Administrative and Procedural issues

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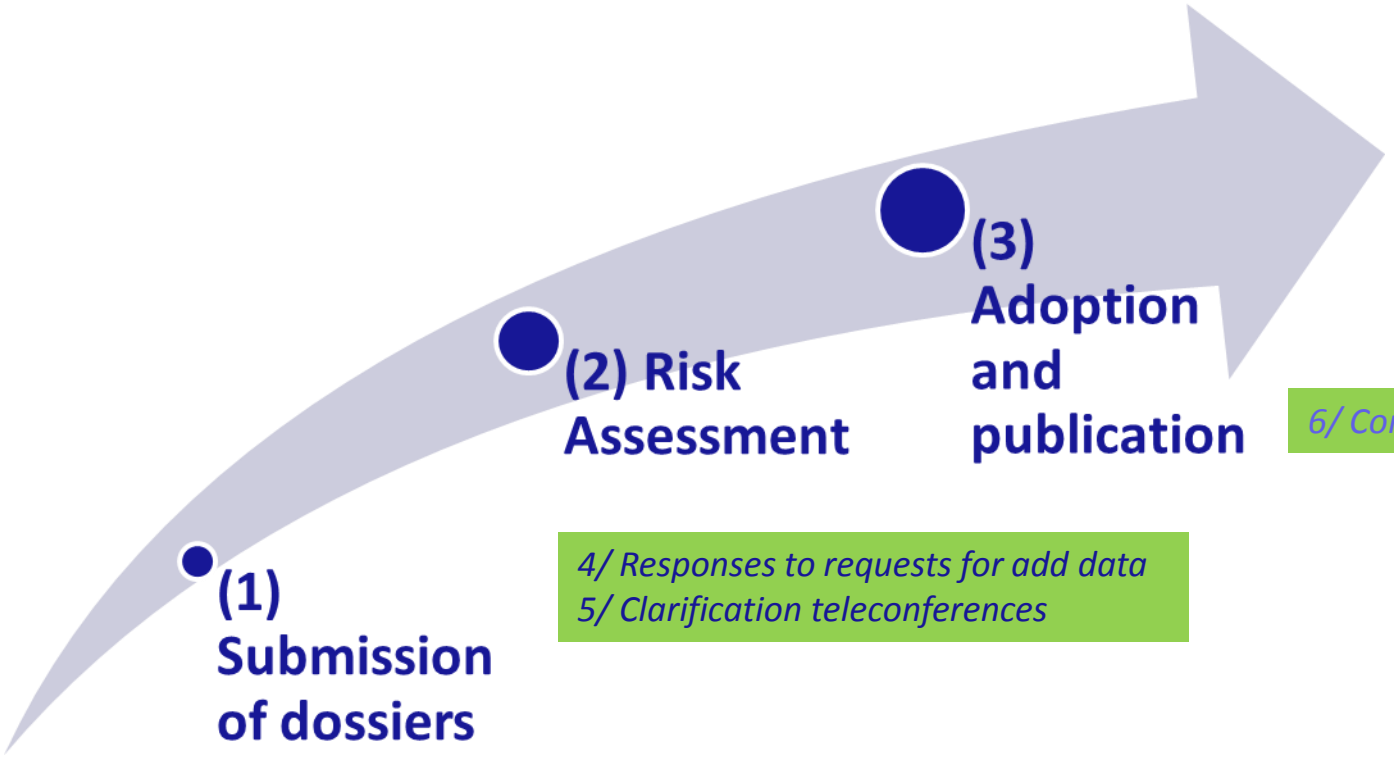
Information & reporting

Ad hoc meeting with GMO industry representatives
Parma, Italy - 9 November 2017

efsa
European Food Safety Authority

OUTLINE



1/ Overall quality of the dossiers
2/ Administrative submission guidance
3/ Technical (notes to) guidance: implementation

4/ Responses to requests for add data
5/ Clarification teleconferences

6/ Confidentiality

I. Submission of dossiers - Overall quality

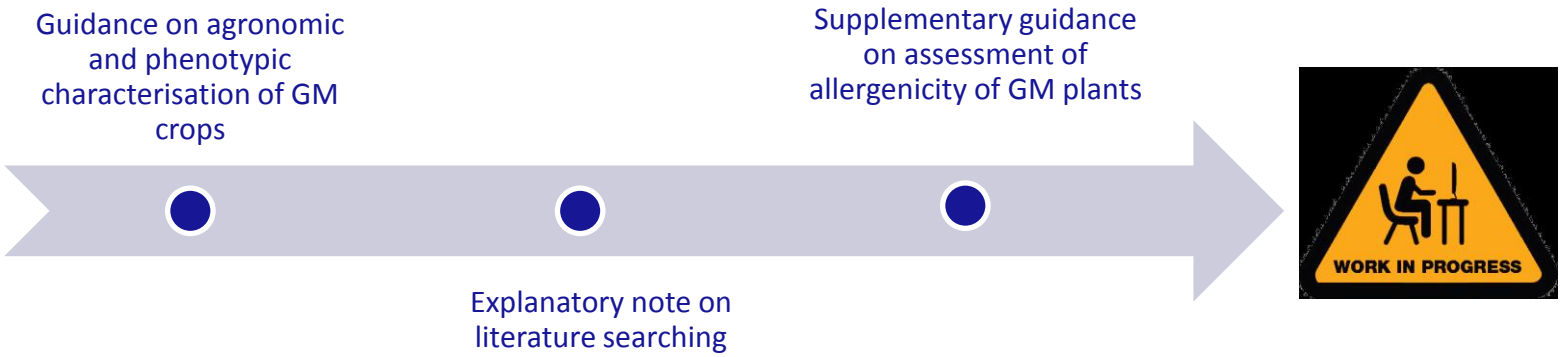
Tool	2013 EFSA Administrative Guidance on the submission of applications for authorisation of GM plants under Regulation (EC) No 1829/2003	
Scope	To guide applicants in preparing and submitting a structured and comprehensive dossier, i.e. made of requested data/information to be presented in the most appropriate format	
Our concern	Dossiers of lower quality	
Consequences	Applicant :	Lengthy completeness check and delayed start of RA
	EFSA :	Time-consuming extensive check of dossiers not up to enter the RA phase (e.g. MS consultation)

I. Submission of dossiers - Overall quality

A few basics to be met …

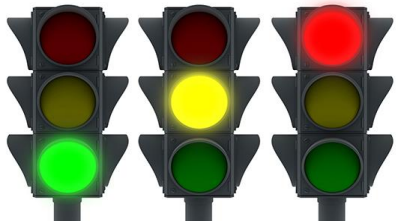
I. Submission of dossiers - Administrative GD

- Administrative GD = living document currently under revision to account for recent guidance documents and explanatory notes



- Publication foreseen end 2017
- Further update in the light of upcoming notes to guidance
- Guidance document on the submission of renewal applications under preparation

I. Submission of dossiers - Applicability of GDs



Principles

GDs not applied retroactively

Transition period , if any

Facts

Not applicable in case of clarifications on existing data/info

Applicable to requests for new data/info that need to be generated

Conclusion

New dossiers should fully comply with

- ❑ Agro/pheno → 24 June 2017
- ❑ Literature search → 10 October 2017
- ❑ Allergenicity → 22 December 2017 — For non-IgE-mediated adverse immune to food
  → 22 June 2018 or 2019 — For endogenous allergenicity depending if plant material needs to be generated

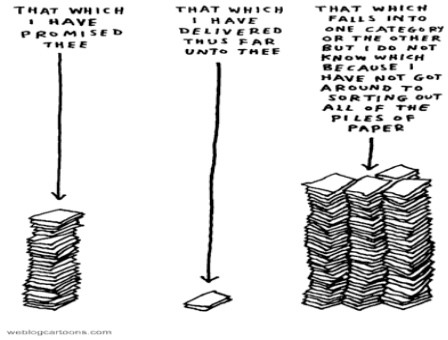
II. Risk assessment - Clock mechanism

Brief reminder of **principles**

- Questions are not reiterated*
- Within 30 WG from receipt of clock-stop letter, applicants are asked (1) to confirm that deadline to submit data can be met, or (2) to propose a new deadline (subject to justifications)
- Clock restarts at (1) receipt of requested datasets (full or partial*), or (2) if requested datasets will not be submitted *
- Spontaneous data are considered during the RA without stopping the clock

FYI Same principle of stop-and-restart the clock is applied to generic mandates based on the timeline set by the EC

II. Risk assessment - Incoming info…



Recent experiences re-additional dataset

- Complete…but of low quality
- Incomplete (e.g. statement referring to initial dossier but no additional evidence provided)
- Not submitted at the time of the request (spontaneously later during RA)
- Not submitted at all

II. Risk assessment - Incoming info…

Possible implications for EFSA and applicants owing to data gap

- To be detrimental to public trust in the RA system
- To trigger further delay in RA process and progress (e.g. additional WG meetings needed, discussion at WGs/Panel meeting postponed)
- Increased likelihood of inconclusive opinion

Our present suggestion Catalogue of services?

II. Risk assessment - Clarifications' teleconferences

- **EFSA's Catalogue of support initiatives** during the life-cycle of applications for regulated products

- Since our last meeting
  - **16 tele-meetings** (14 during RA, 2 post-adoption) on GM products for (continued) placing on the market
  - Broad range of questions

II. Risk assessment - Clarifications' teleconferences

Common goal…common understanding for streamlining the RA

Constraints owing to the scope of such meetings, i.e.

- To clarify the scientific rationale of individual questions raised during the risk assessment;
- To ensure understanding of the question to be answered by the applicant.

Thanks to provide your questions/**points of concern ahead of the meeting**

Follow up e-mail/letter

II. Risk assessment - EuropaBio comments on RA process

Objective

To streamline the RA of GMOs and to reduce the timeline

(Generic) Suggestions

- Questions from JRC-EURL should not prevent WGs to start discussing data
- WGs should kick-off RA of data immediately after validity of dossiers
- Need a procedure for better coordination of contractors' reports

II. Risk assessment - EuropaBio comments on RA process

Objective

To streamline the RA of GMOs and to reduce the timeline

(Specific) Suggestions

- Questions to applicants
  - Critical questions triggering generation of new studies should be sent within 3 month timeline after validity
  - Minor clarifications should be asked within a 4 month timeline and only when major issues were solved
  - Follow-up questions should be sent within 1-3 months after receipt of 'previous' add. Dataset
  - Favouring clusters of questions, irrespective of areas of risk
  - Questions should include a clear rationale
- When a report has been assessed 'positively', it should not be re-assessed owing to new guidelines or experts turn-over.

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Thank you for your attention!