Administrative and procedural aspects of risk assessment of GMOs

Experience and suggestions from EuropaBio members

24 October 2019

Content of presentation

I. Administrative guidance for the processing of applications

II. Overview of guidance documents, explanatory notes, and their applicability

III. Administrative guidance for the renewal of authorization of GMOs

I. Administrative guidance for the processing of applications for regulated products

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24 October 2019

Introduction

EuropaBio welcomed the Administrative guidance for the processing of applications for regulated products. Building on its merits and our feedback from last year, we would like to make some suggestions for further improvement regarding

(1) Procedures and timelines, and
(2) process communication.

1. Procedures and timelines

Resulted improvements

- 2018 positive elements maintained
- Follow-up dialogue on how to implement the allergenicity guidance
    - Transition period implemented to avoid retroactive application for celiac disease analysis
- Separate standardized approach for renewals

1. Procedures and timelines

Areas for further improvement

Risk assessment timelines

> *"… the Authority shall endeavour to respect a time limit of six months …"*

- Need for standarisation of approach to be applied to new applications

1. Procedures and timelines

Suggestion for improvements

- Apply a consistent and standardized approach to the processing of new applications
- Assessment of information always warrants WG input
- Grouping of critical questions and clarification questions
- EuropaBio suggestions from 2018 ad-hoc meeting

2. Process communication

Resulted improvements

- Improved dialogue between EFSA and applicants, trend from 2018 continues:
  - Increased number of Ad-hoc meetings
  - Catalogue of Services (Clarification teleconferences, experts hearings)

2. Process communication

Areas for further improvement

- Engagement with applicants:
  - Connection via stakeholder events and platforms (e.g. ISBR)
  - Early consultation for EFSA documents:
    - Human DEA statement
    - Renewal submission guidance

- Information of the yearly schedule for GMO WG meetings

2. Process communication

Suggestions for further Improvements

- Closer involvement and engagement through:
  - Up-front provision of information and discussion about upcoming guidance
  - Early stage informing and consulting applicants about new/updated EFSA documents
- Communication on GMO WGs planned meetings on a yearly basis

II. Overview of guidance documents and their applicability

Understanding from EuropaBio members

24 October 2019

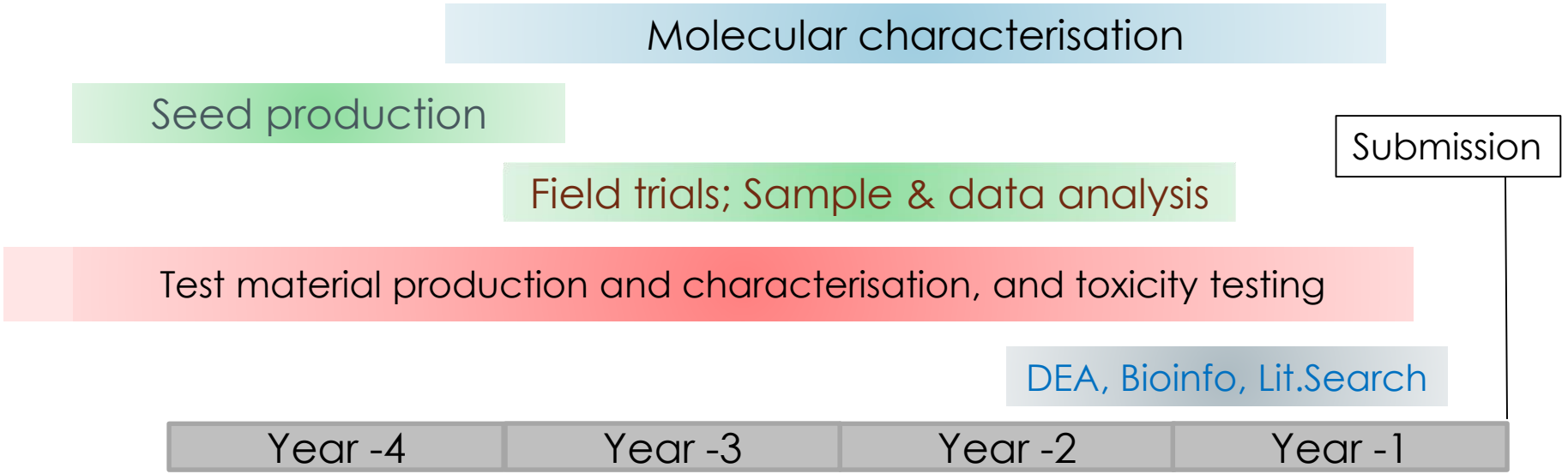
Overview guidelines and notes

Example from our handout

Year	EFSA documents (Type)	Publication date	Application Number (if applicable)	Applicable for applications/data sets submitted as from	Transition period / Comments
2019	11.Human dietary exposure assessment to newly expressed proteins in GM foods (Statement)	31/07/2019	...	1.1/10/2019 2.31/07/2021	1. 2 months consumption and concentration data 2. 24 months in case material needs to be generated (e.g. pollen)

Overview guidelines and notes

Relevance for a solid understanding transition periods



III. Administrative guidance on the submission of applications for renewal of authorisation

Views and understanding of EuropaBio members

24 October 2019

Submission of Studies

Additional documents or studies performed by the applicant or on behalf of the applicant

- Requirements: Admin guidance vs. 2015 Renewal guidance
- Discrepancy with earlier approach

Public Access

Public access

- In line with the EFSA's position presented by M. Detken during the ad-hoc meeting with GMO industry representatives (Parma (IT) - 9 November 2017)
- When the Scientific Opinion is finalised

Year	EFSA documents (Type)	Publication date	Application Number	Applicable for applications/data sets submitted as from	Transition period / Comments
2015	1.Guidance for renewal applications of genetically modified food and feed authorised under Regulations (EC) No 1829/2003 (Scientific Opinion)	18/06/2015		18/06/2015	NA
	2.Guidance on the agronomic and phenotypic characterisation of genetically modified plants (Scientific Opinion)	24/06/2015	AP148	24/06/2017	24 months: Transition period did not apply to requirements for which only the provision of a scientific rationale based on available information is necessary
	3.Explanatory note on DNA sequence similarity searches in the context of the assessment of horizontal gene transfer from plants to microorganisms (Technical Report)	1.21/12/2015 2.Updated note on 26/07/2017		1.21/03/2016 2.immediate	1. 3 months: Requirements applicable to all new data sets generated for HGT 2.NA
2017	4.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 (Technical Report)	1. 01/04/2017 2. Updated note on 04/04/2019		1. 01/10/2017 2. 04/07/2019	1. 6 months 2. 3 months
	5.Guidance on allergenicity assessment of genetically modified plants (Scientific Opinion)	22/06/2017		a) 22/12/2017 b) 22/06/2019 c) 22/06/2018	a) 6 months: Non-IgE-mediated adverse immune reactions to food b) 24 months: Endogenous allergenicity if plant material needs to be generated c) 12 months: Endogenous allergenicity if plant material does not need to be generated d) In vitro protein digestibility – pending further development

Year	EFSA documents (Type)	Publication date	Application Number	Applicable for applications/data sets submitted as from	Transition period / Comments
2018	6.Explanatory note on the selection of forage material suitable for the risk assessment of GM feed of plant origin (Technical Report)	29/01/2018		29/01/2020	24 months
	7.Administrative guidance for the processing of applications for regulated products (Technical Report)	1. 15/01/2018 2. updated on 17/06/2019			NA
	8.Technical Note on the quality of DNA sequencing for the molecular characterisation of genetically modified plants (Scientific Opinion)	16/07/2018		01/10/2018	Applications submitted after 01/10/2018
	9.Explanatory note on the determination of newly expressed protein levels in the context of genetically modified plant applications for EU market authorisation (Technical Report)	20/08/2018		a)20/08/2020 b)20/10/2018	a) 24 months: if plant material needs to be generated b) 2 months: applies to those elements for which only the provision of information is recommended
2019	10.Administrative guidance on the submission of applications for renewal of authorisation of genetically modified food and feed under Articles 11 and 23 of Regulation (EC) No 1829/2003 (Technical Report)	24/06/2019		19/08/2019	8 weeks (EFSA letter of 11/07/2019 - Ref. EW/SM/yog – OC-2019-21679906)
	11.Human dietary exposure assessment to newly expressed proteins in GM foods (Statement)	31/07/2019		a) 01/10/2019 b) 31/07/2021	a) 2 months: consumption and concentration data b) 24 months: in case material needs to be generated (e.g. pollen)