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## **Information note on Article 20 of Regulation (EC) No 396/2005 as regards processing factors, processed and composite food and feed<sup>1</sup>**

Please note that this document focuses mainly on processing factors and processed food and feed in a first step. More detailed provisions as regards composite food and feed (which are covered in principle) can be developed at a later stage, if needed.

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<sup>1</sup> This document has been conceived as an information note of the Commission Services. It does not represent the official position of the Commission. It does not intend to produce legally binding effects. Only the European Court of Justice has jurisdiction to give preliminary rulings concerning the validity and interpretation of acts of the institutions of the EU pursuant to Article 267 of the Treaty.



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## 1. Introduction

The European Commission (the Commission) carried out an evaluation<sup>2</sup> of the plant protection products (PPP)<sup>3</sup> and maximum residue levels (MRL) Regulations<sup>4</sup> covering the period of their respective entry into application until the end of 2018 as part of its regulatory fitness and performance programme (REFIT). The Commission assessed whether the Regulations are fit for purpose, achieve their objectives while keeping the European Union (EU) law simple, and removing unnecessary burdens. One of the findings of the evaluation was that general provisions for processed products are already in place, but those provisions would benefit from clarification. It is therefore necessary to give guidance to all involved parties, in particular the competent authorities in the Member States responsible for enforcement, but also food and feed business operators (FBO), on how to deal with processed products.

This document is an evolving document and will be updated to take account of the experience of the competent authorities or any new information that may become available. In a first step, this document mainly focuses on processing factors (Pf) and processed food and feed. More detailed guidance as regards composite food and feed can be developed at a later stage, if needed.

This information note has been presented to and noted by the representatives of the Member States during the meeting of the Standing Committee on Plants, Animals, Food and Feed (SCPAFF), section Phytopharmaceuticals – Pesticides Residues of 22/23 February 2022.

## 2. Objectives of the Information note

The aim of this document is not to establish EU harmonised processing factors or to work towards setting of specific maximum residue levels (MRLs) for processed food and feed. The intention is to provide guidance to Member States (including Official Control Laboratories) on how to implement Article 20 provisions of Regulation (EC) 396/2005 in a harmonised way, ultimately leading to a situation by which processing factors established by one Member State could be mutually accepted by other Member States. This document also provides indications for FBOs, including importers from third countries, to prepare themselves and have the necessary information at hand if national authorities request further documentation during their official controls. However, it remains ultimately the Member States' responsibility to decide, after analysis of available information, on whether to use or not to use processing

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<sup>2</sup> [COM\(2020\) 208 final.](#)

<sup>3</sup> [Regulation \(EC\) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC \(OJ L 309, 24.11.2009, p. 1\).](#)

<sup>4</sup> [Regulation \(EC\) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC \(OJ L 70, 16.3.2005, p. 1\).](#)



factors and, if used, to decide on an appropriate factor as a basis for taking enforcement action. Some criteria should be laid down for Member States in this note to assist them to take such a decision.

The intention of this information note is not to lay down details on how a company (e.g., a FBO) should organise its own checks. It remains entirely the responsibility and duty of the FBOs to act in due diligence.

### 3. Legal background

Article 20(1) of Regulation (EC) No 396/2005 states that where MRLs are not set out in Annexes II or III for processed and/or composite food or feed, the MRLs applicable shall be those provided in Article 18(1) for the relevant product covered by Annex I, taking into account changes in the levels of pesticide residues caused by processing and/or mixing. Changes caused by processing and/or mixing can be taken into account, for example, by using a processing factor or by an expert assessment of the processing process based on a scientifically robust data. In addition, Article 20 of this Regulation empowers the Commission to establish Annex VI for specific concentration or dilution factors for certain processing and/or mixing operations or for certain processed and/or composite products. The Commission has not used this empowerment and Annex VI has not yet been established. Annex I on products of plant and animal origin to which MRLs apply contains a category 1200000 for “Products or parts of products exclusively used for animal feed production”: this category is empty, as specific MRLs have not yet been set for such products. Annex I contains also a category for processed food products (category 1300000) which is relevant e.g. for processed products in which residues could stem from biocidal uses. This category is still empty as well, therefore, specific MRLs for processed products have not yet been set at European Union (EU) level.

Where specific MRLs are not set out in Annexes II or III of Regulation (EC) No 396/2005 for processed and/or composite food or feed, the MRLs applicable shall be those provided in Article 18(1) for the relevant product covered by Annex I, taking into account changes in the levels of pesticide residues caused by processing and/or mixing. The provisions of Article 20 of Regulation (EC) No 396/2005 therefore apply to products for which MRLs have been established in Annex II and III (Article 18(1)(a)), but also to MRLs established at the default level of 0.01 mg/kg or at a specific limit of quantification (LOQ) (Article 18(1)(b)). Those specific LOQs can be established for a given substance-commodity combination in any of the Annexes II, III or V of Regulation (EC) No 396/2005. For MRLs established at a specific LOQ or the default value of 0.01 mg/kg, specific provisions apply, as set out in Chapter 5.5.

The Regulation does not give any more detail on how compliance of processed or composite food or feed should be established and implementation of these provisions in enforcement practice is the responsibility of the Member States’ national authorities in charge of official controls. This document lays down a standard approach. Specific cases may need to be dealt with separately.

### 4. Definitions

For the purpose of this information note, the following definitions apply:



**Products covered by Annex I of Regulation (EC) No 396/2005:** This information note covers all products covered by Annex I of Regulation (EC) No 396/2005 as those are the products in which MRLs compliance must be evaluated. The listed products in Annex I of this Regulation are mostly unprocessed products, but Annex I also includes some processed (dried) products, such as tea, certain spices or herbal infusions. MRLs apply directly to them and no further drying factor should be applied to them. If other processing operations would be applied to those products, processing factors would still need to be considered.

**Unprocessed products:** Unprocessed products in the context of this document are those listed in Annex I of Regulation (EC) No 396/2005. For the purpose of Regulation (EC) No 396/2005 the most important unprocessed products are the raw agricultural products, including those products that have been chilled, frozen<sup>5</sup>, deep-frozen or thawed.

**Processing:** Processing is defined in Article 2(1)(m) of Regulation 852/2004<sup>6</sup> as “Any action that substantially alters the initial product, including heating, smoking, crushing, curing, maturing, drying, marinating, extraction, extrusion or a combination of those processes”.

In addition, operations that remove a part of the product such as peeling, pitting, cleaning, husking, trimming or milling are considered in general processing operations for the purpose of this document, except a few operations<sup>7</sup> that are defined in column 6 of Annex I of Regulation (EC) No 396/2005 and are related to specific products.

Washing processes would generally not be considered processing operations. However, if washing with for example chlorinated water changes chlorate levels in foodstuffs this step would need to be considered but cannot be covered by processing factors. For chlorate residue in processed food, a footnote A<sup>8</sup> has been introduced into Regulation (EC) No 396/2005.

**Processed products:** Processed products are products resulting from the processing of unprocessed products. These products may contain ingredients that are necessary for their manufacture or to give them specific characteristics.

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<sup>5</sup>Freezing or deep freezing may include a blanching step if such process does not substantially alter the initial product.

<sup>6</sup> [Regulation \(EC\) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs \(OJ L 139, 30.4.2004, p. 1\).](#)

<sup>7</sup> Activities such as cleaning, husking or trimming prior to freezing fruit or vegetables, are not considered to be processing operations for the purpose of this document.

<sup>8</sup> To take into account the specific situation of chlorate residues, in processed food (including for the purpose of this Regulation foodstuffs that have been derived using processes listed in Article 2(1)(n) of Regulation (EC) No 852/2004), that has come in contact with products containing chlorate residues, or that contains ingredients with such residues, such as processing aids or drinking water, used in compliance with the respective legal requirements, these additional contributions of chlorate residues should be taken into account when determining the permitted content of chlorate residues in or on the processed food products in accordance with Article 20 (1) of this Regulation. The burden of proof regarding the level of those additional contributions lies with the food and feed business operator.



Examples of processed products: juice, wine, oil, compote, puree, cooked vegetable, peeled fruits, cereal flour, canned pulses, pulp, meal, bran, plant extracts.

**Processing factor (Pf):** Calculated as the ratio of the residue concentration in the processed product and the residue concentration in the relevant unprocessed product covered by Annex I using the residue definition for enforcement given in Regulation (EC) No 396/2005.

**Fully acceptable processing factor:** Processing factor which is based on a study that complies with the criteria that the trial is based on the Good Laboratory Practice (GLP) or has been conducted before 1993 (GLP not mandatory), the analytical method is fit for purpose<sup>9</sup>, the storage period is covered by storage stability data<sup>10</sup>, the process is considered as representative and the residue in the relevant unprocessed product covered by Annex I is  $\geq$  LOQ.

**Indicative processing factor:** Processing factor which is based on a study that complies with the same criteria as for a fully acceptable processing factor except that information on storage stability was not available.

**Median processing factor:** The median value of a dataset of indicative or fully acceptable processing factors for a given process. An acceptable median Pf should be based on three or more fully acceptable individual Pf values for one combination of active substance, process and commodity or on two or more fully acceptable individual Pf values for one combination of active substance, process and commodity with a variation of less than 50%.

**Composite food or feed (corresponding to compound feed in feed legislation):** Composite food or feed in the context of Art. 20 of Regulation (EC) No 396/2005 means food or feed containing more than one ingredient and at least one ingredient derived from an agricultural product (plant and/or animal origin) processed and/or unprocessed in different amounts. This definition differs from that given in Article 2(14) of Regulation 2019/625 supplementing Regulation (EU) 2017/625<sup>11</sup>.

## 5. General principles for implementation by Member States in their enforcement activities

### 5.1. Calculations

#### **Calculation of a processing factor (see also Chapter 7.1):**

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

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<sup>9</sup> [Guidance Documents on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes, as applied in its latest version.](#)

<sup>10</sup> [Background Document on the EU Database of Processing Factors for Pesticide Residues.](#)

<sup>11</sup> [Regulation - EU - 2017/625 - EN - EUR-Lex](#)



$$Pf = \frac{\text{Residue in the processed fraction (mg/kg)}}{\text{Residue in the raw commodity (mg/kg)}}$$

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 MRL” applicable to a processed product using a processing factor (see also Chapter 7.1):

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

$$\begin{aligned} \text{Derived MRL for processed product (mg/kg)} \\ = Pf * \text{MRL of the relevant unprocessed product covered by Annex I (mg/kg)} \end{aligned}$$

The term “derived MRL” denotes a convenience of a calculation; the processing factors are for converting the MRLs applicable in foods covered by Annex I to a MRL applied to the respective processed product.

### Calculation of an MRL applicable to a composite food or feed made of different ingredients

$$\begin{aligned} \text{Derived MRL for composite food or feed consisting of unprocessed product A and B covered by} \\ \text{Annex I (mg/kg)} \\ = (\text{MRL of the relevant unprocessed product A covered by Annex I (mg/kg)} \\ * \text{percentage of the relevant unprocessed product A in the composite food or feed}) \\ + (\text{MRL of the relevant unprocessed product B covered by Annex I (mg/kg)} \\ * \text{percentage of the relevant unprocessed product B in the composite food or feed}) \end{aligned}$$

If in the composite food or feed the unprocessed products covered by Annex I are used in a processed form (e.g., dried), then processing factors should be considered in addition. It should be noted that this does not apply to those products covered by Annex I which are already dried e.g., tea, herbal infusions and spices.

A derived MRL for composite feed may be calculated only if MRLs or derived MRLs are available for all feed materials from plant or animal origin.



## 5.2 Different types of processing factors

Processing factors can be divided into substance-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.

### *Substance specific processing factors*

A substance-specific processing factor is specific to a certain active substance in a certain commodity that has undergone a certain process (e.g., Pf of 0.31 for ametoctradin in pasteurised grape juice). For some active substances and processes, processing factors may vary considerably even when obtained under comparable conditions. The use of a median factor is therefore preferred over the use of an individual factor. As the median processing factor in the European Food Safety Authority's (EFSA)(EU) database can be indicated as "reliable", "not reliable" or "indicative", the reliable median processing factor should be used.

### *Extrapolation of substance specific processing factors*

In certain cases and provided that processes are comparable, extrapolation between similar commodities could be considered<sup>12,13</sup>. Those cases could include the extrapolation of processing factors for processed products derived from raw material classified in the same commodity (sub)group e.g., cherries to plums treated with the same active substance. Also, in some cases it could be possible to apply the processing factor from an active substance to a different active substance 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 pesticide residue due to evaporation of water from the unprocessed product covered by Annex I of Regulation (EC) No 396/2005 during drying. Drying factors are less suitable because the pesticide residue concentration in the dried commodity may actually be lower than anticipated due to degradation.

Commodity-specific drying factors are calculated based on the dry matter content in the starting material (unprocessed product covered by Annex I) 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

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<sup>12</sup> [OECD Guidelines for the Testing of Chemicals, Section 5 | OECD](#)

<sup>13</sup> [Technical guidelines on data requirements for setting maximum residue levels, comparability of residue trials and extrapolation of residue data of residue data on products from plant and animal origin](#)





starting material and the dried commodity thereof can be obtained from the producer of the dried commodity<sup>14</sup>.

$$\text{Drying factor} = \frac{\text{dry matter in dried commodity, \%}}{\text{dry matter in unprocessed product covered by Annex I, \%}}$$

The MRL of the dried commodity can be calculated by multiplication of the MRL of the unprocessed product covered by Annex I by the drying factor for the corresponding dried commodity.

$$\text{Derived MRL (mg/kg)} = \text{MRL in unprocessed product covered by Annex I (mg/kg)} * \text{drying factor}$$

Default drying factors<sup>9</sup> are based on the dry matter content in the starting material (unprocessed product covered by Annex I) and the dried commodity derived thereof for the most common dried products.

The yield factor (in percentage) is the mass of the processed commodity (in kg) divided by the mass of the corresponding relevant unprocessed product covered by Annex I of Regulation (EC) No 396/2005 (in kg) and multiplied by 100 to get a percentage. In many cases, e.g., when the commodity is heated, the residue can be hydrolysed, or when the commodity is boiled, the residues can be transferred to the water, or when a fraction of the product is removed by the process, most of the residues can be removed with it, the residue level in the unprocessed product covered by Annex I could be highly overestimated if calculated with a yield factor. Therefore, the yield factor could – together with information on the physico-chemical properties of the active substance - give an indication on whether the derived MRL of the processed product is likely to be compliant with the MRL of the unprocessed product covered by Annex I and therefore could be considered only when there are no other processing factors available.

$$\text{Yield factor (\%)} = \frac{\text{mass of the processed commodity (kg)}}{\text{mass of unprocessed product covered by Annex I (kg)}} * 100$$

Example: the yield factor between olive oil (processed commodity) and olives (unprocessed product) is considered to be 20%. If no other processing factors are available, this factor could be considered, but

<sup>14</sup> [RIVM, Bilthoven, Netherlands, 11 june 2020, Processing factors for dried commodities.](#)



only if information on the physico-chemical properties of the residues, in particular their fat/water solubility (via log K<sub>ow</sub>, also known as logP), is also taken into account.

Assuming that residues fully concentrate into the processed commodity of olive oil, the processing factor is derived according to the following equation:

$$Pf = \frac{1}{\text{yield factor}} = \frac{\text{mass olives}}{\text{mass olive oil}} = \frac{100}{20} = 5$$

The derived MRL of the olive oil (processed commodity) can be calculated by multiplication of the MRL of olives (unprocessed product) by the processing factor of 5.

### 5.3 Use of available data sources for processing factors

A description of the most used processes can be retrieved from the [EFSA compendium](#). Processing factors can be retrieved from the [EFSA \(EU\) database](#), national databases or further sources and can be used by the Member States' enforcement authorities. However, processing factors are product and substance specific and processing methods may vary between different producers and/or recipes and often cannot be standardised. The compilation of processing factors can therefore only serve as indication, but it remains the responsibility of FBOs to provide more detailed information on their particular processes (i.e., description of the process including yield factors, temperature, pH, duration, concentration factors, dilution factors, addition of ingredients, fractionation), their effect on the residue concentration, and to ensure, if possible, that retention samples of relevant unprocessed products covered by Annex I of Regulation (EC) No 396/2005 are available. It is advisable to prepare such information proactively so it can be made available to the competent authorities in the Member States on their request without delay.

#### *EFSA publications and EFSA (EU) database*

Processing factors for certain substance-product-process combinations are available in the published EFSA conclusions on the peer review or in the EFSA reasoned opinions for the respective active substance.

The EFSA (EU) database includes processing factors from EFSA publications.. Work is currently ongoing to implement additional processing information from more recent EFSA publications. It has to be noted that the processing factors in the database could be different from those in EFSA's publications as the EFSA (EU) database may contain more recent information (part of the process of adding processing factors to the EFSA (EU) database is the re-assessment of all processing studies). Therefore, the processing factor from the EFSA (EU) database should be preferred when available. Processing factors included in the EFSA (EU) database have been derived from processing studies complying with a minimum of quality criteria (i.e. representativeness of the processing procedures, residue definitions, minimum number of trials, validity of the analytical method, compliance with standards of GLP, sample storage conditions).



The EFSA (EU) database of processing factors for pesticides in food provides substance-specific median processing factors. This database is based on the residue definition for enforcement and substance-specific processing factors derived from this database are suitable to get an indication of the compliance of a sample with the established MRL, if the processing of the food or feed under investigation complies with the process described in the EFSA compendium.

#### *National databases in the European Union and the Joint Meeting on Pesticide Residues (JMPR) reports*

If no such processing factors are established for the respective active substance-product-process combination, processing factors from Member States' national databases could be used, for instance the following (not exhaustive list): [The German Federal Institute for Risk Assessment \(BfR\)](#), [the Dutch National Institute for Public Health and the Environment \(RIVM\)](#), [the Spanish Agency for Food Safety and Nutrition \(AESAN\)](#). There is no hierarchy among Member States' national databases, in case of multiple processing factors are available, the processing factor that is most appropriate for the specific situation should be taken. It should be noted that the RIVM database refers to the residue definitions for risk assessment while the other databases refer to the residue definition for enforcement. Sometimes, the definitions for risk assessment and enforcement can differ.

In addition, the processing factors listed in [the Joint Meeting on Pesticide Residues \(JMPR\) reports](#) could be used, provided that the residue definitions for enforcement derived by JMPR match with the EU residue definitions for enforcement.

#### *Other sources*

If no processing factors are available in the EFSA database, EFSA publications, national databases or JMPR reports and there are no possibilities for extrapolation of substance specific processing factors, the alternative sources e.g., generic processing factors, data from the literature, etc. could be used. Some other sources are listed in the Chapter on Literature. The processing factor which has been selected for the assessment, might be replaced by a process-specific value provided by the concerned FBO, if considered appropriate. For drying factors, different food sectors have established lists with drying factors at the national or European level. However, the drying factors in those lists may differ due to the different methods used for calculating them. The preference should be given to the national databases and only if the necessary information is not available, databases provided by industry or data from literature could be used if the competent authority deems this appropriate.

Drying factors can also be implicitly obtained from the "[Raw Primary Commodity \(RPC\) model](#)"<sup>15</sup> or the "[Compendium of Representative Processing Techniques investigated in regulatory studies for](#)

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<sup>15</sup> [The raw primary commodity \(RPC\) model: strengthening EFSA's capacity to assess dietary exposure at different levels of the food chain, from raw primary commodities to foods as consumed. EFSA Supporting publication 2019:EN-1532.](#)



[pesticides<sup>16</sup>](#). Other sources could be databases from public institutions e.g., universities or stakeholder associations.

#### 5.4 Relevant general issues for consideration when assessing compliance with MRLs for processed/composite food and feed

When assessing MRL compliance of pesticides residues in food and feed which have been processed or composed of more than one ingredient, the following issues should be in general considered, regardless of whether or not a processing factor is available:

- Recalculation of the MRLs applicable to processed products according to Article 20 of Regulation (EC) 396/2005;
  - a) changes of the concentration of the residue caused by water loss by drying or dilution (with water) processes;
  - b) changes of the concentration of the residue caused by processing and by removing part of the products (e.g., peeling, pitting, extracting oil or in milling fractions like bran);
  - c) relative proportions of the ingredients in composite food and feed (i.e., food or feed containing more than one ingredient);
  - d) actual residue definition for enforcement of the active substance;
  - e) changes of the residue concentration caused by the physico-chemical action of the process on the residue (e.g., degradation, chemical reaction, vaporisation).
- Assessment of the compliance of the analytical result with the MRL.

The measurement uncertainty (MU), i.e., specific MU or default MU of 50%<sup>17</sup>, is taken into account when competent authorities take a decision on compliance with MRLs. As regards the use of a measurement uncertainty with a lower confidence level as a precautionary measure the Working Instructions for the Rapid Alert System for Food and Feed (RASFF WI)<sup>18</sup> applies.

However, it is stressed that Article 19 of Regulation (EC) No 396/2005 prohibits the processing, and/or mixing for dilution purposes with the same or other products, of the products covered by Annex I not complying with Articles 18(1) or 20 with a view to placing them on the market as food or feed or feeding them to animals. This principle can never be overruled by the use of a processing factor (e.g., mixing different lots of the same plant material with different levels of residues of an active substance (some compliant with the MRL, others not), in order to get a product that complies with the MRL set in Annex I.

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<sup>16</sup> <https://doi.org/10.5281/zenodo.6564207>

<sup>17</sup> [Document N° SANTE/12682/2019 on analytical quality control and method validation procedures for pesticides residues analysis in food and feed, as applied in its latest version.](#)

<sup>18</sup> [RASFF WI: Guideline for the calculation of consumer intake and evaluation of the risk for pesticide residues, as applied in its latest version](#)



In addition, no processing factor should be used or taken into account if the active substance has been added during or after processing (e.g., a fungicide use after drying or an insecticide use in a flour storage facility).

Due to the physico-chemical properties of the active substance and the processing technique used for the production of a processed product, the concentration of the residue of the active substance may decrease or increase in the processed product compared to the initial concentration in the relevant unprocessed product covered by Annex I of Regulation (EC) No 396/2005.

### 5.5 Application of processing factors to MRLs

Processing factors should be considered and a compliance assessment of the residue should be performed only when data of the raw material is not available or when FBOs cannot demonstrate conformity according to Regulation (EC) 396/2005.

Processing factors are applicable to approved and non-approved active substances in the EU and refer to the residue definition for enforcement laid down in Regulation (EC) No 396/2005. They are applied also to MRLs established at a specific LOQ or at the default level of 0.01 mg/kg. In the cases where the calculated MRL of the processed product is lower than the specific LOQ or the default level of 0.01mg/kg, the existing MRL at the specific LOQ value or the default level should be kept as lower levels would not be analytically achievable.

In case several processing factors are available, it is recommended to use median Pfs from the EFSA (EU) or national databases. In case only single values from the EFSA (EU) or national databases (including indicative processing factors) are available, these could be used. If there are different choices because of different processes used and no information on the process under investigation is available, the most appropriate processing factor for this particular process should be used.

If application of the available and most suitable processing factors (according to the hierarchy set out above) indicates that the product might not be in compliance with the MRL, the competent authority of the Member State responsible for enforcement may give the respective FBO the opportunity to provide:

1. evidence that compliant unprocessed products as listed in Annex I to Regulation (EC) No 396/2005 were used as starting material for processing (this must always be proven), or
2. more specific Pfs for their processes, which could be substance specific or generic processing factors, within a certain deadline. If those were made available within the deadline provided, these could be used provided that the competent authority of the Member State considers them appropriate based on their expert judgement. If that is the case, studies deriving the Pf should also be sent to the Member States' enforcement authority which can later share these with EFSA.



## 6. Use of the processing factors in enforcement practice

A tiered approach is proposed to be followed by Member States' competent authorities if an analytical result of an official control sample (processed or composite) is obtained and a decision about its compliance with MRLs needs to be made. It also contains an additional risk assessment step, if this is needed in view of the result.

### 6.1. The steps for the assessment of analytical results

The steps taken for assessing the MRL compliance are explained below and presented in Appendix I.

#### **Step 1 (Initial estimation of compliance)**

Starting point: analysis of the processed product. Comparison of the analytical result <sup>17,20</sup> to the MRL of the relevant unprocessed product covered by Annex I of Regulation (EC) No 396/2005.

##### 1. Dilution or no change is expected

Residues are expected to be the same or lower in a processed product<sup>19</sup>.

**Case a)** the measured value in the processed products does not exceed the MRL for the relevant unprocessed product covered by Annex I <sup>20</sup>. However, if dilution is expected, the MRL in the unprocessed product covered by Annex I may still be exceeded. In certain cases it is up to the Member State to decide if they want to take further action, e.g., in the case of washing/rinsing of apples and pears, as these are standard procedures therefore Member State may not wish to continue.

To take further action:

- Yes → Move to step 2
- No → No action

**Case b)** the measured value in the processed product exceeds the MRL for the relevant unprocessed product covered by Annex I <sup>20</sup> → Move to step 2

##### 2. Concentration is expected

Residues are expected to be higher in a processed product.

**Case a)** the measured value in the processed product exceeds the MRL for the relevant unprocessed product covered by Annex I <sup>20</sup> → Move to step 2

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<sup>19</sup> It should be noted that if there is a dilution and the analytical value falls below the laboratory's reporting limit then the results might not be reported

<sup>20</sup> Discussion on the use of analytical measurement uncertainty are still ongoing. This document will be updated accordingly.



**Case b)** the measured value in the processed product does not exceed the MRL for the relevant unprocessed product covered by Annex I <sup>20</sup>→ No further action

### **Step 2 (Decision on the use of a Pf)**

In the cases of Step 1a), 1b) and 2a), non-compliances may be expected in some processed products that have undergone processes resulting in expected dilution or concentration of residues. In such cases the use of Pfs should be considered.

Question: Is an appropriate Pf available?

- Yes → Take the Pf into account in the final decision on compliance.
- No → FBO to provide justification on why the processed product complies with the MRL (i.e., data on processing, other relevant information).

### **Evidence of compliant raw materials**

If the FBO can prove beyond any doubt, e.g., by demonstrating through its incoming goods safety management system etc., that compliant commodities according to Annex I of Regulation (EC) No 396/2005 have been used, the processed product made thereof has also to be considered compliant, provided that the same active substance was not added during the processing steps. In this case, it is not necessary to provide processing factors.

### **Step 3: (Final decision on compliance)**

Assess justification and specific process information provided by the FBO and take a decision on enforcement taking into account all elements. When taking the decision on compliance or non-compliance, the MU and the variability of processing factors should be taken into account<sup>17,18</sup>.

In case where non-compliance is established, the Member State will need to assess whether the sample constitutes a possible health risk, taking this additional step 4.

### **Step 4 (If appropriate, decision on health risk)**

Does the amount of pesticide in the processed product constitute a consumer health risk?<sup>18</sup>

**For food:** Analytical result on processed products to be put in EFSA's Pesticide Residue Intake Model (PRIMo) and matched with the consumption data for the relevant product covered by Annex I of Regulation (EC) 396/2005. EFSA PRIMo contains a few processed products. In such cases, the residue in the processed product is matched with the consumption data of the processed product. In cases where there is no consumption information on the processed commodity, the corresponding calculated residue of the unprocessed product is used in PRIMo e.g., raisins and table grapes. PRIMo might not cover all possible processed products to be developed in the future e.g., dried banana peels and onion oil.



Therefore, it is for the FBO to prove that the processed product is safe. It should be noted that the residue definition for enforcement and for risk assessment may be different and therefore conversion factor may need to be considered in order to convert residues based on the residue definition for monitoring into the residue definition for risk assessment.

Alternatively, if there is no consumption data on the processed commodity in PRIMo, other databases or sources could be used.

**For feed:** national residue intake models are used, e.g., the FAVV-PSTI<sup>21</sup> tool in Belgium.

The risk for animal health is estimated taking into account the percentage of the product in the daily ration. In the case of food-producing animals, the safety of food derived from these animals must also be assessed.

#### **Further relevant issues for consideration in risk assessment for processed food or feed**

For the risk assessment of processed food or feed the following should be considered:

- a) the existence or the lack of specific consumption data for the processed product. In the absence of such, the consumption figures for the unprocessed product may be used.
- b) the principles laid down in the [RASFF WI \(in its latest revision\)](#)<sup>18</sup>.

### 6.2. Minimum requirements for data received from a FBO

FBOs are not obliged to provide systematically specific data on processing factors for their products, neither does this note prescribe how they should organise their own checks. It remains up to the FBO to apply due diligence. However, if FBOs wish that Member States' competent authorities consider more specific information on their processes, they can provide additional information to the competent authorities upon their request. This information is intended to assist Member States to take the most accurate decision possible. If such data are submitted, they must however comply with certain minimum requirements.

The minimum requirements are the following:

- Processed product, e.g., olive oil.
- Relevant unprocessed product covered by Annex I or the product from which processing started, e.g., olives for oil production.
- Code of the relevant unprocessed product covered by Annex I of Regulation (EC) 396/2005: the seven-digit code as it appears in the first column of Annex I of Regulation 396/2005 e.g., 0402010 (olives for oil production).
- Proposed processing factor per active substance according to the residue definition for enforcement.

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<sup>21</sup> <https://www.favv-afscab.be>





- Origin of where the proposed processing factor (name of the database, Pf calculated by FBO based on analyses of raw and processed product) was found.

In addition, the following requirements may be needed to complete the minimum requirements in the following circumstances:

- In case processing factors from EFSA or national databases cannot be used, the rationale as to why the processed product complies with the MRL for the corresponding relevant product covered by Annex I of Regulation (EC) No 396/2005. Depending on the active substance/commodity combination, such a rationale may include the following elements:
  - Description/flowchart of the process (including yield factor, conditions during processing such as temperatures, pH, addition of ingredients) to show that it complies with the process mentioned in the EFSA compendium, if applicable, and thus whether the available processing factors can be used;
  - Analytical results of the starting material and the corresponding processed commodity used to calculate processing factors indicating unambiguously the batch numbers of the starting material and the corresponding batch numbers of processed products. Two replicate datasets for each process are required as a minimum. Where results (processing factor) of the two datasets differ by more than 50 %, further studies shall be provided to derive a consistent processing factor.
- The FBO should report values as measured without deducting measurement uncertainty for reporting their results to the competent authority. The MU will be considered by the competent authority as laid down in Chapter 7.1. Residues should be measured according to the residue definition for enforcement as listed in the Annexes to Regulation (EC) 396/2005.
- Information about the storage period of the samples.
- Other supporting data, if appropriate.

### 6.3. Decision by the competent authority

The competent authority assesses the information provided by the FBO. For example:

- In case multiple processing factors are available from a FBO for a certain substance-product-combination, the median value should be applied. As a precondition to this procedure, the underlying studies must be evaluated as acceptable.
- Description/flowchart of the process (including yield factor, conditions during processing such as temperatures, pH, addition of ingredients).
- The analytical method used to determine the Pf and whether it is validated.
- Sufficient information submitted on analytical methods, storage of samples and process details.



If there is no information available in the EFSA (EU) or national databases and if the FBO does not provide the necessary processing factor or if the competent authority deems that factor inappropriate in view of the justification given, the competent authority can itself estimate a substance specific processing factor, based on the available information and with the objective of maximum protection of human health. This includes a processing factor of one, meaning that the MRL of the relevant product covered by Annex I of Regulation (EC) No 396/2005 is applicable.

## 7. Calculation Examples

### 7.1 The calculation of derived MRLs by using processing factors

The following chapter provides some calculation examples for the use of substance specific and generic processing factors in Member States' enforcement activities. For the purpose of the examples, as these illustrate the final decision on a compliance or non-compliance in the context of official controls, a default MU of 50% has been used. MU is considered in favour of the FBO.

$$\text{Derived MRL for the processed product (mg/kg)} \\ = Pf * \text{MRL of the relevant unprocessed product covered by Annex I (mg/kg)}$$

Pf is > 1: Residues concentrated in the processed product.

Pf is < 1: Residues declined in the processed product.

Pf = 1: Processing did not result in a change of residue concentrations.

MRLs marked with an asterisk (\*) indicate the MRLs which have been established at the LOQ or the default value of 0.01 mg/kg.

Residue content in processed product	MRL	Pf	"Derived MRL" for a processed product	Status of the sample according to Regulation (EC) No 396/2005
2.2 ± 1.1 mg/kg of penthiopyrad in unpitted dry prunes	1.5 mg/kg in fresh plums with stones	(Median Pf) 1.4 for dried plums <sup>22</sup> (prunes)	1.5*1.4=2.1 mg/kg	A level of 2.2 ± 1.1 mg/kg penthiopyrad in dried plums is <b>compliant</b> .
2.0 ± 1.0 mg/kg of azoxystrobin in	3 mg/kg in beans (with pods)	(Median Pf) 0.15 for	3*0.15= 0.45 mg/kg	A level of 2.0 ± 1.0 mg/kg azoxystrobin in canned

<sup>22</sup> [European database of processing factors for pesticides residues in food](#)



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Residue content in processed product	MRL	Pf	"Derived MRL" for a processed product	Status of the sample according to Regulation (EC) No 396/2005
beans (with pods), canned		beans (with pods), canned <sup>23</sup>		beans (with pods), is <b>not compliant</b> unless the FBO can demonstrate the compliance of the unprocessed product covered by Annex I.
2.5 ± 1.25 mg/kg of fludioxonil in raisins	5 mg/kg in table grapes	1.1 for dried grapes <sup>23</sup>	5*1.1 = 5.5 mg/kg,	A level of 2.5 mg/kg ± 1.25 fludioxonil in raisins is <b>compliant</b> .
0.03 ± 0.015 mg/kg of carbofuran in dried pulp of grapefruits (citrus pulp, dried (feed))	0.01*mg/kg in fresh grapefruits	2.8 for dried pulp <sup>23</sup>	0.01*2.8 = 0.028 mg/kg	A level of 0.03 mg/kg± 0.015 carbofuran in dried pulp of grapefruits is <b>compliant</b>
0.026 ± 0.013 mg/kg of prochloraz in rice (basmati, polished)	0.03* mg/kg in rice	0.54 for polished rice <sup>23</sup>	0.03*0.54= 0.016mg/kg	A level of 0.026 ± 0.013 mg/kg of prochloraz in polished rice (basmati) is <b>compliant</b> unless the FBO can demonstrate the compliance of the unprocessed product covered by Annex I.
0.50 ± 0.25 mg/kg of benzovindiflupyr in wheat bran	0.10 mg/kg in wheat	(Median Pf) 1.4 <sup>23</sup>	0.10*1.4 = 0.14 mg/kg	A level of 0.50 ± 0.25 mg/kg benzovindiflupyr in wheat bran is <b>not compliant</b> unless the FBO can demonstrate the compliance of the unprocessed product covered by Annex I.
0.36 ± 0.18 mg/kg of boscalid in apple juice (clarified, pasteurised)	2.00 mg/kg in fresh apples	(Median Pf) 0.07 <sup>23</sup>	2.0*0.07 = 0.14 mg/kg	A level of 0.36 ± 0.18 mg/kg boscalid in apple juice (clarified, pasteurised) is <b>not compliant</b> unless the FBO can demonstrate the



Residue content in processed product	MRL	Pf	“Derived MRL” for a processed product	Status of the sample according to Regulation (EC) No 396/2005
				compliance of the unprocessed product covered by Annex I.
<b>0.74 ± 0.37 mg/kg of lambda-cyhalothrin in olive oil</b>	0.50 mg/kg in olives for oil production	(Median Pf) 0.81 pressed, refined oil <sup>23</sup>	$0.5 \times 0.81 = 0.41$ mg/kg	A level of $0.74 \pm 0.37$ mg/kg of lambda-cyhalothrin in olive oil is <b>compliant</b> .

## 7.2 Composite food and feed

If, at a later stage, more detailed guidance as regards composite food and feed is needed, calculation examples will be presented in this chapter. For the way to calculate MRLs for composite products, please see Chapter 5.



## Literature

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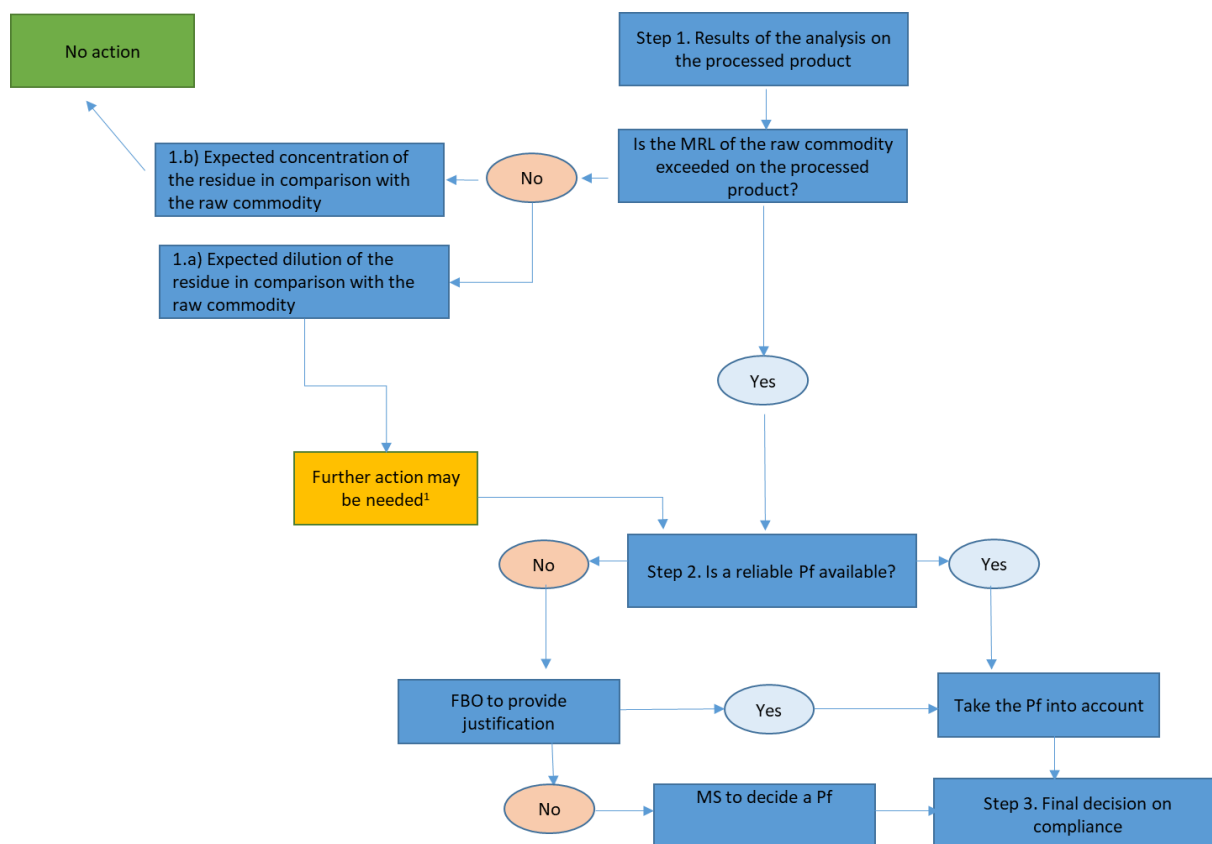


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## Appendix I

### Decision making scheme for assessing MRL compliance



<sup>1</sup> Since dilution is expected, the MRL in the unprocessed product covered by Annex I may still be exceeded.