

FOOD CONSUMPTION DATA AND DIETARY EXPOSURE ESTIMATIONS FOR GMO RISK ASSESSMENT

AD HOC MEETING WITH GMO INDUSTRY REPRESENTATIVES 19 MARCH 2025

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CURRENT SITUATION

- Summary statistics of consumption available in EFSA website for maize, oilseed rape, soybean and cotton (here).
- ➤ Guidance on how to use the summary statistics to estimate chronic and acute dietary exposure to newly expressed proteins is provided in the 2019 EFSA statement (here).
- Mandatory to use this methodology as of August 2021.
- ➤ Last update of the consumption data: March 2022.



CURRENT SITUATION

PROS

- Harmonised approach to estimate dietary exposure.
- > Quick and easy to use, fit for purpose in most of the cases (IR requirements).
- Suitable for both acute and chronic dietary exposure.

CONS

- ➤ Food codification in FoodEx1 system; <u>outdated</u>: only food domain not yet in FoodEx2.
- > Over-conservative dietary exposure estimations that might not be suitable to conclude on safety in certain occasions.
- ➤ Not adequate for the assessment of nutritionally altered crops (e.g., focused only on few crops).



FUTURE

- > For **standard applications** (assessment of newly expressed proteins).
- > For **nutritionally altered crops** (e.g. modification of the fatty acid profile).



STANDARD APPLICATIONS - NEWLY EXPRESSED PROTEINS

- ➤ Summary statistics of consumption to be used until the end of 2026. No update foreseen in 2025; in 2026 to be decided.
- ➤ In 2027, dietary exposure estimations to be conducted with new harmonised tool currently under development.
- Individual consumption data from the EFSA comprehensive food consumption database (EFSA Consumption DB). Data disaggregated to Raw Primary Commodities (RPC) and RPC derivatives using the RPC model.
- ➤ Concentration values from raw primary commodities (e.g., maize grains) to be used in the tool (as submitted in the application dossier). Possibility to exclude food commodities not relevant for the dietary exposure (e.g. oil).

NUTRITIONALLY ALTERED CROPS

- > DietEx tool should be used to conduct nutritional intake assessments.
- ➤ DietEx is a user-friendly tool to estimate **long-term** (chronic) dietary intake/exposure (<u>here</u>).
- DietEx tool makes use of individual consumption data from the EFSA Consumption DB for different countries, age groups and special population groups (i.e. "Pregnant women", "Lactating women" and "Vegetarians").
- ➤ New version was released at the end of February 2025.



NUTRITIONALLY ALTERED CROPS

CONSUMPTION and CONCENTRATION VALUES

- To be used in "replacement intake scenarios" (e.g. nutritionally altered crops) to predict intake during pre-market risk assessment considering intended uses. Dietary exposure tool used in EFSA Novel Food applications to assess intake/exposure.
- Concentration values (e.g., for fatty acids) to be input in processed commodities based on intended uses to be given to GM commodities (e.g., oil).
- ▶ <u>DietEx tool</u> produces mean and 95th percentile CHRONIC dietary exposure estimates by age class across EU countries.



...NEXT STEPS...

- Live demonstrations of **DietEx** to be provided if needed.
- Feedback by applicants to be discussed at next applicant meeting/s.
- EFSA to provide update on the on-going work with the new tool under development for the standard applications (e.g., e-mail, upcoming applicant's meetings).





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