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Information note on Article 20 of Regulation (EC) No 396/2005 as regards processing factors and composite foods¹

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.



1. INTRODUCTION AND SCOPE

Article 20 of Regulation (EC) No 396/2005² states that where maximum residue levels (MRLs) are not set out in Annexes II or III for processed and/or composite food or feed, MRLs applicable to processed foods should be calculated taking into account changes in the levels of pesticide residues caused by processing. In addition, Article 20 gives the Commission empowerment 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 Annex VI has not yet been established. Annex I on products of plant and animal origin referred to in Article 2(1) of Regulation (EC) No 396/2005 to which MRLs apply also contains a category for processed food products. This category is still empty, therefore specific MRLs for processed products do not yet apply. MRLs are established for only a very small number of simply processed commodities by Codex Alimentarius (e.g. flonicamid in tomato paste, pyrethrins in dried fruits).

The Regulation does not give any more detail on how compliance with 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. In order to give some guidance to Member States, some common principles are laid down in this document. This also helps food business operators to be prepared and to have the necessary information at hand, if national authorities request further documentation during their official controls.

National and EU-level databases that list the various processing factors for processed food exists and can be used by Member States' enforcement authorities. However, processing factors are product and substance specific and processing methods vary greatly between different producers, recipes and should not be standardized. A harmonised inventory of processing factors can therefore only serve as guidance, but it remains the responsibility of food business operators to provide more detailed information on processing factors of their particular processes and it is advisable to provide such information proactively to the competent authorities in the Member States.

The Commission carried out an evaluation³ of the plant protection products (PPP) and maximum residue levels (MRL) Regulations covering the period of their respective entry into application until end 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 EU law simple, and remove unnecessary burdens. One of the findings of the evaluation was that general provisions for processed products, including processing factors, 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 business operators, on how

² 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.)

³ [COM\(2020\) 208 final](#)



to deal with processed products. In this respect, the provisions of Regulation (EC) No 1881/2006⁴ should be considered as in the area of contaminants with very similar situations, more specific provisions exist already in EU legislation.

The aim of this document is not to establish harmonised processing factors or to work towards specific MRLs for all processed products. The intention is to use the Article 20 flexibility and reasonably apply processing factors using the best information available and to give some guidance to Member States to ensure a more harmonised procedure. However, Member States remain responsible to decide to use or not to use processing factors, and to take the appropriate measures.

2. IMPLEMENTATION OF THE INFORMATION NOTE

This document is an evolving document and will be updated to take account of the experience of the competent authorities or of information provided.

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 (*insert date of Note Taking*).

3. DEFINITION

For the purpose of this information note, the definitions in Regulation (EC) No 178/2002, and Regulation (EC) No 852/2004 on the hygiene of foodstuffs are used

The following definitions are used:

1. **Processed products:** 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.⁵ (e.g. juice, flour, wine, oil, compote, puree, cooked vegetable, etc.).
2. **Processing:** Means any action that substantially alters the initial product, including heating, smoking, curing, maturing, drying, marinating, extraction, extrusion or a combination of those processes⁶
3. **Processing factor (Pf):** Indication of the ratio of the residue in the processed product to that in the corresponding unprocessed product
4. **Composite food:** Food containing more than one compound
5. **Processing techniques:** Techniques referred in EFSA's Database of processing techniques and processing factors compatible with the EFSA food classification and description system FoodEx 2⁷

⁴ Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs (OJ L 364 20.12.2006, p. 5)

⁵ 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)

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)

⁷ EFSA Supporting publication 2018:EN-1508; <https://doi.org/10.2903/sp.efsa.2018.EN-1508>



6. ...

4. GENERAL PRINCIPLES

Currently, Article 20 of Regulation (EC) No 396/2005 applies to all processed or composite food, as specific MRLs in Annex I for processed products have not yet been established.

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.

When applying the maximum residue levels to foods, which are dried, diluted, processed or composed of more than one ingredient, the following shall be taken into account:

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

The information note is addressed to Member States for their official control activities and all food business operators (including importers from third countries) who want to check the compliance of the product.

Examples of different processing factors being used from EU database to check compliance with MRLs.

In order to calculate compliance with a MRL, the residue level in the processed fraction by multiplying the processing factor (Pf) with the residue level in the raw agricultural commodity:

Residue content in processed fraction = $Pf \times$ Residue content in raw agricultural commodity (mg/kg)

- A Pf value > 1 indicates an increase of residues during processing (due to concentration).

	MRL (mg/kg)	Pf	Residue content in processed fraction (mg/kg)
Penthiopyrad in dried prunes	1.5 in fresh plums	1.5	$1.5 \times 1.5 = 2.25$

Conclusion: A level of 2,25 mg/kg penthiopyrad in dried prunes would still comply with the MRL if applying the provisions of Article 20. A level of 2,4 mg/kg would no longer comply. For the purpose of this example, analytical uncertainty is not considered.

- A PF value < 1 indicates a decrease of residues (due to dilution, removal or degradation).



	MRL (mg/kg)	Pf	Residue content in processed fraction(mg/kg)
Boscalid in apple juice (clarified, pasteurised)	2.0 in apples	0.05	$2.0 \times 0.05 = 0.01$
Lambda-cyhalothrin (includes gamma-cyhalothrin) (sum of R,S and S,R isomers) (F) in olive oil (pressed, refined)	0.5 in olives for oil production	Median Pf=0.81	$0.5 \times 0.81 = 0.41$

Conclusion: A level of 0.01 mg/kg boscalid in apple juice would still be compliant. However, a level of 0.02 mg/kg would no longer be compliant. For the purpose of this example, analytical uncertainty is not considered.

- Composite food

	MRL (mg/kg)	Pf	Residue content in processed fraction (mg/kg)
Isopyrazam in fruit salad Apples 60% Bananas 20% Melons 20%	0.07 in apples 0.05 in bananas 0.3 in melons	Median Pf of 0.05 for apples (canned) Median Pf of 0.71 for bananas (pulp) Median Pf of 0.49 for melons (pulp)	$(0.07 \times 0.05 \times 0.6) + (0.05 \times 0.71 \times 0.2) + (0.3 \times 0.49 \times 0.2) = 0.0386$
Chlorothalonil in vegetable soup (puree) Tomatoes 70% Carrots 20% Leeks 10%	6.0 in tomatoes 0.3 in carrots 8.0 in leeks	Median Pf of 0.001 for tomatoes (puree) Median Pf of 0.67 for carrots (peeled and cooked) Median Pf of 0.18 for leeks (cooked)	$(6 \times 0.001 \times 0.7) + (0.3 \times 0.67 \times 0.2) + (8.0 \times 0.18 \times 0.1) = 0.3492$

Conclusion: A level of 0.04 mg/kg isopyrazam in fruit salad would still be compliant. However, a level of 0.05 mg/kg would no longer be compliant. For the purpose of this example, analytical uncertainty is not considered.

The following principles should apply for using processing factors:

1. Processing factors should be specific for the respective active substances in the specific matrix.



2. The specific concentration or dilution factors for the drying, dilution, processing and/or mixing operations concerned or for the dried, diluted, processed and/or composite foods concerned shall be provided and justified by the food business operator, when the competent authority carries out an official control. The specific process used by the food business operator is best taken into account in this way.
3. In case multiple processing factors are available from a food business operator for a certain substance-matrix-combination (mean or median value out of several individual values) the mean or median value, which is more advantageous for the distributing company, should be applied. As a precondition to this procedure, the underlying studies must be evaluated as acceptable and the data basis has to be comparable for the different values. Otherwise, the mean or median value has to be applied, which is based on the larger data basis.
4. If the food business operator does not provide the necessary concentration or dilution factor or if the competent authority deems that factor inappropriate in view of the justification given, the authority shall itself define that factor (e.g. MRL for raw commodity), based on the available information and with the objective of maximum protection of human health.
5. In cases where the competent authority has to define a processing factor, information from EU database or national database should be used.
6. Processing factors for certain substance-matrix-combinations are available in the reasoned opinions for the respective substance, published by EFSA. Where available, those should be used.
7. If no such processing factors are established for the respective active substance-matrix combination, processing factors from national databases (e.g. The German Federal Institute for Risk Assessment (BfR) or the Dutch National Institute for Public Health and the Environment(RIVM)) or JMPR reports should be used.



5. REFERENCES

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2. 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
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