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Food manufacturing processes and technical data used in the exposure assessment of food enzymes

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Abstract

Food enzymes are used for technical purposes in the production of food ingredients or foods-as-consumed. In the European Union, the safety of a food enzyme is evaluated by EFSA on the basis of a technical dossier provided by an applicant. Dietary exposure is an integral part of the risk assessment of food enzymes. To develop exposure models specific to each food manufacturing process in which food enzymes are used, different input data are required which are then used in tandem with technical conversion factors. This allows the use levels of food enzyme to be related to food consumption data collected in dietary surveys. For each food manufacturing process, EFSA identified a list of food groups (FoodEx1 classification system) and collated technical conversion factors. To ensure a correct and uniform application of these input data in the assessment of food enzyme dossiers, stakeholders were consulted via open calls-for-data. In addition to publishing and updating the identified input parameters on an annual basis, single-process-specific calculators of the Food Enzyme Intake Models (FEIMs) have been developed. These calculators have been deposited at https://zenodo.org/ since 2018 for open access. By 2023, EFSA had compiled the input data for a total of 40 food manufacturing processes in which food enzymes are employed. In this document, the food manufacturing processes are structured, food groups classified initially in the FoodEx1 system are translated into the FoodEx2 system, and technical factors are adjusted to reflect the more detailed and standardised FoodEx2 nomenclature. The development of an integrated FEIM-web tool using this collection of input data is carried out for a possible release in 2024. This tool will be able to estimate the exposure to the food enzyme–total organic solids (TOS) when employed in multiple food manufacturing processes.

Keywords: enzyme, food manufacturing process, conversion factor, dietary exposure, calculator, FEIM

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Introduction

This document should be read in conjunction with Chapter 5 of the 'Scientific Guidance for the submission of dossiers on Food Enzymes' (EFSA CEP Panel, 2021a). It reports the technical input data required to carry out dietary exposure to food enzymes from food manufacturing processes for which EFSA has received applications, and upon which Food Enzyme Intake Models (FEIMs) have been and are still being developed.

It represents a culmination of the work undertaken since 2016, when the need for a new approach for dietary exposure assessment of food enzymes was identified (EFSA CEF Panel, 2016). This need resulted in EFSA mandating a self-task in 2017, to (1) collate technical data for the originally identified 18 food manufacturing processes, (2) develop simple Excel-based exposure calculators for each process (FEIM calculators) and, finally, (3) develop a web-based multi-process exposure tool (FEIM-web).

Deliverable (1) was originally realised in 2018 through the publication of input data as Annex B to the 'Statement on Exposure Assessment of Food Enzymes' (EFSA CEF Panel, 2016). It underwent several revisions and updates since then (EFSA CEP Panel, 2021b,c), reflecting the progress made in collating information for each food manufacturing process.

Simultaneously, work on deliverable (2) commenced in 2018 with the first release of process-specific FEIM calculators developed on the basis of summary statistics of food consumption data derived from the EFSA Comprehensive European Food Consumption Database and the technical data reported thus far in deliverable (1). Since then, new releases and updates of existing calculators in line with updates to the Comprehensive Food Consumption Database have been added and are available for open access at https://zenodo.org/. They can be downloaded at the links presented in the following table. All calculators will be updated with the input data shown in the Annexes, to be concluded by the end of 2023.

Chapter in this document	Calculator	Hyperlink
3.1	FEIM_LactoseMilk	https://doi.org/10.5281/zenodo.6674203
3.2	FEIM_Cheese	https://doi.org/10.5281/zenodo.6674074
3.3	FEIM_FermentedMilk	https://doi.org/10.5281/zenodo.6794319
3.4	FEIM_EMDI	https://doi.org/10.5281/zenodo.6794765
3.5	FEIM_ProteinMilk	https://doi.org/10.5281/zenodo.7798887
3.6	FEIM_Egg	https://doi.org/10.5281/zenodo.4353055
3.7	FEIM_MeatFish	https://doi.org/10.5281/zenodo.7799145
3.8	FEIM_ProteinHydroAnimal	https://doi.org/10.5281/zenodo.7799078
3.9	FEIM_Flour	https://doi.org/10.5281/zenodo.7795675
3.11	FEIM_Baking	https://doi.org/10.5281/zenodo.1297332
3.12	FEIM_Cereal	https://doi.org/10.5281/zenodo.3560577
3.13	FEIM_Brewing	https://doi.org/10.5281/zenodo.1299218
3.16	FEIM_Juice	https://doi.org/10.5281/zenodo.6674148
3.17	FEIM_FruitVeggi	https://doi.org/10.5281/zenodo.7685017
3.18	FEIM_Wine	https://doi.org/10.5281/zenodo.6794661
3.19	FEIM_FruitAlcoholicBev	https://doi.org/10.5281/zenodo.6794386
3.20	FEIM_NonWineVinegar	https://doi.org/10.5281/zenodo.7795548
3.21	FEIM_Molasses	https://doi.org/10.5281/zenodo.4354557
3.24	FEIM_Coffee	https://doi.org/10.5281/zenodo.6673958
3.25	FEIM_CoffeeSubstitutes	https://doi.org/10.5281/zenodo.7943819
3.26	FEIM_TeaInfu	https://doi.org/10.5281/zenodo.7684974
3.27	FEIM_PlantExtract	https://doi.org/10.5281/zenodo.7798783
3.28	FEIM_PlantAnalogue	https://doi.org/10.5281/zenodo.7656050
3.29	FEIM_SoySauce	https://doi.org/10.5281/zenodo.7799133
3.30	FEIM_ProteinHydroPlant	https://doi.org/10.5281/zenodo.7799097
3.31	FEIM_Yeast	https://doi.org/10.5281/zenodo.7656240
3.33	FEIM_ModifiedFats	https://doi.org/10.5281/zenodo.4354781

Chapter in this document	Calculator	Hyperlink
3.37	FEIM_Confectionery	https://doi.org/10.5281/zenodo.7684923
3.38	FEIM_GosFos	https://doi.org/10.5281/zenodo.6794488
3.40	FEIM_Acrylamide	https://doi.org/10.5281/zenodo.7655959

In 2021, the 'Statement on exposure assessment of food enzymes' (EFSA CEF Panel, 2016) was incorporated into the revised 'Scientific Guidance for the submission of dossiers on Food Enzymes' (EFSA CEP Panel, 2021a). Annex D of the guidance provides a description of food manufacturing processes to which food enzymes are added and links to existing FEIM Excel calculators. However, Annex D does not provide the source or the details of the technical conversion factors derived for each food manufacturing process and which underpin the existing FEIM calculators and those under development. Consequently, a stand-alone document 'Process-specific technical data used in exposure assessment of food enzymes' (EFSA CEP Panel, 2021c) was published, which contains all technical conversion factors for existing and newly added food manufacturing processes. The stand-alone document demonstrated how the existing process-specific FEIM calculators were developed and, where FEIM models were not yet available, illustrated the kind of data required by EFSA to carry out exposure assessments.

In 2023, EFSA completed the calls-for-data to collate all the process-specific technical data for each food manufacturing process. This is the final version of the document, in which all food manufacturing processes reported in the dossiers provided by the applicants and all related technical factors have been collated. Overall, the number of food manufacturing processes identified increased from originally 18 to a total of 40. It should be noted that this 2023 edition replaces the Annex D of the enzyme guidance (EFSA CEP Panel, 2021a).

For deliverable (3), concerning the development of a multi-process exposure tool (FEIM-web), work started in early 2023 and its release is envisaged in 2024. This tool will facilitate the assessment of exposure to food enzymes used in multiple food manufacturing processes and will utilise individual food consumption data from the Comprehensive database together with the technical input data to provide mean and accurate high percentile population exposures (e.g. 95th percentile).

1. Background as provided by EFSA in 2017

"The CEF Panel has resumed the evaluation of several food enzyme dossiers by implementing the strategy and methodology outlined in the "Statement on exposure assessment of food enzymes" published in November 2016. This methodology follows the best practice in the area of dietary exposure assessment. For dossiers that have been received by EFSA, as individual consumption data in the EFSA Comprehensive Consumption Database are only directly accessible in EFSA, dietary exposure to the food enzyme is being calculated in-house at EFSA.

The recently published Food Additive Intake Model (FAIM)[1] has shown that it is feasible to allow third parties utilising the individual consumption data in the EFSA Comprehensive Consumption Database without infringing confidentiality issues.

With the efforts made in defining food-process-relevant food groups and in consolidating technical conversion factors necessary to combine the use levels and consumption data, the CEF Panel is in the position to develop an intake model that is specific to food enzymes. Such a model will contribute to speeding up the evaluation of the food enzyme dossiers, as well as enable applicants to prepare future food enzyme dossiers."

2. Terms of Reference

In accordance with Article 29(1) of Regulation (EC) No 178/2002[2], the European Food Safety Authority asks its scientific Panel on Food Contact materials, Enzymes, Flavourings and Processing Aids (CEF) to develop a web-based Food Enzyme Intake Model. The deliverables should include:

[1] Accessible online: https://www.efsa.europa.eu/en/applications/food-improvement-agents/tools

[2] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, pp. 1–24.

- Intermediate output 1: an addendum to the already published Panel statement, entitled 'Annex B - Process-specific recipe and technical conversion factors'.
- Intermediate output 2: a series of Excel-based tools for calculating exposure to food enzymes used in specific processes.
- Final output: a web-based food enzyme intake model (FEIM).

Data and methodologies

1. Data

Process-specific technical conversion factors are derived from several sources, which include the EFSA Raw Primary Commodity (RPC) Model,[3] publicly available recipe information, food label information, as well as the FAO technical conversion factors.[4]

2. Methodology

For each food manufacturing process where the food enzyme– total organic solids (TOS) may remain (EFSA CEF Panel, 2016, 2021b,c), EFSA selects a list of food groups from the Comprehensive European Food Consumption Database (FoodEx categories) and derives food-specific technical conversion factors. This list is then published as a call-for-data on the EFSA website to seek feedback from stakeholders. A full list of all calls-for-data can be retrieved at https://www.efsa.europa.eu/en/search?s=enzyme+calls.

All the calls-for-data displayed food consumption data coded in the FoodEx1 classification system. In this final edition, food groups originally coded using FoodEx1 categories have been translated into FoodEx2 categories, which contains a more detailed list of foods.

Development of assessment tools

1. Process-specific technical data

In order to develop food manufacturing process-based exposure models, different input data are required, i.e. food consumption data, food enzyme use levels and technical conversion factors to allow for a combination of use levels expressed on raw material together with food consumption data, which are typically reported as consumed. Food enzyme use levels are specific to each application and are provided by the applicant. Food consumption data and conversion factors need to be derived for each process as follows:

1) Food consumption data are recorded in accordance with the FoodEx classification system in the EFSA Comprehensive European Food Consumption Database. The assignment of food groups (FoodEx categories) to a specific food manufacturing process is guided by the food manufacturing processes in which food enzymes are intended to be used. In some cases, the selection of food groups was straight forward, for example in the case of 'Production of baked products' and 'Production of brewed products', where the selection of relevant food categories focused on food products having undergone a baking process (e.g. bread, fine bakery ware) or a brewing process (e.g. beer, malt drinks). However, for most cases, where the resulting food product is an ingredient (e.g. glucose syrups) that can be added to a number of foods, more detailed information is required. Such details are either provided by the applicant or obtained through searches in the EFSA raw primary commodity (RPC) model,[3] the Mintel Global New Products Database (GNPD)[5] or other relevant sources (e.g. recipe data).
2) Technical conversion factors are used to facilitate the combination of food enzyme use levels and food consumption data, as food enzyme usage data are typically expressed on a raw material basis, whereas food consumption data typically refer to food as consumed. These technical conversion factors are specific to each food manufacturing process and are based

[3] The model is accessible at http://doi.org/10.2903/sp.efsa.2019.EN-1532
[4] Available online: http://www.fao.org/fileadmin/templates/ess/documents/methodology/tcf.pdf
[5] The database is accessible at https://www.mintel.com/global-new-products-database

on several sources, such as factors reported in the EFSA RPC Model,[3] publicly available recipe information, the FAO technical conversion factors,[6] as well as food label information from the Global New Products Database.[7] The selection of relevant technical conversion factors is thus based on expert judgement and associated with a certain degree of uncertainty. Therefore, to ensure uniform use of FoodEx food categories and technical conversion factors in the assessment of food enzyme dossiers, stakeholders were consulted on the selected food categories and technical conversion factors through open calls-for-data and feedback received was incorporated in the final output. A full list of all calls-for-data can be retrieved at https://www.efsa.europa.eu/en/search?s=enzyme+calls.

The selected food groups and corresponding technical factors for each food manufacturing process are presented in the Annexes 1–30 in the format of Excel files. Each Excel file contains two sheets, each presenting the information in accordance with the FoodEx1 and FoodEx2 food classification systems, respectively. An update to FoodEx2 was carried out due to the more precise nomenclature of FoodEx2 compared to FoodEx1. For this reason, several broader food groups used previously could be narrowed down, allowing a more precise estimation of exposure. For example, whereas FoodEx1 distinguished beer only by alcoholic strength (strong, regular, light), FoodEx2 separate 'Lager beer (strong, regular, light, alcohol-free)' from 'Ale beer', 'Stout beer' and 'Wheat beer'. This detail is particularly useful when an enzyme is applied only under cold or warm fermentation conditions.

The information provided in the Annexes of this document is presented in tables containing the following details:

FoodEx code	EFSA FoodEx classification food category code
FoodEx category	EFSA FoodEx classification food category name – food category relevant to the food manufacturing process and included in the exposure assessment
Technical conversion factor f1	Conversion factor converting the food or ingredient consumed into the material to which the food enzyme is added
Technical conversion factor f2	Ingredient fraction reflecting the amount of ingredient in the food as consumed in which the food enzyme is present
Technical conversion factor f3	Fraction of the overall food group selected that is likely to actually contain the food enzyme

- Factor f1 is a technical conversion factor applied to a food or food ingredient in order to bring it on par with the raw material to which the food enzyme is added. For example, beer is converted to barley grain, to which the food enzyme is added during the brewing process.
- Factor f2 represents the ingredient fraction of interest in a food included in the exposure assessment. For example, bread contains 70% flour, therefore, consumption of bread is corrected by a factor of 0.7 to reflect the flour component only.
- Factor f3 is only used in those cases where a certain percentage of food products within a larger food category is likely to contain the food enzyme. This factor is derived from the Mintel Database (GNPD)[8] that monitors worldwide product launches of packaged foods. It contains information on over 2 million food and beverage products of which more than 800,000 are or have been available on the EU food market. It started covering the EU food market in 1996, currently covering 20 EU Member States and Norway. Factor f3 represents the fraction of food items within the entire food category searched likely to contain the ingredient of interest (as declared on the product label). For example, only a fraction of biscuits within the overall category of 'biscuits with cream filling' is likely to contain coffee. Hence, factor f3 equals the number of biscuit products declaring coffee as ingredient divided by the total number of biscuit products listed in the food category.

2. Structure of food manufacturing processes

This list of food manufacturing processes represents those processes for which a food enzyme application has been made. EFSA does not attempt to anticipate future submissions not already covered in this document.

[6] Available online, see http://www.fao.org/fileadmin/templates/ess/documents/methodology/tcf.pdf
[7] The database is accessible at https://www.mintel.com/global-new-products-database
[8] The database is accessible at https://www.mintel.com/global-new-products-database

Since the first development of food-manufacturing-process-specific exposure data in 2018, a total of 34 calls-for-data resulting in 40 food-manufacturing-process-specific exposure models have been published, of which 26 calls-for-data were launched on the EFSA website and eight were targeted to specific food business operators (EFSA CEF Panel, 2016, 2021b[9],c). The hitherto published lists of processes reflected the order in which they were developed, rather than following a logical hierarchy.

In this edition, the list of food manufacturing processes is re-structured to reflect firstly the raw materials to which the food enzymes are applied and secondly the resulting food ingredients/foods-as-consumed. Each process is coded as follows:

- Level code: the descriptor refers to the raw material used in the manufacturing process (i.e. 'processing of raw material')
- Sub-level code: the descriptor refers to the final product resulting from the manufacturing process (i.e. 'production of food ingredients or foods-as-consumed')

The following table presents the individual food manufacturing processes; it includes a column, which provides the former titles in use prior to this new system.

Code	Food manufacturing process	Raw material	Chapter	Food manufacturing process former title[(a)]
01	Processing of dairy products	Dairy products	–	–
01.01	Production of lactose-reduced dairy products	Milk	3.1	Lactose degradation in milk and dairy products
01.02	Production of cheese	Milk	3.2	Cheese production and byproducts in milk and dairy processing
01.03	Production of fermented dairy products	Milk	3.3	Milk processing to improve fermented milk product properties
01.04	Production of flavouring preparation from dairy products	Cheese, cream, butter etc.	3.4	Manufacture of enzyme-modified dairy ingredients
01.05	Production of modified milk proteins	Milk proteins	3.5	Whey processing
02	Processing of eggs and egg products	Eggs	3.6	Egg processing
03	Processing of meat and fish products	Meat and fish	–	–
03.01	Production of modified meat and fish products	Meat and fish	3.7	Processing of meat and fish products
03.02	Production of protein hydrolysates from meat and fish proteins	Meat and fish proteins	3.8	Protein extracts processing
04	Processing of cereals and other grains	Cereals	–	–
04.01	Production of flour	Cereals	3.9	Processing of grains for the production of flour
04.02	Production of starch and gluten fractions	Cereals	3.10	Grain treatment for the production of starch and gluten fractions
04.03	Production of baked products	Flour	3.11	Baking processes
04.04	Production of cereal-based products other than baked	Flour	3.12	Cereal-based processes
04.05	Production of brewed products	Cereals	3.13	Brewing processes
04.06	Production of glucose syrups and other starch hydrolysates	Starch	3.14	Starch processing for glucose syrup production and other starch hydrolysates
04.07	Production of distilled alcohol	Fermentable carbohydrates	3.15	Distilled alcohol production
05	Processing of fruits and vegetables	Fruit and vegetables	–	–

[9] This is the last version of Annex B, which has a question number of EFSA-Q-2020-00168. Two earlier versions had question numbers of EFSA-Q-2018-00585 and EFSA-Q-2018-00087.

Code	Food manufacturing process	Raw material	Chapter	Food manufacturing process former title[a]
05.01	Production of juices	Fruit and vegetables	3.16	Fruit and vegetables juices production
05.02	Production of fruit and vegetable products other than juices	Fruit and vegetables	3.17	Fruit and vegetable processing for products other than juices
05.03	Production of wine and wine vinegar	Grapes	3.18	Wine production
05.04	Production of alcoholic beverages other than grape wine	Fruits	3.19	Fruit-derived alcoholic beverage processing
05.05	Production of non-wine vinegar	Fruits	3.20	Production of non-wine vinegar
06	Processing of plant- and fungal-derived products	Plant and fungal components	–	–
06.01	Production of refined and unrefined sugar	Sugar beets and sugar canes	3.21	Refined sugar production (molasses as a by-product)
06.02	Production of edible oils from plant and algae	Plants and algae	3.22	Treatment of plant and algae for edible oil production
06.03	Production of green coffee beans by demucilation	Coffee cherries	3.23	Coffee bean demucilation
06.04	Production of coffee extracts	Demucilated coffee beans	3.24	Coffee processing
06.05	Production of coffee substitutes	Cereals, chicory, etc.	3.25	Coffee substitutes processing
06.06	Production of tea and other herbal and fruit infusions	Tea leaves or other plants	3.26	Tea processing as well as herbal and fruit infusions Processing
06.07	Production of plant extracts	Plants	3.27	Production of plant extracts
06.08	Production of plant-based analogues of milk and milk products	Plant-based raw materials	3.28	Plant processing for production of dairy analogues
06.09	Production of soy sauce	Soya	3.29	Production of soya sauce
06.10	Production of protein hydrolysates from plants and fungi	Plant and fungal proteins	3.30	Protein extracts processing
07	Processing of yeast and yeast products	Yeast	3.31	Yeast processing
08	Processing of fats and oils	Fats and oils	–	–
08.01	Production of refined edible fats and oils by degumming	Crude fats and oils	3.32	Degumming of fats and oils
08.02	Production of modified fats and oils by interesterification	Fats and oils	3.33	Fats and oils processing for interesterification
08.03	Production of free fatty acids by hydrolysis	Fats and oils	3.34	–
08.04	Production of flavour compounds by esterification	Fats and oils and alcohols	3.35	–
08.05	Production of modified lecithins	Lecithin	3.36	Modified lecithin production from egg
09	Processing of sugars	Mono-, di- and oligo-saccharides	–	–
09.01	Production of confectionery products and beverages	Sucrose, fructose, other saccharides	3.37	Confectionery processes
09.02	Production of oligosaccharides	Mono- to poly-saccharides	3.38	Manufacture of indigestible oligosaccharides
09.03	Production of specialty carbohydrates (excluding oligosaccharides)	Mono-, di- and oligo-saccharides	3.39	Manufacture of speciality carbohydrates

Code	Food manufacturing process	Raw material	Chapter	Food manufacturing process former title[(a)]
10	Prevention of acrylamide formation in foods	Carbohydrate and asparagine containing foods	3.40	Acrylamide reduction

(a): These titles were used when EFSA launched open calls-for-data on the website.

3. Food manufacturing processes

Processing of dairy products [01]

3.1. Production of lactose-reduced dairy products [01.01]

This process has been adapted from the 'EC working document on food processes in which food enzymes are used' as follows[10]:

this food manufacturing process relies on milk as the raw materials and leads to the production of dairy foods such as, but not limited to, lactose-reduced milk, cheese and dairy ice cream.

Food enzymes are used to hydrolyse lactose in milk for purposes such as:

- *to reduce lactose content;*
- *to increase sweetness;*
- *to reduce sandiness of ice creams.*

The food enzyme that can typically be used in these processes is lactase.

Fermented milk products, such as yoghurt and kefir, are excluded.

Lactose-reduced milk is readily available in the EU. Other dairy products, such as cheese and quark produced from lactose-reduced milk, are also available. The Comprehensive Database currently does not provide sufficient detail to estimate food intake specifically for lactose-intolerant population groups. The selection of food categories was, therefore, based on the assumption that lactose-intolerant people may have similar consumption patterns (such as eating habits) of dairy products as non-lactose-intolerant population groups. Dairy products naturally containing negligible amounts of lactose, such as hard cheeses, are excluded.

Following the open call-for-data,[11] feedback was received from the European Dairy Association (EDA). It was clarified that lactose-reduced whey or lactose-reduced milk are not used in the production of infant formulae and follow-on formulae. It was also clarified that lactose-reduced dairy variants (except for milk) are still niche products. Therefore, factors (f3) have been assigned to reflect the proportion of dairy products within each category that are likely to have been treated with a food enzyme to hydrolyse lactose.

The input data used to estimate dietary exposure to food enzyme–TOS in foods relevant to this intended use are summarised in Annex 1.

3.2. Production of cheese [01.02]

This process has been adapted from the 'EC working document on food processes in which food enzymes are used' as follows[10]:

this food manufacturing process relies on milk as the raw materials and leads to the production of dairy foods such as, but not limited to, cheese and processed cheese. Whey is obtained as a by-product.

Various food enzymes may be used in cheesemaking for purposes such as:

- *to clot milk by hydrolysing casein;*
- *to modify viscosity and texture, solubility and stability;*
- *to enhance flavour production during ripening.*

[10] Unpublished at the time of this publication – Disclaimer: The document has not been officially adopted nor endorsed by the European Commission and it represents the preliminary views of the Commission services.

[11] https://www.efsa.europa.eu/en/call/call-input-data-exposure-assessment-food-enzymes-7th-call

Food enzymes that can typically be used in this process are peptidases (e.g. chymosin), phospholipases and lipases.

The process includes whey (liquid and powder) as by-products of cheese making.

It includes coagulation of milk proteins through use of enzymes and takes into account the partition of the enzymes between curd and whey that are separated. Enzyme partition factors were provided by Specialised Nutrition Europe: 20% in curd and 80% in whey.[12,13]

Cheese and food products that contain cheese can be clearly identified in the EFSA Raw RPC model. However, this is not the case for food products containing whey as an ingredient. The selection of these food categories was aided by information available in recipes and in databases, such as the Mintel Database (GNPD).

Following the open call-for-data,[14] feedback was received from the EDA.

The input data used to estimate dietary exposure to food enzyme–TOS in foods relevant to this intended use are summarised in Annex 2.

3.3. Production of fermented dairy products [01.03]

This process has been adapted from the 'EC working document on food processes in which food enzymes are used' as follows[10]:

this food manufacturing process relies on milk as the raw materials and leads to the production of dairy foods such as, but not limited to yoghurt, kefir, sour cream and buttermilk.

Food enzymes can be added during the fermentation process to act on various substrates present in milk such as proteins, lipids and lactose for purposes such as:

- *to improve viscosity and texture;*
- *to reduce lactose content;*
- *to increase sweetness*.

Food enzymes that can typically be used in this process are, peptidases (e.g. chymosin, pepsin), transglutaminases and lactases.

Following the open call-for-data,[15] feedback was received from the EDA.

The input data used to estimate dietary exposure to food enzyme–TOS in foods relevant to this intended use are summarised in Annex 3.

3.4. Production of flavouring preparations from dairy products [01.04]

This process has been adapted from the 'EC working document on food processes in which food enzymes are used' as follows[10]:

this food manufacturing process relies on dairy products (e.g. cheese, cream, butter etc.) as the principal raw materials and leads to the manufacturing of products such as, but not limited to, enzyme modified dairy ingredients.

Various food enzymes may be used to obtain enzyme modified dairy ingredients for purposes such as:

- *to increase flavour intensity*.

Food enzymes that can typically be used in these processes are peptidases and lipases.

This process is on the production of Enzyme-Modified Dairy Ingredients (EMDI). EMDI are flavoured ingredients derived by enzymatic processes from dairy ingredients, such as cheese, butter and cream. The selection of food groups that contain EMDI as an ingredient could not be clearly identified in the EFSA RPC model. Therefore, the selection of these food categories was informed through use of literature data and the Mintel Database (GNPD).

Following the open call-for-data,[16] feedback from the European Flavour Association (EFFA) clarified that in the European Union it is not permitted to add dairy flavouring substances to dairy products, such as milk.

[12] Feedback from the SNE to the call for input data for the Exposure Assessment of Food Enzymes related to Protein components in infant formulae and follow-on formulae. April 2019.
[13] https://www.efsa.europa.eu/en/consultations/call/call-input-data-exposure-assessment-food-enzymes-3rd-call
[14] https://www.efsa.europa.eu/en/call/call-input-data-exposure-assessment-food-enzymes-8th-call
[15] https://www.efsa.europa.eu/en/call/call-input-data-exposure-assessment-food-enzymes-12th-call
[16] https://www.efsa.europa.eu/en/call/call-input-data-exposure-assessment-food-enzymes-13th-call

The input data used to estimate dietary exposure to food enzyme–TOS in foods relevant to this intended use are summarised in Annex 4.

3.5. Production of modified milk proteins [01.05]

This process has been adapted from the 'EC working document on food processes in which food enzymes are used' as follows[10]:

this food manufacturing process relies on milk proteins as the principal raw materials and leads to the production of milk protein isolates, concentrates and milk protein hydrolysates.

Various food enzymes may be used in the manufacturing of modified milk proteins for purposes such as:

- *to partially or fully hydrolyse proteins primarily for production of infant and follow-on formulae or products for special medical uses;*
- *to catalyse lactose hydrolysis in whey;*
- *to modify rheology;*

Food enzymes that can typically be used in these processes are lactases, peptidases and transglutaminases.

It includes the production of protein hydrolysates intended for infant and follow-on formulae and Food for Special Medical Purposes, as defined by Reg (EU) no 609/2013.

Following the open call-for-data,[17] feedback was received from the European Dairy Association (EDA), Specialised Nutrition Europe (SNE) and two companies (DSM FOOD SPECIALTIES B.V. and FrieslandCampina).

The input data used to estimate dietary exposure to food enzyme–TOS in foods relevant to this intended use are summarised in Annex 5.

3.6. Processing of eggs and egg products [02]

This process has been adapted from the 'EC working document on food processes in which food enzymes are used' as follows[10]:

this food manufacturing process relies on raw eggs (without shell) and/or components of egg (yolk or egg white) as raw materials and leads to products such as dried egg and pasteurised egg.

Various food enzymes may be used in egg processing for purposes such as:

- *removal of glucose to reduce browning (Maillard reaction) and associated off-flavour development during pasteurisation and spray drying of eggs;*
- *to crosslink and, hence, stabilise the egg protein;*
- *to hydrolyse triacylglycerols and phospholipids in egg yolk and release emulsifying compounds*.

Food enzymes that can typically be used in this process are glucose oxidases, lipases, phospholipases and peptidases.

It excludes modified lecithin production from egg, when used as a food additive (see Section 3.36).

Following the open call-for-data,[18] no response was received from any stakeholders.

The input data used to estimate dietary exposure to food enzyme–TOS in foods relevant to this intended use are summarised in Annex 6.

Processing of meat and fish products [03]

3.7. Production of modified meat and fish products [03.01]

This process has been adapted from the 'EC working document on food processes in which food enzymes are used' as follows[10]:

this food manufacturing process relies on meat and fish products as raw materials.

[17] https://www.efsa.europa.eu/en/call/call-input-data-exposure-assessment-food-enzymes-17th-call
[18] http://www.efsa.europa.eu/en/consultations/call/call-input-data-exposure-assessment-food-enzymes-6th-call

Various food enzymes may be used in processing of meat and fish products for purposes such as:

- *to improve processability;*
- *to inhibit the bitter taste caused by free peptides;*
- *to bind meat or fish pieces in order to obtain formed meat or fish products;*
- *to tenderise meat;*
- *to produce meat broth and concentrates*.

Food enzymes that can typically be used in this process are phospholipases, transglutaminases and peptidases.

It includes the production of protein concentrates from meat and fish.

Following the open call-for-data,[19] no response was received from any stakeholders.

The input data used to estimate dietary exposure to food enzyme–TOS in foods relevant to this intended use are summarised in Annex 7.

3.8. Production of protein hydrolysates from meat and fish proteins [03.02]

This process has been adapted from the 'EC working document on food processes in which food enzymes are used' as follows[10]:

this food manufacturing process relies on protein-containing side streams from meat and fish processing as the raw materials.

Various food enzymes may be used to produce protein hydrolysates from meat and fish products for purposes such as:

- *to hydrolyse proteins and obtain a range of products that can be used in a wide range of foods (savoury foods, e.g. soups, bouillons, dressings, snacks, meat-derived processed foods or foods supplemented with protein)*.

Food enzymes that can typically be used in this process are peptidases.

This process concerns enzymatic treatment of animal protein, including collagen, i.e. protein-rich extracts from animal-derived materials. The resulting protein hydrolysates are used as a common ingredient in many types of foods-as-consumed.

Food products containing animal protein hydrolysates or gelatine as an ingredient could not easily be identified in the EFSA RPC model. The food categories were selected from databases such as Mintel Database (GNPD).

Feedback to the open call-for-data[20] was received from the Gelatine Manufacturers of Europe (GME) and three companies (DSM FOOD SPECIALTIES B.V., Kerry Ingredients & Flavours Ltd and DEVRO PLC). The open call-for-data was launched including both animal and plant protein hydrolysates. However, following public consultation, the dataset was separated into animal and plant.

The input data used to estimate dietary exposure to food enzyme–TOS in foods relevant to this intended use are summarised in Annex 8.

Processing of cereals and other grains [04]

3.9. Production of flour [04.01]

This process has been adapted from the 'EC working document on food processes in which food enzymes are used' as follows[10]:

this food manufacturing process relies on cereals or other grains as the raw materials. Food enzymes facilitate the degradation of cell wall components, increasing the effectiveness of the mechanical treatments, such as milling and peeling.

Food enzymes that can be typically used in this process are hemicellulases and glucanases.

Following the open call-for-data,[21] no response was received from any stakeholders.

The input data used to estimate dietary exposure to food enzyme–TOS in foods relevant to this intended use are summarised in Annex 9.

[19] https://www.efsa.europa.eu/en/call/call-input-data-exposure-assessment-food-enzymes-15th-call
[20] https://www.efsa.europa.eu/it/call/call-input-data-exposure-assessment-food-enzymes-22nd-call
[21] https://www.efsa.europa.eu/en/call/call-input-data-exposure-assessment-food-enzymes-25th-call

3.10. Production of starch and gluten fractions [04.02]

This process has been adapted from the 'EC working document on food processes in which food enzymes are used' as follows[10]:

this food manufacturing process relies on cereals (grains or grist) as the raw materials. Cereals are milled and processed in order to be fractioned into starch, gluten and solubles. The separated fractions are then further processed, notably the starch fraction which is either used as a food ingredient (e.g. in baking) or transformed enzymatically into starch derivatives which are themselves used in a number of food products. The solubles are used only as feeding stuff.

Various food enzymes may be used to treat grains for purposes such as:

- *to facilitate the fractionation by opening the grain structure;*
- *to ensure high purity/yield of the separated polysaccharide, gluten and solubles fractions.*

Food enzymes that can typically be used in these processes are amylases, glucosidases, hemicellulases, cellulases, peptidases, glucanases and phospholipases.

It excludes production of glucose syrups and other starch hydrolysates.

The technical information provided by AMFEP[22] clarified that milled grains are further processed and fractionated into starch, gluten and solubles. Solubles are not used in food production, rather they are generally used in animal feed and as starting material for ethanol production. Therefore, the fraction 'solubles' is not further considered.

Starch and gluten fractions obtained following grain treatment are excluded from dietary exposure calculation, as the presence of residual amounts of TOS after repeated washing during production is negligible. This assumption was supported by information submitted by AMFEP and Starch Europe,[23] which included (i) a description of the main steps of the production process of the different fractions in relation to the addition and removal of food enzymes, (ii) theoretical calculations based on measured amounts of intermediate and final fractions and (iii) measurement of enzymatic activities for several different food enzymes in the weighed intermediate and final products (e.g. process water, dough, tricanter feed, crude starch, crude and dry gluten). When using both the final calculated residual amount and measured enzyme activity in the final products, respectively, it is estimated that > 99% of enzyme added to the raw material (e.g. grain, flour) are removed during production.

The evidence was considered as sufficient to conclude that residual amounts of TOS are removed by the washing steps applied during the production of the starch and gluten fractions (by > 99%).

3.11. Production of baked products [04.03]

This process has been adapted from the 'EC working document on food processes in which food enzymes are used' as follows[10]:

this food manufacturing process relies on flours as raw materials and leads to the manufacturing of bakery wares such as, but not limited to, bread, biscuits, cakes, pastries, tortillas and baking specialties (e.g. gluten free baking, cookies, doughnuts etc.).

Food enzymes are usually added to the flour or during the mixing of the dough ingredients and act on the various substrates present in the flour or other ingredients, such as starch and other carbohydrates, lipids proteins etc.

Food enzymes may be used in baking processes for purposes such as:

- *to facilitate the handling of the dough;*
- *to improve its structure and behaviour during the baking step;*
- *to ensure machinability and improve the production process;*
- *to improve the characteristics of the final bakery products (e.g. volume, crumb softness, extension of shelf life by delaying stalling).*

Food enzymes that can typically be used in this process are amylases, hemicellulases, lipases, glucose oxidases, peroxidases, glucosidases, cellulases, peptidases and transglutaminases.

The process excludes the use of asparaginase to prevent acrylamide formation.

[22] Information on 'Grain processing/Fate of the food enzymes'. April 2018 and July 2018.
[23] Information on 'Food enzyme carry-over in glucose syrups'. February 2017.

Following the open call-for-data,[24] feedback was received from the European Association of Manufacturers and Formulators of Enzyme Products (AMFEP), the Federation of European Union Manufacturers and Suppliers of Ingredients to the Bakery, Confectionery and Patisserie Industries and the Association of Chocolate, Biscuits and Confectionery Industries of Europe (CAOBISCO).

The input data used to estimate dietary exposure to food enzyme–TOS in foods relevant to this intended use are summarised in Annex 10.

3.12. Production of cereal-based products other than baked [04.04]

This process has been adapted from the 'EC working document on food processes in which food enzymes are used' as follows[10]:

this food manufacturing process relies on flours as raw materials and leads to the manufacturing of products such as, but not limited to, pasta, noodles, breakfast cereals and snacks (e.g. muesli bars, popcorn, maize and rice crisps), extruded and/or puffed cereals.

Food enzymes may be used in the cereal-based processes for purposes such as:

- *to facilitate the handling of the dough;*
- *to reduce checking;*
- *to improve dough strength;*
- *to accelerate the drying step, thereby shortening the process time*.

Food enzymes that can typically be used in this process are amylases, hemicellulases, lipases, glucose oxidases, peroxidases, glucosidases, cellulases, peptidases and transglutaminases.

The use of asparaginase to prevent acrylamide formation is excluded.

Following the open call-for-data,[25] no response was received from any stakeholders.

The input data used to estimate dietary exposure to food enzyme–TOS in foods relevant to this intended use are summarised in Annex 11.

3.13. Production of brewed products [04.05]

This process has been adapted from the 'EC working document on food processes in which food enzymes are used' as follows[10]:

this food manufacturing process relies on cereals (malted or not) as the principal raw materials and, usually following a fermentation, leads to products such as, but not limited to, beer and other cereal-based beverages (including non-alcoholic beverages).

The brewing process involves extracting and breaking down the carbohydrates and proteins from these cereals. This process results in a transformation of starch, proteins and other raw material components into dextrin and fermentable sugars, peptides and amino acids.

Food enzymes may be added e.g. during mashing or fermentation for purposes such as:

- *to increase or facilitate the production of fermentable sugars;*
- *to facilitate the mash filtration;*
- *to ensure clarity of the final products;*
- *to reduce the gluten content*.

Food enzymes that can typically be used in this process are amylases, hemicellulases, lipases, glucanases, cellulases, tannases, acetolactate decarboxylase, peptidases and ureases.

Food enzymes may be added during bottling for purposes such as:

- *to prevent or delay growth of beer spoilage microorganisms of unpasteurised beer.*

The food enzyme that is typically used in this process is lysozyme.

Following the open call-for-data,[24] feedback was received from the Brewers of Europe.

The input data used to estimate dietary exposure to food enzyme–TOS in foods relevant to this intended use are summarised in Annex 12.

[24] http://www.efsa.europa.eu/en/data/call/161110
[25] http://www.efsa.europa.eu/en/data/call/171130

3.14. Production of glucose syrups and other starch hydrolysates [04.06]

This process has been adapted from the 'EC working document on food processes in which food enzymes are used' as follows[10]:

this food manufacturing process relies on starch as the raw materials. The starch fraction obtained from grain is transformed enzymatically into starch derivatives such as maltodextrins, glucose syrup and glucose which are used in a number of food products.

Food enzymes may be used for purposes such as:

- *starch liquefaction for the production of syrups with certain sensory and technological characteristics (different dextrose equivalent values);*
- *to convert liquefied starch into fermentable sugars*.

Food enzymes that can typically be used in this process are amylases, glucosidases and phospholipases.

It excludes the manufacture of specialty carbohydrates.

Glucose syrups derived through starch processing are excluded from dietary exposure calculation, as the presence of residual amounts of TOS after filtration and purification during processing is negligible.

Production of carbohydrate-rich syrups for food use, typically involves decolourisation with activated charcoal or similar and treatment with ion-exchange resins. These purification processes are expected to remove food enzyme–TOS from the final syrup products. This assumption was supported by information submitted by AMFEP and Starch Europe,[23] which included a description of the main steps of the manufacturing process of the glucose syrups production in relation to the addition and inactivation/removal of food enzymes, and analytical data on the intermediate products and final ingredients of wheat glucose syrup. When using the total protein and true protein-specific nitrogen as the proxy to consider the residual food enzyme–TOS, it is estimated that 99.35–99.97% of enzymes added to wheat starch are removed in the commercial syrup. The evidence was considered as sufficient to conclude that residual amounts of TOS are removed by the purification steps applied during the production of glucose syrups (by > 99%), i.e. filtration, ion exchange chromatography, treatment with active carbon and crystallisation.

Depending on the enzymes used to hydrolyse the starch and the extent of the hydrolysis, syrups containing different proportions of mono-, di- and oligosaccharides with varying degree of polymerisation can be obtained. In the food enzyme dossiers received, these products are referred to as starch syrup, glucose syrup, high-maltose glucose syrups, maltodextrin, maltose, *etc*.

As all these products are obtained from starch and the purification steps applied during their production are virtually the same as for glucose syrup, for which TOS removal has been demonstrated in food enzyme dossiers evaluated, these types of starch hydrolysates are also excluded from the exposure calculation.

3.15. Production of distilled alcohol [04.07]

This process has been adapted from the 'EC working document on food processes in which food enzymes are used' as follows[10]:

this food manufacturing process relies on fermentable carbohydrates as the principal raw materials and leads to the production of distilled alcoholic beverages such as, but not limited to vodka, gin and whisky or whiskey.

In the process of alcohol production, the carbohydrates contained in raw materials may be hydrolysed by enzymes, followed by yeast fermentation. The ethanol is subsequently concentrated by distillation.

Different food enzymes are added, for purposes such as:

- *to facilitate the hydrolysis of starch and non-starch polysaccharides into fermentable sugars;*
- *to improve the fermentation and alcohol yield;*
- *to allow the use of higher process temperatures and lower pH, which reduces the risk of contamination during the fermentation step;*
- *to reduce the viscosity of the mash and enable higher yield;*
- *to facilitate the ethanol distillation and processing of side streams*.

Food enzymes that can typically be used in this process are amylases, glucosidases, glucanases, cellulases, pectinolytic enzymes, hemicellulases, phospholipases and peptidases.

Foods/ingredients derived through alcohol (distillation) processes, i.e. spirits, are excluded from the dietary exposure calculation, as the presence of residual amounts of TOS after distillation is negligible.

Food enzyme–TOS is not expected to be carried over into the distillate. This assumption was supported by information submitted by AMFEP,[26] which included a description of the main steps in the manufacturing process of the distilled alcohol production in relation to the addition and inactivation/ removal of food enzymes, and analytical data on the final products. When using the total protein as the proxy to consider the residual food enzyme–TOS, it is assumed that the enzymes added to the cereal or potato starch are removed in the final ethyl alcohol. The evidence was considered as sufficient to conclude that residual amounts of TOS are removed by distillation.

Processing of fruits and vegetables [05]

3.16. Production of juices [05.01]

This process has been adapted from the 'EC working document on food processes in which food enzymes are used' as follows[10]:

this food manufacturing process relies on fruit and vegetables as raw materials and leads to the production of juices.

Various food enzymes may be used in fruit and vegetable juices' production for purposes such as:

- *to facilitate the hydrolysis of cell walls and the release of cellular components;*
- *to improve processing;*
- *to increase yield;*
- *for the development of texture and appearance*.

Food enzymes that can typically be used in these processes are cellulases, glucanases, hemicellulases, pectinolytic enzymes, amylases and glucosidases.

Following the open call-for-data,[27] feedback was received from the European Fruit Juice Association (AIJN).

The input data used to estimate dietary exposure to food enzyme–TOS in foods relevant to this intended use are summarised in Annex 13.

3.17. Production of fruit and vegetable products other than juices [05.02]

This process has been adapted from the 'EC working document on food manufacturing processes in which food enzymes are used' as follows[10]:

this food manufacturing process relies on fruit and vegetable raw materials and leads to the production of products, such as but not limited to, purees, compotes, jams and marmalades, canned fruits and vegetables, fruits and vegetables preparations.

Various food enzymes may be used in fruit and vegetable treatments for purposes such as:

- *to facilitate maceration;*
- *to improve processing;*
- *for the development of texture and appearance*.

Food enzymes that can typically be used in these processes are cellulases, glucanases, hemicellulases, pectinolytic enzymes, peptidases, amylases and glucosidases.

The process excludes the use of asparaginase for the prevention of acrylamide formation. Based on the feedback received through the call-for-data,[28] fruit or vegetables concentrates obtained following a treatment with enzymes are included.

The input data used to estimate dietary exposure to food enzyme–TOS in foods relevant to this intended use are summarised in Annex 14.

[26] Information on 'Food enzyme removal during the production of cereal-based distilled alcoholic beverages'. February 2017.
[27] https://www.efsa.europa.eu/en/call/call-input-data-exposure-assessment-food-enzymes-9th-call
[28] https://www.efsa.europa.eu/en/call/call-input-data-exposure-assessment-food-enzymes-10th-call

3.18. Production of wine and wine vinegar [05.03]

This process has been adapted from the 'EC working document on food processes in which food enzymes are used' as follows[10]:

this food manufacturing process relies on grapes as raw materials. The process involves ethanolic fermentation of grapes or grape musts with yeast, optionally followed by the malolactic fermentation with bacteria.

Wine vinegar is produced by acetic acid fermentation of wine.

Food enzymes may be used during wine processing for purposes such as:

- *to improve the maceration, extraction and processing of grapes;*
- *to improve wine quality due to the improved extraction of aroma and colour;*
- *to reduce pressing time;*
- *to enhance wine filterability;*
- *to aid the ageing of wine on yeast lees;*
- *to prevent wine spoilage with undesired lactic acid bacteria;*
- *to increase the yield of the process due to rapid viscosity reduction*.

Food enzymes typically used in these processes are pectinolytic enzymes, glucanases, cellulases and hemicellulases, β-glucosidases and other glycosidases and lysozyme.

Following the open call-for-data,[29] no response was received from any stakeholders.

The input data used to estimate dietary exposure to food enzyme–TOS in foods relevant to this intended use are summarised in Annex 15.

3.19. Production of alcoholic beverages other than grape wine [05.04]

This process has been adapted from the 'EC working document on food processes in which food enzymes are used' as follows[10]:

this food manufacturing process relies on fruits as the raw materials (except grapes) and leads to the production of alcoholic beverages obtained by the complete or partial fermentation of the juice or the pulp of fresh fruits or reconstituted concentrated fruit juice.

Various food enzymes may be used in fruit derived alcoholic beverages' processing for purposes such as:

- *to facilitate maceration of the raw materials and release of cellular components;*
- *to facilitate processing;to enhance fermentation*.

Food enzymes that can typically be used in these processes are pectinolytic enzymes and hemicellulases.

Distilled alcohols made from fruits are covered in the process 'Production of distilled alcohol'.

Following the open call-for-data,[28] feedback was received from the European Cider and Fruit Wine Association (AICV).

The input data used to estimate dietary exposure to food enzyme–TOS in foods relevant to this intended use are summarised in Annex 16.

3.20. Production of non-wine vinegar [05.05]

This process has been adapted from the 'EC working document on food processes in which food enzymes are used' as follows[10]:

this food manufacturing process relies on agricultural origin other than grapes (e.g. fruits, cereal grains) as the raw materials. By alcoholic and acetous fermentation, it leads to the production of non-wine vinegars.

Food enzymes that can be typically used in this process are amylases and phytases.

It excludes wine vinegar production covered by the process 'Production of wine and wine vinegar'.

Following the open call-for-data,[30] feedback was received from CULINARIA EUROPE e.V.

[29] https://www.efsa.europa.eu/en/consultations/call/190617
[30] https://www.efsa.europa.eu/en/call/call-input-data-exposure-assessment-food-enzymes-26th-call

The input data used to estimate dietary exposure to food enzyme–TOS in foods relevant to this intended use are summarised in Annex 17.

Processing of plant- and fungal-derived products [06]

3.21. Production of refined and unrefined sugar [06.01]

This process has been adapted from the 'EC working document on food processes in which food enzymes are used' as follows[10]:

this food manufacturing process relies on sugar cane and sugar beet as raw materials and leads to the production of products such as, but not limited to, beet sugar, cane sugar, refined sugar and sugar syrups.

Different food enzymes may be used during sugar production for purposes such as:

- *to hydrolyse polysaccharides such as dextran and starch;*
- *to enable a higher throughput;*
- *to increase yield of sugar;*
- *to improve filtration and crystallisation*.

Food enzymes that can typically be used in these processes are amylases, dextranases, hemicellulases, cellulases, pectinolytic enzymes, α-galactosidases, β-fructosidases and α-glucosidases.

The resulting food products, refined white beet/cane sugar, are excluded from the dietary exposure calculation, as the presence of residual TOS in the refined sucrose is negligible.

This assumption was supported by information submitted by AMFEP,[31] which included a description of the main steps employed in the sugar production from sugar beet. In case of microbial spoilage of beets, dextranase can be added to the beet juice during the diffusion step to breakdown the mucous polymers (dextrans) formed by lactic acid bacteria. During diffusion sucrose and other beet constituents are extracted from the beet slices. The raw beet juice then undergoes liming and carbonation with carbon dioxide, during the 'juice purification' step. In this step, the precipitating solubles (proteins, beet minerals and amino acids etc.) are removed from the beet juice by decantation or centrifugation. Sucrose is further purified by bleaching and crystallisation. It is assumed that at least 99% of the food enzyme–TOS is eliminated during the beet sugar-production process.

Similarly, dextranase is used in the production of cane sugar to degrade dextran resulting from microbial spoilage. In addition, α-amylase is used to break down starch, present in the cane and carried over into the cane juice. The elimination of the food enzyme–TOS during the cane sugar-making process is also estimated to be at least 99%, according to the European Association of Sugar Manufacturers (CEFS). This assumption was supported by information submitted by CEFS which included a description of the main steps of the manufacturing process of both beet and cane sugar production in relation to the addition and inactivation/removal of food enzymes, and analytical data on the intermediate products and final purified white sugar. When using sucrose content as the proxy to consider the residual food enzyme–TOS, it is estimated that 98.2–99.9% (beet) and 98.7–99.8% (cane) of enzymes added to the raw material are removed in the commercial sugar. The evidence was considered as sufficient to conclude that residual amounts of TOS are removed by the purification steps applied during the production of sugar (by > 98%), i.e. decantation, centrifugation, discoloration and crystallisation.[32]

This consideration, however, is not applicable to unrefined beet/cane sugar products, including unrefined sugar, beet molasses and cane syrups. Molasses (also referred to as black treacle) are a by-product of the refined beet sugar production in the form of an uncrystallised syrup. In the EU, molasses are mainly used as animal feed and in biofuel production. However, due to its nutritional value and flavour characteristics, molasses have also emerged as an alternative to sweeten and flavour foods, e.g. breakfast cereals, sauces, bread. Certain products, e.g. Speculaas and Lebkuchen, have traditionally been produced with molasses. Data from the CEFS on the raw beet juice suggest that the beet molasses for human consumption are at least 90% pure.[32] No data was provided to establish the purity of cane syrups.

As the Comprehensive Database does generally not provide information on the raw material used (i.e. cane, beet) to produce the unrefined sugar products, consumption of such products could not be

[31] Information on the transfer of enzymes into foods for refined sugar production and processing. October 2017.
[32] Information on the transfer of enzymes into foods for refined sugar production and processing. October 2020.

separated into the different categories according to plant source. While it is acknowledged that use of such products may not be equal to each other, in the absence of being able to distinguish products coming from the two different sources, dietary exposure assessment of these products was combined, and which was reflected in the undifferentiated inclusion of both the beet molasses and the unrefined cane syrup in the open call-for-data.

Following the open call-for-data,[18] which focused on the possible intake of food enzyme–TOS via consuming unrefined beet/cane sugar products, a response was received from CEFS.[33]

CEFS further clarified that 'brown sugar', which is currently not legally defined at EU level, covers a broad range of different sugars with brown colour, and which do not all correspond to raw cane sugar. According to CEFS' members, brown sugars containing cane molasses or caramelised sugar syrup are considered to be niche products in the EU and only make up a small fraction. Such sugars were therefore excluded from the exposure assessment.

The input data used to estimate dietary exposure to food enzyme–TOS in foods relevant to this intended use are summarised in Annex 18.

3.22. Production of edible oils from plant and algae [06.02]

This process has been adapted from the 'EC working document on food processes in which food enzymes are used' as follows[10]:

this food manufacturing process relies on oil-rich plant parts (pulp and seeds) or microalgae as the raw materials and leads to the recovery of plant or algal oils for human consumption.

Different food enzymes may be used to treat plant and algae for purposes such as:

- *to disrupt the integrity of cell walls to promote liberation of oils*.

Food enzymes that can typically be used in these processes are those degrading plant cell walls (pectinolytic enzymes, cellulases, hemicellulases).

This process excludes the production of virgin olive oils as defined in Regulation (EU) No 1308/2013.[34]

This process allows the aqueous extraction of crude vegetable oils. The food enzyme–TOS is predominantly separated from the oil phase and stays within the aqueous phase. Residual amounts of TOS may remain in the crude oils. For crude oils that are degummed and refined further, these steps are expected to reduce any residual TOS in edible vegetable oils down to a negligible amount.

This assumption was supported by information submitted by AMFEP,[35] which included (i) a process diagram showing steps from treating fruit and vegetable material with cell-wall degrading enzymes to the first extraction of crude oils; (ii) a process diagram showing steps for treating microalgae with cell-wall degrading enzymes for the extraction of crude oils; (iii) proximate analysis on the intermediate products and final algal oils; (iv) a theoretical calculation. Using the hydrophilic properties of enzymes and the residual moisture of algal oil as the proxy, it is estimated that the amount of TOS in refined edible oils would not exceed 0.0001%.

The evidence provided by AMFEP was considered sufficient to support the exclusion of refined final oil products derived from enzymatically treated plants and algae from dietary exposure calculation. However, for non-refined oils intended for human consumption, minor amounts of TOS are expected to remain in the final oil. To exclude such non-refined edible oils from exposure estimation, the applicant should provide analytical data to substantiate TOS removal of at least 99%.

3.23. Production of green coffee beans by demucilation [06.03]

This process has been adapted from the 'EC working document on food processes in which food enzymes are used' as follows[10]:

this food manufacturing process relies on raw coffee cherries as raw materials and leads to the production of green coffee beans.

[33] Information on 'EFSA call for input data for the exposure assessment of food enzymes: refined sugar production (molasses as a by-product) CEFS comment'. July 2020.

[34] Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products (OJ L 347, 20.12.2013), part VIII, Annex VII.

[35] Information on 'Transfer of enzymes into food, as consumed in fruit and vegetable processing for vegetable oil production'. February and July 2021.

Food enzymes may be used to treat coffee cherries for purposes such as:

- *to remove the mucilage coat from the coffee cherries in the fermentation step, which can accelerate the fermentation stage*.

Food enzymes that can typically be used in this process are pectolytic enzymes and mannanases.

The resulting product, i.e. green coffee beans, is excluded from the dietary exposure calculation, as the presence of residual TOS after demucilation is negligible. This assumption was supported by information submitted by AMFEP,[36] which included (i) a description of the main steps employed in coffee processing from the harvested coffee cherries to soluble ground coffee and (ii) in relation to the addition and inactivation/removal of food enzymes, measurement of enzymatic activity for two different food enzymes on the surface of the harvested coffee cherries, intermediate coffee bean under fermentation and final green coffee beans.

Although it was not possible to quantify the extent of TOS removal based on the residual enzyme activity measured, considering that the food enzyme is used only on the coat of the raw coffee cherries to aid removal of same and followed by washing steps, it is reasonable to conclude that food enzymes are removed during demucilation of coffee beans.

3.24. Production of coffee extracts [06.04]

This process has been adapted from the 'EC working document on food processes in which food enzymes are used' as follows[10]:

this food manufacturing process relies on coffee beans as raw materials and leads to the production of coffee extracts.

Food enzymes may be used in the coffee processing for purposes such as:

- *to reduce viscosity of coffee extracts;*
- *to improve product stability;*
- *to improve aroma and flavour of instant coffee;*
- *to decompose chlorogenic acid*.

Food enzymes that can typically be used in this process are pectinolytic enzymes, β-mannanases, cellulases, chlorogenic acid esterase and lipases.

It excludes the use of asparaginase to prevent acrylamide formation.

Following the open call-for-data,[29] feedback was received from the European Coffee Federation.

The input data used to estimate dietary exposure to food enzyme–TOS in foods relevant to this intended use are summarised in Annex 19.

3.25. Production of coffee substitutes [06.05]

This process has been adapted from the 'EC working document on food processes in which food enzymes are used' as follows[10]:

this food manufacturing process relies on grain (e.g. rye, wheat, oats, barley) and other plant materials (e.g. chicory) as raw materials and leads to the production of products such as, but not limited to, chicory coffee, malt coffee and other coffee substitutes.

Food enzymes may be used in the coffee substitute processing for purposes such as:

- *to reduce viscosity of the extracts;*
- *to decompose polysaccharides in coffee substitutes*.

Food enzymes that can typically be used in this process are pectinolytic enzymes, β-mannanases and lipases.

It excludes the use of asparaginase to prevent acrylamide formation.

Following the open call-for-data,[37] feedback was received from a company (GRANA sp. z o.o.).

The input data used to estimate dietary exposure to food enzyme–TOS in foods relevant to this intended use are summarised in Annex 20.

[36] Information on 'Coffee processing/demucilation'. September 2019.
[37] https://www.efsa.europa.eu/en/call/call-input-data-exposure-assessment-food-enzymes-21st-call

3.26. Production of tea and other herbal and fruit infusions [06.06]

This process has been adapted from the 'EC working document on food processes in which food enzymes are used' as follows[10]:

This food manufacturing process relies on leaves and tender shoots of varieties of the species Camellia sinensis *(L.) O. Kuntze as raw materials and lead to the production of tea and tea extracts. Herbal and fruit infusions rely on plants or parts of plants that do not originate from the tea plant as the raw material obtained by aqueous extraction*.

Different food enzymes may be used during tea processing for purposes such as:

- *to improve the extraction;*
- *to improve sensory properties*.

Food enzymes that can typically be used in these processes are cellulases, hemicellulases, peptidases, pectinolytic enzymes, laccases, amylases and tannases.

It excludes the extraction of essential oils; the production of plant extracts is covered by the category 'Production of plant extracts'.

Following the open call-for-data,[38] feedback was received from the association Tea and Herbal Infusions Europe (THIE) and from an enzyme manufacturer (DSM FOOD SPECIALTIES B.V.).

The input data used to estimate dietary exposure to food enzyme–TOS in foods relevant to this intended use are summarised in Annex 21.

3.27. Production of plant extracts [06.07]

This process has been adapted from the 'EC working document on food processes in which food enzymes are used' as follows[10]:

this food manufacturing process relies on a broad variety of plant materials as the main raw materials to extract products e.g. with oils or solvents (including water). These extracts are used for a variety of purposes in food and beverage applications, including but not limited to food fortification, colouring and flavouring.

Food enzymes may be used during the production of plant extracts for purposes such as:

- *treatment of plant material to facilitate any further processing such as the extraction of flavourings or colouring agents*.

Food enzymes that can be typically used in this process are cellulases, hemicellulases, amylases, pectinolytic enzymes and α-glucosidase.

Coffee extracts are excluded from this process and are included in the category 'production of coffee extracts'.

Depending on the respective process, the food enzyme–TOS may be removed or may remain in the final foods. A call-for-data[39] was launched for those situations where the food enzyme–TOS is expected to remain. Feedback was received from EFFA and from an enzyme manufacturer (DSM FOOD SPECIALTIES B.V.).

The input data used to estimate dietary exposure to food enzyme–TOS in foods relevant to this intended use are summarised in Annex 22.

3.28. Production of plant-based analogues of milk and milk products [06.08]

This process has been adapted from the 'EC working document on food processes in which food enzymes are used' as follows[10]:

this food manufacturing process relies on plant-based raw materials, such as cereals (e.g. oat, rice, buckwheat), legumes, oil seeds, nuts (e.g. coconut, almond). These ingredients can be ground or pureed and mixed with water before applying the enzymes.

[38] https://www.efsa.europa.eu/en/call/call-input-data-exposure-assessment-food-enzymes-11th-call
[39] https://www.efsa.europa.eu/it/call/call-input-data-exposure-assessment-food-enzymes-23rd-call

Food enzymes are usually added during processing to act on various substrates present in plants such as starch and other polysaccharides, proteins and lipids for purposes such as:

- *to reduce viscosity;*
- *to improve texture;*
- *to improve sensory properties;*
- *to improve solubility;*
- *to increase bioavailability and digestibility of proteins*.

Food enzymes that can typically be used in this process are amylases, glucosidases, hemicellulases, glucanases, pectinolytic enzymes, peptidases, lipases, phospholipases, cellulases, phytases and peroxidases.

Following the open call-for-data,[40] feedback was received from five companies (DSM FOOD SPECIALTIES B.V., Oatly AB, Valio Group, Zentis GmbH & Co and Amano Enzymes Inc.).

The input data used to estimate dietary exposure to food enzyme–TOS in foods relevant to this intended use are summarised in Annex 23.

3.29. Production of soy sauce [06.09]

This process has been adapted from the 'EC working document on food processes in which food enzymes are used' as follows[10]:

this food manufacturing process relies on soya beans and other ingredients as the raw materials. By fermentation it leads to the production of soy sauce. Food enzymes that can be typically used in this process are phytases and peptidases.

Following the open call-for-data,[41] no response was received from any stakeholders.

The input data used to estimate dietary exposure to food enzyme–TOS in foods relevant to this intended use are summarised in Annex 24.

3.30. Production of protein hydrolysates from plants and fungi [06.10]

This process has been adapted from the 'EC working document on food processes in which food enzymes are used' as follows[10]:

this food manufacturing process relies on protein-rich raw materials from plants and fungi and leads to the production of plant and fungal protein hydrolysates.

Various food enzymes may be used in plant and fungal protein processing to produce protein hydrolysates for purposes such as:

- *to hydrolyse proteins and obtain products that can be used in a wide range of foods (savoury foods e.g. soups, bouillons, dressings, snacks, meat-derived processed foods or foods supplemented with protein)*.

Food enzymes that can typically be used in this process are peptidases, pectinolytic enzymes, hemicellulases and cellulases.

This process involves enzymatic treatments of protein-rich extracts from plant and fungal materials, such as soy protein. The resulting protein hydrolysates are used as ingredients in many types of foods-as-consumed.

Food products containing plant and fungal protein hydrolysates as an ingredient could not easily be identified in the EFSA RPC model. The food categories were selected from databases like the Mintel Database (GNPD).

Following the open call-for-data,[20] feedback was received from three companies (DSM FOOD SPECIALTIES B.V., Kerry Ingredients & Flavours Ltd and DEVRO PLC). The open call-for-data was launched including both animal and plant protein hydrolysates. However, following public consultation, the dataset was separated into two sets, one for animal and one for plant protein hydrolysates.

The input data used to estimate dietary exposure to food enzyme–TOS in foods relevant to this intended use are summarised in Annex 25.

[40] https://www.efsa.europa.eu/it/call/call-input-data-exposure-assessment-food-enzymes-20th-call
[41] https://www.efsa.europa.eu/en/call/call-input-data-exposure-assessment-food-enzymes-24th-call

3.31. Processing of yeast and yeast products [07]

This process has been adapted from the 'EC working document on food processes in which food enzymes are used' as follows[10]:

this food manufacturing process relies on yeast as the raw materials to produce yeast extracts, yeast cell walls and yeast hydrolysates which are used mainly as food ingredients in a wide range of foods (savoury foods, e.g. soups, bouillons, dressings, snacks, meat-derived processed foods or foods supplemented with protein).

Food enzymes are added at different stages in the process depending on the product and for purposes such as:

- *to hydrolyse biopolymers into smaller units such as peptides, free amino acids, mannans and nucleotides.*

Food enzymes that can be typically used in this process are phosphodiesterases, nucleotide deaminases, cellulases, amylases and peptidases.

This process involves enzymatic treatment of yeast to obtain derivatives such as yeast extracts, yeast autolysates and yeast cell walls. Mannoproteins extracted from the yeast cell walls and used to inhibit crystal formation in wine[42] are included.

Only very few food products containing yeast extract as an ingredient could be found in the EFSA RPC model. The food categories were, therefore, selected from the Mintel Database (GNPD).

Following the open call-for-data,[43] feedback was received from the European Association for Specialty Yeast Products (EURASYP), who clarified that yeast cell walls can also be used in food applications and not only in animal feed.

The input data used to estimate dietary exposure to food enzyme–TOS in foods relevant to this intended use are summarised in Annex 26.

Processing of fats and oils [08]

3.32. Production of refined edible fats and oils by degumming [08.01]

This process has been adapted from the 'EC working document on food processes in which food enzymes are used' as follows[10]:

crude oils extracted from various plant sources (e.g. oilseeds, fruit pulps) are the raw materials. Water refining, usually called degumming, is the treatment of crude oils and fats with a small amount of water repeatedly to remove water-soluble impurities.

Food enzymes that can typically be used in these processes are phospholipases.

Edible fats and oils derived through degumming are excluded from dietary exposure calculation, as the degummed oil is further washed with water and centrifuged to remove the water/gum phase. The enzyme is retained in the water/gum phase. Repeated refining to remove impurities after degumming, filtration and purification steps also removes any residual TOS to a negligible amount.

This assumption was supported by information submitted by AMFEP together with the Federation representing the European Vegetable Oil and Protein Meal Industry in Europe,[44] which included a description of the main steps of the refined vegetable oil production through enzymatic degumming in relation to the addition and inactivation/removal of food enzymes, and analytical data on the intermediate products and final refined edible oils. When using the total protein and true protein-specific nitrogen as the proxy to consider the residual food enzyme–TOS, it is estimated that > 99% of enzymes added to the raw material are removed during the process. The evidence was considered as sufficient to conclude that residual amounts of TOS are removed by the purification steps applied during the production of plant fats and oils (by > 99%), i.e. repeated washing and centrifugation.

3.33. Production of modified fats and oils by interesterification [08.02]

This process has been adapted from the 'EC working document on food processes in which food enzymes are used' as follows[10]:

[42] Source: https://www.fao.org/3/cb3376en/cb3376en.pdf
[43] https://www.efsa.europa.eu/en/call/call-input-data-exposure-assessment-food-enzymes-19th-call
[44] Information on 'Transfer of enzymes into food, for fat and oil processing'. October 2017 and February 2019.

this food manufacturing process covers any modification of oils and fats designed to improve functionality through inter- esterification. It relies on fats and oils as the raw materials.

Various food enzymes may be used in these processes for purposes such as:

- *to rearrange the position of fatty acids in triacylglycerols, thus altering their physical properties (melting point) without creating trans-isomers and/or altered sensory characteristics*.

Food enzymes that are typically used in this process are lipases. Interesterification is operated as a 'continuous' process with immobilised lipases.

Concerning the interesterification of fats and oils, AMFEP, in October 2017, provided technical information, which indicated that (i) immobilised lipases are used for enzymatic interesterification of oil/fat, (ii) interesterification is operated as a 'continuous' process and (iii) 1 kg food enzyme–TOS is used for the production of at least 20–100 tons refined oil. Assuming that all TOS would leach into the final oil product, AMFEP estimated that 1 kg food enzyme–TOS/100,000 kg oil would correspond to 0.001% TOS in final oil products.[45]

This information was not considered sufficient to waive the need for calculating exposure. In particular, since different approaches to immobilising food enzymes are in use, and are often specific to the individual application, relevant technical information and/or experimental data may be required on a case-by-case basis.

In February 2020, EFSA launched a call-for-data on interesterified fats. The input data contained a list of FoodEx categories and respective technical conversion factors. Due to the difficulty of distinguishing enzymatically interesterified fats from chemically modified plant fats, EFSA decided to use all plant fats (except fats and oils consumed as such or used as ingredient in chocolate[46]) as a proxy for enzymatically interesterified fats. Consequently, the FoodEx categories cover foods that contain processed plant fats, such as margarine and shortening.

Following this call-for-data,[47] a response was received from the EU vegetable oil and protein meal industry association (FEDIOL) with input from FoodDrinkEurope, CAOBISCO, Federation of Associations and Enterprises of Industrial Culinary Product Producers in Europe, European Snack Association, European Ice Cream Association and the European Margarine Association. It is clarified that butter biscuits contains only butter as the fat component. These associations also specified the amount of enzymatically interesterified fats in margarine.[48]

The input data used to estimate dietary exposure to food enzyme–TOS in foods relevant to this intended use are summarised in Annex 27.

3.34. Production of free fatty acids by hydrolysis [08.03]

This process has been adapted from the 'EC working document on food processes in which food enzymes are used' as follows[10]:

this food manufacturing process relies on fats and oils as the raw materials and leads to the production of free fatty acids by hydrolysis.

Various food enzymes may be used in these processes for purposes such as:

- *to produce free fatty acids such as eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA)*.

Food enzymes that are typically used in this process are lipases.

The amount of food enzyme–TOS in the final products may be negligible, depending on the purification process. However, since different purification processes are in use, and are often specific to the individual application, relevant technical information and/or experimental data may be required to substantiate TOS removal on a case-by-case basis.

[45] AMFEP answer to EFSA's request for additional information on the transfer of enzymes into food, for fat and oil processing. October 2017.

[46] Directive 2000/36/EC of the European Parliament and of the Council of 23 June 2000 relating to cocoa and chocolate products intended for human consumption (OJ L 197, 3.8.2000, p.19) specifies that vegetable fats used in chocolate are to be obtained only by the processes of refining and/or fractionation, which excludes enzymatic modification of the triglyceride structure.

[47] https://www.efsa.europa.eu/en/consultations/call/call-input-data-exposure-assessment-food-enzymes-5th-call

[48] Feedback regarding FEDIOL input into the 5th EFSA call for input data for the Exposure Assessment of Food Enzymes related to fats and oils processing for interesterification. October 2020 & May 2021.

3.35. Production of flavour compounds by esterification [08.04]

This process has been adapted from the 'EC working document on food processes in which food enzymes are used' as follows[10]:

this food manufacturing process relies on chemically defined substances (carboxylic acids and alcohols) as the raw materials and leads to the production of esters.
Food enzymes that are typically used in this process are lipases.

For volatile esters, EFFA has provided analytical data showing the extensive purification of these esters by distillation.[49] The evidence provided by EFFA was considered as sufficient to support the exclusion of distilled enzymatically produced flavouring esters from dietary exposure calculation.

3.36. Production of modified lecithins [08.05]

This process has been adapted from the 'EC working document on food processes in which food enzymes are used' as follows[10]:

this food manufacturing process covers the modification of lecithins from egg and plant sources designed to improve functionality.
Various food enzymes may be used in these processes for purposes such as:

- *to produce substances with emulsifying properties*.

Food enzymes that are typically used in this process are phospholipases.
Lecithins and modified lecithins (E 322) are authorised food additives in the EU according to Annex II and Annex III to Regulation (EC) No 1333/2008[50] on food additives.
In the framework of Regulation (EC) No 1333/2008 on food additives and of Commission Regulation (EU) No 257/2010[51] regarding the re-evaluation of approved food additives, the ANS panel, in 2017, re-evaluated lecithin used as food additive and in support of this opinion issued public calls for occurrence data (usage level and/or concentration data) on lecithins (E 322). In response to this public call, updated information on the actual use levels of lecithins (E 322) in foods was made available to EFSA by industry.
Since an exposure assessment to lecithins (E 322) was carried out by the EFSA ANS panel as part of the re-evaluation programme and published in 2017,[52] the already derived exposure estimates were combined with the food enzyme use levels for the assessment of exposure to food enzymes used in the production of lecithin.

Processing of sugars [09]

3.37. Production of confectionery products and beverages [09.01]

This process has been adapted from the 'EC working document on food processes in which food enzymes are used' as follows[10]:

This food manufacturing process relies on sugars (e.g. sucrose, fructose, glucose and other saccharides) as raw materials during confectionery and beverage production for purposes such as:

- *to increase humectant properties of sweet fillings;*
- *to achieve a more homogenous distribution of the filling by incorporating food enzymes in candy filling together with other ingredients;*
- *to isomerise glucose* in situ.
- *to hydrolyse sucrose before fermentation*.

Food enzymes that can typically be used in these processes are β-fructofuranosidase (invertases), glucosidases and isomerases.

[49] EFFA Submission from December 2012.
[50] Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food. OJ L 354, 31.12.2008, p. 16–33.
[51] Commission Regulation (EU) No 257/2010 of 25 March 2010 setting up a programme for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives. OJ L 80, 26.3.2010, p. 19–27.
[52] Available online: https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2017.4742

Following the open call-for-data,[53] no response was received from any stakeholders.

The input data used to estimate dietary exposure to food enzyme–TOS in foods relevant to this intended use are summarised in Annex 28.

3.38. Production of oligosaccharides [09.02]

This process has been adapted from the 'EC working document on food processes in which food enzymes are used' as follows[10]:

*this food manufacturing process relies on disaccharides (*i.e. *lactose, sucrose) or polysaccharides (*i.e. *inulin) as raw materials and leads to the production of products such as, but not limited to, fructo- and galacto- oligosaccharides (FOS and GOS)*.

Various food enzymes may be used in the production of oligosaccharides for purposes such as:

- *to hydrolyse polysaccharides;*
- *to catalyse the synthesis of oligosaccharides*.

Food enzymes that can typically be used in this process are glycosidases and glycosyltransferases.

It includes oligosaccharides that are used as ingredients in infant Formulae and Follow-on Formulae.

The term 'oligosaccharides' is not always found on food labels; FOS and GOS are not always and not clearly labelled and could not be identified in the EFSA RPC model. Therefore, the food groups were selected from literature data and from the Mintel Database (GNPD). The key word 'fructo-oligosaccharides', 'galacto-oligosaccharides', 'inulin', 'dietary fiber' and their variants were used in the search to derive the f3 factors. In addition, the selection of food categories was supported by the information provided in food enzyme applications.

Following the open call-for-data,[54] feedback was received from the Comité Européen des Fabricants d'Inuline (CEFI) and from two companies (DSM FOOD SPECIALTIES B.V. and TEREOS).

The input data used to estimate dietary exposure to food enzyme–TOS in foods relevant to this intended use are summarised in Annex 29.

3.39. Production of specialty carbohydrates (excluding oligosaccharides) [09.03]

This process has been adapted from the 'EC working document on food processes in which food enzymes are used' as follows[10]:

this food manufacturing process relies on carbohydrates (e.g. sucrose, lactose, glucose) as raw materials and leads to products such as, but not limited to trehalose, allulose, tagatose and cyclodextrins.

Food enzymes may be used in the carbohydrate processing and conversion for purposes such as:

- *to hydrolyse di- or oligosaccharides to monomers or short-chain sugars to generate sensory and technological advantages;*
- *to produce low glycaemic sugar substitutes;*
- *to synthesise cyclodextrins;*

Food enzymes that can be used during such manufacture are amylases, glucosidases, alternansucrase, cyclomaltodextrin glucanotransferase, D-fructose 3-epimerase, D-psicose 3-epimerase, isomaltulose synthase, β-galactosidases/galactosyltransferases, inulinase fructosyltransferase, β-fructofuranosidase (invertase) and transglucosidases.

It excludes oligosaccharides.

The food enzyme may be used in free form or as an immobilised preparation. When immobilised, the carry-over of TOS into the speciality carbohydrates is likely to be reduced.[55] Independent of the methods of application, the final products undergo extensive purification.

[53] https://www.efsa.europa.eu/en/call/call-input-data-exposure-assessment-food-enzymes-18th-call
[54] https://www.efsa.europa.eu/en/call/call-input-data-exposure-assessment-food-enzymes-14th-call
[55] Information on 'Transfer of enzymes into food, for refined sugar production and processing', provided by AMFEP. October 2017.

Nonetheless, as different approaches to immobilising food enzymes are in use, and are often specific to the individual application, the request the relevant technical information and/or experimental data will be decided on a case-by-case basis.

3.40. Prevention of acrylamide formation in foods [10]

This process has been adapted from the 'EC working document on food processes in which food enzymes are used' as follows[10]:

acrylamide is formed in starchy food products during thermal processing of foods at low moisture. Prevention of acrylamide formation applies to carbohydrate and asparagine containing foods as raw materials, such as potatoes, cereals, coffee or cocoa, and leads to food products with reduced contents of acrylamide.

The food enzyme that can typically be used in these processes is asparaginase.

Following the open call-for-data,[56] feedback was received from AMFEP and from two companies (DSM FOOD SPECIALTIES B.V. and WEETABIX Ltd).

The input data used to estimate dietary exposure to food enzyme–TOS in foods relevant to this intended use are summarised in Annex 30.

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Abbreviations

AICV	European Cider and Fruit Wine Association
AIJN	European Fruit Juice Association
AMFEP	European Association of Manufacturers and Formulators of Enzyme Products
ANS	EFSA Panel on Food Additives and Nutrient Sources Added to Food
CAOBISCO	Association of Chocolate, Biscuits and Confectionery Industries of Europe
CEF	EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids
CEFI	Comité Européen des Fabricants d'Inuline
CEFS	European Association of Sugar Manufacturers
CEP	EFSA Panel on Food Contact Materials, Enzymes and Processing Aids
DHA	docosahexaenoic Acid
EDA	European Dairy Association
EFFA	European Flavour Association
EMDI	enzyme modified dairy ingredients
EPA	eicosapentaenoic acid
EURASYP	European Association for Specialty Yeast Products
FAIM	Food Additive Intake Model
FAO	Food and Agricultural Organization of the United Nations
FEDIOL	EU vegetable oil and protein meal industry association

[56] https://www.efsa.europa.eu/en/call/call-input-data-exposure-assessment-food-enzymes-16th-call

FEIM	Food Enzyme Intake Model
FSMP	Food for Special Medical Purposes
GME	Gelatine Manufacturers of Europe
GNPD	Global New Products Database
IFF	International Flavors and Fragrances
RPC	raw primary commodity
SC	EFSA Scientific Committee
SNE	Specialised Nutrition Europe
TOS	total organic solids
THIE	Tea and Herbal Infusions Europe

Annexes

Annexes are downloadable at https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.8094#support-information-section).

Annexes 1–30 reports the food manufacturing process-specific input data for FEIM. The selected food groups and corresponding technical factors for each food manufacturing process are presented in the format of Excel files. Each file contains two sheets, representing the input data in the Foodex1 and Foodex2 food classification systems, respectively.

Annex 31 reports the outcome of the public consultation and information session for the draft guidance 'Food manufacturing processes and technical data used in the exposure assessment of food enzymes'.

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Annex 24: Production of soy sauce [06.09] – input data
Annex 25: Production of protein hydrolysates from plants and fungi [06.10] – input data
Annex 26: Production of yeast and yeast products [07] – input data
Annex 27: Production of modified fats and oils by interesterification [08.02] – input data
Annex 28: Production of confectionery products and beverages [09.01] – input data
Annex 29: Production of oligosaccharides [09.02] – input data
Annex 30: Prevention of acrylamide formation in foods [10] – input data
Annex 31: Outcome of the public consultation and information session