6.MS COMMENTS ON WHOLE FOOD AND FEED INCLUSION RATES IN 90-DAY STUDIES

***Ad hoc* meeting with GMO Industry Representatives**

25 March 2026

EUROPEAN FOOD SAFETY AUTHORITY

ITEM PRESENTED AT THE GMO NETWORK MEETING

Background

- From MS comments, in some cases concerns have emerged about inclusion rates used in 90-day toxicity studies with whole GM food/feed.

GMO network role

- Review the issue and its implications;
- Assess whether EFSA (2014) inclusion-rate recommendations should be updated;
- Identify gaps and gather scientific evidence to support potential future recommendations.

EFSA 2014 RECOMMENDATIONS

European Food Safety Authority

EFSA Journal 2014;12(10):3871

STATEMENT OF EFSA

Explanatory statement for the applicability of the Guidance of the EFSA Scientific Committee on conducting repeated-dose 90-day oral toxicity study in rodents on whole food/feed for GMO risk assessment[1]

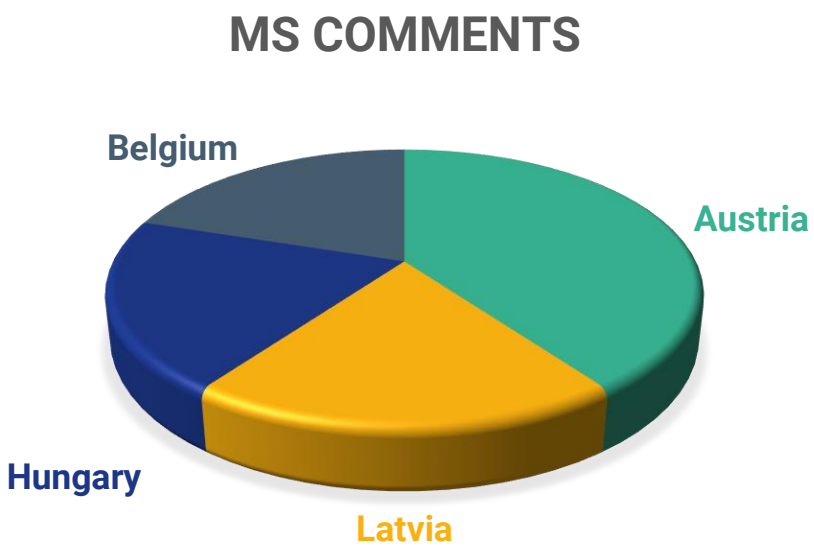
European Food Safety Authority[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

2.2.3. Dose groups and dose levels selection

On the basis of current knowledge the following incorporation rates are proposed as reference values for high doses in 90-day studies in rodents: 60% for rice (dehulled) (e.g. Wang et al., 2013); 50% for maize (e.g. Zhu et al., 2013); 30% for soybean meal (e.g. Snell et al., 2012); 25% for rapeseed meal (e.g. Delaney et al., 2014), 20% for fullfat soybean (Seerly et al., 1974), potatoes (heated, dried) (Nouri-Ellouz et al., 2014). For other whole GM food/feed, reference to to the best knowledge of the formulator and to the available literature is recommended;preliminary exploratory studies (e.g. dose range studies) might also be considered to set the high dose if necessary.

DEVIATIONS/UNCLARITIES FROM EFSA (2014)



Oilseed rape meal

- Applicants used **15%** inclusion rate
- EFSA (2014) recommends **25%**
- Several MS questioned whether **15%** is sufficiently sensitive according to EFSA (2014)

Sugar beet pulp

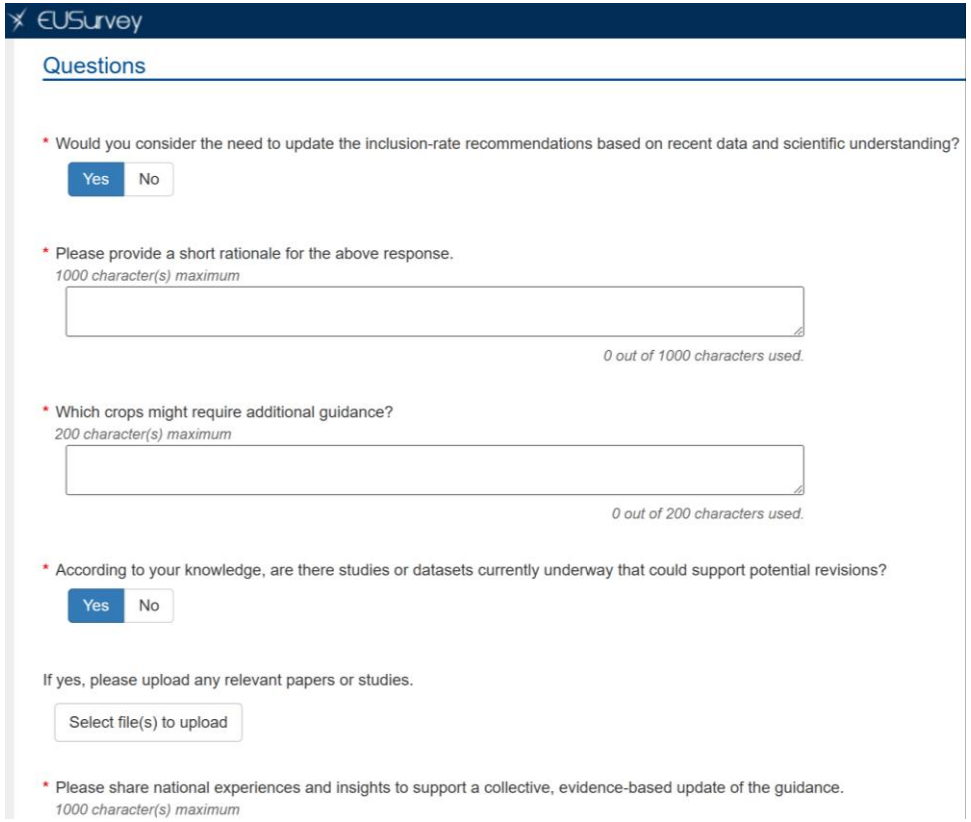
- Applicants used 5% inclusion rate
- Lack of recommendations in EFSA (2014)
- Several MS questioned whether 5% is too low to detect possible effects

Only for **soybean** is specified the inclusion rate to be used in case of defatted (**30%**) or full fat meal (**20%**).

EU SURVEY – EFSA QUESTIONS

The survey focused on assessing:

1. The need for **updating inclusion-rate recommendations** based on recent data and scientific insights;
2. Identified which **crops** might require additional guidance;
3. Requested **relevant studies or datasets** to support any proposed revisions.


EUSurvey

Questions

* Would you consider the need to update the inclusion-rate recommendations based on recent data and scientific understanding?

Yes No

* Please provide a short rationale for the above response.

1000 character(s) maximum

0 out of 1000 characters used.

* Which crops might require additional guidance?

200 character(s) maximum

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* According to your knowledge, are there studies or datasets currently underway that could support potential revisions?

Yes No

If yes, please upload any relevant papers or studies.

Select file(s) to upload

* Please share national experiences and insights to support a collective, evidence-based update of the guidance.

1000 character(s) maximum

EU SURVEY – FEEDBACK RECEIVED

- An update might be needed based on **more recent and robust scientific data** to reflect current knowledge;
- **Absence of recommendations** for certain crops have been confirmed (e.g. sugar beet);
- Few relevant studies have been provided;
- Inclusion rates should match **livestock feeding practices**.

These comments will be proposed for discussion with Food & Feed experts at the upcoming meetings

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