Statement on human dietary exposure assessment to newly expressed proteins in GM foods (2019)

23 October 2019

CropLife International Dietary Exposure Assessment Working Group

- Industry group working to advance best practices in conducting dietary exposure assessments (DEA)
- DEA proposal update on publication status
- Welcomes the opportunity to provide feedback to EFSA
- Crop specific files are highly appreciated

General principles

Most risk assessors use stepwise approach

- Problem formulation to design fit for purpose DEA
- Develop a simple, straight-forward, and fit for purpose DEA to address relevant concerns
- Detailing refinements if a more comprehensive DEA is needed

In line with EFSA statement

- ✓ "*Irrefutable scientific evidence showing that the compounds under assessment are shortly degraded/removed during food processing or after ingestion without generating other compounds that may represent a hazard would indicate that dietary exposure estimations are not needed (EFSA GMO Panel, 2019)*"
- ✓ Case-by-case additional needs are indicated in different parts of the EFSA statement

Concentration data

- Consider plant tissues and growth stages most representative for consumption
- Matching raw primary commodities (RPC) newly expressed protein (NEP) concentration with food product consumption
  - Which food composition database is recommended by EFSA
- For bulk commodities use mean concentration data
- NEP not present in e.g. oil, syrup, starch, sugar, and distilled alcohol
- Info on processed fractions on case-by-case basis
  - Use mean NEP concentration instead of highest quartile data

Concentration data

Guidance on determination on NEP concentration is provided in

- Impl. Reg. 503/2013 & EFSA Expl. Note NEP determination: number of sites = 3
- EFSA Expl. Note*: flexibility regarding the specific experimental approach
- EFSA Expl. Note*: reporting on number of samples, acceptance criteria…
- Out of the scope of the Human DEA Statement

EFSA, 2018: Explanatory note on the determination of newly expressed protein levels in the context of genetically modified plant applications for EU market authorisation. DOI: 10.2903/sp.efsa.2018.EN-1466

Consumption data

- If not sufficient consuming days for Acute or number of consumers for Chronic high consumer assessment
  - if <60 but >5 → use mean
  - If <5 → exclude data because also mean might not be robust

- Use of Pesticide Residue Intake Model (PRIMo)

Overestimation

- 100% substitution rule
- Inclusion of single consumer findings
- Processed fractions (if applicable) use of high quartile of NEP conc combined with 95th percentile of dominant food

With addition of uncertainty statements will it be transparent enough that values are large overestimations?

Overestimation

Solution to avoid overestimation

1. Considering market share of GM crop and GM constituents in food in EU
2. Remove consumers/days less than 5
3. Use mean of NEP conc for processed fraction, if applicable

Ad-hoc scenarios

What would trigger these?

In cases of new food/food uses of GM crop

Protein isolates

Pollen supplements

Reporting

- Include access date to EFSA GMO tool website
- Information on how protein concentrations are available in the related study report and this report will be referenced

Transition Period

- End of two months transition period: 1 Oct 2019
- No NEP conc in pollen available: extended transition phase 1 Aug 2021
- Human DEA done before 1 Oct 2019 remain valid and should not need an update

Feedback on EFSA Recommendations

Concluding remarks on Human Exposure:

- Stepwise approach: straight forward screening, refinement only if needed
- Crop specific data available
- Confirmation NEPs not present in e.g. oil, syrup, starch, sugar, distilled alcohol
- Match RPC with food product: use conversion factor or protein ratio

Feedback on EFSA Recommendations

Concluding remarks on Human Exposure:

- DEA done by default, even if no hazard was identified
- Scenario is too conservative: combination of 100% substitution, single consumer findings, calculation with high quartile data for processed fraction (if applicable)
- Determination of NEP conc out of scope

Feedback on EFSA Recommendations

Animal Exposure, reiteration of 2018 suggestions:

- Exposure estimates for forage in import applications
- Estimates of livestock exposure should be used as surrogates for other animal species

Applicants are willing to get involved in future discussions and development of documents

Back-up Slide

Inclusion of pollen supplements in human DEA:

- Bee-collected pollen mainly from bee-attractive flowers.
- Less relevant for self-pollinating or wind-pollinated crops (i.e. soybean, corn, cotton, rice, etc.). There are studies refuting bee exposure to pollen of self-pollinating crops.
- Results from pollen analysis showed low percentage of soybean, corn, cotton and brassica pollen in bee-collected pollen samples*
- 100% substitution rule is a >> overestimation of the actual presence of GM species pollen
- Few consumers in UK, France, and Estonia who eat 1-13 g/day. Total population consumption of pollen supplement is very low; scattered and not robust data for DEA.

* Reference:

Bonvehi and Jorda, 1997; Feas et al., 2012; Nogueira et al., 2012; Smart et al., 2016; Lau et al., 2019.