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

<table>
<thead>
<tr>
<th>Real examples</th>
<th>Impact for risk assessment</th>
<th>Conclusions (after request for add info)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lack of data on dietary exposure</td>
<td>Incomplete assessment of possible impact on human health and nutrition</td>
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<tr>
<td>Lack of data on compositional data + lack of toxicological study (28-days)</td>
<td>Incomplete toxicological, allergenicity, nutritional assessment</td>
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<tr>
<td>Lack of data to characterise new product/nutrient</td>
<td>Incomplete assessment on safety</td>
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<tr>
<td>Lack of complete set of data (AMES test) to conclude on absence of gene mutation</td>
<td>Incomplete assessment on genotoxicity</td>
<td>Inconclusive scientific opinion</td>
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<td>Lack of adequate methodology of <em>in vitro</em> test</td>
<td>Incomplete assessment on genotoxicity</td>
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<td>Insufficient quality of 90-day oral toxicity study</td>
<td>Incomplete assessment</td>
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<tr>
<td>Inadequate characterisation of process (e.g. challenge test) + lack of evidence of level of contamination</td>
<td>Incomplete safety assessment to human health</td>
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### REASONS FOR INCONCLUSIVENESS 3/3

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<td>Lack of efficacy studies + lack of data skin/eyes/dermal sensitisation</td>
<td>Incomplete assessment on safety and efficacy for specific target species</td>
<td>Inconclusive scientific opinion</td>
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<tr>
<td>Uncertainties related to the potential accumulation of product over time</td>
<td>Incomplete assessment on safety and efficacy</td>
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<tr>
<td>Lack of data identification + lack of data skin/eyes/dermal sensitisation + inadequate efficacy study design</td>
<td>Incomplete assessment safety and efficacy</td>
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<td>Waiving of data (e.g. metabolites relevant for surface water)</td>
<td>Gaps in risk assessment</td>
<td>Gaps in EFSA conclusions (Peer review)</td>
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<tr>
<td>Inadequate <em>in vitro</em> genotoxicity study design</td>
<td>Gaps in risk assessment</td>
<td></td>
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<tr>
<td>Incomplete data per crops</td>
<td>Gaps in risk assessment for specific crops</td>
<td>Gaps in EFSA reasoned opinions (MRL)</td>
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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
- Ad-hoc mtg with industry representatives
- Webinars & Info sessions
- Stop-the-clock mechanism
- Clarification teleconference during RA
- Applicants’ hearing
- Post-adoption teleconference

Before submission (general aspects)
During entire life-cycle of applications
During Risk assessment
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
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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