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**SANTE/** **10704/2021 Rev. 5**

**Information note on Article 20 of Regulation (EC) No 396/2005 as regards processing factors and composite food and feed[[1]](#footnote-1)**

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

1. **INTRODUCTION**

The Commission carried out an evaluation[[2]](#footnote-2) of the plant protection products (PPP)[[3]](#footnote-3) and maximum residue levels (MRL) Regulations[[4]](#footnote-4) 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. I

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 focusses on processing factors. More detailed guidance as regards composite foods 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 23/24 September 2021.

1. **Objectives of this 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 products. The intention is to provide guidance to Member States (including Official Control Laboratories) on how to implement Article 20 provisions of Regulation EC396/2005 in a harmonised way. This document also ensures predictability 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, to use or not to use processing 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.

1. **Legal background**

Article 20(1) of Regulation (EC) No 396/2005[[5]](#footnote-5) states that where MRLs are not set out in Annexes II or III for processed and/or composite food or feed, the MRLs applicable to processed foods and feed should be calculated taking into account changes in the levels of pesticide residues caused by processing. In addition, Article 20 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 also contains a category for processed food products (category 1300000). This category is still empty, therefore, specific MRLs for processed products have not yet been set at European Union (EU) level.

Annex I also contains a category 1200000 for “Products or parts of products exclusively used for animal feed production”: this category is empty as well, as specific MRLs have not yet been set for processed feed. Moreover, according to Footnote 1 of Annex I, existing MRLs do not apply to products or parts of products that by their characteristics and nature are used exclusively as ingredients of animal feed. However, these apply to products which can be used in food as well as feed.

Therefore the principles of this note apply also to:

* Processed/composite feed that, by its characteristics and nature, could also be used as food ;
* Processed/composite feed that, by its characteristics and nature, is used exclusively as feed, but which is obtained from processing/mixing raw commodities that can be used in food as well as feed; in this case the MRL of the raw commodity is applicable (taking into account a processing factor). This is notably the case for by-products of the food industry which are used as ingredients of animal feed.

Where specific 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. The provisions of Article 20 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.

The Regulation does not give any more detail on how compliance of processed or composite products 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.

1. **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 to which MRLs apply. The listed products in Annex I 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 are generally defined in Article 2(1)(n) of Regulation (EC) 852/2004 on the hygiene of foodstuffs[[6]](#footnote-6) . Several examples of unprocessed products are given, not all of them fully compatible with the concept of Annex I to Regulation (EC) No 396/2005. For the purpose of Regulation (EC) No 396/2005 the most important unprocessed products are products that have been chilled, frozen, deep-frozen or thawed.

**Processing:** Processing is defined in Article 2(1)(m) of Regulation 852/2004 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 or milling and the process of blanching are also considered processing operations for the purpose of this document.

For washing operations the following should be noted: for MRL setting, gentle washing is only allowed for roots to remove loosely adhering soil, scrubbing is not allowed. For all other agricultural products washing is not allowed when setting an MRL as it may remove residues from the surface. Therefore, for the purpose of this document as water may change the residue level of the initial product, washing is considered a processing operation. This also may include washing with chlorinated water, if it changes chlorate levels in foodstuffs.

**Processed products:** Processed products are products as defined in Article 2(1)(o) of Regulation 852/2004 as ‘Food and feed resulting from the processing of unprocessed products. These products may contain ingredients that are necessary for their manufacture or to give them specific characteristics. Examples of processed products: juice, wine, oil, compote, puree, cooked vegetable, peeled fruits, husked rice, cereal flour, trimmed head cabbages, canned pulses, pulp, meal, bran.

**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, the storage period is covered by storage stability data, the process is considered as representative and the residue in the relevant unprocessed product covered by Annex I is ≥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 fully acceptable individual Pf values for one combination of active substance, process and commodity with a variation of less than 50%.

**Composite food:** food 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.

1. **General principles for Implementation by Member States in their enforcement activities**

**Calculation of 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 processing factor (Pf) with the MRL of the relevant unprocessed product covered by Annex I:

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.

**Calculation of an MRL applicable to a composite food made of different ingredients**

If in the composite food the unprocessed products covered by Annex I are used in a processed form (e.g. dried) then processing factors should be considered in addition.

**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 0.32 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.

*Extrapolation of substance specific processing factors*

In certain cases and provided that processes are comparable, extrapolation between similar commodities could be considered[[7]](#footnote-7),[[8]](#footnote-8). 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 expert judgement 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 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 starting material and the dried commodity thereof can be obtained from the producer of the dried commodity[[9]](#footnote-9).

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.

Default drying factors8  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 (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, the residue level in 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 physico-chemical properties of the active substance - give an indication whether the MRL of the original product is likely to be compliant with the MRL and therefore could be considered only when there are no other processing factors available.

**Use of available data sources**

A description of the most used processes can be retrieved from the [EFSA compendium](https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2018.EN-1508). Processing factors can be retrieved from the [EFSA (EU) database](https://zenodo.org/record/1488653#.YHBgL44zZaQ), 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 that retention samples of relevant unprocessed products covered by Annex I 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 until June 2016. 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)](https://www.bfr.bund.de/cm/349/bfr-data-collection-on-processing-factors.pdf), [the Dutch National Institute for Public Health and the Environment (RIVM)](https://www.rivm.nl/en/chemkap/fruit-and-vegetables/processing-factors), [the Spanish Agency for Food Safety and Nutrition (AESAN)](https://www.aesan.gob.es/AECOSAN/docs/documentos/seguridad_alimentaria/gestion_riesgos/LMR_en_alimentos_transformados.pdf). 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 e.g. the plant residue definition for risk assessment: sum of fluopyram and fluopyram-benzamide (M25), expressed as fluopyram and the plant residue definition for enforcement: fluopyram. [OECD Guidance for the Definition of Residue](https://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV/JM/MONO(2009)30&doclanguage=en) provides a common approach to residue identification of the pesticide and its metabolites and degradation products.

In addition, the processing factors listed in [the Joint Meeting on Pesticide Residues (JMPR) reports](http://www.fao.org/agriculture/crops/core-themes/theme/pests/jmpr/jmpr-rep/en/) 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, more recent EFSA publications, national databases, EFSA publication or JMPR reports and there are no possibilities for extrapolation of substance specific processing factors, the alternative sources e.g. the values provided by food business operators or, pesticides industry, generic processing factors, data from the literature, etc. could be used.

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 in case there are no substance specific processing factors for the drying process 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 [EFSA’s RPC model](https://www.efsa.europa.eu/en/supporting/pub/en-1532). Other sources are for example the Souci-Fachmann-Kraut database (SFK) for food composition, the database from the European Spice Association (ESA), the dataset of the Association of Organic Processors, Wholesalers and Retailers (BNN) and others.

**Relevant issues for consideration when assessing compliance with MRLs for processed/composite products**

When assessing MRL compliance of pesticides residues in food and feed, which have undergone drying or fractionation, have been processed or composed of more than one ingredient, the following steps should be considered with the specific information to be taken into account:

* The recalculation of the MRLs applicable to processed products according to Article 20 of Regulation (EC) 396/2005.
1. changes of the concentration of the residue caused by water loss by drying or dilution (with water) processes;
2. 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);
3. the relative proportions of the ingredients in composite food and feed (i.e. food or feed containing more than one ingredient);
4. the actual residue definition for enforcement of the active substance.
5. changes of the residue concentration caused by the physico-chemical action of the process on the residue (e.g. degradation, chemical reaction, vaporisation).
* The assessment of the compliance of the analytical result with the MRL.
1. the measurement uncertainty (MU) (i.e. specific MU or default MU of 50%). The measurement uncertainty is taken only into account when taking the decision on compliance or non-compliance.

However, it should be stressed that Article 19 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. In addition, a processing factor should not be used or taken into account if the active substance has been added after processing (e.g. a fungicide use after drying or an insecticide use in a flour storage facility).

Due to physico-chemical properties of the residue, the concentration of the residue may decrease or increase in the processed product compared to the initial concentration in the relevant unprocessed product covered by Annex I. Where the residue definition for enforcement is the same for the processed and the relevant unprocessed product covered by Annex I, the processing factor is derived as the ratio of residues (according to the residue definition for enforcement) in processed products and the residues in the relevant unprocessed product covered by Annex I (residue definition for enforcement). Where the residue definition for enforcement is different for processed products compared to the corresponding relevant unprocessed product covered by Annex I, the processing factor is calculated as ratio between residues in processed products (according to residue definition for enforcement in processed products) to the residues in the relevant unprocessed product covered by Annex I (residue definition for enforcement).

**Application of processing factors to MRLs**

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 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) 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 processing factor leading to the highest residue 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. undisputable 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) and
2. more specific Pfs within a certain deadline for their processes. 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 and the specific cases.
3. **Use of the processing factors in the assessment of MRL compliance**

The steps for assessing the MRL compliance:

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

Starting point: analysis of the processed product. Comparison of the analytical result (without MU) to the MRL of the relevant unprocessed product covered by Annex I of Regulation (EC) No 396/2005.

1. Dilution is expected

**Case a)** the measured value in the processed products does not exceed the MRL for the relevant unprocessed product covered by Annex I (numerical value of MRL, no consideration of measurement uncertainty). However, since dilution is expected, the MRL in the unprocessed product covered by Annex I may still be exceeded 🡪 Move to step 3

**Case b)** the measured value in the processed product exceeds the MRL for the relevant unprocessed product covered by Annex I (numerical value of MRL, no consideration of MU)🡪 Move to step 2

1. Concentration is expected

**Case a)** the measured value in the processed product exceeds the MRL for the relevant unprocessed product covered by Annex I (numerical value of MRL, no consideration of MU)🡪Move to step 2

**Case b)** the measured value in the processed product does not exceed the MRL for the relevant unprocessed product covered by Annex I (numerical value of MRL, no consideration of measurement uncertainty)🡪 no further action

**Step 2 (Decision on health risk):** Does the exceedance of the MRL in the processed product constitute a consumer health risk[[10]](#footnote-10)?

**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. 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 FBO to prove that the processed product is safe.

**For feed:** national residue intake models are used, e.g. FAVV-PSTI 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.

**Relevant issues for consideration for the risk assessment for processed/composite products**

For the risk assessment of processed/composite products the following should be considered:

1. the existence or not of specific consumption data for the processed product. In the absence of such, the consumption figures for the unprocessed product should be used
2. the principles laid down in the Working instructions for the Rapid Alert System for Food and Feed ([RASFF WI rev. 2](https://ec.europa.eu/food/system/files/2017-02/rasff_reg-guid_sops_wi-2-2_en.pdf)).

**Case a)** Yes 🡪 Action to address the health risk (e.g. removal of the product) is considered. However, in case there is no specific consumption figures for the processed product and no information on processing effects expert judgement of the specific case is needed and moving to Step 3 first may be more appropriate.

**Case b)** No 🡪 Move to step 3

**Step 3 (Decision on the use of a Pf):** In the cases of Step 1 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 a processing factor (Pf) available?

* Yes 🡪 take the Pf into account in the final decision on compliance (Step 4)
* No 🡪 FBO to provide justification why the processed product complies with the MRL (data on processing, other relevant information, analysis of raw materials proving compliance)

**Step 4: (Final decision on compliance):** Assess justification provided by the FBO and take a decision on enforcement taking into account all elements. When taking the decision on compliance or noncompliance, the measurement uncertainty and the variability of processing factors should be taken into account10,[[11]](#footnote-11).

The specific process used by the food business operator is best taken into account in this way.

**Evidence of compliant raw materials**

If the FBO can prove beyond any doubt that compliant relevant products covered by Annex I have been used (commodities according to Annex I of Regulation (EC) No 396/2005), the processed product made thereof has also to be considered compliant. In this case, it is not necessary to provide processing factors.

**Minimum requirements for data received from a food business operator**

* Processed product

The name of the processed product e.g. olive oil

* Relevant unprocessed product covered by Annex I or the product from which processing started

The origin of the processed products e.g. if the processed product is olive oil, the relevant unprocessed product covered by Annex I is olive for oil production.

* Code of the relevant unprocessed product covered by Annex I of Regulation (ΕC) 396/2005

The seven-digit code as it appears in the first column of Annex I of Regulation 396/2005

**The additional requirements below depend on the outcome of the assessment of the MRL compliance and on the information provided by the FBO beforehand**

* Proposed processing factor per active substance according to the residue definition for enforcement

Name of the database if applicable

* + 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 and whether it is validated
	+ Is the submitted information on analytical methods, storage of samples and process details sufficient?
* Analytical results of a minimum of 4 batches of the starting material and the corresponding batches of processed products
	+ Is a sufficient number of replicates obtained from the process? (4 replicates or 3 replicates if the variation is less than 50% of the full process is satisfying)
	+ Are the results in compliance with the physicochemical properties of the substance?
* Food business operators should report values as measured without deducting measurement uncertainty for reporting their results to the competent authority. 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
* List of studies if available
* Other supporting data
* In case processing factors from EFSA or national databases can’t be used the rationale why the processed product complies with the MRL for the corresponding relevant product covered by Annex I should be given

In addition, depending on the active substance/commodity combination, such a rationale may also include:

1. a description/flowchart of the process to show it complies with the process mentioned in the EFSA compendium and thus the available processing factors can be used or
2. it could include analytical results of the starting material and the corresponding processed commodity or
3. it could include a processing study according to [OECD guidelines](https://www.oecd-ilibrary.org/environment/test-no-508-magnitude-of-the-pesticide-residues-in-processed-commodities_9789264067622-en) and preferably conducted by the manufacturer of the pesticide in question.

**Decision by the competent authority**

If there is no information available in the EFSA (EU) or national databases or in other reliable sources of processing information 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.

1. **Calculation Examples**

**7.1 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, a default MU of 50% has been used.

As already set out in Chapter 5, in order to assess compliance with an MRL, the derived MRL for the processed product is obtained by multiplying the processing factor (Pf) with the MRL of the relevant unprocessed product covered by Annex I:

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.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Residue content in processed product** | **MRL**  | **Pf**  | **MRL applicable to 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 (1.1-3.3 mg/kg)** | 1.5mg/kg in fresh plums with stones | 1.4 for dried plums (prunes)  | 1.5\*1.4=2.1mg/kg | Measurement uncertainty is considered in favour of the producer/distributor. A level of 2.2 ± 1.1mg/kg penthiopyrad in dried plums is compliant. |
| **0.49 ± 0.25 mg/kg imidacloprid in green/yellow raisins** | 1 mg/kg in table grapes | 2.5 for dried grapes (raisins) | 1\*2.5= 2.5 mg/kg | A level of 0.49 ± 0.25 mg/kg imidacloprid in green/yellow raisins is compliant |
| **2.5 mg/kg ± 1.25 chlorothalonil in raisins** | 0.01\*mg/kg in table grapes  | 0.50 for dried grapes (raisins) | 0.01\*0.5 = 0.005mg/kg | A level of 2.5 mg/kg ± 1.25 chlorothalonil in raisins is **not compliant**  |
| **0.026 ± 0.013 mg/kg of profenofos in rice (basmati, polished)** | 0.01\* mg/kgin rice | 0.5 for polished rice | 0.01\*0.5= 0.005mg/kg | A level of 0.026 ± 0.013 mg/kg of profenofos in polished rice (basmati) is **not compliant** |
| **0.50 ± 0.25 mg/kg of benzovindiflupyr in gluten feed meal** | 0.1 mg/kg in wheat | 3.3 | 0.1\*3.3 = 0.33 mg/kg | A level of 0.50 ± 0.25 mg/kgbenzovindiflupyr in gluten feed meal is compliant. |
| **0.36 ± 0.18 mg/kg boscalid in apple juice (clarified, pasteurised)** | 2.0 mg/kg in fresh apples | 0.08 | 2.0\*0.08 = 0.16 mg/kg | A level of 0.36 ± 0.18 mg/kg boscalid in apple juice (clarified, pasteurised) is **not compliant.** |
| **0.74 ± 0.37 mg/kg lambda-cyhalothrin in olive oil** | 0.5 mg/kg in olives for oil production | Median Pf=0.81 | 0.5\*0.81 = 0.41 mg/kg | A level of 0.74 ± 0.37 mg/kg of lambda-cyhalothrin in olive oil is compliant. |
| **1.4 ± 0.7 mg/kg boscalid in soybean meal, extracted** | 3.0 mg/kg in soybeans | < 0.17 | 3.0\* (< 0.17) = < 0.51 mg/kg | A level of 1.4 ± 0.7 mg/kgboscalid in soybean meal is **not compliant.** |

**7.2 COMPOSITE FOODS**

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

1. **Literature**
2. European database of processing factors for pesticides in food

<https://zenodo.org/record/1488653>

1. Database of processing techniques and processing factors compatible with the EFSA food classification and description system FoodEx 2 Objective 1: Compendium of Representative Processing Techniques investigated in regulatory studies for pesticides

<https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2018.EN-1508>

1. Database of processing techniques and processing factors compatible with the EFSA food classification and description system FoodEx2 related to pesticide residues Objective 2: Linking the processing techniques investigated in regulatory studies with the EFSA food classification and description system FoodEx2

<https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/sp.efsa.2018.EN-1509>

1. Database of processing techniques and processing factors compatible with the EFSA food classification and description system FoodEx 2 Objective 3: European database of processing factors for pesticides in food

<https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2018.EN-1510>

1. List of processing factors to evaluate pesticides residues measured in the Netherlands <https://www.rivm.nl/en/chemkap/fruit-and-vegetables/processing-factors>
2. The German Federal Institute for Risk Assessment data collection on processing factors

<https://www.bfr.bund.de/cm/349/bfr-data-collection-on-processing-factors.pdf>

1. The German Federal Institute for Risk Assessment compilation of processing factors and Evaluation of Quality Controlled Data of Food Processing Studies

<https://www.bfr.bund.de/cm/349/bfr-compilation-of-processing-factors.xlsx>

1. Spanish Agency for Food Safety and Nutrition (AESAN) list of processing factor <https://www.aesan.gob.es/AECOSAN/docs/documentos/seguridad_alimentaria/gestion_riesgos/LMR_en_alimentos_transformados.pdf>
2. Joint Meeting on Pesticide Residues (JMPR) Reports and evaluations

<http://www.fao.org/agriculture/crops/core-themes/theme/pests/jmpr/jmpr-rep/en/>

1. OECD Guideline for testing of Chemicals, Test No. 508: Magnitude of the Pesticide Residues in Processed Commodities

<https://www.oecd-ilibrary.org/environment/test-no-508-magnitude-of-the-pesticide-residues-in-processed-commodities_9789264067622-en>

1. OECD Guidance document on the definition of residue

<https://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV/JM/MONO(2009)30&doclanguage=en>

1. 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. [↑](#footnote-ref-1)
2. [COM(2020) 208 final](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020DC0208) [↑](#footnote-ref-2)
3. 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). [↑](#footnote-ref-3)
4. 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). [↑](#footnote-ref-4)
5. 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.) [↑](#footnote-ref-5)
6. 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. 1–54) [↑](#footnote-ref-6)
7. OECD Guidelines for the Testing of Chemicals, Section 5, Test No. 508: Magnitude of the Pesticide Residues in Processed Commodities [↑](#footnote-ref-7)
8. 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 <https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_mrl_guidelines_app-d.pdf> [↑](#footnote-ref-8)
9. RIVM, Bilthoven, Netherlands, 11 june 2020, Processing factors for dried commodities [↑](#footnote-ref-9)
10. RASFF WI 2.2: Guideline for the calculation of consumer intake and evaluation of the risk for pesticide residues

as applied in its latest version [↑](#footnote-ref-10)
11. Document Nº 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 [↑](#footnote-ref-11)