



Dietary Exposure Assessment

16 November 2022

Content



CropLife Europe comments on the draft EFSA Statement:

Animal dietary exposure in the risk assessment of feed derived from genetically modified plants



CLE comments on the draft EFSA Statement

A general principle applied in risk assessment is that exposure assessment is performed only in case a hazard has been identified.

- CLE asks that the GMO Panel provide a rationale for why it is proportionate to deviate from the general risk assessment principle.
- The statement referring to the requirement in IR 503/2013 should also consider and refer to the derogation article (Article 5) in the regulation that allows to not submit specific information (in this specific case, the animal dietary exposure) provided that is not scientifically necessary.

CLE comments on the draft EFSA Statement

The statement provides guidance for ADE of NEPs and only NEPs not identified as hazards

- Even for NEP for which a hazard cannot be excluded the same process can be applied since it is sufficient conservative.
- The terms “dietary exposure” and “maximum dietary burden” in the Statement should be replaced by “dietary intake estimation”

Selection of animal species:

- Reg 503/2013 requires an estimate of the expected intake of genetically modified food and feed. The regulation does not mention or distinguish farmed or companion animals or any specific animal category or species.
 - "particular groups of the EU population" refers to human population
- Can EFSA provide definitions for farmed and companion animals?

CLE comments on the draft EFSA Statement

The draft Statement is missing information:

- EU-based feed consumption data
- Inclusion rates in Tables 5a-e.
- Processing factors in Tables 6a+b, references for processing factors
- Procedure if IR% is exceeding 100%

NEP concentration data and adjusting/processing factors:

- Can the ad hoc adjusting/processing factors be revised based on experimental data?

Timelines

- CLE would like to know when the statement is going to be implemented
- The transition period should be discussed