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First update of the EU database of processing factors for pesticide residues

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Abstract

The EU database of processing factors for pesticide residues has been set up in 2018 and was now updated for the first time. 1301 processing studies were added to the database extending it to more than double size. The studies were either provided to EFSA in MRL setting procedures or pesticide peer reviews or they were submitted to BfR in the framework of national or zonal authorization procedures. All studies have been thoroughly (re-)evaluated with respect to the well-proven set of quality parameters already applied in the EU database. Processing factors were derived and their reliabilities judged. For newly reported processes such as palm oil and palm kernel oil production, sugar production from sugar cane and sake production from rice the representative processes have been described. Furthermore, new processed matrices such as selected cooked vegetables or pulses have been added to the database and to the accompanying documents.

Key words: Food processing, pesticide residue, processing study, processing factor, EU database

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Summary

EFSA is regularly evaluating pesticide occurrence data in food generated under the official monitoring programs of Member States with respect to consumer exposure and risk assessment. Most of these data refer to raw commodities, because maximum residue levels established under European legislation reflect pesticide residues only in the raw agricultural commodity. However, food processing operations can have decisive effects on pesticide residue levels and consumer exposure. To evaluate these effects, EFSA and other stakeholders make use of the EU database of processing factors for pesticides. Since this database was originally relying on studies provided to EFSA until, but not later than June 2016, the inclusion of more recently evaluated studies was considered necessary. Moreover, studies submitted for zonal authorization procedures only and not yet included in the database, were considered a reasonable extension of the database. EFSA therefore launched the project "First update of the EU database of processing factors for pesticide residues".

BfR scrutinised all EFSA publications from June 2016 onwards with respect to reported processing factors and processing studies. If processing information was contained, BfR traced it back to the underlying studies using the corresponding Evaluation Report or Assessment Report. EFSA launched data calls among the Member States to collect the missing original study reports. The studies were evaluated based on current data requirements of OECD Test Guideline 508 as well as with respect to additional harmonized quality parameters allowing an informed conclusion on the reliability of PFs derived therefrom and they were included in the EU database.

In a previous attempt to compile substantial information on the change of pesticide residue levels during food processing, BfR already gathered and published a data collection on processing factors. The original reports of all underlying studies were available to BfR. In 2019, all entries related to studies already described in the EU database were removed from the BfR data collection to avoid inconsistent reporting. During the current project, the remaining set of studies described in the BfR data collection were thoroughly re-evaluated in accordance with the same quality criteria applied in the EU database and the studies were added to the actual EU database.

In total, 1301 processing studies have been added to the original EU database of processing factors in the framework of this project. The EU database now contains 2152 processing studies resulting in 2104 acceptable/indicative median PFs.

The studies were also integrated in BfR's internal residue database RUEDIS, which is used to store raw data from crop field trials and processing studies. This was done for two reasons: First, to be prepared for future developments, as another ongoing project is currently exploring possibilities to open access to RUEDIS for competent authorities in other EU Member States and to apply RUEDIS as an information management tool on EU level. Second, to use the specific RUEDIS features for quality control of data entries.

During the exercise, not only the database itself, but also three accompanying documents were updated, which have been prepared in 2018 together with the original EU database and are now available as supporting documents to the present report. From now on, they will be published as stand-alone documents.

Three additional representative processes as well as a couple of processed commodities have been identified, which are now reported in the EU database for the first time. They were also added to the compendium of representative processing techniques (Scholz et al., 2022a) and the mapping of processed commodities to the FoodEx2 classification system (Kittelmann et al., 2022). In particular, new representative processes have been described for palm oil and palm kernel oil production, sugar production from sugar cane and sake production from rice. Cooked vegetables like broccoli, cauliflower, celeries and leek, as well as cooked pulses like lentils and chickpeas were added to the EU database. Composite foods such as bread, pasta, chocolate or ketchup have been disregarded, because processing factors would have required recalculation for one or more of the initial constituents to match them with

the currently used consumption data. Pulp/peel trials for commodities with edible peel were also disregarded, as they are normally not applicable for consumer risk assessment.

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1. Introduction

1.1. Terms of reference

Beneficiary: This grant was awarded by the European Food Safety Authority (EFSA) to the German Federal Institute for Risk Assessment (BfR).

Grant title: First update of the EU database of processing factors for pesticide residues

Grant number: Specific Agreement No 04 under Framework Partnership Agreement No GP/EFSA/AMU/2020/02

EFSA is regularly evaluating pesticide occurrence data in food generated under the official monitoring programs of Member States with respect to consumer exposure and risk assessment. Most of these data refer to raw commodities, because maximum residue levels (MRLs) established under European legislation reflect pesticide residues only in the raw agricultural commodity (RAC). Legally binding processing factors have not been introduced to EU legislation so far. However, food processing operations can have decisive effects on pesticide residue levels and consumer exposure. To evaluate these effects, a specific residue distribution ratio between processed and raw commodity can be determined as processing factor (PF) to be used in exposure assessments.

EFSA therefore initiated in 2016, together with a consortium led by BfR, a pilot project compiling processing factors at EU level (Project GP/EFSA/PRAS/2016/01; Question number EFSA-Q-2017-00658). This project resulted in the delivery of the first EU database of processing factors for pesticides in 2018. Although the pilot database was successfully used by EFSA for cumulative exposure assessments, the number of processing factors available in the database is still very limited. Sensitivity analyses conducted by EFSA have revealed that missing data may affect cumulative exposure estimates by a factor of 2 to 6 because around 80% of PF are missing (EFSA, 2020a; b). Hence, in order to increase the evidence base for both single and multiple chemical risk assessments, the database of processing factors needed to be updated with the most recent data provided to EFSA and processing factors from other sources (i.e. Member States and food industry).

1.2. Background

1.2.1. EU database of processing factors for pesticide residues

In 2016, EFSA launched the project "Database of processing techniques and processing factors compatible with the EFSA food classification and description system FoodEx 2". The overall objective of this project was developing a database of validated processing factors, which is compatible with the EFSA food classification and description system FoodEx 2. This database provides information on the fate of pesticide residues when processing the monitored raw agricultural commodities (RACs) into food items. The database has first been published in 2018. It can be accessed under the following link: https://zenodo.org/record/1488652. Further explanation on the database was provided in the project report (Scholz et al., 2018a), supported by a compendium of representative processing techniques (Scholz et al., 2018b) and a mapping of processed commodities to the FoodEx2 classification system (van Donkersgoed et al., 2018). In the context of the present project it was decided to provide updates of these three documents as stand-alone documents. The updated versions are available as **supporting documents** to the present report.

The compendium describes the main processing operations typically used in industrial food processing. Altogether, roughly 30 different processes have been identified which are considered relevant in food processing. These processes have been compiled from representative processing studies, published literature and inquiry in the food processing industry. Compliance of a processing study with the representative processing procedure outlined in the compendium is one of the key quality criteria applied during study evaluation for the EU database of processing factors.

EFSA´s comprehensive food consumption database follows the food classification and description system FoodEx2, which consists of a comprehensive catalogue of food items and facet descriptors, aggregated into food groups and broader food categories. As this consumption database is used by EFSA together with available processing factors (PFs), it is indispensable for data interconnection that the EU database of processing factors contains FoodEx2 Codes, too. The FoodEx2 Code is a specific denominator used to describe raw and processed food/feed items and processing operations. FoodEx2 coding is further based on facets. Facets are the collections of additional terms specifying properties of foods from various perspectives. The terms "raw primary commodity" (RPC) and "raw agricultural commodity" (RAC) are used synonymously in this context. RPC is the more common term within the FoodEx system, while RAC is preferably used in pesticide risk assessment and MRL setting.

All processing studies entering the EU database were evaluated with respect to a set of quality parameters allowing an informed conclusion on the reliability of PFs derived therefrom. These parameters include availability of a study protocol with full and detailed documentation of all relevant processing parameters like heating regimes (temperature, duration), the representativeness of the processing techniques used in the study, the employment of a fully validated analytical method (EC, 2021) and sample storage conditions for which storage stability has been demonstrated.

1.2.2. BfR data collection on processing factors

In a previous attempt to compile substantial information on the change of pesticide residue levels during food processing, BfR gathered and published a data collection on processing factors, which was last updated in July 2019. First and foremost, it contained processing factors from processing studies which were submitted to the BfR in the course of pesticide approval or authorisation procedures. Additionally, it contained 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). Additional residue data on pulp/peel distribution in citrus fruit was provided by a food business operator (Ahlers and Reichert, 2007) and collected within the framework of the German food monitoring programme (BVL, 2013). In the past, the BfR data collection also contained countless factors assessed in the course of evaluations of active substances within the EU and/or for MRL setting. Most of these studies were removed in 2019 since they were already contained in the EU database in better quality and with more up to date assessments.

In comparison to the EU database, the BfR database was lacking mainly three decisive features:

- FoodEx2 code mapping
- Verification of representativeness of the employed processing procedures
- Verification of appropriateness of the employed analytical methods

These features are central part of the quality parameters employed in the EU database and therefore the data collections could not simply be merged. In the context of the present project, all studies in the BfR data collection were thoroughly re-evaluated in accordance with the same quality criteria applied in the EU database. With the publication of the updated EU database on processing factors by EFSA, the BfR data collection on processing factors will no longer be available.

1.2.3. BfR database RUEDIS

The database RUEDIS ("RUEckstandsDaten-InformationsSystem", "Residue Data Information System") has been developed by BfR and preceding authorities more than 20 years ago. Since then it has continuously been improved and extended. RUEDIS is an INFORMIX database, which uses the programming environment Adobe Coldfusion 11. RUEDIS can be used as a web application.

RUEDIS is internally applied by BfR to manage detailed information from crop field trials and processing trials submitted in the framework of regulatory procedures for pesticides. RUEDIS contains approximately 61.500 individual trials on 676 active substances, conducted in 217 different crops grown in 63 countries (27 April 2022). Of these trials, approximately 8.500 are processing trials. A general overview of the database is provided in Figure 1.

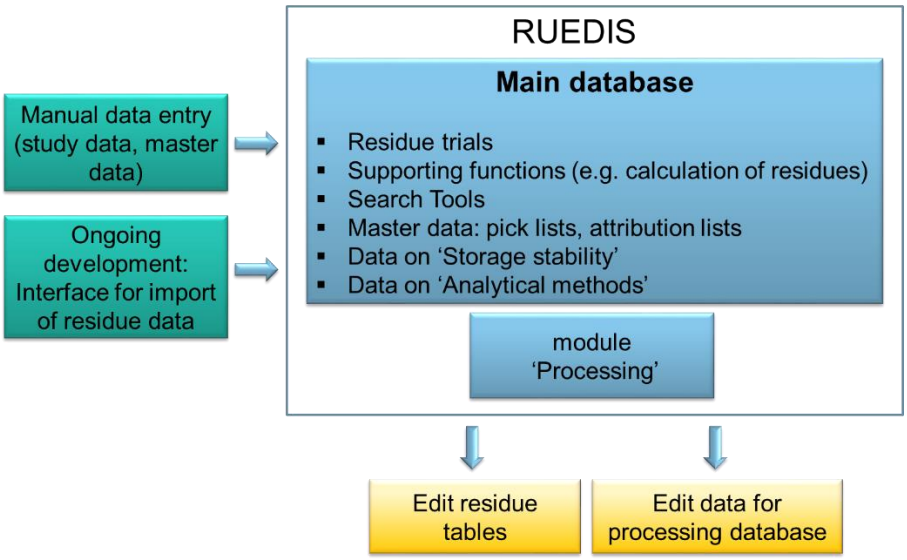


Figure 1: Overview of the database RUEDIS. The RUEDIS database is a continuously evolving data platform and search engine for pesticide residue trials developed at the BfR. It compiles study raw data and makes use of master data including matrix group assignments, storage stability data and data for analytical methods. A newer feature is the processing module, which allows *i.a.* the automated output of processing factors.

In an ongoing EFSA project (FPA GP/EFSA/AMU/2020/02 - SA02 - RUEDIS), BfR is currently exploring possibilities to open access to RUEDIS for competent authorities in other EU Member States and to apply RUEDIS as a tool to support the information management of pesticide residues data on EU level. To be prepared for future developments, one of the aims of the current project (see chapter 1.3) is to integrate all additional processing studies not only in the EU database of processing factors for pesticide residues, but also in the BfR database RUEDIS.

RUEDIS started as a database for crop field trials and the processing module was added later on. For this reason, a couple of entries relating to the field part of a study are mandatory even for processing trials. As a consequence, processing trials can only be entered in the RUEDIS database, if sufficient information on the field part has been reported. Separate entry of the processing part only is not possible.

The RUEDIS processing module offers a couple of features used to ensure high quality inputs in the present project (see also chapter 2.3). For example the harmonised calculation rules for processing factors (Scholz et al., 2022b) are applied in the database for automated PF calculation. Harmonised denominations of raw and processed products as well as the most recent residue definitions and PARAM Codes are available from up-to-date picklists in the database. Furthermore, an Excel output of most of the fields of the EU database of processing factors for pesticide residues can be generated automatically.

RUEDIS also contains storage stability data for pesticide/matrix combinations, allowing an automated comparison with storage durations reported in crop field trials or processing studies.

1.3. Aim of the project

The main objective under this specific agreement is to update the EU database of processing factors with all processing studies formerly included in the BfR data collection on processing factors and with any additional processing study evaluated by EFSA after June 2016. The tasks included the following:

- Enlist all processing studies assessed by EFSA between June 2016 and December 2021.
- Integrate all these processing studies in the BfR database RUEDIS if they meet the requirements for RUEDIS.
- Update the evaluation of all processing studies already available to BfR but not yet included in the European database.
- Establish quality control procedures to ensure the accuracy of data entries.
- Evaluate all processing studies in accordance with the compendium of representative processing techniques and the criteria used for the development of the first European database of processing factors for pesticides in food.
- Identify, among above reported processing studies, new processed commodities that were not previously considered in the European database of processing factors and update the compendium of representative processing techniques and the mapping of processed commodities to the FoodEx2 classification system accordingly to accommodate these new food items.
- Derive processing factors for all evaluated processing trials.
- Update the European database of processing factors for pesticides in food accordingly and describe in a scientific report the data, methods and criteria considered.

1.4. Project structure

The work in the project was organised as follows:

- Preparation of the inventory of additional studies by 31 December 2020 (Deliverable 1).
- Continuous update of this inventory during the whole project until 31 December 2021.
- Evaluation of all studies listed in Deliverable 1 and re-evaluation of all studies included in the BfR database (Deliverable 2).
- Evaluation of the studies additionally provided to BfR during the project and finalization of the project by 30 April 2022 (Deliverable 3).

The study evaluation procedure includes the FoodEx2 code mapping of all processes and processed products as well as an assessment of the appropriateness of the employed analytical method and the representativeness of the employed processing procedures. Additional representative processing procedures are described and included in the updated version of the compendium of representative processing techniques (Scholz et al., 2022a). The Excel spreadsheet of employed FoodEx2 codes is amended as appropriate (Kittelmann et al., 2022). Furthermore, the updated description of the EU database (Scholz et al., 2022b) and the addition to the EU database of processing factors as Excel spreadsheet (Zincke et al., 2022) are made available.

The complete updated EU database refers to residue definitions established for monitoring and storage stability data available at the reference date 31 December 2021.

2. Data and Methodology

The project comprises all processing studies currently included in the BfR data collection on processing factors and any additional processing study that was evaluated by EFSA between June 2016 and December 2021. The following chapters and included figures provide an overview of relevant data.

2.1. Method for retrieval of processing studies

While the studies underlying the BfR database on processing factors were already available to BfR from various regulatory procedures, this had to be checked case by case for those processing studies assessed by EFSA since June 2016.

At the beginning of the project, EFSA provided a reference list of all EFSA Conclusions and EFSA Reasoned Opinions that had been issued after June 2016 and before the starting date of this project. During the project, this list was updated by EFSA on a monthly basis.

BfR scrutinised all EFSA publications with respect to reported processing factors and processing studies. If processing information was contained, BfR traced it back to the underlying studies using the corresponding Evaluation Report or Assessment Report, respectively. Relevant bibliographic and study information was retrieved (author, title, year, processed product).

For processing study reports identified as unavailable to BfR, EFSA organised a call for data, inviting those national competent authorities, which had been responsible for the Evaluation or Assessment Report, to submit the study reports. An electronic platform was created by EFSA, where all processing studies uploaded by national competent authorities were accessible to BfR.

During the project, the identification and retrieval of processing studies was continued until 31 December 2021.

2.2. Processing studies evaluated in the project

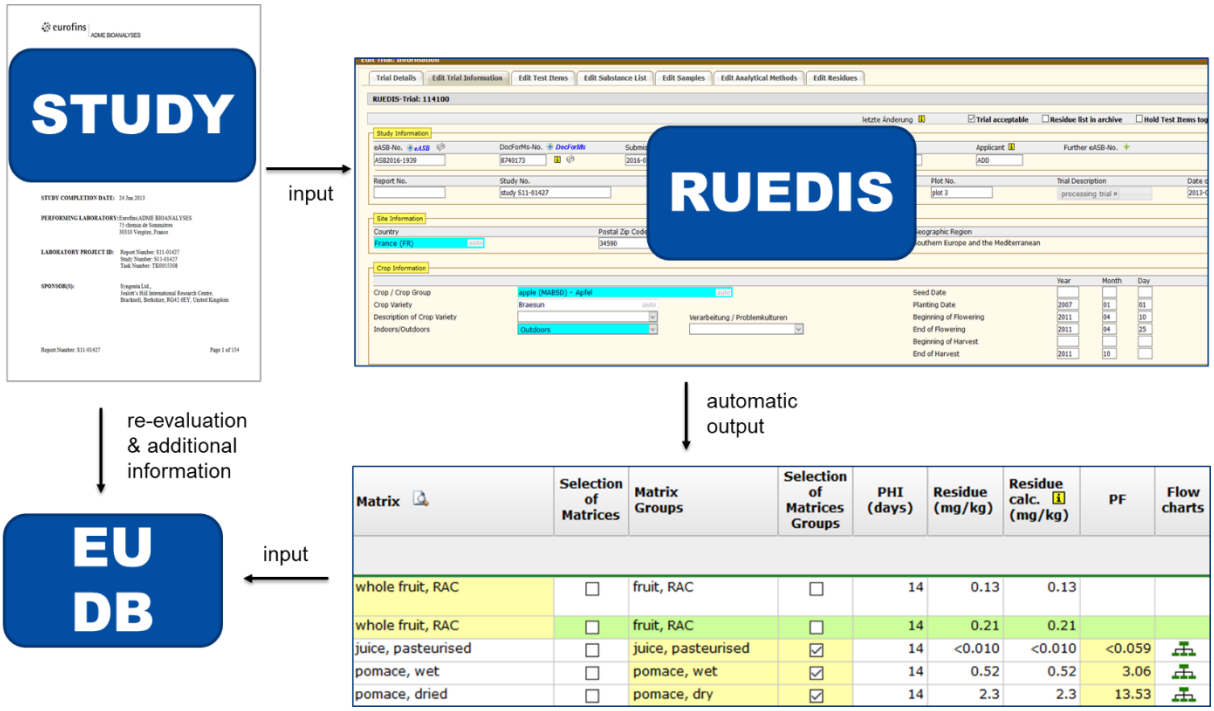
In total, 922 processing studies have been identified from EFSA Conclusions and EFSA Reasoned Opinions in the intended timeframe. Some of the studies have already been reported in the previous version of the EU database. 215 of the identified studies were not available to BfR and were requested from the respective Member States in the course of the project. With the exception of 63 studies, all studies could be included in the EU database. Reasons for not including the 63 studies are explained in chapter 3.1.2.

Furthermore, 716 studies from the BfR database were re-evaluated according to the quality criteria applied in the EU database. 35 studies from the BfR database were not considered for the EU database (see chapter 3.1.2 for further explanation).

The EU database was considerably extended during the project from 851 to a total of 2152 studies.

2.3. Study evaluation and integrated quality control procedures

The study evaluation was organised as a tiered process with implemented quality control at different checkpoints. It consisted of two independent evaluation strands, which are depicted in Figure 2. They have been preceding each other depending on the evaluation history of a study and the timelines within the project. Each study was assessed by a scientist who extracted relevant information and calculated processing factors. A second scientist extracted relevant study data and entered them into the RUEDIS database, which in turn automatically calculated processing factors. Either of the steps can be the starting point and the respective second task serves as a quality control of the first.



Matrix	Selection of Matrices	Matrix Groups	Selection of Matrices Groups	PHI (days)	Residue (mg/kg)	Residue calc. (mg/kg)	PF	Flow charts
whole fruit, RAC	☐	fruit, RAC	☐	14	0.13	0.13		
whole fruit, RAC	☐	fruit, RAC	☐	14	0.21	0.21		
juice, pasteurised	☐	juice, pasteurised	☑	14	<0.010	<0.010	<0.059	
pomace, wet	☐	pomace, wet	☑	14	0.52	0.52	3.06	
pomace, dried	☐	pomace, dry	☑	14	2.3	2.3	13.53	

Figure 2: Basic work-flow of study evaluation. Study evaluation for the EU database (EU DB) of processing factors is performed independently by two trained scientists. RUEDIS data entry and automated output of processing factors is complemented by individual study assessment and processing factor calculation.

As described previously, the RUEDIS database has been developed and continuously improved for organised and structured pesticides residue data management. Data entry to the processing module of RUEDIS represents one of the central quality measures for the evaluation of processing studies in this project. It provides a defined entry mask including drop-down menus for structured and restricted data entry. Data entry includes all raw data from the field part yielding the raw agricultural commodity (RAC), residue data on RAC and processed commodity (PC), analytical method and method performance and storage duration. With this information, RUEDIS generates an automated data output including calculated processing factors.

The information gathered during individual study evaluation and during RUEDIS data entry followed by automated data outputs was compared, discrepancies and mistakes were identified and consolidated information was transferred to the EU database of processing factors.

The quality measures consisted of implemented technical solutions on the one hand and individual assessments by trained scientists on the other hand. Figure 3 gives an overview of all employed quality control procedures, attributed to three quality checkpoints. It should be noted that checkpoints 1 and 2 sometimes where interchanged, depending on the sequence of evaluation steps (as detailed in the first paragraph of this chapter).

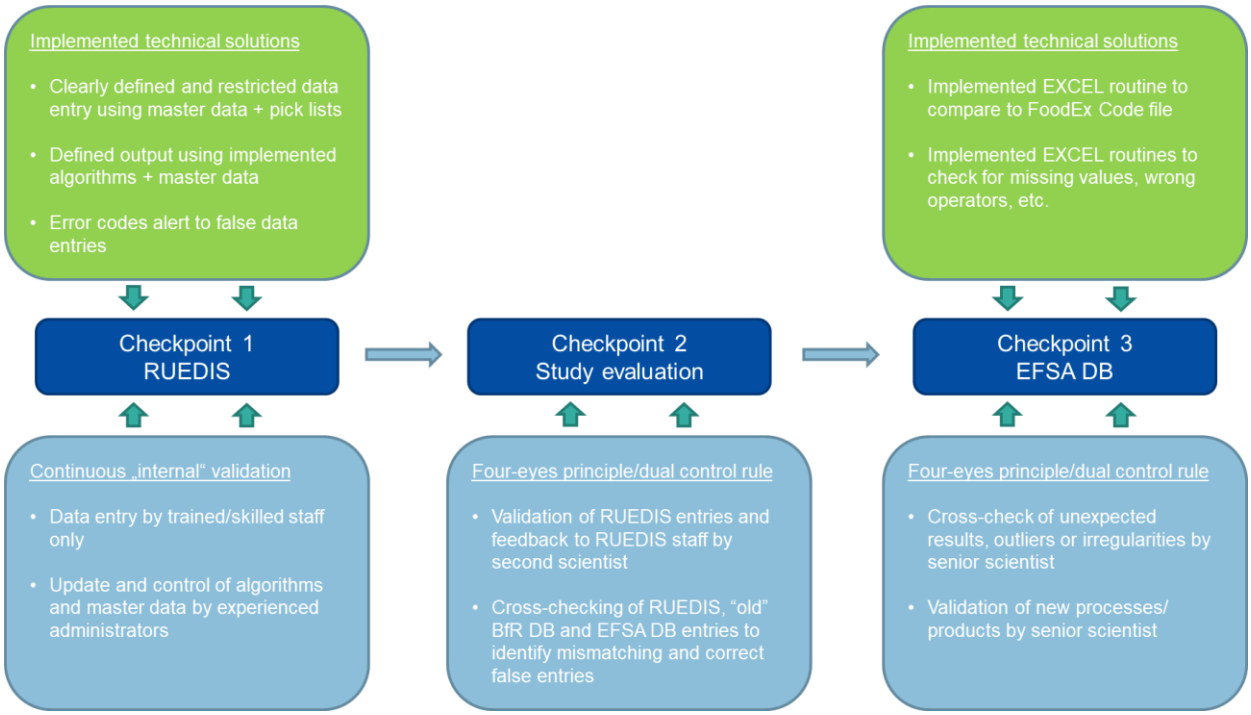


Figure 3: Quality control procedures during data entry. The quality of database entries is ensured by several implemented technical solutions, such as restricted data entry by defined master data, and scientific validation of evaluations by trained scientists at three quality checkpoints.

The first checkpoint was the RUEDIS data entry, which is performed via defined and restricted data forms and defined master data. This includes the harmonised assignment of individual matrices to matrix groups, the harmonised denominations of raw and processed products as well as the most recent residue definitions, PARAM codes and FoodEx2 codes. Automated error coding limits accidental mistakes during data entry. Automated data output is governed by the implemented master data and algorithms as well. The whole system is continuously updated and controlled by experienced administrators. Proper data entry is ensured by trained staff.

By separately evaluating the processing studies in the next step (second checkpoint), a second scientist completed and validated the RUEDIS data entries. By cross-checking entries in the RUEDIS database, the BfR data collection on processing factors and the EU database of processing studies, data mismatching or false entries could additionally be revealed.

In a third quality checkpoint, again automated technical features supported correct FoodEx2 coding of all data entries in the EU database and identified missing values, wrong operators, etc. Furthermore, a third scientist was involved in this step to cross-check unexpected results or irregularities as well as newly identified processes and products (four-eyes principle).

This multi-tiered control procedure ensured a maximum level of data quality in the final EU database of processing factors.

3. Results

3.1. Update of the processing studies

3.1.1. New processing studies

As described previously (2.1. and following), 1183 processing studies have been (re-)evaluated and added to the EU database.

The updated EU database now comprises a total of 14781 processing factors of which 10197 are considered acceptable, 1351 indicative and 3233 not acceptable. In 2477 cases no PF could be retrieved. For 2104 combinations of active substance, matrix and process, acceptable/indicative median PFs could be derived. Reasons for flagging a PF as "indicative" or "not acceptable" are displayed in detail in the EU database (Zincke et al., 2022). The most frequent reason for the status "not acceptable" is a RAC with residues below the LOQ (RAC<LOQ) followed by missing details on the processing procedure.

3.1.2. Studies not considered for evaluation

A few studies submitted were not considered for the EU database due to different reasons, which are briefly outlined in the following table.

Table 1: Detailed reasons for not including studies in the EU database of processing factors

Reason	Explanation / example
no RAC reported	• only residue data for pulp reported, no residue information for whole fruit • no RAC according to Reg. (EC) No 396/2005 (EC, 2005) reported (e.g. brown rice, dried tea leaves) • RAC not sufficiently defined (e.g. "cleaned grain for milling")
no relevant processed commodity reported	• no matrix defined as feedstuff (as a by-product of food production), important intermediate food product or food end product is reported in the study report • residue data for straw, hay or silage
study not readable	• partially illegible text passages • insufficient scan of the original document
no processing study	• study does not describe any processing steps or provide residue data for processed foods • analytical method report only
no residue data reported	• missing residue data for RAC, processed product or both • residues for RAC not reported according to current residue definition
no RAC reported (no information for required PHI)	• see criteria for PF derived for pulp/whole fruit (chapter 2.4.6.,(Scholz et al., 2022b)): residue data for same PHI must be available for RAC and pulp
study not submitted	• full study not submitted by Member State

3.2. Update of compendium of representative processing techniques

During evaluation of the newly identified processing studies, three new representative processes have been identified. Details of the processing of palm fruits to palm oil and palm kernels to palm kernel oil, respectively, sugar cane to refined sugar, and rice to sake have been added to the compendium of representative processing techniques. Furthermore, a new chapter was inserted in the compendium to briefly explain the contact of chlorinated water with food causing chlorate residues and why processing factors are not a solution for this issue. In addition, some minor changes have been made in the following chapters: chapter 3 (thermal processes), chapter 7 (oil production), chapter 10 (milling processes), and Appendix A (tabular summary of recommended extrapolations). Furthermore, new processing codes and representative studies were added to appendices B and C of the compendium (Scholz et al., 2022a).

3.3. Update of the processed commodities

3.3.1. New processed commodities

As part of the evaluation of a considerable amount of new processing studies, processed commodities have been identified which have not yet been reported in the EU database. In addition to commodities resulting from newly described processes (see 3.2), cooked vegetables like broccoli and cauliflower, celeries and leek, as well as cooked pulses like lentils and chickpeas were added to the EU database. They have also been included in the updated Excel spreadsheet displaying the FoodEx2 coding (Kittelmann et al., 2022).

3.3.2. Composite foods

Only few composite foods are considered in the database. Processing factors would require recalculation for one or more of the initial RACs to match them with RAC-converted consumption data. As most of the composite foods are composed of many ingredients, it was agreed not to collect processing factors for them except for beer and jams/jellies/marmalades. When possible, not only the processing factor for beer-making, but also for hop extract preparation and malting were reported. For jams/jellies/ marmalades, PFs were calculated and supplemented by further processing factors calculated for the respective cooked fruit only. Standard factors for sugar addition to different fruit have already been reported in the compendium. If the sugar content of the jam was reported in the processing study, this information was used instead to calculate the processing factor for cooked fruit.

3.3.3. Commodities not considered for the database

BfR identified several processed commodities in the BfR data collection, the transfer of which to the EU database was not considered necessary by EFSA. Mainly, these include composite foods such as bread, pasta, chocolate or ketchup (see 3.3.2 for reasoning).

Pulp/peel trials for commodities with edible peel (e.g. apple, pear, peach, carrot) were also not included in the EU database, as they are normally not applicable for consumer risk assessment which relies on the whole edible commodity in this case.

Moreover, residues on inedible peels which are not used for feeding purposes (e.g. melon) were not considered for the database, because they are no relevant processed commodities according to the compendium of representative processing techniques (Scholz et al., 2022a).

An exception is made for malt germs. Though it is not a relevant feed item according to the Animal model, a couple of inquiries from feed monitoring authorities showed that they nevertheless consider it

as relevant. It was decided that processing factors for malt germs will continue to be made available in the EU database of processing factors (Zincke et al., 2022). The same holds true for dry pomace resulting from apple processing, peach processing, pear processing, table and wine grape processing, tomato processing, and citrus fruit processing.

3.4. Update of FoodEx2 codes

The identification of new processed commodities and processing procedures required the generation of or connection to new FoodEx2 codes. For instance, new FoodEx2 codes were included for the processing of rice to sake. In some cases, existing FoodEx2 codes were adapted accordingly.

Additionally, some FoodEx2 codes in the previously published database have been updated to increase the level of specification. E.g., the FoodEx2 code for the process of peeling and cooking potatoes now reflects the sequence of peeling and cooking within this process. The entire list of updated FoodEx2 codes is available in a separate document (Kittelmann et al., 2022).

3.5. Additional results

3.5.1. Dehydration factors

A frequently occurring process is the drying of fruit or vegetables. The amount of available data varies strongly between different matrices. For instance, robust data is available for the drying of grapes to raisins whereas data for drying of other berries is scarce. Therefore, a recommendation for the extrapolation of processing factors would be helpful. The extrapolation options as well as the use of generic factors (calculated from the water content in the processed and the raw commodity) should be discussed further. Several sources of generic drying factors are known. As such factors are also contained in the RPC model and this model is currently under revision, the issue has to be tackled in a follow-up project.

3.5.2. RAC name selection

BfR noted that there are single processing studies conducted on a commodity which is only contained in part B of Annex I to Reg. (EC) No 396/2005 (EC, 2005). It was agreed to include in the database both the FoodEx2 code (for the commodity listed in part B only) and the matrix code and name of the respective part A commodity (e.g. Tangelo in part B attributed to Grapefruit in part A). These changes have been made in the updated database (Zincke et al., 2022) and the updated list of FoodEx2 codes (Kittelmann et al., 2022).

3.5.3. Clarification concerning pulp/peel trials

During data entry, it was recognised that a large part of pulp/peel trials was based on recalculated residues in the RAC. This means that pulp and peel residues were measured separately and recalculated to the theoretical residue in the RAC (whole commodity) by making use of mass balances . As recalculation is not considered a reason for invalidating the study, this was not specifically indicated in the database.

Furthermore, some general calculation rules have been updated and specified and can be found in the background document to the database (Scholz et al., 2022b). This regards the calculation of averages with <> operators or the consideration of retain samples.

4. Conclusions

According to the agreed terms, an update of the EU database of processing factors for pesticide residues has been prepared. It contains 2152 studies comprising 14781 individual and 2104 median processing factors, extending it to more than double of its initial size. Only few new processing procedures and processed commodities have been identified within the framework of this project suggesting a strongly increased data basis for already existing processes. This results in more robust processing factors for individual substance/matrix/process combinations and a larger number of active substances for which processing factors are now available.

The updated database (Zincke et al., 2022) is supported by an updated database description (Scholz et al., 2022b) and the updated compendium of representative processing techniques describing roughly 30 different processes considered relevant in food processing (Scholz et al., 2022a). These processes have been compiled from representative processing studies, published literature and inquiry in the food processing industry. Furthermore, the database follows the food classification and description system FoodEx2. The Excel spreadsheet of employed FoodEx2 codes, which provides an easy link to other databases handled by EFSA, has been amended as appropriate (Kittelmann et al., 2022)

The reliability of processing studies and processing factors derived therefrom was judged by making use of defined quality criteria, such as the availability of a study protocol with full and detailed documentation of all relevant processing parameters like heating regimes (temperature, duration), the representativeness of the processing techniques used in the study, the employment of a fully validated analytical method and sample storage conditions for which storage stability has been demonstrated. According to these integrated quality parameters, several processing factors have been marked as "not acceptable" or just as "indicative". This provides support for database users.

In addition to these database quality requirements, BfR employed internal quality control procedures including cross-checking with the BfR database RUEDIS, which provides a couple of implemented technical solutions for quality control.

The entire assessment shows that study data quality is quite heterogeneous, which is partly due to very different points in time where the studies have been originally conducted (1969 - 2020). Some were conducted before the respective OECD Guideline 508 became available. Moreover, especially analytical methods and their performance and reporting developed a lot over the last decades. Even though for most studies a fit analytical method and validated LOQs could be identified, a higher level of data quality would sometimes be desirable.

The database was extended with respect to considered processes and processed commodities, while for some commodities it was decided to not include them. These were mainly composite foods and peeled commodities with edible peel. Furthermore, update and revision of the compendium of representative processing techniques as well as of the FoodEx2 coding led to further improvement by adding more details and specifications. Some general calculation rules have also been updated or specified in the background document to the database (Scholz et al., 2022b).

Further improvements could be envisaged for future work packages: Apparently, a large part of pulp/peel trials was based on recalculated residues in the RAC. These could be indicated in the database to discriminate them from measured values. Another aspect requiring improvement is the use of dehydration factors. Some "drying studies" are contained in the EU database. On the other hand, a large number of generic drying factors (calculated from the water content in the processed and the raw commodity) is available from different sources. A set of quality criteria for generic drying factors has to be established to select suitable ones. Thorough cross-checking of both kinds of factors is required to propose reasonable extrapolations.

In conclusion, this first update of the EU database of processing factors not only added a significant amount of new processing studies to the existing data pool but also increased the database quality, thus providing a broader and more robust set of processing factors.

5. Recommendations

First of all it is recommended to establish a mechanism for regular updates of the EU database of processing factors, as new studies are conducted and submitted continuously and residue definitions keep changing. A suitable workflow for the extraction of processing studies from the different regulatory procedures will have to be developed in a follow-up project. It is suggested that also other sources for processing studies are further explored, such as studies submitted as part of national/zonal authorisation procedures for plant protection products in EU Member States. Furthermore, information on pesticide residues in raw and processed commodities obtained from the self-monitoring in food processing industry would provide a valuable source of real-world processing factors, beyond laboratory-scale experiments, provided that data are complete and comply with the current data requirements to derive robust processing factors.

During evaluation of the acceptability of processing studies and processing factors, the following general recommendations were developed:

- An alignment of raw commodity categories used with respect to storage stability and to analytical methods is desirable. This should be kept in mind when updating the respective OECD guideline and guidance document.
- An improvement of transparency and traceability of processing studies underlying a PF is desirable. Unambiguous study citations (title, author, year, study number) were often missing for processing studies evaluated in EFSA's Reasoned Opinions and in the underlying Evaluation Reports. No such problems were observed with DAR and RAR.
- For more than 30% of all investigated combinations of active substance/raw agricultural commodity/processed commodity, no reliable PF could be calculated because only one individual processing factor or two processing factors with more than 50% deviation were available. To provide a reliable median PF output, a sufficient number of independent processing trials should always be envisaged when setting up a study. In future also extrapolation possibilities should be further explored.
- Processing factors often exhibit a high variability for a given combination of active substance/raw agricultural commodity/processed commodity. It should be discussed at OECD level if the current minimum requirement of 2 studies (sufficient if variability is < 50%) or 3 studies (required if variability of results in 2 studies is > 50%) is sufficient to yield reliable median factors.
- In 16% of all cases no acceptable/indicative processing factor could be calculated because the residues in the RAC were below the LOQ. It is therefore important, that the application rate is high enough to yield measurable residues in the raw product.

With respect to further development of the database, the following aspects are highlighted:

- PARAM Code updates published by EFSA sometimes contrast the residue definitions published in the EU pesticide database and respective EU MRL legislation. It is recommended that EFSA aligns their PARAM codes with the wording used in the legal text.
- It might be worthwhile to extend the processing database in future by including physico-chemical properties of active substances to allow for comparison with and maybe even for extrapolation to other compounds.
- It is widely assumed that drying factors are independent of the pesticide and the commodity. There are currently various sources that provide generic drying factors ((ESA, online), (BNN, 2012) and others). Some processing factors for dried commodities are also available from

processing studies. A set of quality criteria for drying factors should be established and a list of suitable factors provided together with recommendations for extrapolation.

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Glossary and Abbreviations

BfR	German Federal Institute for Risk Assessment
DB	Database
EFSA	European Food Safety Authority
EU	European Union
FoodEx2	EFSA´s food classification and description system
GLP	Good laboratory practice
JMPR	FAO/WHO Joint Meeting on Pesticide Residues (JMPR)
MRL	Maximum residue level for pesticides. The maximum amount of a pesticide residue allowed in foods or animal feeds, expressed as milligrams per kilogram.
OECD	Organisation for Economic Co-operation and Development
PARAM	Parameter EFSA's PARAM Code describes the parameter/analyte according to the Substance Code of the PARAM catalogue.
PC	Processed commodity
PF(s)	Processing factor(s)
RAC	Raw agricultural commodity; synonymous to RPC
RPC	Raw primary commodity; synonymous to RAC
RUEDIS	BfR database ("RUEckstandsDaten-InformationsSystem", "Residue Data Information System")

Overview of supporting documents

Compendium of Representative Processing Techniques Investigated in Regulatory Studies for Pesticides

The compendium of representative processing techniques can be found online on EFSA's knowledge junction: https://doi.org/10.5281/zenodo.6564208

Linking Processed Foods and Processing Techniques to the FoodEx2 Coding System (Excel Spreadsheet)

The list of FoodEx2 codes can be found online on EFSA's knowledge junction: https://doi.org/10.5281/zenodo.6564210

Background Document on the EU Database of Processing Factors for Pesticide Residues

The background document can be found online on EFSA's knowledge junction: https://doi.org/10.5281/zenodo.6564214

EU Database of Processing Factors for Pesticide Residues (Excel Spreadsheet)

The EU database of processing factors can be found online on EFSA's knowledge junction: https://doi.org/10.5281/zenodo.1488652