

STATEMENT OF EFSA

Use of EFSA Comprehensive European Food Consumption Database for estimating dietary exposure to genetically modified foods¹

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ABSTRACT

Dietary exposure is an essential element of a risk assessment of genetically modified (GM) foods. This is primarily used following the identification and characterisation of a hazard, or for the assessment of the nutritional consequences after consumption of GM foods with altered nutritional profile and then for the full risk characterisations. A crude estimate of dietary exposure may also be used during hazard identification / characterisation to support the choice of dose regimes. Implementing Regulation (EU) No 503/2013 requires that a dietary exposure assessment is carried out on the basis of representative consumption data, and that it should consider also particular consumer groups. The EFSA Comprehensive European Food Consumption Database is currently the only available single source of consumption data in Europe, its use is encouraged for all GM applications. This statement provides technical advice on the use of the EFSA Comprehensive database for the dietary exposure assessment of GM foods.

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KEY WORDS

Comprehensive Food Consumption Database, dietary exposure, GM foods

¹ On request from EFSA, Question No EFSA-Q-2014-00674, approved on 19 February 2015.

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³ Acknowledgement: EFSA wishes to thank Yi Liu, Davide Arcella, Hildegard Przyrembel and Andrew Chesson for drafting this scientific output, and members of the Working Group on Food and Feed Safety Assessment for the review. This scientific output is endorsed by the EFSA Panel on Genetically Modified Organisms on 21 January 2015.

Suggested citation: European Food Safety Authority, 2015. Use of EFSA Comprehensive European Food Consumption Database for estimating dietary exposure to genetically modified foods. EFSA Journal 2015;13(2):4034, 11 pp., doi:10.2903/j.efsa.2015.4034

Available online: www.efsa.europa.eu/efsajournal

SUMMARY

This statement is written to provide further clarification on the use of the Comprehensive European Food Consumption Database for exposure assessments of GM foods, as requested by stakeholders.

In the European Union (EU), foods derived from genetically modified organisms (GMOs) are subjected to a risk assessment before authorisation. Dietary exposure is one essential element of the risk assessment of GM foods. Implementing Regulation (EU) No 503/2013 requests that the anticipated dietary intake is estimated on the basis of representative consumption data. Data on import and production quantities may provide additional information for the intake assessment.

In collaboration with Member States, EFSA established the Comprehensive European Food Consumption Database. This database provides summary statistics of data from national dietary surveys for different age classes, from infants to the very elderly. Two sets of data are provided, one suitable to estimate chronic consumption of substances in food and the other for acute consumption. The calculation for chronic consumption is based on individual average consumption over the total survey period, whereas, for acute consumption, the calculation is based on data from every single reporting day. This database is currently the only available single source of consumption data for Europe; therefore, its use is encouraged for GM applications.

Within the risk assessment of GM foods, a crude estimate of dietary exposure to GM foods is used during hazard identification / characterisation to support the choice of dose regimes. If a hazard is identified, then a more refined dietary exposure is necessary to determine the associated risk. A refined exposure assessment will be needed to assess the consequences following consumption of GM foods with altered nutritional profiles. This statement provides the technical advice on how to make the best use of the EFSA Comprehensive Database for estimating dietary exposure to GM foods, and to meet the requirements stipulated by Implementing Regulation (EU) No 503/2013.

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BACKGROUND AS PROVIDED BY EFSA

Before being released into the European Union (EU) market, food/feed products derived from genetically modified organisms (GMOs) are subjected to a risk analysis and regulatory approval. A core activity of the European Food Safety Authority (EFSA) is to assess applications submitted under Regulation (EC) No 1829/2003, and publish the outcome in scientific opinions. To ensure consistent and transparent risk assessment, guidance documents are published by EFSA to further specify the guiding principles of the risk assessment topics and data required in the applications (EFSA GMO Panel, 2011). On 8 June 2013 Implementing Regulation (EU) No 503/2013⁴ came into force, specifying scientific requirements for the risk assessment of GM food/feed.

Dietary exposure is an essential element of the risk assessment on GM foods. Depending on the objectives of a study, the choice of method for assessing dietary exposure differs. The accuracy of any exposure assessment will ultimately depend on the accuracy of the two calculation inputs – food consumption and concentration of the materials under consideration in foods. In 2011, EFSA created the EFSA Comprehensive European Food Consumption Database (Comprehensive Database). It has been built from existing national information on food consumption at a detailed level. Competent organisations in the European Union's Member States provided EFSA with data from the most recent national dietary surveys in their country, at the level of consumption by the individual consumer. Summary statistics from this database are publically available on the EFSA website, together with guidance on how to use it (EFSA, 2011a).

In September 2013 and May 2014, CropLife International and EuropaBio sought clarification regarding the assessment of dietary exposure to newly expressed proteins or other constituents in genetically modified (GM) foods, and how to make the best use of the EFSA Comprehensive Database to estimate dietary intake. On 23 July 2014, one applicant submitted additional technical questions to EFSA on the use of this database.

As some of these technical requests go beyond what is included in the existing relevant guidance documents, in line with EFSA's commitment to openness and transparency, EFSA publishes this statement to make the technical advice publicly available to all stakeholders.

TERMS OF REFERENCE AS PROVIDED BY EFSA

EFSA requests the GMO and DATA units to publish a technical explanatory note, in the form of a 'Statement of EFSA', on the use of the Comprehensive Database for dietary exposure assessment for GM foods.

This technical explanatory note should provide technical instructions on how to best use summary statistics from the Comprehensive Database to estimate dietary exposure to newly expressed proteins or constituents in genetically modified (GM) foods. It should provide explanations/guidance to the following key items: general feature of the database, food classification and aggregated food groups, population groups (e.g. total populations vs. consumers only), chronic consumption and acute consumption, possibility of making comparison across EU countries, etc. The output should also discuss occurrence data in generic terms, but technical details concerning the choice of materials from which to derive the occurrence data will be addressed in a separate document.

CONTEXT OF THE SCIENTIFIC OUTPUT

In GMO applications submitted for risk assessment under Regulation (EC) No 1829/2003, applicants have been generally using the food balance sheets from the Food and Agriculture Organization Corporate Statistical Database (FAOSTAT)⁵ to estimate dietary exposure. The food balance sheets are based on data from import, production and food spoilage. They show primarily raw commodity availability for human consumption, but do not provide data on the amount of foods consumed. The

⁴ <http://eur-lex.europa.eu/JOHtml.do?uri=OJ:L:2013:157:SOM:EN:HTML>

⁵ Accessible at <http://faostat.fao.org/>

food balance sheets can only be used to estimate the per capita consumption of primarily raw commodities but do not provide information on high or low consumers and neither on acute consumption.

Individual dietary (i.e. consumption) surveys are the only surveys that provide information on the distribution of food consumption in well-defined groups of individuals and data from individual dietary surveys are understood to reflect more closely actual consumption (Kroes et al., 2002; WHO, 2009). Consumption data collected through individual dietary surveys are, therefore, the preferred choice for the assessment of dietary exposure within the risk assessment process (Kroes et al., 2002). In 2011, EFSA created the Comprehensive Database, together with guidance on its use in dietary exposure assessment (EFSA, 2011a). Authorisation of GM products occurs at EU level. The EFSA Comprehensive Database is currently the only available single source of consumption data covering the majority of EU Member States.

This statement is addressed to applicants wishing to submit a technical dossier for the pre-market safety evaluation of food products derived from GM plants in the European Union. It is intended to provide technical advice on how to make the best use of the Comprehensive Database for estimating dietary exposure to GM foods, and to meet the requirements stipulated by Implementing Regulation (EU) No 503/2013.

CONSIDERATION

1. Introduction

A crude estimate of dietary exposure to GM foods is used during hazard identification / characterisation to support the choice of dose regimes. If a hazard is identified, then a more refined dietary exposure is necessary to determine the associated risk. A refined exposure assessment will be needed to assess the consequences following consumption of GM foods with altered nutritional profiles.

The exposure assessment of a hazardous substance is based on estimates of the observed consumption of all foods that may contain that substance - preferably in representative samples of the population. This is followed by multiplication of the amounts of food consumed by the known or predicted concentrations of the substance in each food, to arrive at the total daily exposure to that substance by members of a defined population group. These data are then compared with toxicological data to assess risk.

The outcome of the compositional analysis decides whether a detailed nutritional assessment is required for specific nutrient(s) (EFSA GMO Panel, 2011; EC, 2013). The nutritional assessment of GM foods is intended to demonstrate that the GM food is not nutritionally disadvantageous to humans. This can be a consequence of new constituents, or constituents that occur naturally in the concerned crop but at altered levels in the GM crop as a consequence of the genetic modification (EC, 2013).

1.1. Needs for exposure assessment of GM foods

To date, the majority of GM plants have been engineered to express one or more novel proteins intended to confer tolerance to herbicide or resistance to insect pests. Levels of expression of such proteins are not expected to have a nutritional impact, and so any need for a refined exposure assessment is restricted to the cases where a potential adverse event can be identified. However, a crude estimate of exposure may be required to support the choice of dose regimes used during hazard identification / characterisation (e.g. toxicological tests of the newly expressed proteins in GM crops). In this context, worst-case exposure scenarios should be considered, such as acute exposure. For this purpose, the EFSA Comprehensive Database is the preferred source of consumption data.

For those GM plants which (a) contain new constituents other than the newly expressed proteins or (b) have a modified nutritional profile, a more refined assessment of consumer exposure relevant to European consumption patterns would be required. In this context, more realistic exposure scenarios should be considered; the focus should be chronic exposure in the habitual diet of the general population and subsets of consumers particularly at risk (e.g. both high and low consumers of particular nutrients). In the first instance, other types of consumption data, such as the FAO food balance sheets or literature, can help in identifying the countries or geographical areas for which a dietary exposure should be made. The European country with the highest consumption should be selected to estimate the dietary intake. However information at the level of individual consumers might not be available to an applicant for the country identified. In this situation, the EFSA Comprehensive Database can be used to identify alternative datasets for countries with a comparable consumption pattern.

For GM plants that are engineered to overexpress a particular constituent, there is likely to be an accompanying reduction in other constituents. These accompanying changes must be taken into consideration in the exposure assessment. Finally a judgement should be made on the impact of the predicted changes on the overall diet and its impact on human health. An example is the GM soybean producing fat with a high concentration of oleic acid, where the nutritional assessment needs to address not only the increased intake of oleic acid, but equally importantly, the nutritional impact of the associated changes in other fatty acid(s) in the soybean oil.

1.2. EFSA Comprehensive Database

The EFSA Comprehensive European Food Consumption Database (Comprehensive Database) is a compilation of existing national information on food consumption at the individual level. It was first built in 2010 (EFSA, 2011b; Huybrechts et al., 2011; Merten et al., 2011). Dietary data were accepted for inclusion in the database only if they were collected at the individual level by means of (replicates of) 24-hour dietary recalls or dietary records. Data providers mapped all food descriptors present in their national food consumption database according to a unique classification system developed by EFSA. The first version of which is referred to as FoodEx 1 (EFSA, 2011b). Since 2014 food consumption data have also been codified according to the FoodEx2 system⁶ (EFSA, 2011c). The hierarchical classification of this system is further complemented by additional information which describes properties and aspects of foods from various perspectives. As a result of the use of the FoodEx2 system, the food consumption data included in the Comprehensive Database provide a higher level of detail of the food descriptors than the previous release.

Owing to methodological differences in the various surveys, the collected dietary data between different dietary surveys cannot be reliably collated to allow an assessment of dietary exposure at an overall European level. Consequently, dietary exposure has to be assessed at the country level, in order to be protective of public health for the whole of Europe (EFSA, 2005; WHO, 2009). Multinational calculations should provide exposure estimates that are equal to or greater than the highest exposure observed at national level.

Only summary statistics from the Comprehensive Database are currently available to applicants. Food consumption data for each country are presented according to either 20 broad categories or around 160 sub-categories. The database is classified by age (Infants⁷, Toddlers⁸, Other children⁹, Adolescents¹⁰, Adults¹¹, Elderly¹² and Very elderly¹³), and for each class and dietary survey food consumption summary statistics are given for the total population and for consumers only. The Comprehensive Database provides a good coverage of European food habits in the adult population and, in particular, with the second release, a reasonable coverage for the other age classes, including toddlers and infants.

Summary statistics of food consumption data for the most common GM food crops (e.g. maize, soybean, potato) are available to applicants on EFSA's website¹⁴ to assist in carrying out both chronic and acute exposure assessments.

1.3. Use of summary statistics from the EFSA Comprehensive Database

In the absence of actual consumption data on GM foods, the possible dietary intake of GM foods should be estimated by substituting a GM ingredient for its non-GM counterpart. In the first instance, a scenario using full substitution should be carried out, and only if concerns are identified (e.g. health-based guidance value exceeded), should a more realistic scenario be considered. For example, when assessing the dietary exposure to foods derived from a GM soybean, all ready-to-eat soybean-based foods should be considered (such as e.g. soya cheese, soya drink, soybean oil, soya yoghurt and soya-based infant formula, etc.) but also other foods using soybean as ingredient at industrial level (e.g. soybean oil in composite foods such as fine bakery wares) should be considered.

Summary statistics from the Comprehensive Database can be used as a screening tool to assess chronic and acute exposure to hazardous substances. They can be used to identify substances that might be a safety concern and to prioritise the use of resources for risk assessments. For example,

⁶ <http://www.efsa.europa.eu/it/datex/datexfoodclass.htm>

⁷ up to and including 11 months

⁸ from 12 up to and including 35 months of age

⁹ from 36 months up to and including 9 years of age

¹⁰ from 10 up to and including 17 years of age

¹¹ from 18 up to and including 64 years of age

¹² from 65 up to and including 74 years of age

¹³ from 75 years of age and older

¹⁴ available at <http://www.efsa.europa.eu/en/datexfooddb/datexfooddbspecificdata.htm>

because of elevated levels of N-acetylated amino acids in GM plants expressing the glyphosate N-acetyltransferase, a refined assessment of dietary exposure was conducted (EFSA GMO Panel, 2013).

Potential exposure for median and high-level consumers (e.g. 95th centile) can be calculated for each food category. However, summing up the high-level exposure estimates from all relevant food categories in order to estimate the overall high-level exposure will result in an overestimation, since it assumes that high-level consumers of one food are also high-level consumers of all the other foods. It is very unlikely that individuals are high-level consumers of more than one food category when a limited number of food categories is used. An alternative is to assume that an individual might be a high-level consumer of one food category only and an average consumer of all the remaining food groups. In practice, this method entails adding the 95th centile of exposure from the identified dominant food category (calculated for consumers only) to the mean exposure values for the remaining categories (calculated for the total population).

This approach was tested for five different food additives, including preservatives, colours and sweeteners, and nutrient sources (EFSA, 2014). In this study, the calculated exposure estimates were compared with the estimates obtained by using the food consumption data at the individual level (e.g. food consumption data by the individual consumer). The two methods yielded similar results. For this reason, to avoid excessively conservative estimates, the preferred method to estimate high-level exposure by means of summary statistics food consumption data is to assume that an individual might be a high-level consumer of one food category only and an average consumer of all the remaining food groups. This method can be used as a screening tool also in the case of dietary exposure to hazardous substances from GM foods.

1.4. Reliability and use of centiles

The methodologies to assess exposure to hazardous substances through the diet must take into consideration non-average individuals, and in particular those who consume relatively large quantities of foods containing higher concentrations of substances that may lead to a health risk (EC, 1998; WHO, 2009). The definition of high consumers is crucial to the outcome of the risk assessment because, in practice, it provides a measure of the proportion of the population that could exceed health-based guidance values and indicates if risk management measures should be considered. For GM plants with an altered nutritional profile, it is necessary to consider the impact on subjects who due to their dietary habits may be deficient for a specific nutrient or a nutrient group (so called low consumers). When the dietary exposure to a nutrient is below the recommended adequate intake level, this should initiate a more detailed dietary exposure assessment.

Centiles calculated on a limited number of subjects should be treated with caution, as the results may not be statistically robust. Wherever possible, the highest centile supported by the data should be selected. In the case of the EFSA Comprehensive Database, different options are presented and discussed in the guidance on the “Use of the Comprehensive Database in exposure assessment” (EFSA, 2011a). The summary statistics published on the EFSA website include centiles for all food categories, even if calculated on a very limited number of subjects/days. However centiles calculated over a number of subjects/days lower than 60 (for the 95th centile) and lower than 299 (for the 99th centile) have been flagged with a warning, indicating the need for a cautious interpretation of the results, which may not be statistically robust. The choice of centile for low consumers follows the same principles as for the high consumers, depending on the robustness of the data. Where possible, the 5th centile is preferred for low consumers, and the 95th centile is preferred for high consumers.

1.5. Concentration data in the exposure assessment

In GM applications, the concentrations of many substances are determined in the compositional analysis of raw agriculture commodity (e.g. grain or seeds). Concentration data of a substance measured in raw agriculture commodity are generally used by applicants to estimate dietary exposure. It should be recognised that such estimates may not necessarily represent “worst-case” situations, other factors, such as food processing, can enrich or reduce the concentration of a substance under

consideration. Therefore, the source of concentration data should be specified in the exposure assessment, and the choice of such source should be justified.

When the goal is to assess the safety and adequacy of nutrient intake (nutritional assessment) or to determine the possibility of harm (assessment of hazardous substances), the concentration of the substance under consideration should be quantified from foods as consumed, as this represents more realistic exposure conditions. One example could be the determination of fatty acid concentration from refined deodorised bleached (RDB) oil, as RDB oil represents the oil used for cooking or as a food ingredient in dishes or processed foods.

The concentration of a substance of concern in ingredients derived from a GM plant and the composition of the food itself are needed to calculate the amount of the substance in each food item. At present, the EFSA does not publish food compositional data. Consequently, such data have to be obtained from other sources (e.g. food composition database or tables of a single EU country), and combined with the relevant food consumption data from the EFSA Comprehensive Database. It is recommended that food compositional data should be taken primarily from European national food composition databases (or tables). Other sources should be used when information on a particular food or food groups (e.g. one with restricted distribution or availability) are not included in the primary composition database.

To estimate the exposure to a specific food component, the most relevant food composition data should be used. The selection of such information may involve a judgement based on the quality and suitability of the data, and on how similar the GM food is to the food items reported in the database. When a product derived from the GM plant is used as an ingredient in composite foods, the overall recipe would be the starting point to derive the amount of GM-derived ingredient in that food.

For acute exposure, a high concentration value, e.g. the 95th or 99th centile or even the highest reported level in case of a limited number of samples, should be used. For chronic exposure scenarios, the mean concentration of the substance in the foods is generally sufficient. However, in cases where the concentration of a substance in GM foods varies widely, both the low and the high concentration levels should be used in the chronic exposure assessment.

RECOMMENDATIONS

Consumption data should be primarily derived from dietary surveys. Food/ingredient disappearance figures should be used only as additional source of information.

When dietary intake estimates are made based on consumption data from a limited number of countries, the dietary exposure assessment must consider the comparability of the country-specific consumption data to other European consumption data.

EFSA encourages applicants to use summary statistics food consumption data from the Comprehensive European Food Consumption Database as a screening tool in the dietary exposure assessment. When using the EFSA summary statistics to estimate the dietary intake, food composition data for exposure assessment should preferably be obtained from a single EU national source and avoid mixing composition data from different databases for different foods.

For GM plants with altered nutritional profile, the impact of both increased and reduced concentration of constituents should be considered within the context of the total diet.

In a refined exposure assessment the concentration of a constituent should be derived from food items as consumed.

CORRESPONDENCE

1. Email from CropLife International and EuropaBio, sent to EFSA on 6 September 2013.

2. Reply from EFSA (Ref. MH/MG/cg (2013)-out-8061610), sent on 3 December 2013.
3. Email from CropLife International and EuropaBio, sent to EFSA on 27 May 2014.
4. Reply from EFSA (Ref. PB/EW/MG/YL/shv-2014 out-9099180), sent on 21 July 2014.
5. Request received via AskeFSA (AD-2014-000678) on 16 July 2014.
6. EFSA reply to AD-2014-000678 on 28 July 2014.

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