

EU database on processing factors

Updated communication No 003/2023 of the BfR from 17 January 2023

Agricultural products are often not consumed raw, but rather, processed first. This can alter the amount of pesticide residues that they contain. The ratio of residue in the processed product to that in the corresponding unprocessed product is known as the processing factor. It indicates whether residues are enriched or reduced during food processing procedures. Processing factors are typically determined under processing conditions simulated in the laboratory. Details of such studies, which have to be submitted by the manufacturers of plant protection products within the scope of authorisation processes, cannot be accessed by the general public.

For this reason, since 2007, the German Federal Institute for Risk Assessment (BfR) has provided a compilation of processing factors on its website, which was regularly updated to the latest level of knowledge. The BfR evaluated each processing factor derived from a processing study using transparent quality criteria. The robustness and reliability of the study results were commented on. By providing relevant information on the most important parameters of the underlying studies, users are enabled to assess the significance of processing factors for themselves.

In November 2018, the European Food Safety Authority (EFSA) also published a database on processing factors with significant assistance from the BfR. This database reports all processing factors that have been assessed by EFSA as part of their evaluations of active substances and/or maximum residue level adjustments within the EU up to July 2016. The appraisal of studies was elaborated upon even further compared with the BfR data collection since all studies were also assessed with regard to the representativeness of the chosen processing conditions and more detailed information was provided for each study. In addition, the EU database can easily be linked with other databases since the foods and substances have a standardised code.

The EU database on processing factors has now been updated again by the BfR on behalf of EFSA. Using the same quality criteria as before, all processing studies and factors additionally reported by EFSA as part of active substance reviews and/or maximum residue level adjustments up to December 2021 have been assessed and included. Furthermore, all processing studies and factors contained in the previous BfR data collection were re-assessed according to the quality criteria and transferred into the EU database. All entries have been checked to verify that they are up to date (for example, the residue definition). The new EU database on processing factors has been available to the public since 13 September 2022. At the same time, the previous BfR data collection on processing factors has been discontinued. The BfR is now also offering access to the EU database via its website and is providing a user interface that provides more clarity and guides users in selecting processing factors.

The EU database on processing factors is aimed primarily at a professional audience. It serves to support the risk assessment in refining the exposure assessments for consumers as well as for agricultural livestock in relation to processed food and feed. The data collection also supports the official food monitoring authorities and risk managers in assessing whether the raw agricultural product has complied with legal requirements are not. However, the published processing factors are unsuitable as sole basis to determine the marketability of a processed product and justify further administrative actions.



<u>Disclaimer</u>: Despite paying the greatest care and attention when compiling the relevant information from the processing studies, the BfR does not accept any liability for the correctness of the information. The processing factors contained in the EU database are not legally binding. The database should be used primarily by experts who are familiar with the assessment of plant protection product residues in food and feed.

1 Background information on processing factors

Processing studies are conducted in order to examine the influence of processing procedures on pesticide residues in agricultural products. They focus on the most important processing steps which are relevant in industry and households such as peeling, pitting, blanching, cooking, puréeing and frying, the manufacture of juice, wine, beer, sugar and vegetable oils as well as the manufacture of ground cereal products. Depending on the particular processing conditions and the physico-chemical properties of a substance, processing can lead to an increase or reduction of residue.

Processing factors are derived from processing studies. They indicate the ratio of the residue in the processed product to that in the corresponding unprocessed product. An enrichment of the pesticide residue is indicated by processing factors greater than 1, whereas a reduction in the residue concentration in the processed product is expressed in a factor of less than 1.

Processing factors are important tools which serve two main purposes: The first is in risk assessment to refine the exposure assessments for consumers and agricultural livestock in regard to pesticide residues in processed food and/or feed. The other is to equip the food monitoring authorities with information about the extent to which the residue level can alter during processing. Such information is helpful in order to be able to assess whether a processed food has been manufactured from a raw product which probably adhered to the legal maximum residue level or not. However, the published processing factors are normally unsuitable as sole basis to determine the marketability of a processed product and justify further in administrative actions. The factors are not legally binding. The EU Commission has recently published rules for dealing with processing factors [1].

Experimental details of processing studies are usually not accessible to the public but rather are only available to the authorities involved in the regulatory procedures for pesticides. Data is also collected as part of self-monitoring by food business operators. This is also not publicly accessible and is also rarely available to the authorities.

Maximum residue levels in the EU are established in Annexes II and III of Regulation (EC) No. 396/2005 for unprocessed products such as apples, tomatoes or wheat grain, but not for processed or composite products such as apple juice or flour. [2]. The Codex Alimentarius established by FAO/WHO sets the maximum residue levels for the global movement of goods [3]. They alsopredominantly refer to unprocessed goods, but are established for selected processed products in cases where enrichment is expected.

Normally, processing studies are conducted according to the specifications of OECD Test Guideline no 508 ("Magnitude of the Pesticide Residues in Processed Commodities") [4] and the OECD Guidance Document on Magnitude of Pesticide Residues in processed commodities [5]. These documents do not stipulate any specific process parameters which need to be taken into account during lab tests. It is rather recommended to simulate conditions which reflect typical processes in the food processing industry. This results in a highvariability of the



test conditions, and thereby also of the results, which has to be taken into account when interpreting the processing factors.

2 EU database on processing factors

The EU database on processing factors has existed since 2018 and was updated in 2022 by the BfR on behalf of EFSA according to the current state of knowledge [6]. It contains all processing factors that have been assessed by EFSA as part of their evaluations of active substancesand/or MRL adjustments within the EU up to December 2021. Furthermore, all processing factors contained in the previous BfR data collection were re-assessed according to the quality criteria and transferred to the EU database. These are mainly factors from processing studies submitted to the BfR in the context of plant protection product authorisation procedures. Additionally, the database contains some factors from sources accessible to the public such as the reports on the assessment of pesticide residues published each year by the FAO/WHO Joint Meeting on Pesticide Residues (JMPR). Information on the distribution of residues between peel and pulp was added to the database from residue studies and, for citrus fruits, additionally from national monitoring programmes [7] as well as from a commercial company's self-monitoring [8]. All entries have been checked to verify that they are up to date (for example, the residue definition).

Further to data on the distribution between the peel and the pulp, a few other processing data from the food and feed processing industry resulting from self-monitoring was added to the EU database and evaluated according to the same quality criteria as conventional processing studies. The BfR provides a form to submit such information from self-monitoring in the industry or from research projects, which can be accessed using the following link:

https://www.bfr.bund.de/de/expositionsschaetzung fuer pflanzenschutzmittel-205027.html

The BfR welcomes any expansion of the database through self-monitoring data. The more of these data are included, the more realistic and significant the resulting median processing factors output will be.

Aside from the processing factors, the EU database also contains additional information such as on the validity of the analytical method, on the storage conditions of samples or on the representativeness of the processing conditions chosen. With this information the significance of every processing factor can be evaluated by the user themselves. In addition, the EU database has the advantage of easily being linked with other databases since the foods and substances have a standardised code.

Where several suitable processing factors from various individual trials have been reported for a particular processed food, the median is listed in addition to the individual values in the database. More details on the structure and content of the EU database and the interpretation of the data can be taken from a current publication [9].

The EU database can be accessed as an Excel table under the following link:

https://zenodo.org/record/6827098

The BfR is now also offering access to the EU database via its website and is providing a webbased user interface that provides more clarity and guides users in selecting processing factors.



The web tool is based on the open source software KNIME (Konstanz Information Miner) and can be accessed free of charge and barrier-free by all interested users via the following link on the BfR website:

https://knimehpc.bfr.berlin/knime/webportal/space/EFSA Processing

This user-friendly and clearly arranged search and output tool nevertheless provides all the information needed for an assessment. The desired processing factors can be easily retrieved for all combinations of active substance and processed product published in the EU database. The tool offers both a graphic and a tabular output of processing factors and their median values, provided that the criteria for their derivation are met. These median processing factors are usually preferred to single factors because they are more robust.

Although the database contains approximately 15,000 individual processing factors, acceptable factors are not available for every pesticide-matrix combination searched for. The web application also displays recommended extrapolations from other matrices to the searched matrix on request. These are based on the expert judgement and can be looked up in one of the documents accompanying the EU database [10].

3 Graphic illustration of typical processing procedures

The graphic illustration of typical processing procedures in the form of flow charts can be found together with detailed process descriptions in the "Compendium of Representative Processing Techniques" [10]. Database users can therefore gain a quick overview of the relevant end products and intermediate products from processing procedures and can more easily assign processed matrices. In addition, they will find further information on all the processed products reported.

4 References

[1] EC (2022). Information note on Article 20 of Regulation (EC) No 396/2005 as regards processing factors, processed and composite food and feed. SANTE/ 10704/2021, Brussels, 22.02.2022. https://ec.europa.eu/food/document/download/071dce96-d916-4615-87fa-148f1491bfc8 en?filename=pesticides mrl guidelines proc imp_sante-2021-10704.pdf (accessed 04.10.2022)

[2] EC (2005). 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 70/1, 16.3.2005

[3] Codex Alimentarius (2018). Codex Pesticides Residues in Food Online Database, http://www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/pestres/en/ (accessed 04.10.2022)

[4] OECD (2008). Test No. 508: Magnitude of the Pesticide Residues in Processed Commodities, OECD Guidelines for the Testing of Chemicals, Section 5, OECD Publishing, Paris, https://doi.org/10.1787/9789264067622-en (accessed 04.10.2022)



- [5] OECD (2008). Series on Testing and Assessment No 96: Guidance Document on Magnitude of Pesticide Residues in processed commodities, 29 Jul 2008, http://www.oecd.org/officialdocuments/displaydocument/?cote=env/jm/mono(2008)23&doclanguage=en (accessed 04.10.2022)
- [6] Zincke F., Fischer A., Kittelmann A., Kraus C., Scholz R and Michalski B. (2022). EU database of processing factors for pesticide residues. https://doi.org/10.5281/zenodo.1488653
- [7] BVL (2011). Berichte zur Lebensmittelsicherheit 2011 Monitoring, <u>doi:10.1007/978-3-0348-0580-3</u>
- [8] Ahlers, W. und Reichert, T. (2007). Oberflächen-Konservierungsstoffe und Akute Referenzdosis Ergebnisse einer Testreihe bei Zitrusfrüchten, Kooperation des Iebensmittelchemischen Untersuchungsrings des Landesverbands Baden-Württemberg des Früchte-Importund -Großhandels e.V. und der Atlanta AG (heute: Univeg Deutschland GmbH)
- [9] Scholz et al. (2022a). Scholz R., Herrmann M., Kittelmann A., von Schledorn M., Zincke F., van Donkersgoed G., Graven C., van der Velde-Koerts T., Anagnostopoulos C., Bempelou E. and Michalski B. Background Document on the EU Database of Processing Factors for Pesticide Residues. https://doi.org/10.5281/zenodo.6564214
- [10] Scholz et al. (2022b). Scholz R., van Donkersgoed G., Herrmann M., Kittelmann A., Kraus C., von Schledorn M., Mahieu C. G. K., van der Velde-Koerts T., Anagnostopoulos C., Bempelou E. and Michalski B. Compendium of Representative Processing Techniques Investigated in Regulatory Studies for Pesticides. https://doi.org/10.5281/zenodo.6564208

About the BfR

The German Federal Institute for Risk Assessment (BfR) is a scientifically independent institution within the portfolio of the German Federal Ministry of Food and Agriculture (BMEL). The BfR advises the Federal Government and the German federal states ("Laender") on questions of food, chemicals, and product safety. The BfR conducts independent research on topics that are closely linked to its assessment tasks.

This text version is a translation of the original German text which is the only legally binding version.