# EFSA scientific outputs: Special focus on inconclusive opinions

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# ABOUT THIS PRESENTATION

- Reasons for inconclusiveness
- Preventing and follow-up measures by EFSA
- Follow-up procedure
- REPRO Administrative guidance

# REASONS FOR INCONCLUSIVENESS (1/3)

- Lack of sufficient data to conclude the risk assessment (e.g.)
  - Lack of toxicological study
  - Incomplete set of data linked to genotoxicity
  - Lack of complete set of compositional data,
  - data to characterise the process / the product
  - Lack of data on efficacy
  - Waiving of data
  - Inadequate study design

# REASONS FOR INCONCLUSIVENESS 2/3

| Real examples | Impact for risk assessment | Conclusions (after request for add info) |
|---|---|---|
| Lack of data on dietary exposure | Incomplete assessment of possible impact on human health and nutrition | Inconclusive scientific opinion |
| Lack of data on compositional data + lack of toxicological study (28-days) | Incomplete toxicological, allergenicity, nutritional assessment | |
| Lack of data to characterise new product/nutrient | Incomplete assessment on safety | |
| Lack of complete set of data (AMES test) to conclude on absence of gene mutation | Incomplete assessment on genotoxicity | |
| Lack of adequate methodology of *in vitro* test | Incomplete assessment on genotoxicity | |
| Insufficient quality of 90-day oral toxicity study | Incomplete assessment | |
| Inadequate characterisation of process (e.g. challenge test) + lack of evidence of level of contamination | Incomplete safety assessment to human health | |

# REASONS FOR INCONCLUSIVENESS 3/3

| Real examples | Impact for risk assessment | Conclusions (after request for add info) |
|---|---|---|
| Lack of efficacy studies + lack of data skin/eyes/dermal sensitisation | Incomplete assessment on safety and efficacy for specific target species | Inconclusive scientific opinion |
| Uncertainties related to the potential accumulation of product over time | Incomplete assessment on safety and efficacy | |
| Lack of data identification + lack of data skin/eyes/dermal sensitisation + inadequate efficacy study design | Incomplete assessment safety and efficacy | |
| Waiving of data (e.g. metabolites relevant for surface water) | Gaps in risk assessment | Gaps in EFSA conclusions (Peer review) |
| Inadequate *in vitro* genotoxicity study design | Gaps in risk assessment | |
| Incomplete data per crops | Gaps in risk assessment for specific crops | Gaps in EFSA reasoned opinions (MRL) |

# PREVENTING AND FOLLOW-UP MEASURES BY EFSA

Some activities have been put in place (Catalogue of services) by EFSA **to prevent inconclusive opinions** and to clarify doubts on adopted scientific outputs:

- Roundtable with industry associations

  } Before submission (general aspects)

- Ad-hoc mtg with industry representatives
- Webinars & Info sessions

  } During entire life-cycle of applications

- Stop-the-clock mechanism
- Clarification teleconference during RA
- Applicants' hearing

  } During Risk assessment

- Post-adoption teleconference

  } After adoption

# FOLLOW-UP PROCEDURE

Based on the information available in the application and in the **additional/supplementary information** provided by the applicant, **EFSA** proceeds with the finalisation of the risk assessment and **concludes on the available data**.

Several **follow-ups** are possible:

- The **EC concludes** on available data and assessment performed by EFSA
- The **EC requests** the applicant to submit **complementary information** to address the data gaps. The **EC mandates EFSA** to perform the RA on the supplementary information putting it into context of the previous assessment
- The **applicant resubmits a full dossier** including the information originally not provided. EC/MS mandates EFSA to assesses the newly submitted application

→ Procedure to include in next update of the EFSA Administrative guidance for processing applications for Regulated Products

# REPRO ADMINISTRATIVE GUIDANCE

**Added value in:**

- Providing clear procedure and timelines
- Describing key steps of the scientific risk assessment
- Positioning EFSA's engagement to comply with general and specific principles
- Clarifying the possibility of interactions between EFSA and applicants (Link to **Catalogue of services**)

**Applicants to pay attention to:**

- Rules to stop-the-clock (chapter 2.6)
- Rules to re start-the-clock (chapter 2.7)
- Respect legal deadlines
- Rules for publications (chapters 2.11; 2.12)
- Not yet covering all workflows

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