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Food Safety, Sustainability, and Innovation
Food Processing Technologies and Novel Foods

Guidelines on the determination of processing factors¹ (version 10 September 2026)

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¹ Source ‘ANAFACO – Considerations for the Processing Factor – 30.04.25 vdef’ and ‘SANTE/10704/2021 Rev.1 – Information note on Article 20 of Regulation (EC) No 396/2005 as regards processing factors, processed and composite food and feed.’

Introduction

Commission Regulation (EU) 2023/915 of 25 April 2023,² on maximum levels for certain contaminants in foodstuffs, lists in its Annex I the maximum levels for contaminants in food, which are applicable in the EU. Article 3 of this Regulation foresees that,

where no specific Union maximum levels are set out in Annex I for food which is dried, diluted, processed or compound food (i.e. composed of more than one ingredient), the following aspects shall be taken into account when applying the maximum levels set out in Annex I to such food:

- a) changes of the concentration of the contaminant caused by drying or dilution processes;*
- b) changes of the concentration of the contaminant caused by processing;*
- c) the relative proportions of the ingredients in the product;*
- d) the analytical limit of quantification.*

Where the competent authority carries out an official control, the food business operator shall provide and justify the specific concentration, dilution or processing factors for the drying, diluting or processing operations concerned or the specific concentration, dilution or processing factors for the dried, diluted, processed or compound food concerned as well as the proportion of ingredients for mixing operations concerned.

Where the food business operator does not provide the necessary concentration, dilution or processing factor or where the competent authority deems that factor inappropriate in view of the justification given, the competent authority shall itself define that factor, based on the available information and with the objective of maximum protection of human health.

This guidance document is intended to provide guidance when setting up specific (research) projects to determine the processing factors for general use in application of article 3 of Regulation (EU) 2023/915.

This guidance is also useful for food business operators (FBO) to determine the correct processing factor for their specific process. While the use of accredited laboratories /accredited methods of analysis by FBOs is preferred, if this is not possible, they can also use a validated method of analysis. A statistical evaluation of the results is also recommended for FBOs, but can be omitted, in case that this is not feasible.

² <http://data.europa.eu/eli/reg/2023/915/oj>

Definitions of processing and processed products

‘Processing’³ means any action that substantially alters the initial product, including heating, smoking, curing, maturing, drying, marinating, extraction, extrusion or a combination of those processes.

‘Processed products’⁴ means foodstuffs resulting from the processing of unprocessed products. These products may contain ingredients that are necessary for their manufacture or to give them specific characteristics.

Processing factor (PF): Calculated as the ratio of the contaminant concentration in the processed product and the contaminant concentration in the relevant unprocessed product covered by Annex I of Regulation (EU) 2023/915.

General principles

Calculation of a processing factor (PF)

The processing factor is calculated from the contaminant concentration in the processed product divided by the contaminant concentration in the corresponding raw commodity (unprocessed product):

$$PF = (\text{contaminant concentration in the processed fraction} / \text{contaminant concentration in the raw agricultural commodity})$$

- PF is > 1: Residues concentrated in the processed product.
- PF is < 1: Residues declined in the processed product (due to dilution, removal or degradation).
- PF = 1: Processing did not result in a change of residue concentrations.

Calculation of a “derived ML” applicable to a processed product using a processing factor:

In order to assess compliance with an ML, the “derived ML” for the processed product is obtained by multiplying the PF with the ML of the relevant unprocessed product covered by Annex I:

Different types of processing factors

Processing factors can be divided into contaminants-specific processing factors and generic processing factors for certain standard processing operations (e.g., drying by removing of water). Generic processing factors should only be used when substance specific factors are not available.

³ <http://data.europa.eu/eli/reg/2004/852/oj>

⁴ <http://data.europa.eu/eli/reg/2004/852/oj>

Substance specific processing factors

A substance-specific processing factor is specific to a certain contaminant in a certain commodity that has undergone a certain process.

Extrapolation of substance specific processing factors

In certain cases and provided that processes are comparable, extrapolation between similar commodities could be considered. Those cases could include the extrapolation of processing factors for processed products derived from raw material classified in the same commodity (sub)group. Also, in some cases it could be possible to apply the processing factor from a contaminant (for example a certain metal) to a different contaminant (for example another metal) for the same commodity based on physical properties such as e.g., fat solubility. Extrapolations of this kind are left to the expert judgement of the Member States and no general rules can be provided.

Generic processing factors

Generic processing factors are specific to a certain process (e.g., dehydration or dilution with water).

The drying factor only takes into account concentration of the contaminant due to evaporation of water from the unprocessed product for which an ML is established under Regulation (EU) 2023/915.

Commodity-specific drying factors are calculated based on the dry matter content in the starting material and the dried commodity derived thereof, and are thus specific for the drying process used by a certain producer of dried commodities. Dry matter contents for the starting material and the dried commodity thereof can be obtained from the producer of the dried commodity.

The ML of the dried commodity can be calculated by multiplication of the ML of the unprocessed product by the drying factor for the corresponding dried commodity.

Requirements for studies for the determination of processing factors

In order to conduct a study for the determination of a processing factor, it is necessary to establish a methodology that enables the experimental identification of a statistically significant relationship between batches of raw material and the final transformed product. Such a study could be outlined in the following steps:

1. Analysis of the manufacturing process, standards in use.
2. Representative sampling of the batches of raw material and final product.
3. Analysis in accredited laboratories.
4. Statistical evaluation of results, and the significance of their correlation.

Analysis of the manufacturing process, standards in use.

The processing factor study should be conducted under conditions that reflect the common production process of the product. Any relevant and significant change in the core operations that influence the concentration of the contaminant, would compromise the representativeness of the results.

In general terms, good manufacturing practices (GMP) and operational standards should be taken into account in relation to the processing factor, as they directly impact its validity and reproducibility:

- Type of raw material: specific species, harvest or fishing area, wild or cultivated products, ...
- Thermal processes: cooking and sterilization time/temperature.
- Packaging materials: type of material.
- Storage conditions: exposure to light/heat.
- Hygiene practices: effectiveness of equipment cleaning protocols or possible cross-contamination.

Particular considerations for cooked, fried, sterilised and canned foods:

- Cooking and frying processes typically lead to greater dehydration and, consequently, a higher concentration of contaminants. In contrast, sterilization can result in different outcomes depending on the type of covering medium used and the specific contaminant being studied. Although sterilization itself contributes to dehydration, the addition of a covering medium within a hermetically sealed container generally produces a dilution effect, which may compensate for the dehydration that occurred in earlier stages.
- Experience shows that cooking—a process commonly used across various food products—has a greater impact on the processing factor than sterilization in hermetically sealed containers. This distinction is important when considering the processes involved in producing a commercial canned product.

Representative sampling of the batches of raw material and final product.

Special attention must be given to ensuring the identity and representativeness of the samples collected for the analysis of contaminant concentrations—both in the raw materials and in the final product—on which the processing factor is calculated, with full traceability.

The purpose of sampling is to obtain a representative sample of the lot or batch, in order to verify whether contaminant levels comply with legal limits. Therefore, the definitions of a lot and the sampling requirements of the following Regulations should be followed:

- For the control of levels of mycotoxins: Commission Implementing Regulation (EU) 2023/2782^{5, 6}

⁵ http://data.europa.eu/eli/reg_impl/2023/2782/2024-03-24

⁶ For auto-controls on mycotoxins a sampling procedure that is equivalent to the sampling procedures established by Commission Implementing Regulation (EU) 2023/2782 or a sampling procedure for which evidence is available that the samples are representative for the lot might alternatively be used (SANTE PLAN 2026/324)

- For the control of levels of plant toxins: Commission Implementing Regulation (EU) 2023/2783^{7, 8}
- For the control of levels of trace elements and processing contaminants in foodstuffs: Commission Regulation (EC) No 333/2007⁹
- For the control of levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in certain foodstuffs: Commission Regulation (EU) 2017/644 of 5 April 2017 laying down methods of sampling and analysis for the control of levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in certain foodstuffs and repealing Regulation (EU) No 589/2014¹⁰
- For the control of levels of nitrates: Commission Regulation (EC) 1882/2006¹¹
- For the control of perfluoroalkyl substances: Commission Implementing Regulation (EU) 2022/1428¹²

Analysis in accredited laboratories.

The selected sample should be analysed in a laboratory using accredited analytical methods.

Number of required data sets

Three replicate sample pairs (datasets) for each process are required as a minimum. Where the results (processing factors) of the three datasets statistically differ (see below), more samples should be taken.

Statistical evaluation of results, and their significant correlation

The data obtained in the experimental study must be verified statistically so that the data sets obtained, both for raw material and final product, are statistically robust.

The following statistical tests could be applied:

Dixon's Q for the rejection of anomalous results.

If any of the obtained processing factor values are considered suspicious (i.e., discrepant or anomalous), the decision to exclude them will be based on the calculation of Dixon's Q coefficient before determining the mean, standard deviation, and relative standard deviation (RSD). Dixon's Q is a statistical test that calculates the relative difference between

⁷ http://data.europa.eu/eli/reg_impl/2023/2783/oj

⁸ For auto-controls on plant toxins a sampling procedure that is equivalent to the sampling procedures established by Commission Implementing Regulation (EU) 2023/2783 or a sampling procedure for which evidence is available that the samples are representative for the lot might alternatively be used (SANTE PLAN 2026/324)

⁹ <http://data.europa.eu/eli/reg/2007/333/2012-09-01>

¹⁰ <http://data.europa.eu/eli/reg/2017/644/oj>

¹¹ <http://data.europa.eu/eli/reg/2006/1882/oj>

¹² http://data.europa.eu/eli/reg_impl/2022/1428/oj

the most extreme values in a data set. For small sample sizes, ideally between 3 and 30 data points, Dixon's Q test has sufficient statistical power to assess suspicious extreme values. This test is used to determine whether an extreme value can be statistically identified as an outlier.

To perform this calculation, the following formula is applied, and the computed value is compared against the tabulated value for the corresponding sample size.

$$Q = (\text{Suspect value} - \text{Closest value}) / (\text{Largest value} - \text{Smallest value})$$

If the calculated Q value is greater than the critical value, the suspect value is rejected.

Test of Homogeneity of Variances (Levene's test))

Before calculating the mean value of the processing factors, we will first check whether the variances are homogeneous between the data groups.

Levene's test is performed, and the p-value obtained from the ANOVA is checked. If the p-value is greater than 0.05, the variances are considered homogeneous.

If the variances are homogeneous, the mean and standard deviation can be directly applied to calculate the processing factor. If they are not homogeneous, it is advisable to use the Bootstrapping method to increase the number of cases, thereby improving the reliability of the mean value obtained.

Bootstrapping mean

In case the Levene's test reveals heterogeneity of the data, i.e. $p < 0.05$ of Levene's test, the Bootstrapping method of resampling with replacement will be applied to the data to obtain a reliable estimate of the mean value of the processing factors in the data set. This statistical technique consists of obtaining 1000 random subsamples from a sample of existing data in order to enlarge the sample size and obtain "replicates" of that sample, and from them estimate a reliable mean value.

If the processing factor data are heterogeneous and the coefficients of variation calculated from the standard deviations and the means obtained from the different processing factors calculated are high (greater than 10-20 %), the sample size of raw materials and final products will have to be increased in order to obtain statistically significant data. In case of excessive variability, the homogeneity of the raw material batches should be reviewed.

If the data are statistically representative, the processing factor of the contaminant in the processed product can be estimated by dividing the concentration in the processed product by the concentration in the raw material, which was used for producing the processed product.

Once the processing factor is estimated, it is recommended to maintain historical data from these analyses. This practice helps to re-check the factor without requiring additional specific studies.

Report of studies on processing factors

The report of studies on processing factors should clearly describe

- the starting material, the process and the final processed food;
- the contaminant;
- the sampling method of the batches of raw material and final product;
- the analysis method and the laboratory, performing the analysis;
- the analytical results of the starting materials and the processed products from the same batch;
- the statistical evaluation of results, and the significance of their correlation;
- the conclusions as regards the determined processing factor.