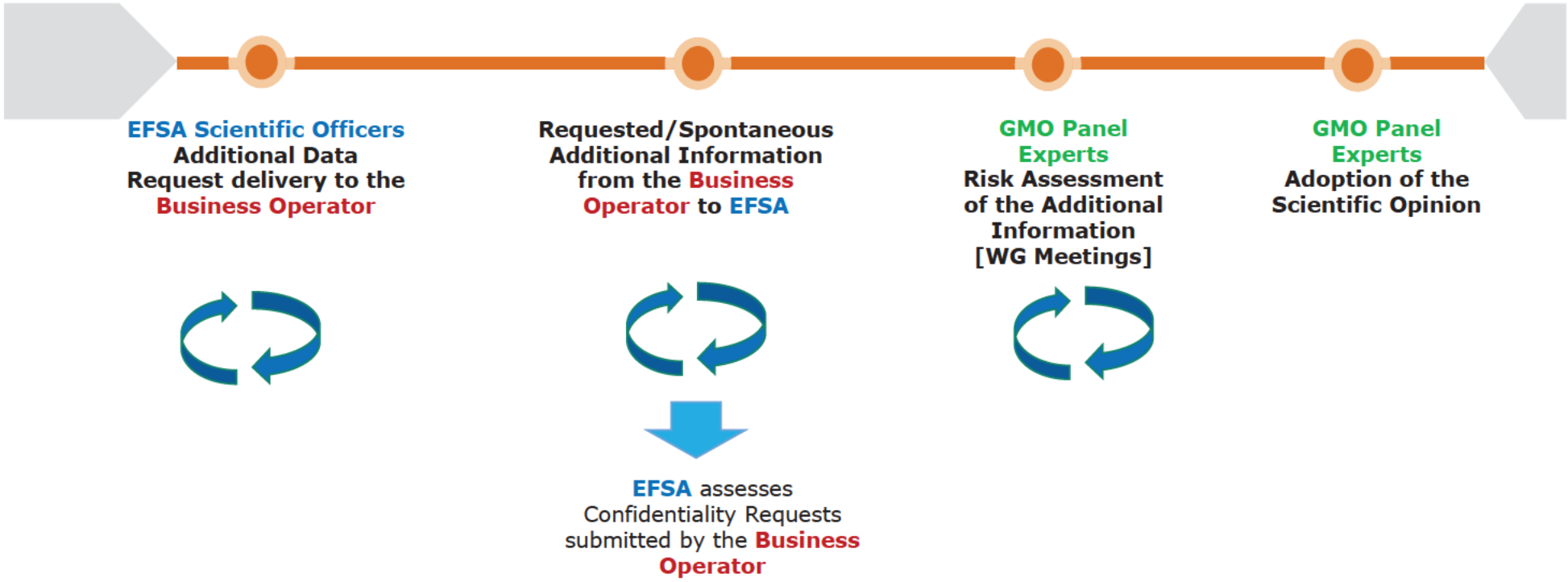
GFL Regulation (Regulation (EC) No 178/2002), Article 32c(2)

GMO GMFF Dossier: Risk Assessment by the GMO Panel 1



Administrative guidance for the processing of applications for regulated products [update 2021]

GMO GMFF Dossier: Risk Assessment by the GMO Panel 2



Risk Assessment Workflow @EFSA

European Food Safety Authority

1 Mandate & Dossier intake

- Mandate and dossier **receipt from EC**
- **Completeness Check**
- **Dossier Valid**
- **Publication** of the public access version of the GMFF dossier

post-TR

2 Risk Assessment

- **MS Targeted Consultation** [3 months] CI version
- **Public Consultation** [3 weeks] nCI version

post-TR

- **Risk Assessment** by the GMO Panel Experts
- **Additional Data Request** (ADR), if needed
- **Adoption** of the Scientific Opinion by the GMO Panel

3 Output publication & dissemination

- **Notification** of the adopted Scientific Opinion to **Business Operator**, NCA, EC, JRC[EURL]
- **Publication** of the Scientific Opinion [28 working days post-adoption]
- **Publication** of the revised public access [nCI] version of the dossier and of the additional information following **EFSA assessment of the Confidentiality Requests** made by the applicant upon submission

post-TR

Documentation

Legal documents:

- TR: Regulation (EU) 2019/1381
- General Food Law: consolidated text of Regulation (EC) No 178/2002
- Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32003R1829
- PAs on transparency and confidentiality: Practical Arrangements concerning transparency and confidentiality
- PA on pre-submission phase and public consultations;https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/210111-PAs-pre-submission-phase-and-public-consultations.pdf
- Q&A on Practical arrangements: https://www.efsa.europa.eu/en/corporate-pubs/questions-and-answers-efsa-practical-arrangements

Guidance/training material:

GMO guidance web section:

- Administrative guidance for the preparation of applications on genetically modified plants;
- Administrative guidance for the preparation of renewal applications on genetically modified food and feed
- Catalogue of services (update 2021)

Administrative guidance for the processing of applications for regulated products (update 2021)

Training programme on Transparency Regulation

Toolkit page (ESFC and Portalino): https://www.efsa.europa.eu/en/applications/toolkit

User Guide - Notification of Studies (updated on 4 Feb 2022)
User Guide - Pre-application ID (updated on 4 Feb 2022)

Bilateral Meeting EU-Canada 23/09/2022

Risk Assessment Applications of GM food and feed containing **stacked events** for import/processing in the EU

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European Food Safety Authority

Single vs Stacked Events [by conventional breeding]

The RA of GM food and feed containing **single** events is essential to identify possible hazards and unintended effects linked to a specific genetic modification

The RA of food and feed containing **stacked** events is required to identify possible **interactions** between the single events.

The RA of **stacked** events shall focus on:

- Integrity of each event when combined in the stacked GM plant
  [same molecular properties and characteristics as in the plants with the single transformation events]
- Expression of the transformation events: potential additive synergistic or antagonistic effects [for humans, animals, and the environment] resulting from the combination of the transformation events [toxicology, allergenicity, nutritional assessment]
  [RA of phenotypic characteristics and agronomic properties [field trials]

Risk Assessment of single vs stacked events

Risk Area	Single Event	Stacked Event
Genetic stability of event across generations	**Yes**	
Integrity of events		**Yes**
NEP levels in treated/untreated samples	**Yes**	
Interaction of NEPs		**Yes**
NEP characterisation	**Yes**	
Comparative analysis	**Yes**	**Yes**
Toxicology	**Yes**	**Yes** focused on potential additive synergistic or antagonistic effects TOX 90-day study is not required on stacked events Updated bioinformatics is required
Allergenicity	**Yes**	**Yes** focused on potential additive synergistic or antagonistic effects Updated bioinformatics is required
Nutrition	**Yes**	**Yes** focused on potential additive synergistic or antagonistic effects
ERA for I&P	**Yes**	**Yes**
PMEM	**Yes**	**Yes**