Revision 3.0, 30 May 2016

User Guide

to the

Pesticide Residues Overview File

PROFile

BACKGROUND

The Pesticide Residues Overview File (PROFile) is an Excel file that was designed by EFSA for collecting and processing pesticide residue data into a structured format. When entering data in the PROFile, users need to follow a very specific procedure where entries are subject to a high level of data validation. This means that the ability to enter data in the PROFile is case-sensitive depending on the uses authorized within the Member States and the data already inserted. The PROFile can therefore be used as a check list for the pesticide residues risk assessment. After having inserted all the data for a given active substance, the PROFile automatically generates report sheets, allowing users to consult all available data without any risk of unintentionally modifying the data.

A first version of the PROFile has been issued by EFSA on 15 July 2008. After a consultation of all Member States from 11/06/2009 to 10/07/2009, PROFile 2.0 and its user guide have been issued in September 2009. Between 2009 and 2013, subsequent revisions of the PROFile (versions 2.1, 2.2 and 2.3) were issued to fix minor bugs and to consider some developments in the pesticide residues risk assessment (see details is the user guide of PROFile 2.3). Due to the recent major changes that occurred in the field of pesticide risk assessment, in particular due to the consideration of the OECD dietary burden calculator, a new revision of PROFile was deemed necessary in 2016. Considering the important modifications made on the structure of the document, PROFile 3.0 was issued by EFSA in March 2016.

A user guide was initially developed for PROFile 2.0 and was updated at several occasions along with the subsequent revisions of the PROFile (2.1, 2.1 and 2.3). As for the previous user guide, the purpose of the present document is to provide the users of PROFile 3.0 with some very specific guidance on how to enter, import or consult data in this new version of the PROFile. For reasons of transparency, an overview of the revisions and the changes made in the PROFile 3.0 is provided below.

Changes included in PROFile 3.0 (issued on March 2016):

- In line with Commission Regulation 752/2014, names of food commodities, crops and scientific nomenclature are modified;
- New entries for feed commodities (raw and processed) are added in order to consider all feed items taken into account in the OECD livestock dietary burden calculator);
- An update on the default processing factors for feed items is proposed;
- The OECD dietary burden calculator is integrated (replacing the old calculation method);
- In line with the OECD dietary burden calculator, new groups of livestock are added and names and codes for livestock commodities are reconsidered;
- Additional methodologies for the livestock MRL calculation are included and these are more transparently reflected in the overview mode;
- An additional worksheet is included to report the list of references;
- Modifications on some editing functionalities are included to facilitate the use of the PROFile and to increase the flexibility for specific situations.

It should be noted that the validation of data in the PROFile is mainly based on the current EC guidance for pesticide risk assessment (now also including OECD recommendations). In some cases, however, where guidance at EC level was too limited, other international guidance documents and/or recommendations were considered. These cases are further elaborated in the grey text boxes in this document (for information).

TABLE OF CONTENTS

USER GUIDE

1. Enter data manually in the PROFile

When opening PROFile 3.0, users will be prompted with a sheet called '*Data_management'*. At this stage, users have the possibility to choose whether they want to start from a blank template and enter all data manually or whether they would like to import the data from a previous version of the PROFile.

In order to enter the data manually, the user should press the button called '*Enter/update data in the PROFile'*. In contrast with the previous versions, a new copy of the PROFile is not generated automatically and the user is directly requested to enter the data in the same document according to a very specific procedure (see Figure 1). If the user wants to duplicate the document and save a new copy, he/she can still do it manually. This procedure comprises 5 steps and at each step users will always be able to return to a previous step without any loss of data. Specific guidance for the individual steps will be detailed in the following sections, but before starting the procedure, ***the user may wish to consider the following general instructions:***

- PROFile 3.0 is only intended for reporting pesticide uses and/or import tolerances which have been evaluated at European level. Consequently there is ***no need to insert Codex levels (CXLs)*** or any other related information in the PROFile.
- At each step of the procedure, ***only the yellow cells should be completed or modified***. If any other cell is modified, the inserted value will not be taken into account. If the user is not able to conclude on a certain entry, the user should preferably insert "-" in the yellow cell.
- ***PROFile 3.0 only allows for one enforcement residue definition***, while some active substances might have several enforcement residue definitions (e.g. there are 2 different enforcement residue definitions resulting from the use of carbosulfan: carbosulfan and carbofuran). In such cases, the PROFile should be completed for each residue definition separately (i.e. one PROFile per residue definition).
- ***PROFile 3.0 can only contain data for one active substance*** while in practice some active substances may result into one combined residue definition for enforcement (e.g. the enforcement of all dithiocarbamate pesticides is based on the common CS_2 residue definition). In such cases the PROFile should be completed for each active substance individually.

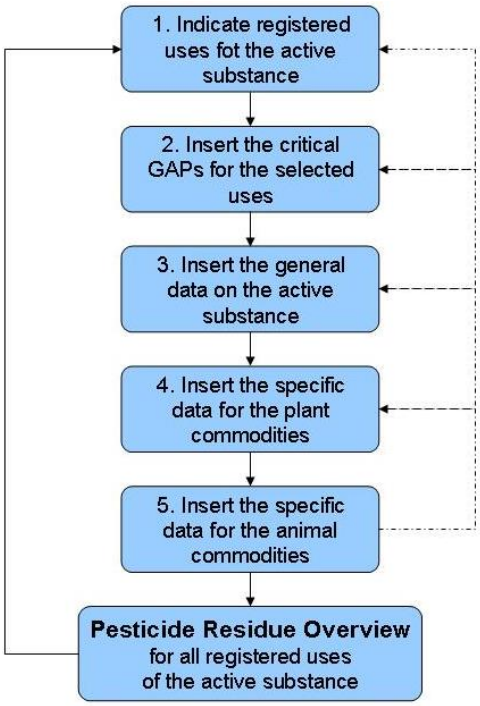

Figure 1. Flowchart for insertion of data in the PROFile

1.1. Indicate registered uses for the active substance

The ***name of the active substance*** should be inserted on the top of the sheet that is named *Registered_uses*. In order to avoid any misunderstanding, the name that was agreed at EU level should be used. The agreed spelling of all active substances can be found in Document 3010 on the Commission's website:

http://ec.europa.eu/food/plant/protection/pesticides/index_en.htm

Afterwards the ***registered uses*** for which data need to be entered in the PROFile should be indicated by clicking the corresponding check boxes. A distinction is made between:

- Outdoor, Northern Europe (Outdoor uses in Northern Europe)
- Outdoor, Southern Europe (Outdoor uses in Southern Europe)
- Indoor, North and South (Indoor uses in Northern or Southern Europe)
- Import tolerances (Uses outside of Europe)

When indicating the registered uses on this sheet, ***the user should also consider the following assumptions:***

- ***Post-harvest treatments*** within the European Union are not expected to be affected by climatic conditions. Therefore they should be considered as an indoor use. Post-harvest treatments performed outside of the European Union should be considered as import tolerances.
- Although ***seed treatments*** are usually performed under indoor conditions, the residue level in the harvested commodity might be affected by the field conditions. Seed

treatments should therefore be considered as outdoor treatments, unless the treated seeds are grown under indoor conditions.

- According to Annex I to Regulation (EC) N° 396/2005, some ***very minor crops*** are related to the crops listed in the PROFile. In case users want to insert a GAP which is applicable to one of the related crops only and not to the main crop listed in the PROFile, this should be reported in the comment field of the GAP.
- ***PROFile 3.0 is not intended for collecting data on CXLs*** and should only reflect GAPs which have been evaluated at European level by a rapporteur or evaluating Member State. Consequently, the check boxes for import tolerances are only meant for non-European uses that have been fully evaluated at European level and not for CXLs.
- ***PROFile 3.0 is also not suitable for reporting post-harvest treatments on processed commodities***. Such uses should be reported to EFSA by means of an evaluation report.

After having indicated all registered uses and import tolerances, the user can proceed to the next step of the procedure by clicking one of the buttons at the top or at the bottom of the page.

1.2. Indicate the critical GAPs for the selected uses

On this sheet the user should insert the critical GAPs for the 4 different climatic zones (NEU outdoor, SEU outdoor, EU indoor and non-EU). Data should be entered in the ***yellow cells only***, using the drop-down menu when available. If possible, the user should complete all the yellow cells. It is noted however that some fields are not essential to the risk assessment and only ***the following fields are considered mandatory:***

- Member state or country where the critical GAP is registered
- Method of application
- Latest growth stages at application
- Maximum number of applications
- Minimum interval between applications
- Maximum application rates
- PHI or withholding period

Particular attention should be given to the following data validations:

- ***Outdoor/indoor***: fixed dropdown menu.
- ***Member state or country***: no data validation applies. However, only member states or countries where the critical GAP is registered should be entered, using Interinstitutional Country Codes and a comma as separator between the country codes (e.g. FR, BE, NL). For the list of country codes the user is referred to the following website:

  http://publications.europa.eu/code/en/en-5000600.htm
- ***Pest controlled***: no data validation applies.
- ***Formulation type***: fixed dropdown menu.

- ***Formulation content***: decimal number.
- ***Formulation content unit***: flexible dropdown menu that can be overwritten by another entry if necessary.
- ***Method of application***: fixed dropdown menu. Since it is not possible to provide all possible application methods in the dropdown menu, the system provides some flexibility by defining very specific application methods in the comment field. In cases where the critical GAP is a combination of two different methods of application (e.g. seed treatment followed by a foliar treatment), the user should insert the most critical treatment (e.g. the foliar treatment) in the GAP table and indicate in the comment field that it is preceded by another method of application (e.g. the seed treatment).
- ***Growth stage at application***: fixed dropdown menu that corresponds to the 2-digit codes of the BBCH scale. Additional information on the BBCH scale can be found on the following website:

  http://www.jki.bund.de/fileadmin/dam_uploads/_veroeff/bbch/BBCH-Skala_englisch.pdf
- ***Number of applications***: whole number.
- ***Interval between applications***: whole number.
- ***Application rates***: decimal number.
- ***Application rate units***: flexible dropdown menu that can be overwritten by another entry if necessary. It should be noted however that the critical GAPs should be expressed in a way that is useful for risk assessment at EU level. It should also be possible to compare the application rates with the application rates in the residue trials and with the application rates registered in the several member states. Consequently application rates which are very specific to the member states (e.g. expressions in leaf wall area, tree height,...) should be avoided and recalculated to units that are generally used at EU level (e.g. expressions in ha or hL). The application rate that is originally authorised in the MS can be provided in the comment field.
- ***PHI or withholding period***: flexible dropdown menu that can be overwritten by another entry if necessary.
- ***Comments***: text string of max. 250 characters.

After having inserted all the critical GAPs, the user can proceed to the next step of the procedure by clicking the button down the page. If the user realizes that a use was forgotten on the previous page, it is possible to return to the previous step without any loss of data.

1.3. Insert the general data on the active substance

1.3.1. General instructions

On this sheet the ***general data on the active substance*** should be inserted. This sheet consists of a questionnaire concerning generic data of the active substance which are not related to a single crop or commodity and which will be copied automatically to all the related commodities afterwards. This step was mainly introduced so that data related to groups of commodities only need to be entered once. The crop groupings applied in the PROFile are

reported in Appendix 1 to this document. During the whole process of completing the PROFile, a copy of this list is also available as an individual sheet allowing users to consult the groupings at any time.

Going through the questionnaire, the user should enter data in the ***yellow cells and yellow check boxes only***. These cells are subject to some very specific validation which is also related to some aspects of the assessment. Consequently, depending on the values that are entered in the questionnaire, new questions and new yellow cells will appear. If the user is not able to conclude on a certain entry, the user should preferably insert "-" in the yellow cell.

The ***questionnaire is composed of different sections***. Specific instructions related to each of these sections will be detailed below. After having completed the questionnaire, the user can proceed to the next step by clicking the button down the page. If mistakes were made at a previous step, it is possible to go back to step 2 without losing the data already entered (see also section 1.4.3).

1.3.2. Metabolism in plant commodities

The user needs to indicate for which ***application method*** and for which ***crop group*** metabolism studies are available. In the comment field, the user can indicate on which crops the metabolism studies were performed. Some specific cases might arise where ***a metabolism study performed according to a certain method of application can also be used for another method of application***. In this case, the user can tick the boxes for both methods of application indicating in the comment field that only one metabolism study is available. If sufficient application methods and crop groups are covered (see below), the user will be asked whether a general residue definition can be proposed.

General plant residue definitions can be proposed if at least one representative metabolism study is available for each method of application with authorized uses. Additionally, a total of 3 crop groups should be covered by the available metabolism studies, regardless of the methods of application. If these requirements are met, the user will be able to enter general residue definitions which will be copied automatically to all plant commodities. If the requirements are not met, it will not be possible to insert general residue definitions and residue definitions will need to be entered later on for each commodity individually.

1.3.3. Analytical methods for the plant commodities

If general plant residue definitions can be proposed the user will be prompted to enter information on the analytical methods for each relevant group of plant commodities. When reporting the availability of analytical methods, particular attention should be given to the following issues:

- The method reported should be the ***primary analytical method*** for enforcement in foods of plant origin because this is considered to be the most useful method for enforcement purposes.
- The ***independent laboratory validation*** is considered to be part of the primary method validation and should therefore not be reported separately. However, it would be useful to mention in the comment field when the independent method validation is not available.

- A ***confirmatory method*** might not be required in all cases. If available, this can be reported in the comment field.
- When different analytical methods are available, priority should be given to ***multi-residue methods*** because these methods are considered to be the most useful for enforcement purposes.
- Where different ***LOQs*** are available, there is no need to report the lowest analytical method, unless higher LOQs might lead to exceedances of the toxicological reference values. Within the group of commodities with high water content, some commodities might be more difficult to analyse (e.g. brassica plants, onions) resulting in higher LOQs. In such cases, it is suggested that only one general LOQ is reported for all commodities, indicating in the comment field that for some commodities higher LOQs might be applicable.
- The analytical method should cover ***all compounds included in the enforcement residue definition*** and the reported LOQ should be the combined LOQ for all compounds of the enforcement residue definition.
- With regard to the type of analytical method and the LOQ of the analytical method, the user is strongly encouraged to use the available ***dropdown menus***. However, other values may be entered if necessary.

Finally, if it is not possible to propose general plant residue definitions the user will need to enter the analytical methods later on for each commodity individually considering that the validity of the analytical methods is dependent on the enforcement residue definition (see also section 1.4.4).

1.3.4. Storage stability in plant commodities

If a plant residue definition applicable to all plant commodities can be proposed the user will be prompted to enter information on the storage stability of residues for each relevant group of plant commodities. The user should report storage stability covering the complete risk assessment residue definition. The ***storage temperature*** and ***storage time*** should be reported ***for the most limiting compound of the risk assessment residue definition***. There is no need to indicate in these fields when storage stability data are not required.

If it is not possible to propose general plant residue definitions the user will need to enter the storage stability data later on for each commodity individually considering that storage stability is dependent on the risk assessment residue definition (see also section 1.4.5).

1.3.5. Nature of residues in processed commodities

In this section the user should indicate whether ***hydrolysis studies*** are available covering the main food processes (baking, sterilization and pasteurization). This section is limited to hydrolysis studies only. In case very specific metabolism studies are available for a certain processed commodity, these data can be entered later on for each individual commodity (see also section 1.4.8).

If hydrolysis studies are available and if it was possible to propose a general residue definition for all plant commodities (see point 1.3.2) the user will be asked whether the ***degradation pattern is similar to the metabolic pattern in the primary crops***. If this is not the case, the

user will be invited to enter a residue definition for processed commodities. This residue definition should apply to all processed commodities.

For some active substances, it might be possible to conclude that the metabolic patterns in unprocessed and processed commodities are similar based on the chemical properties of the active substance. Such a ***waiver for hydrolysis studies*** can be included in the PROFile by using the appropriate entry of the drop-down menu.

Crop groupings

The crop groupings that are applied in the PROFile have been defined in accordance with current EC guidance, but some exceptions have been applied as explained below.

✓ Plant metabolism

The crop groupings for plant commodities are mainly based on the crop grouping listed in the European guidance document on metabolism and distribution in plants (SANCO 7028/VI/95). For some commodities, however, no guidance at European level was available, EFSA referred to OECD Guideline 501, except for coffee and cocoa where metabolism studies in fruiting trees are considered more relevant than metabolism studies in pulses and/or oilseeds. When no guidance was available, EFSA aimed to identify the most relevant crop group based on the appearance and the botanical properties of the plant.

✓ Analytical methods and storage stability

Both regarding the analytical methods and the storage stability, a large number of guidance documents are available (SANCO/825/00, SANCO/3029/99, SANCO 207/3131, OECD Guidance document ENV/JM/MONO(2007)17, SANCO 7032/VI/95, OECD Guideline 506). The majority of crops groupings was found to be similar in most guidance documents and therefore implemented as such in the PROFile. For some commodities, however, available documents were found to apply different crop groupings and in some cases, no guidance was available at all. EFSA therefore aimed to harmonize the crop groupings of the different guidance documents by selecting the most appropriate grouping for each commodity. The following considerations were also taken into account:

- Crop groupings for storage stability and analytical methods should be in line with each other.
- The distinction between commodities with high protein content and commodities with high starch content was disregarded by EFSA because the so called commodities with high protein content have in fact starch contents much higher than the protein content. These two groups were consequently combined to the dry commodities.
- According to some guidance documents, root and tuber vegetables were classified as commodities with high starch content. This was changed to commodities with high water content because the water content in these crops ranges between 70-90 %. They can therefore not be compared with dry commodities like cereals and pulses.
- For the miscellaneous fruits, decision on high acidity or high water content was taken based on the pH values that can be retrieved from the US FDA. For the most exceptional fruits, searches for scientific articles were performed.

- All commodities that are identified as 'difficult-to-analyse' crops in any of the guidance documents were not included in any crop group, leaving the flexibility to decide on a case-by-case basis.

1.3.6. Metabolism in rotational crops

First of all the user will need to ***indicate whether rotational crop metabolism studies are required***. Rotational crop metabolism studies are normally not required when:

- uses are only registered for perennial crops,
- the active substance and its relevant soil metabolites have a DT90 of less than 100 days or
- a theoretical calculation demonstrates that residues in rotational crops are not expected.

Preferably the DT90 value should be based on a field study when available. If no field study is available, the DT90 should be based on the most critical value of the aerobic laboratory study.

Even if rotational crop metabolism studies are not required the user will still have the possibility to ***indicate availability of metabolism studies for the different crop groups***. If more than three crop groups are covered, the user will be able to insert a residue definition for the rotational crops.

1.3.7. Residue levels in rotational crops

The user will need to indicate whether it is possible to ***conclude whether significant residue levels in rotational crops are to be expected***. This is usually concluded based on the rotational crop metabolism and available rotational crop residue trials. Significant residue levels in rotational crops are also not expected when:

- uses are only registered for perennial crops,
- the active substance and its relevant soil metabolites have a DT90 of less than 100 days or
- a theoretical calculation demonstrates that residues in rotational crops are not expected.

Preferably the DT90 value should be based on a field study when available. If no field study is available, the DT90 should be based on the most critical value of the aerobic laboratory study.

If residue levels exceeding 0.01 mg/kg are to be expected in rotational crops, the user will be requested to propose risk mitigating measures.

1.3.8. Metabolism in animal commodities

The user needs to indicate the types of livestock for which metabolism studies are available. If metabolism studies are available for ruminants but not for pigs, the user will also need to indicate whether ruminant metabolism can be extrapolated to pigs (see also EU guidance document SANCO/7030/VI/95 – Rev.3). If the three livestock groups are covered by data, the user will also have the possibility to propose ***general residue definitions*** for all livestock

commodities. Otherwise the user will need to insert residue definitions later on for each livestock commodity individually (see also section 1.5.3).

Finally, the user should also indicate whether the defined residue for enforcement is fat soluble. A decision on ***fat solubility*** should be based on the Log Po/w value as well as on the distribution of residues identified in the livestock metabolism studies or feeding studies. In cases where the residue definition for enforcement comprises metabolites having different chemical properties, it should first be questioned whether these metabolites are really essential for enforcement purposes because residue definitions for enforcement should be restricted to the parent compound as much as possible. If it is not possible to exclude certain compounds from this residue definition, the decision on fat solubility should be based on the compounds representing the largest fraction of the residue.

1.3.9. Analytical methods for the animal commodities

If general livestock residue definitions can be proposed the user will be prompted to enter information on the analytical methods for each relevant group of livestock commodities. When reporting the availability of analytical methods, particular attention should be given to the following issues:

- The method reported should be the ***primary analytical method*** for enforcement in foods of animal origin because this is considered to be the most useful method for enforcement purposes.
- The ***independent laboratory validation*** is considered to be part of the primary method validation and should therefore not be reported separately. However, it would be useful to mention in the comment field when the independent method validation is not available.
- A ***confirmatory method*** might not be required in all cases. If available, this can be reported in the comment field.
- When different analytical methods are available, priority should be given to ***multi-residue methods*** because these methods are considered to be the most useful for enforcement purposes.
- Where different ***LOQs*** are available, there is no need to report the lowest analytical method, unless higher LOQs might lead to exceedances of the toxicological reference values.
- The analytical method should cover ***all compounds included in the enforcement residue definition*** and the reported LOQ should be the combined LOQ for all compounds of the enforcement residue definition.
- With regard to the type of analytical method and the LOQ of the analytical method, the user is strongly encouraged to use the available ***dropdown menus***. However, other values may be entered if necessary.

Finally, if it is not possible to propose general livestock residue definitions the user will need to enter the analytical methods later on for each commodity individually considering that the validity of the analytical methods is dependent on the enforcement residue definition (see also section 1.5.4).

1.3.10. Storage stability in animal commodities

If general livestock residue definitions can be proposed the user will be prompted to enter information on the storage stability of residues for each relevant group of livestock commodities. The user should report storage stability covering the complete risk assessment residue definition. The ***storage temperature*** and ***storage time*** should be reported ***for the most limiting compound of the risk assessment residue definition***. There is no need to indicate in these fields when storage stability data are not required.

If it is not possible to propose general livestock residue definitions the user will need to enter the storage stability data later on for each commodity individually considering that storage stability is dependent on the risk assessment residue definition (see also section 1.5.5).

1.4. Insert the specific data for the plant commodities

1.4.1. General instructions

On this sheet the ***specific data for the plant commodities*** should be inserted. As for the previous step this sheet consists of different sections which will be detailed below.

For each plant commodity the user should go through each section and, as for the previous step, data should be entered in the ***yellow cells only***. These cells are subject to some very specific validation which is also related to some aspects of the assessment. Consequently, depending on the values that are entered in the form, new questions and new yellow cells will appear. If any other cell is modified, the inserted value will not be taken into account. Finally, if the user is not able to conclude on a certain entry, the user should preferably insert "-"in the yellow cell.

Users are encouraged to ***repeat this process for each commodity*** using the selection box on top of the page, in particular when the PROFile is being completed for the first time. Alternatively, users can also decide to go directly to the next step by using the button down the page. In this case, validation of data that were not reviewed by the user will be performed automatically. If mistakes were made at a previous step, it is possible to go back to the previous step without losing the data already entered.

1.4.2. Summary of critical GAPs

This section summarizes the GAPs for each climatic zone which were inserted at a previous step. This section is only included for user's information.

1.4.3. Metabolism in primary crop

If general residue definitions for plant commodities have been proposed at the previous step, these residue definitions will be inserted automatically in this section of the PROFile and it will not be possible to modify these entries.

However, if it was not possible to propose general residue definitions for all plant commodities, the user will have to ***enter the residue definitions for the individual commodity*** in this section. In order to avoid duplication of work for the different commodities, users may decide to ***copy the entries to all plant commodities belonging to the same metabolic group*** by using the appropriate button.

If no metabolism data are available at all for the relevant crop group and for the relevant method(s) of application, it will not be possible to propose residue definitions for the commodity.

1.4.4. Analytical method

If general residue definitions for plant commodities have been proposed at the previous step, the corresponding analytical methods will be inserted automatically in this section of the PROFile and it will not be possible to modify these entries.

However, if it was not possible to propose general residue definitions for all plant commodities, the user will be able ***to enter an analytical method for the individual commodity*** in this section. As for the previous step, particular attention should be given to the following issues:

- The method reported should be the ***primary analytical method*** for enforcement in foods of plant origin because this is considered to be the most useful method for enforcement purposes.
- The ***independent laboratory validation*** is considered to be part of the primary method validation and should therefore not be reported separately. However, it would be useful to mention in the comment field when the independent method validation is not available.
- A ***confirmatory method*** might not be required in all cases. If available, this can be reported in the comment field.
- When different analytical methods are available, priority should be given to ***multi-residue methods*** because these methods are considered to be the most useful for enforcement purposes.
- Where different ***LOQs*** are available, there is no need to report the lowest analytical method, unless higher LOQs might lead to exceedances of the toxicological reference values. Within the group of commodities with high water content, some commodities might be more difficult to analyse (e.g. brassica plants, onions) resulting in higher LOQs. In such cases, it is suggested that only one general LOQ is reported for all commodities, indicating in the comment field that for some commodities higher LOQs might be applicable.
- The analytical method should cover ***all compounds included in the enforcement residue definition*** and the reported LOQ should be the combined LOQ for all compounds of the enforcement residue definition.
- With regard to the type of analytical method and the LOQ of the analytical method, the user is strongly encouraged to use the available ***dropdown menus***. However, other values may be entered if necessary.

In order to avoid duplication of work for the different commodities, users may decide to ***copy the entries for a certain commodity to all plant commodities belonging to the same analytical group*** by using the appropriate button. It should also be noted that some commodities are not included in any crop group (e.g. straw, hops,…). For these commodities analytical methods will have to be inserted individually. If no analytical method is available for that specific commodity, the user may decide on a case by case basis that analytical

methods validated in other commodities can also be considered acceptable for the commodity under assessment. If so, this should be reported in the comment field.

In case no residue definition can be proposed, users still have the possibility to insert information on the available analytical method. Considering that the availability of a method is dependent on the enforcement residue definition, it is advisable to indicate which analytes are covered by the analytical method reported.

1.4.5. Storage stability

If general residue definitions for plant commodities have been proposed at the previous step, the corresponding data on storage stability will be inserted automatically in this section of the PROFile and it will not be possible to modify these entries.

However, if it was not possible to propose general residue definitions for all plant commodities, the user will be able to ***enter storage stability data for the individual commodity*** in this section. As for the previous step, the user should report storage stability covering the complete risk assessment residue definition. The ***storage temperature and storage time*** should be reported ***for the most limiting compound of the risk assessment residue definition***. There is no need to indicate in these fields when storage stability data are not required.

In order to avoid duplication of work for the different commodities, users may decide to ***copy the entries to all plant commodities belonging to the same analytical group*** by using the appropriate button. It should also be noted that some commodities are not included in any crop group (e.g. straw, hops,…). For these commodities storage stability data will have to be inserted individually. If no data are available for that specific commodity, the user may decide on a case by case basis that storage stability data for other commodities can also be considered acceptable for the commodity under assessment. If so, this should be reported in the comment field.

In case no residue definition can be proposed, users still have the possibility to insert information on the storage stability. Considering that storage stability data are dependent on the residue definition for risk assessment, it is advisable to indicate which compounds are covered by the storage conditions reported.

1.4.6. Residue levels in primary crop

In this section all information concerning the available supervised residue trials for each climatic zone can be inserted. Special consideration should be given to the following issues.

1.4.6.1. Waiver for residue trials

There are mainly two situations where the need for supervised residue trial might be waived:

- ***Based on the GAP and the properties of the active substance***, it is sometimes possible to conclude without residue trials that residue levels will be below the LOQ. This should be indicated in the PROFile, also mentioning the scientific reasoning supporting the statement. The MRLs, STMRs and HRs will then be set automatically at the enforcement LOQ. The conversion factor for risk assessment will be set at 1.
- For some ***post-harvest treatments***, it might be possible to calculate the MRL based on the application rate. This should also be indicated in the PROFile and the

corresponding MRL will need to be inserted manually by the user. The HR and the STMR however will be automatically set at the same level as the MRL. The conversion factor will be set at 1 because it is EFSA's understanding that such situations can only occur when residue definitions for enforcement and risk assessment are the same.

1.4.6.2. Extrapolation of residue trials

The PROFile allows for extrapolation of residue trials between plant commodities taking into account that:

- Extrapolations should be applied ***only when the critical GAPs (cGAPs) and the supporting residue trial data sets are identical***. If for a certain commodity the residue data package consists of a combination of residue trials performed with different commodities, the data should be entered for one of the commodities only indicating in the comment field how much trials were performed on each of the commodities. For the other commodities, the extrapolation function can then be used. For example, if 4 trials are available for apples and 4 trials are available for pears supporting the same cGAP, the data should only be entered for apples indicating in the comment field that 4 trials were performed on apples and 4 trials on pears. For pears it is then possible to extrapolate from apples.
- There are ***registered uses for the commodity from which data are being extrapolated***. If there are no registered uses for the commodity on which the trials were performed, the residue trials data should be entered for the registered commodity indicating in the comment field that the residue trials were performed with another commodity. For example, if residue trials have been performed with peaches but there is only a registered use for apricots, in this case the peach trials should be inserted in the apricot sheet indicating that they were performed on peaches.
- Residue trials data are first inserted for the commodity from which data are being extrapolated.

1.4.6.3. Individual trial results

Individual trial results should be entered using ";" (semi colon) and "<" can be used to indicate that residue levels were below the LOQ (e.g. <0.02; <0.02; <0.02; 0.05; 0.07; 0.04; 0.15; 0.10).

In addition, if residue definitions for enforcement and risk assessment are different, residue levels should be entered separately for each of them. MRLs, HRs and STMRs will be calculated based on the enforcement residue definition. The conversion factor between enforcement residue definition and risk assessment residue definition will be calculated based on both sets of results. In order to calculate the correct conversion factors between enforcement and risk assessment, the user should also enter the related values for enforcement and risk assessment in the same order. If a certain enforcement value has no corresponding risk assessment value, the user should insert "-".

1.4.6.4. Calculation of MRLs, HRs, STMRs and conversion factors

MRLs, HRs, STMRs and conversion factors are calculated automatically using the methodologies commonly accepted at EU level (Rmax, Rber and OECD calculator). If the user agrees with the calculated MRLs, HRs, STMRs, and conversion factors, the ***'Confirm values!'*** button should be clicked. If the user does not agree, the correct STMRs, HRs, MRLs and conversion factors should be inserted in the yellow cells.

If the user is of the opinion that ***residues data for different climatic zones may be pooled***, he/she can still report the residue trials for each climatic zone independently. The MRL, HR, STMR (and conversion factor) resulting from the combined data set should be then calculated manually and reported in the yellow cells as "confirmed values". For clarity and transparency, the user should indicate in the comment field that MRL, HR, STMR (and conversion factor) are calculated from a combined data set of different climatic zones.

1.4.7. Variability trial

If variability trials are available for the commodity, a summary of these trials can be inserted in this section.

1.4.8. Nature of residues in processed commodities

If ***hydrolysis studies*** are available or if it was possible to conclude that residue patterns in raw and processed commodities are similar based on the chemical properties of the active substance (see section 1.3.5.), the resulting residue definitions will automatically be taken over in this section. Nevertheless, if this was not the case, there is still the possibility to ***insert information which is specific to the commodity***.

If it is not possible to conclude on the similarity of metabolic patterns between the raw and the processed commodities or if there is no information available for the processed commodities, it will not be possible to propose a residue definition.

1.4.9. Residue levels in processed commodities

Data related to processing studies can be inserted in this section. When entering the outcome of the processing studies, the user should take into consideration the following definitions:

- The ***processing factor*** of a processing study expresses the ratio of the residue level identified in the processed commodity according to the residue definition for enforcement and the residue level identified in the raw agricultural commodity according to the residue definition for enforcement. The median processing factor is considered to be the median value of all available processing factors for a given process.

$$PF = \frac{RL\ in\ proc\ com\ (RD\ \ for\ enforcement)}{RL\ in\ RAC\ (RD\ \ for\ enforcement)}$$

- The ***conversion factor*** of a processing study expresses the ratio of the residue level identified in the processed commodity according to the residue definition for risk assessment and the residue level identified in the processed commodity according to the residue definition for enforcement. The median conversion factor is considered to be the median value of all available conversion factors for a given process.

$$CF = \frac{RL\ in\ proc\ com\ (RD\ \ for\ RA)}{RL\ in\ proc\ com\ (RD\ \ for\ enforcement)}$$

Although some ***extrapolations may be justified*** (e.g. within the group of citrus fruits), there is currently very few guidance on the extrapolation of processing factors. A feature for extrapolation of processing factors was therefore not included in the PROFile. Nevertheless, users may decide on a case by case basis to extrapolate processing factors by inserting the same processing factors for each commodity individually. It should then be indicated in the comment field from which commodity processing factors were extrapolated.

In the very specific case of ***wine***, it should be noted that ideally processing factors should be derived separately for the different types of wine (white wine, unheated red wine and heated red wine). However, from the available data it is often not clear with which type of wine the processing studies were performed. In that case it is advisable to insert the most conservative processing factor (the highest) for all types of wine. This should then also be mentioned clearly in the comment field.

If processing studies are not available for processed feed commodities, the PROFile 3.0 will consider default processing factors for the dietary burden calculation (see also section 1.5.2). It is noted that these factors represent the worst case (but possible) situation where residues are concentrated in feed items. Nevertheless, there is always a possibility to waive the use of these default processing factors if sufficient argumentation is provided (eg. in case of a no-residue situation). In PROFile 3.0, a specific box is available for that purpose and can be ticked by the users when appropriate.

1.5. Insert the specific data for the livestock commodities

Users of the previous PROFile versions will notice that PROFile 3.0 includes significant changes regarding this section. This is mainly due the inclusion of the OECD dietary burden calculator which required considering additional feed items (raw and processed) and additional types of livestock (7 instead of 4). In addition, EFSA also took the opportunity of this revision to include more transparency regarding dietary burden and MRL calculations and more flexibility for confirming the calculated values.

1.5.1. General instructions

On this sheet the ***specific data for the livestock commodities*** should be inserted. This sheet consists of different sections which will be detailed below.

For each type of livestock (cattle (all), cattle (dairy), poultry (all), poultry (layer), swine (all), sheep (all) and sheep (ewe)) the user should go through each section and, as for the previous steps, data should be entered in the ***yellow cells only***. These cells are subject to some very specific validations which are also related to some aspects of the assessment. Consequently, depending on the values that are entered in the form, new questions and new yellow cells will appear. If any other cell is modified, the inserted value will not be taken into account. Finally, if the user is not able to conclude on a certain entry, the user should preferably insert "-" in the yellow cell.

Users are encouraged to ***repeat this process for each type of livestock*** using the selection box on top of the page, in particular when the PROFile is being completed for the first time. Alternatively, users can also decide to go directly to the next step by using the button down

the page. In this case, validation of data that were not reviewed by the user will be performed automatically. If mistakes were made at a previous step, it is possible to go back to the previous step without losing the data already entered.

1.5.2. Dietary burden

In this section the dietary burden for the relevant livestock is reported. Dietary burdens are calculated automatically in the PROFile. If the user agrees with the calculated values, he/she should click the ***'Confirm Values!'*** buttons present in this section. However, in exceptional cases, if the user has made more relevant calculation in a separate document (eg. to take into account exposure from several sources), he/she can still insert the correct values manually in the yellow fields. In order to facilitate comparison between the calculated values and the data to be entered in the PROFile, the results are reported both in mg/kg bw/d and in mg/kg dry feed. It should be noted however that for calculations in the PROFile the data expressed in mg/kg bw/d are used as a reference.

Based on the result of the calculated dietary burden, the PROFile automatically proposes a conclusion on the need to set MRLs in livestock commodities: 'Yes' if the maximum dietary burden is ≥ 0.1 mg/kg DM and 'No' if the maximum dietary burden is < 0.1 mg/kg DM. In some exceptional cases, however, the users might need to reconsider this conclusion. For example, for active substances that show very high toxicity or which are expected to accumulate in the fat tissues, it might be decided on a case-by-case basis to establish MRLs even if the maximum dietary burden is < 0.1 mg/kg DM. On the contrary, a dietary burden above the trigger value of 0.1 mg/kg DM might be deemed overestimated by the user in specific situations (e.g. if DB is mainly driven by high LOQs in feed items). Therefore, the need for establishing MRLs in livestock commodities can always be confirmed or reconsidered by the user.

Calculation of the livestock dietary burden

In previous versions of the PROFile, the calculation of the livestock dietary burden was based on the methodology and the feed consumption data reported in the European guidance document on livestock feeding studies (SANCO 7031/VI/95 rev.4) and completed by the recommendations from the 2004 JMPR.

In PROFile 3.0, the most important change includes the implementation of the calculator recommended by OECD Guidance 73 on residues in livestock. This tool runs dietary burden calculations for seven types of livestock relevant in the EU (cattle (all), cattle (dairy), poultry (all), poultry (layer), swine (all), sheep (all) and sheep (ewe)). Since the OECD dietary burden calculator takes into account additional feed items compared to the previous model, PROFile 3.0 includes additional raw and processed commodities. Users should pay attention to them when importing data in PROFile 3.0 (see all details in Appendix 2), in particular for corn stover (fodder), rice straw, millet straw and turnips leaves which are feed commodities newly considered in the dietary burden and which are linked to GAPs that were already included in the previous PROFile (maize grain, rice grain, millet grain and sugar beet). If these GAPs are authorised, the user should ideally check whether residue data are available for the new feed commodities because they would probably not have been reported before. The following principles for the selection of the input values remain the same:

- The maximum dietary burden is based on the HRs for all fresh feed items, the STMRs for bulked items (unless residue levels result from post-harvest treatments) and the STMR-p for processed items.
- The median dietary burden is based on the STMRs for all feed items.

For processed feed items, there is also the need to consider processing factors. Often processing factors are not available. Therefore, default processing factors (PF) have been included in the PROFile. These default processing factors were derived from the weight ratios of processed and raw agricultural commodities and correspond therefore to "yield factors". The detailed rationales for all default PFs proposed by EFSA are reported in Appendix 3 of the present document. EFSA is aware that such processing factors have never been discussed and/or agreed at European level. Nevertheless, there is the scientific need to consider the possible concentration of residues in these commodities. It should also be noted that these factors only represent the worst case situation where no studies are available. There is always the possibility to lower these processing factors based on processing studies or to waive the use of these default processing factors if sufficient argumentation is provided, as for example in the case of a no-residue situation (see also section 1.4.9).

Finally, in line with the current guidance, the PROFile also considers that dietary burden intake calculations should incorporate all metabolites included in the residue definition for risk assessment. Therefore, a conversion factor for enforcement to risk assessment is applied when residue definitions for enforcement and risk assessment were found to be different.

1.5.3. Metabolism in livestock

If general residue definitions for livestock commodities have been proposed at the third step, these residue definitions will be inserted automatically in this section of the PROFile and it will not be possible to modify these entries.

However, if it was not possible to propose general residue definitions for all livestock commodities, the user will be able to ***enter the residue definitions for each livestock commodity*** individually. The user should also indicate whether the defined residue for enforcement is fat soluble. A decision on ***fat solubility*** should be based on the Log Po/w value as well as on the distribution of residues identified in the livestock metabolism studies or feeding studies. In cases where the residue definition for enforcement comprises metabolites having different chemical properties, it should first be questioned whether these metabolites are really essential for enforcement purposes because residue definitions for enforcement should be restricted to the parent compound as much as possible. If it is not possible to exclude certain compounds from this residue definition, the decision on fat solubility should be based on the compounds representing the largest fraction of the residue.

If no metabolism data are available for the relevant group of livestock, it will not be possible to propose residue definitions for this group of livestock.

1.5.4. Analytical methods

If general residue definitions for livestock commodities have been proposed at the third step, the corresponding analytical methods will be inserted automatically in this section of the PROFile and it will not be possible to modify these entries.

However, if it was not possible to propose general residue definitions for all livestock commodities, the user will be able to ***enter an analytical method for the individual livestock commodities***. As for the previous steps, particular attention should be given to the following issues:

- The method reported should be the ***primary analytical method*** for enforcement in foods of animal origin because this is considered to be the most useful method for enforcement purposes.
- The ***independent laboratory validation*** is considered to be part of the primary method validation and should therefore not be reported separately. However, it would be useful to mention in the comment field when the independent method validation is not available.
- A ***confirmatory method*** might not be required in all cases. If available, this can be reported in the comment field.
- When different analytical methods are available, priority should be given to ***multi-residue methods*** because these methods are considered to be the most useful for enforcement purposes.
- Where different ***LOQs*** are available, there is no need to report the lowest analytical method, unless higher LOQs might lead to exceedances of the toxicological reference values.

- The analytical method should cover ***all compounds included in the enforcement residue definition*** and the reported LOQ should be the combined LOQ for all compounds of the enforcement residue definition.
- With regard to the type of analytical method and the LOQ of the analytical method, the user is strongly encouraged to use the available ***dropdown menus***. However, other values may be entered if necessary.
- With regard to the type of analytical method and the LOQ of the analytical method, the user is strongly encouraged to use the available ***dropdown menus***. However, other values may be entered if necessary.

In case no residue definition can be proposed, users still have the possibility to insert information on the available analytical method. Considering that the availability of a method is dependent on the enforcement residue definition, it is advisable to indicate which analytes are covered by the analytical method reported.

1.5.5. Storage stability

If general residue definitions for livestock commodities have been proposed at the third step, the corresponding storage stability data will be inserted automatically in this section of the PROFile and it will not be possible to modify these entries.

However, if it was not possible to propose general residue definitions for all livestock commodities, the user will be able to ***enter storage stability data for the individual livestock commodities***. As for the previous steps, the user should report storage stability covering the complete risk assessment residue definition. The ***storage temperature and storage time*** should be reported ***for the most limiting compound of the risk assessment residue definition***. There is no need to indicate in these fields when storage stability data are not required.

In case no residue definition can be proposed, users still have the possibility to insert information on the storage stability. Considering that storage stability data are dependent on the residue definition for risk assessment, it is advisable to indicate which compounds are covered by the storage conditions reported.

1.5.6. Residue levels in livestock

In this section, the user should insert all available data concerning the livestock feeding studies.

1.5.6.1. Waiver for a livestock feeding study

In some cases it is possible to conclude based on the livestock metabolism studies that residue levels exceeding the enforcement LOQ are not expected in the livestock commodities, meaning that a livestock feeding study is not required. This can be directly indicated by the user in the PROFile and MRL, HR and STMR will be set automatically at the level of the LOQ.

1.5.6.2. Individual results of the livestock feeding study

When a livestock feeding study is available, the user should insert the ***dosing levels*** of the livestock feeding study (expressed in mg/kg bw/d) as well as the ***individual results*** of the

livestock feeding study for each commodity at each dosing levels. PROFile 3.0 allows for three feeding levels to be inserted. If a livestock feeding study was performed with more than 3 feeding levels, the user should choose the 3 most relevant feeding levels with regard to the calculated dietary burden (usually the closest ones are preferred). If only 1 or 2 feeding levels are available, PROFile 3.0 is still able to derive MRL, HR and STMR but the empty cells (corresponding to the missing dose group(s)) should in any case be completed. The best and simplest option is to repeat the results of the available feeding level(s) in the empty cells, as in the following examples.

- If data for 1 feeding level are available:

	Dose 1	Dose 2	Dose 3
Dosing levels	DL1	DL1	DL1
Tissue (mg/kg)	Results at DL1	Results at DL1	Results at DL1

- If data for 2 different feeding levels are available:

	Dose 1	Dose 2	Dose 3
Dosing levels	DL1	DL1	DL2
Tissue (mg/kg)	Results at DL1	Results at DL1	Results at DL2

Individual results for a certain commodity at a certain dosing level should be entered using ";" (semi colon) and "<" can be used to indicate that residue levels were below the LOQ (e.g. <0.002; 0.010; 0.005). The inserted residue values should always be expressed on a whole product basis because this is the way that livestock feeding results are expressed, regardless of the fat solubility.

If some (or all) results of the livestock feeding study are below the LOQ of the study, they should be reported as such in the PROFile. However, in such a case, users will notice that STMR, HR and MRL cannot always be derived by the calculator (reported as “n.c.” in the PROFile). In this situation, an expert judgement or additional external calculations may be necessary.

In addition, if residue definitions for enforcement and risk assessment are different, residue levels should be entered separately for each of them. MRLs, HRs and STMRs will be calculated based on the enforcement residue definition. The conversion factor between enforcement residue definition and risk assessment residue definition will be calculated based on both sets of results.

In order to calculate the correct conversion factors between enforcement and risk assessment, the user should also enter the related values for enforcement and risk assessment in the same order. If a certain enforcement value has no corresponding risk assessment value, the user should insert "-".

1.5.6.3. Calculation of MRLs, HRs, STMRs and conversion factors

MRLs, HRs, STMRs and conversion factors are calculated automatically in the PROFile. If the user agrees with the calculated values, he/she should click the ***‘Confirm Values!’*** buttons

present in this section. If the user does not agree, he/she should insert the correct values manually in the yellow fields.

Calculation of MRLs in food of animal origin

✓ STMRs, HRs and MRLs

For the calculation of MRLs HRs and STMRs, EFSA refers to the recommendations provided in the OECD Guidance 73 on residues in livestock. The MRLs, HRs and STMRs are therefore calculated as follows:

- STMRs and HRs can be calculated using three different methodologies (transfer factors, interpolation between the closest dose levels and linear regression). The relevance of these methodologies depends on the value of the calculated dietary burden compared to the feeding dose levels. If several methodologies are relevant, PROFile 3.0 retains the most critical one to derive STMRs and HRs. Detailed information on the livestock MRL calculation is reported in Appendix 4 of the present document.
- the STMRs are all derived from the mean residue levels of the relevant samples at the median dietary burden.
- the HRs are derived from the highest residue levels of the relevant samples at the maximum dietary burden. An exception applies to milk where the mean value of the milk samples is taken rather than the highest value.
- the MRLs are derived by rounding the HRs up to the closest MRL class.

✓ Conversion factors for risk assessment

There is currently no internationally agreed guidance on the use and/or calculation of conversion factors for risk assessment. Although the use of conversion factors for risk assessment is often criticised due to the unstable nature of such factors, EFSA is of the opinion that this methodology is the most transparent way to correlate the residues according to the enforcement residue definition to the residues that are relevant for the risk assessment. For foods of animal origin, the conversion factor was therefore defined as the ratio of the mean risk assessment residue level at the median dietary burden over the mean enforcement residue level at the median dietary burden, both values obtained by interpolation with the closest dosing levels.

$$CF = \frac{mean\ RL\ (RA)\ at\ median\ dietary\ burden}{mean\ RL\ (enforcement)\ at\ median\ dietary\ burden}$$

1.6. Other useful tips

Below, some general tips have been listed which might be useful when inserting or updating data in the PROFile:

- The macro's in excel prevent the storage of information on the clipboard. Users can therefore make use of a 'sticky note' or of the ***scratch pad***. The scratch pad is an individual sheet of the PROFile which allows the user to temporarily store data that need to be entered repeatedly in the PROFile.
- PROFile 3.0 contains a separate sheet where ***crop groupings*** are reported. This sheet (also available in Appendix 1 of the present document) is available during the whole process of inserting information and should unable to identify the groupings more easily.
- In case a ***run-time error*** occurs and users are no longer able to proceed with the different steps of the PROFile, data from the 'crashed' PROFile may be imported in a blank template of the PROFile using the foreseen functionality (see also section 2).

2. Import of data from a previous version of the PROFile

When opening PROFile 3.0, users will be prompted a sheet called *Data_management*. At this stage, users have the possibility to choose whether they want to start from a blank template and enter all data manually or whether they want to import the data from a previous version of the PROFile.

In order to import data from a previous version, users should ***make sure that both the blank template and the previous version of the PROFile are open*** in the same Excel window. The user should then ***enter the name of the source file*** (the previous version) in the appropriate cell of the *Data_management* sheet. This can be done manually or by using the search function underneath the cell. After having inserted the name of the source file, the user should indicate whether the source file is already in version 3.0 (or higher). It is highlighted that import of data can be done from any version of the PROFile; however the information on the version is crucial for a successful import of data from the source file. Only after having indicated the PROFile version of the source file, the user shall ***press the Import data button***. In contrast with the previous versions, a new copy of the PROFile 3.0 is not generated automatically and data from the source file are directly imported in the same document. However, if the user wants to duplicate the document and save a new copy, he/she can still do it manually.

It should be noted, however, that some data validations have been modified compared to the previous versions of the PROFile. Users will therefore be requested to re-validate the data according to the procedure elaborated under section 1. While doing so, particular ***attention should be paid to the new features of PROFile 3.0***:

- New feed items might need to be assessed (see also grey text box in section 1.5.2 and Appendix 2 of the present document)

- The livestock dietary burden calculator has been significantly modified and may result in different dietary burdens for the type of livestock that were already present in the previous versions: cattle (all), cattle (dairy), poultry (all) and swine (all).
- Additional types of livestock need to be assessed: poultry (layer), sheep (all) and sheep (ewe).
- While the import of livestock feeding studies (dose levels and individual study results) is automatically done for cattle (all), cattle (dairy) and swine (all) and poultry (all), the user still needs to do it manually for poultry (layer) because feeding dose levels and individual study results in eggs are not reported automatically.
- There is now the possibility to confirm (or modify) the dietary burden automatically calculated by PROFile 3.0 and the need to establish MRLs in livestock can always be confirmed (or reconsidered) by the user.
- New MRL calculation for livestock commodities may be proposed due to the new dietary burden calculator or to the updated methodology (see Appendix 4 for details). Therefore, confirmation of the calculated MRLs, HRs and STMRs for all types of livestock is required.

If the import of data is made from a version previous to PROFile 2.3, the following features of PROFile 2.3 remain relevant to be checked:

- Modified crop groupings for chestnuts, sugar cane, alfalfa forage, clover forage, sugar beet tops and fodder beet tops.
- Modified conditions for a general residue definition in plant commodities.
- Possibility to include a waiver for studies on the nature of residues in processed commodities.
- Hydrolytic conditions for processed commodities have been corrected and might now be inverted.
- The MRL calculator for plant commodities has been modified and might now result in different calculated MRLs.

3. Consult data in the PROFile

After having entered all the pesticide residues data according the above mentioned procedures the PROFile will automatically generate the reporting sheets which allow users to consult all the data that were entered. Each of these sheets is explained below.

3.1. Overview of the critical GAPs

This sheet provides an overview of all the critical GAPs which have been evaluated at EU level for the given active substance.

3.2. Overview of the general data for the active substance

For each plant commodity this sheet provides an overview of all the pesticide residues data that are not related to specific crops or commodities (e.g. data on metabolism, analytical methods, storage stability, rotational crops, etc.).

3.3. Overview of the available data for each plant commodity

For each plant commodity this sheet provides an overview of all the pesticide residue data supporting the proposed MRLs. The relevant commodity can be selected by using the selection box on top of the page.

3.4. Overview of the available data for each animal commodity

For each livestock group this sheet provides an overview of all the pesticide residue data supporting the proposed MRLs. The relevant livestock group can be selected by using the selection box on top of the page.

4. Summarize the data in the PROFile

As for the versions 2.0, 2.1, 2.2 and 2.3, ***PROFile 3.0 does not contain summary sheets on the recommended MRLs and processing factors***. Such sheets only based on the PROFile data would not be relevant because MRL recommendations do not only depend on the GAPs supported by residues trials data, but also on the existing EC MRLs, existing CXLs as well as the calculated consumer exposure. The tool which was elaborated in order to summarize the data from PROFile 2.0 was updated in order to fit with the structure of the PROFile 3.0. Therefore, when users want to use this tool, they should use the version related to PROFile 3.0.

The user instructions for this tool related to PROFile 3.0 is the same as for the previous one. When opening the tool, users will be prompted by a sheet called *Summarize_PROFile*, where the user should ***enter the name of the source file*** (the completed PROFile that needs to be summarized). This can be done manually or by using the search function underneath the cell. For this purpose, users should ***make sure that both the summary file and the PROFile are open*** in the same Excel window. After having inserted the name of the source file, the user should ***press the Summarize data button***. The following summary sheets will be generated automatically.

4.1. Summary of all proposed plant MRLs

This sheet provides a table of all MRLs that can be proposed for plant commodities based on the available data. For each plant commodity the following items are reported:

- the commodity code (according to Regulation 396/200)
- the commodity name
- the enforcement residue definition
- the MRL (it is also indicated when the MRL is set at the LOQ level)
- the conversion factor for enforcement to risk assessment
- the risk assessment residue definition
- the STMR for risk assessment in the edible portion (corresponds with the enforcement STMR multiplied by the above mentioned conversion factor, for commodities that are eaten peeled this takes also into consideration the peeling factor when available)
- the HR for risk assessment in the edible portion (corresponds with the enforcement HR multiplied by the above mentioned conversion factor, for commodities that are eaten peeled this takes also into consideration the peeling factor when available)
- the reduced variability factor, if available

4.2. Summary of all proposed livestock MRLs

This sheet provides a table of all livestock MRLs that can be proposed based on the available data. For each livestock commodity the following items are reported:

- the commodity code (according to Regulation 396/200)
- the commodity name
- the enforcement residue definition
- the fat solubility of the enforcement residue definition
- the MRL (it is also indicated when the MRL is set at the LOQ level)
- the conversion factor for enforcement to risk assessment
- the risk assessment residue definition
- the STMR for risk assessment (corresponds to the enforcement STMR multiplied by the above mentioned conversion factor)
- the HR for risk assessment (corresponds to the enforcement HR multiplied by the above mentioned conversion factor)

4.3. Summary of all proposed processing factors

This sheet provides a table of all the processing factors that can be proposed based on the available data. For each processing factor the following items are reported:

- the commodity code
- the description of the processed commodity

- the enforcement residue definition
- the processing factor for enforcement
- the conversion factor for enforcement to risk assessment
- the risk assessment residue definition
- the processing factor for risk assessment (corresponds to the enforcement processing factor multiplied by the above mentioned conversion factor)

APPENDIX 1 – CROP GROUPINGS

Commodity - code	Commodity - name	Metabolism - group	Analytical method - group	Storage stability - group
110010	Grapefruits	fruits and fruiting vegetables	high acid content commodities	high acid content commodities
110020	Oranges	fruits and fruiting vegetables	high acid content commodities	high acid content commodities
110030	Lemons	fruits and fruiting vegetables	high acid content commodities	high acid content commodities
110040	Limes	fruits and fruiting vegetables	high acid content commodities	high acid content commodities
110050	Mandarins	fruits and fruiting vegetables	high acid content commodities	high acid content commodities
120010	Almonds	fruits and fruiting vegetables	high oil content commodities	high oil content commodities
120020	Brazil nuts	fruits and fruiting vegetables	high oil content commodities	high oil content commodities
120030	Cashew nuts	fruits and fruiting vegetables	high oil content commodities	high oil content commodities
120040	Chestnuts	fruits and fruiting vegetables	dry commodities	dry commodities
120050	Coconuts	fruits and fruiting vegetables	high oil content commodities	high oil content commodities
120060	Hazelnuts/cobnuts	fruits and fruiting vegetables	high oil content commodities	high oil content commodities
120070	Macadamias	fruits and fruiting vegetables	high oil content commodities	high oil content commodities
120080	Pecans	fruits and fruiting vegetables	high oil content commodities	high oil content commodities
120090	Pine nut kernels	fruits and fruiting vegetables	high oil content commodities	high oil content commodities
120100	Pistachios	fruits and fruiting vegetables	high oil content commodities	high oil content commodities
120110	Walnuts	fruits and fruiting vegetables	high oil content commodities	high oil content commodities
130010	Apples	fruits and fruiting vegetables	high water content commodities	high water content commodities
130020	Pears	fruits and fruiting vegetables	high water content commodities	high water content commodities
130030	Quinces	fruits and fruiting vegetables	high water content commodities	high water content commodities
130040	Medlars	fruits and fruiting vegetables	high water content commodities	high water content commodities

Commodity - code	Commodity - name	Metabolism - group	Analytical method - group	Storage stability - group
130050	Loquats/Japanese medlars	fruits and fruiting vegetables	high water content commodities	high water content commodities
140010	Apricots	fruits and fruiting vegetables	high water content commodities	high water content commodities
140020	Cherries (sweet)	fruits and fruiting vegetables	high water content commodities	high water content commodities
140030	Peaches	fruits and fruiting vegetables	high water content commodities	high water content commodities
140040	Plums	fruits and fruiting vegetables	high water content commodities	high water content commodities
151010	Table grapes	fruits and fruiting vegetables	high acid content commodities	high acid content commodities
151020	Wine grapes	fruits and fruiting vegetables	high acid content commodities	high acid content commodities
152000	Strawberries	fruits and fruiting vegetables	high acid content commodities	high acid content commodities
153010	Blackberries	fruits and fruiting vegetables	high acid content commodities	high acid content commodities
153020	Dewberries	fruits and fruiting vegetables	high acid content commodities	high acid content commodities
153030	Raspberries (red and yellow)	fruits and fruiting vegetables	high acid content commodities	high acid content commodities
154010	Blueberries	fruits and fruiting vegetables	high acid content commodities	high acid content commodities
154020	Cranberries	fruits and fruiting vegetables	high acid content commodities	high acid content commodities
154030	Currants (black, red and white)	fruits and fruiting vegetables	high acid content commodities	high acid content commodities
154040	Gooseberries (green, red and yellow)	fruits and fruiting vegetables	high acid content commodities	high acid content commodities
154050	Rose hips	fruits and fruiting vegetables	high acid content commodities	high acid content commodities
154060	Mulberries (black and white)	fruits and fruiting vegetables	high acid content commodities	high acid content commodities
154070	Azaroles/Mediterranean medlars	fruits and fruiting vegetables	high acid content commodities	high acid content commodities
154080	Elderberries	fruits and fruiting vegetables	high acid content commodities	high acid content commodities
161010	Dates	fruits and fruiting vegetables	high water content commodities	high water content commodities

Commodity - code	Commodity - name	Metabolism - group	Analytical method - group	Storage stability - group
161020	Figs	fruits and fruiting vegetables	high water content commodities	high water content commodities
161030	Table olives	fruits and fruiting vegetables	high oil content commodities	high oil content commodities
161040	Kumquats	fruits and fruiting vegetables	high water content commodities	high water content commodities
161050	Carambolas	fruits and fruiting vegetables	high acid content commodities	high acid content commodities
161060	Kaki/Japanese persimmons	fruits and fruiting vegetables	high water content commodities	high water content commodities
161070	Jambuls/jambolans	fruits and fruiting vegetables	high water content commodities	high water content commodities
162010	Kiwi fruits (green, red, yellow)	fruits and fruiting vegetables	high acid content commodities	high acid content commodities
162020	Litchis/lychees	fruits and fruiting vegetables	high water content commodities	high water content commodities
162030	Passionfruits/maracujas	fruits and fruiting vegetables	high acid content commodities	high acid content commodities
162040	Prickly pears/cactus fruits	fruits and fruiting vegetables	high water content commodities	high water content commodities
162050	Star apples/cainitos	fruits and fruiting vegetables	high water content commodities	high water content commodities
162060	American persimmons/Virginia kaki	fruits and fruiting vegetables	high water content commodities	high water content commodities
163010	Avocados	fruits and fruiting vegetables	high oil content commodities	high oil content commodities
163020	Bananas	fruits and fruiting vegetables	high water content commodities	high water content commodities
163030	Mangoes	fruits and fruiting vegetables	high water content commodities	high water content commodities
163040	Papayas	fruits and fruiting vegetables	high water content commodities	high water content commodities
163050	Granate apples/pomegranates	fruits and fruiting vegetables	high acid content commodities	high acid content commodities

Commodity - code	Commodity - name	Metabolism - group	Analytical method - group	Storage stability - group
163060	Cherimoyas	fruits and fruiting vegetables	high water content commodities	high water content commodities
163070	Guavas	fruits and fruiting vegetables	high water content commodities	high water content commodities
163080	Pineapples	fruits and fruiting vegetables	high acid content commodities	high acid content commodities
163090	Breadfruits	fruits and fruiting vegetables	high water content commodities	high water content commodities
163100	Durians	fruits and fruiting vegetables	high water content commodities	high water content commodities
163110	Soursops/guanabanas	fruits and fruiting vegetables	high water content commodities	high water content commodities
211000	Potatoes	root and tuber vegetables	high water content commodities	high water content commodities
212010	Cassava roots/manioc	root and tuber vegetables	high water content commodities	high water content commodities
212020	Sweet potatoes	root and tuber vegetables	high water content commodities	high water content commodities
212030	Yams	root and tuber vegetables	high water content commodities	high water content commodities
212040	Arrowroots	root and tuber vegetables	high water content commodities	high water content commodities
213010	Beetroots	root and tuber vegetables	high water content commodities	high water content commodities
213020	Carrots	root and tuber vegetables	high water content commodities	high water content commodities
213030	Celeriacs/turnip rooted celeries	root and tuber vegetables	high water content commodities	high water content commodities
213040	Horseradishes	root and tuber vegetables	high water content commodities	high water content commodities
213050	Jerusalem artichokes	root and tuber vegetables	high water content commodities	high water content commodities

Commodity - code	Commodity - name	Metabolism - group	Analytical method - group	Storage stability - group
213060	Parsnips	root and tuber vegetables	high water content commodities	high water content commodities
213070	Parsley roots/Hamburg roots parsley	root and tuber vegetables	high water content commodities	high water content commodities
213080	Radishes	root and tuber vegetables	high water content commodities	high water content commodities
213090	Salsifies	root and tuber vegetables	high water content commodities	high water content commodities
213100	Swedes/rutabagas	root and tuber vegetables	high water content commodities	high water content commodities
213110	Turnips	root and tuber vegetables	high water content commodities	high water content commodities
220010	Garlic	root and tuber vegetables	high water content commodities	high water content commodities
220020	Onions	root and tuber vegetables	high water content commodities	high water content commodities
220030	Shallots	root and tuber vegetables	high water content commodities	high water content commodities
220040	Spring onions/green onions and Welsh onions	root and tuber vegetables	high water content commodities	high water content commodities
231010	Tomatoes	fruits and fruiting vegetables	high water content commodities	high water content commodities
231020	Sweet peppers/bell peppers	fruits and fruiting vegetables	high water content commodities	high water content commodities
231030	Aubergines/eggplants	fruits and fruiting vegetables	high water content commodities	high water content commodities
231040	Okra/lady's fingers	fruits and fruiting vegetables	high water content commodities	high water content commodities
232010	Cucumbers	fruits and fruiting vegetables	high water content commodities	high water content commodities
232020	Gherkins	fruits and fruiting vegetables	high water content commodities	high water content commodities

Commodity - code	Commodity - name	Metabolism - group	Analytical method - group	Storage stability - group
232030	Courgettes	fruits and fruiting vegetables	high water content commodities	high water content commodities
233010	Melons	fruits and fruiting vegetables	high water content commodities	high water content commodities
233020	Pumpkins	fruits and fruiting vegetables	high water content commodities	high water content commodities
233030	Watermelons	fruits and fruiting vegetables	high water content commodities	high water content commodities
234000	Sweet corn	cereals	high water content commodities	high water content commodities
241010	Broccoli	leafy vegetables	high water content commodities	high water content commodities
241020	Cauliflowers	leafy vegetables	high water content commodities	high water content commodities
242010	Brussels sprouts	leafy vegetables	high water content commodities	high water content commodities
242020	Head cabbages	leafy vegetables	high water content commodities	high water content commodities
243010	Chinese cabbages/pe-tsai	leafy vegetables	high water content commodities	high water content commodities
243020	Kales	leafy vegetables	high water content commodities	high water content commodities
244000	Kohlrabies	leafy vegetables	high water content commodities	high water content commodities
251010	Lamb's lettuces/corn salads	leafy vegetables	high water content commodities	high water content commodities
251020	Lettuces	leafy vegetables	high water content commodities	high water content commodities
251030	Escaroles/broad-leaved endives	leafy vegetables	high water content commodities	high water content commodities
251040	Cresses and other sprouts and shoots	leafy vegetables	high water content commodities	high water content commodities

Commodity - code	Commodity - name	Metabolism - group	Analytical method - group	Storage stability - group
251050	Land cresses	leafy vegetables	high water content commodities	high water content commodities
251060	Roman rocket/rucola	leafy vegetables	high water content commodities	high water content commodities
251070	Red mustards	leafy vegetables	high water content commodities	high water content commodities
251080	Baby leaf crops (including brassica species)	leafy vegetables	high water content commodities	high water content commodities
252010	Spinaches	leafy vegetables	high water content commodities	high water content commodities
252020	Purslanes	leafy vegetables	high water content commodities	high water content commodities
252030	Chards/beet leaves	leafy vegetables	high water content commodities	high water content commodities
253000	Grape leaves and similar species	leafy vegetables	high water content commodities	high water content commodities
254000	Watercresses	leafy vegetables	high water content commodities	high water content commodities
255000	Witloofs/Belgian endives	leafy vegetables	high water content commodities	high water content commodities
256010	Chervil	leafy vegetables	high water content commodities	high water content commodities
256020	Chives	leafy vegetables	high water content commodities	high water content commodities
256030	Celery leaves	leafy vegetables	high water content commodities	high water content commodities
256040	Parsley	leafy vegetables	high water content commodities	high water content commodities
256050	Sage	leafy vegetables	high water content commodities	high water content commodities
256060	Rosemary	leafy vegetables	high water content commodities	high water content commodities

Commodity - code	Commodity - name	Metabolism - group	Analytical method - group	Storage stability - group
256070	Thyme	leafy vegetables	high water content commodities	high water content commodities
256080	Basil and edible flowers	leafy vegetables	high water content commodities	high water content commodities
256090	Laurel/bay leave	leafy vegetables	high water content commodities	high water content commodities
256100	Tarragon	leafy vegetables	high water content commodities	high water content commodities
260010	Beans (with pods)	pulses and oilseeds	high water content commodities	high water content commodities
260020	Beans (without pods)	pulses and oilseeds	high water content commodities	high water content commodities
260030	Peas (with pods)	pulses and oilseeds	high water content commodities	high water content commodities
260040	Peas (without pods)	pulses and oilseeds	high water content commodities	high water content commodities
260050	Lentils (fresh)	pulses and oilseeds	high water content commodities	high water content commodities
270010	Asparagus	leafy vegetables	high water content commodities	high water content commodities
270020	Cardoons	leafy vegetables	high water content commodities	high water content commodities
270030	Celeries	leafy vegetables	high water content commodities	high water content commodities
270040	Florence fennels	leafy vegetables	high water content commodities	high water content commodities
270050	Globe artichokes	leafy vegetables	high water content commodities	high water content commodities
270060	Leeks	leafy vegetables	high water content commodities	high water content commodities
270070	Rhubarbs	leafy vegetables	high acid content commodities	high acid content commodities

Commodity - code	Commodity - name	Metabolism - group	Analytical method - group	Storage stability - group
270080	Bamboo shoots	leafy vegetables	high water content commodities	high water content commodities
270090	Palm hearts	leafy vegetables	high water content commodities	high water content commodities
280010	Cultivated fungi	fruits and fruiting vegetables	high water content commodities	high water content commodities
280020	Wild fungi	fruits and fruiting vegetables	high water content commodities	high water content commodities
290000	Algae and prokaryotes organisms	leafy vegetables	high water content commodities	high water content commodities
300010	Beans (dry)	pulses and oilseeds	dry commodities	dry commodities
300020	Lentils (dry)	pulses and oilseeds	dry commodities	dry commodities
300030	Peas (dry)	pulses and oilseeds	dry commodities	dry commodities
300040	Lupins/lupini beans (dry)	pulses and oilseeds	dry commodities	dry commodities
401010	Linseeds	pulses and oilseeds	high oil content commodities	high oil content commodities
401020	Peanuts/groundnuts	pulses and oilseeds	high oil content commodities	high oil content commodities
401030	Poppy seeds	pulses and oilseeds	high oil content commodities	high oil content commodities
401040	Sesame seeds	pulses and oilseeds	high oil content commodities	high oil content commodities
401050	Sunflower seeds	pulses and oilseeds	high oil content commodities	high oil content commodities
401060	Rapeseeds/canola seeds	pulses and oilseeds	high oil content commodities	high oil content commodities
401070	Soyabeans	pulses and oilseeds	high oil content commodities	high oil content commodities
401080	Mustard seeds	pulses and oilseeds	high oil content commodities	high oil content commodities
401090	Cotton seeds	pulses and oilseeds	high oil content commodities	high oil content commodities
401100	Pumpkin seeds	pulses and oilseeds	high oil content commodities	high oil content commodities
401110	Safflower seeds	pulses and oilseeds	high oil content commodities	high oil content commodities
401120	Borage seeds	pulses and oilseeds	high oil content commodities	high oil content commodities

Commodity - code	Commodity - name	Metabolism - group	Analytical method - group	Storage stability - group
401130	Gold of pleasure seeds	pulses and oilseeds	high oil content commodities	high oil content commodities
401140	Hemp seeds	pulses and oilseeds	high oil content commodities	high oil content commodities
401150	Castor beans	pulses and oilseeds	high oil content commodities	high oil content commodities
402010	Olives for oil production	fruits and fruiting vegetables	high oil content commodities	high oil content commodities
402020	Oil palms kernels	fruits and fruiting vegetables	high oil content commodities	high oil content commodities
402030	Oil palms fruits	fruits and fruiting vegetables	high oil content commodities	high oil content commodities
402040	Kapok	fruits and fruiting vegetables	high oil content commodities	high oil content commodities
500010	Barley grains	cereals	dry commodities	dry commodities
500020	Buckwheat and other pseudo-cereal grains	cereals	dry commodities	dry commodities
500030	Maize/corn grains	cereals	dry commodities	dry commodities
500040	Common millet/proso millet grains	cereals	dry commodities	dry commodities
500050	Oat grains	cereals	dry commodities	dry commodities
500060	Rice grains	cereals	dry commodities	dry commodities
500070	Rye grains	cereals	dry commodities	dry commodities
500080	Sorghum grains	cereals	dry commodities	dry commodities
500090	Wheat grains	cereals	dry commodities	dry commodities
610000	Teas	leafy vegetables	no group	no group
620000	Coffee beans	fruits and fruiting vegetables	no group	no group
631000	Herbal infusions from flowers	leafy vegetables	no group	no group
632000	Herbal infusions from leaves and herbs	leafy vegetables	no group	no group
633000	Herbal infusions from roots	root and tuber vegetables	no group	no group
640000	Cocoa beans	fruits and fruiting vegetables	no group	no group
650000	Carobs/Saint John's breads	fruits and fruiting vegetables	no group	no group
700000	Hops	leafy vegetables	no group	no group

Commodity - code	Commodity - name	Metabolism - group	Analytical method - group	Storage stability - group
810000	Seed spices	fruits and fruiting vegetables	no group	no group
820000	Fruit spices	fruits and fruiting vegetables	no group	no group
830000	Bark spices	leafy vegetables	no group	no group
840000	Root and rhizome spices	root and tuber vegetables	no group	no group
850000	Bud spices	leafy vegetables	no group	no group
860000	Flower pistil spices	leafy vegetables	no group	no group
870000	Aril spices	fruits and fruiting vegetables	no group	no group
900010	Sugar beet roots	root and tuber vegetables	high water content commodities	high water content commodities
900020	Sugar canes	cereals	high water content commodities	high water content commodities
900030	Chicory roots	root and tuber vegetables	high water content commodities	high water content commodities
1210010	Alfalfa forage	pulses and oilseeds	high water content commodities	high water content commodities
1210020	Bean vines	pulses and oilseeds	high water content commodities	high water content commodities
1210030	Clover forage	pulses and oilseeds	high water content commodities	high water content commodities
1210040	Cowpea forage	pulses and oilseeds	high water content commodities	high water content commodities
1210050	Lespedeza forage	pulses and oilseeds	high water content commodities	high water content commodities
1210060	Pea vines	pulses and oilseeds	high water content commodities	high water content commodities
1210070	Soyabean forage	pulses and oilseeds	high water content commodities	high water content commodities
1210080	Trefoil forage	pulses and oilseeds	high water content commodities	high water content commodities
1210090	Vetch forage	pulses and oilseeds	high water content commodities	high water content commodities

Commodity - code	Commodity - name	Metabolism - group	Analytical method - group	Storage stability - group
1220010	Barley forage	cereals	high water content commodities	high water content commodities
1220020	Common millet forage	cereals	high water content commodities	high water content commodities
1220030	Grass forage	cereals	high water content commodities	high water content commodities
1220040	Maize/corn forage	cereals	high water content commodities	high water content commodities
1220050	Oat forage	cereals	high water content commodities	high water content commodities
1220060	Rye forage	cereals	high water content commodities	high water content commodities
1220070	Sorghum forage	cereals	high water content commodities	high water content commodities
1220080	Wheat forage	cereals	high water content commodities	high water content commodities
1230010	Barley straw	cereals	no group	no group
1230020	Common millet straw	cereals	no group	no group
1230030	Maize/corn stover	cereals	no group	no group
1230040	Oat straw	cereals	no group	no group
1230050	Rice straw	cereals	no group	no group
1230060	Rye straw	cereals	no group	no group
1230070	Sorghum stover	cereals	no group	no group
1230080	Wheat straw	cereals	no group	no group
1240010	Fodder beet roots	root and tuber vegetables	high water content commodities	high water content commodities
1240020	Fodder beet tops	root and tuber vegetables	high water content commodities	high water content commodities
1240030	Sugar beet tops	root and tuber vegetables	high water content commodities	high water content commodities
1240040	Turnip tops	root and tuber vegetables	high water content commodities	high water content commodities
1250010	Rape/canola forage	pulses and oilseeds	high water content commodities	high water content commodities

APPENDIX 2 – FEED ITEMS CONSIDERED IN OECD LIVESTOCK DIETARY BURDEN CALCULATOR (EU DIETS)

Feed items considered in the OECD calculator		Corresponding PROFile entry		Information for users who want to update a previous dietary burden calculation considering the OECD calculator (using PROFile 3.0)			
OECD Feed Crop	**OECD Feed Commodity**	**RAC code**	**Default PF**	**New feed item?**	**Related to a crop previously considered?**	**New default PF?**	**Conclusion**
1 - Forage							
Alfalfa	forage (green)	1210010	N/A	No	N/A	N/A	No change of the input values is expected.
Alfalfa	hay (fodder)	1210010	2.5	No	N/A	Yes	New default PF of 2.5 (previously 4) might change the input value.
Alfalfa	meal	1210010	2.5	Yes	Yes (alfalfa)	Yes	If GAP on alfalfa was authorised, the relevant residue trials were already reported and are now taken into consideration in the livestock DB. Additional processing studies might be available and useful.
Alfalfa	silage	1210010	1.1	No	N/A	Yes	New default PF of 1.1 (previously 1) might change the input value.
Barley	forage	1220010	N/A	Yes	No	N/A	Feed item to be considered only if a specific GAP on barley for forage is now authorised.
Barley	straw	1230010	N/A	No	N/A	N/A	No change of the input values is expected.
Barley	silage	1220010	1.3	Yes	No	Yes	Feed item to be considered only if a specific GAP on barley for forage is now authorised. Additional processing studies might be available and useful.

Feed items considered in the OECD calculator		Corresponding PROFile entry		Information for users who want to update a previous dietary burden calculation considering the OECD calculator (using PROFile 3.0)			
OECD Feed Crop	**OECD Feed Commodity**	**RAC code**	**Default PF**	**New feed item?**	**Related to a crop previously considered?**	**New default PF?**	**Conclusion**
Bean	vines (fodder green)	1210020	N/A	Yes	No	N/A	Feed item to be considered only if a specific GAP on beans for forage is now authorised.
Beet, mangel	roots	1240010	N/A	No	N/A	N/A	No change of the input values is expected.
Beet, mangel	tops	1240020	N/A	No	N/A	N/A	No change of the input values is expected.
Beet, sugar	tops	1240030	N/A	No	N/A	N/A	No change of the input values is expected.
Cabbage, heads	leaves	242020	N/A	No	N/A	N/A	No change of the input values is expected.
Clover	forage	1210030	N/A	No	N/A	N/A	No change of the input values is expected.
Clover	hay	1210030	3.0	No	N/A	Yes	New default PF of 3 (previously 4) might change the input value.
Clover	silage	1210030	1.0	No	N/A	No	No change of the input values is expected.
Corn, field	forage/silage	1220040	N/A	No	N/A	N/A	No change of the input values is expected.
Corn, field	stover (fodder)	1230030	N/A	Yes	Yes (maize grain)	N/A	If a GAP on maize grain was authorised, additional data on maize stover might be available and useful.
Corn, pop	stover	1230030	N/A	Yes	Yes (maize grain)	N/A	If a GAP on maize grain was authorised, additional data on maize stover might be available and useful.
Cowpea	forage	1210040	N/A	Yes	No	N/A	Feed item to be considered only if a specific GAP on cowpea for forage is now authorised.

Feed items considered in the OECD calculator		Corresponding PROFile entry		Information for users who want to update a previous dietary burden calculation considering the OECD calculator (using PROFile 3.0)			
OECD Feed Crop	**OECD Feed Commodity**	**RAC code**	**Default PF**	**New feed item?**	**Related to a crop previously considered?**	**New default PF?**	**Conclusion**
Cowpea	hay	1210040	2.9	Yes	No	Yes	Feed item to be considered only if a specific GAP on cowpea for forage is now authorised. Additional processing studies might be available and useful.
Grass	forage (fresh)	1220030	N/A	No	N/A	N/A	No change of the input values is expected.
Grass	hay	1220030	3.5	No	N/A	Yes	New default PF of 3.5 (previously 4) might change the input value.
Grass	silage	1220030	1.6	No	N/A	Yes	New default PF of 1.6 (previously 1) might change the input value.
Kale	leaves (forage)	243020	N/A	No	N/A	N/A	No change of the input values is expected.
Lespedeza	forage	1210050	N/A	Yes	No	N/A	Feed item to be considered only if a specific GAP on lespedeza for forage is now authorised.
Lespedeza	hay	1210050	4.0	Yes	No	Yes	Feed item to be considered only if a specific GAP on lespedeza for forage is now authorised. Additional processing studies might be available and useful.
Millet	forage	1220020	N/A	Yes	No	N/A	Feed item to be considered only if a specific GAP on millet for forage is now authorised.
Millet	straw (fodder, dry)	1230020	N/A	Yes	Yes (millet grain)	N/A	If a GAP on millet grain was authorised, additional data on millet straw might be available and useful.

Feed items considered in the OECD calculator		Corresponding PROFile entry		Information for users who want to update a previous dietary burden calculation considering the OECD calculator (using PROFile 3.0)			
OECD Feed Crop	**OECD Feed Commodity**	**RAC code**	**Default PF**	**New feed item?**	**Related to a crop previously considered?**	**New default PF?**	**Conclusion**
Oat	forage	1220050	N/A	Yes	No	N/A	Feed item to be considered only if a specific GAP on oats for forage is now authorised.
Oat	hay	1220050	3.0	Yes	No	Yes	Feed item to be considered only if a specific GAP on oats for forage is now authorised. Additional processing studies might be available and useful.
Oat	straw	1230040	N/A	No	N/A	N/A	No change of the input values is expected.
Pea	vines (green)	1210060	N/A	Yes	No	N/A	Feed item to be considered only if a specific GAP on pea for forage is now authorised.
Pea	hay (hay or fodder)	1210060	3.5	Yes	No	Yes	Feed item to be considered only if a specific GAP on pea for forage is now authorised. Additional processing studies might be available and useful.
Pea	silage	1210060	1.6	Yes	No	Yes	Feed item to be considered only if a specific GAP on pea for forage is now authorised. Additional processing studies might be available and useful.
Rape	forage	1250010	N/A	No	N/A	N/A	No change of the input values is expected.
Rice	straw	1230050	N/A	Yes	Yes (rice grain)	N/A	If a GAP on rice grain was authorised, additional data on rice straw might be available and useful.
Rye	forage (greens)	1220060	N/A	Yes	No	N/A	Feed item to be considered only if a specific GAP on rye for forage is now authorised.

Feed items considered in the OECD calculator		Corresponding PROFile entry		Information for users who want to update a previous dietary burden calculation considering the OECD calculator (using PROFile 3.0)			
OECD Feed Crop	**OECD Feed Commodity**	**RAC code**	**Default PF**	**New feed item?**	**Related to a crop previously considered?**	**New default PF?**	**Conclusion**
Rye	straw	1230060	N/A	No	N/A	N/A	No change of the input values is expected.
Sorghum, grain	forage	1220070	N/A	Yes	No	N/A	Feed item to be considered only if a specific GAP on sorghum for forage is now authorised.
Sorghum, grain	stover	1230070	N/A	Yes	No	N/A	Feed item to be considered only if a specific GAP on sorghum for forage is now authorised.
Sorghum, grain	silage	1220070	0.6	Yes	No	Yes	Feed item to be considered only if a specific GAP on sorghum for forage is now authorised. Additional processing studies might be available and useful.
Soybean	forage (green)	1210070	N/A	Yes	No	N/A	Feed item to be considered only if a specific GAP on soybean for forage is now authorised.
Soybean	hay (fodder)	1210070	1.5	Yes	No	Yes	Feed item to be considered only if a specific GAP on soybean for forage is now authorised. Additional processing studies might be available and useful.
Soybean	silage	1210070	0.5	Yes	No	Yes	Feed item to be considered only if a specific GAP on soybean for forage is now authorised. Additional processing studies might be available and useful.
Trefoil	forage	1210080	N/A	Yes	No	N/A	Feed item to be considered only if a specific GAP on trefoil for forage is now authorised.

Feed items considered in the OECD calculator		Corresponding PROFile entry		Information for users who want to update a previous dietary burden calculation considering the OECD calculator (using PROFile 3.0)			
OECD Feed Crop	**OECD Feed Commodity**	**RAC code**	**Default PF**	**New feed item?**	**Related to a crop previously considered?**	**New default PF?**	**Conclusion**
Trefoil	hay	1210080	2.8	Yes	No	Yes	Feed item to be considered only if a specific GAP on trefoil for forage is now authorised. Additional processing studies might be available and useful.
Triticale	forage	1220080	N/A	Yes	No	N/A	Feed item to be considered only if a specific GAP on wheat/triticale for forage is now authorised.
Triticale	hay	1220080	2.9	Yes	No	Yes	Feed item to be considered only if a specific GAP on wheat/triticale for forage is now authorised. Additional processing studies might be available and useful.
Triticale	straw	1230080	N/A	No	N/A	N/A	No change of the input values is expected.
Turnip	tops (leaves)	1240040	N/A	Yes	Yes (turnips)	N/A	If a GAP on turnips was authorised, additional data on turnips leaves might be available and useful.
Vetch	forage	1210090	N/A	Yes	No	N/A	Feed item to be considered only if a specific GAP on vetch for forage is now authorised.
Vetch	hay	1210090	2.8	Yes	No	Yes	Feed item to be considered only if a specific GAP on vetch for forage is now authorised. Additional processing studies might be available and useful.
Wheat	forage	1220080	N/A	Yes	No	N/A	Feed item to be considered only if a specific GAP on wheat/triticale for forage is now authorised.

Feed items considered in the OECD calculator		Corresponding PROFile entry		Information for users who want to update a previous dietary burden calculation considering the OECD calculator (using PROFile 3.0)			
OECD Feed Crop	**OECD Feed Commodity**	**RAC code**	**Default PF**	**New feed item?**	**Related to a crop previously considered?**	**New default PF?**	**Conclusion**
Wheat	hay (fodder dry)	1220080	3.5	Yes	No	Yes	Feed item to be considered only if a specific GAP on wheat/triticale for forage is now authorised. Additional processing studies might be available and useful.
Wheat	straw	1230080	N/A	No	N/A	N/A	No change of the input values is expected.
2 - Roots and tubers							
Carrot	culls	213020	N/A	Yes	Yes (carrots)	N/A	If GAP on carrots was authorised, the relevant residue trials were already reported and are now taken into consideration in the livestock DB.
Cassava/tapioca	roots	212010	N/A	Yes	Yes (cassava)	N/A	If GAP on cassava was authorised, the relevant residue trials were already reported and are now taken into consideration in the livestock DB.
Potato	culls	211000	N/A	No	N/A	N/A	No change of the input values is expected.
Swede	roots	213100	N/A	No	N/A	N/A	No change of the input values is expected.
Turnip	roots	213110	N/A	No	N/A	N/A	No change of the input values is expected.
3 - Cereals grain/ Crop seeds							
Barley	grain	500010	N/A	No	N/A	N/A	No change of the input values is expected.
Bean	seed (dry)	300010	N/A	No	N/A	N/A	No change of the input values is expected.
Corn, field (Maize)	grain	500030	N/A	No	N/A	N/A	No change of the input values is expected.

Feed items considered in the OECD calculator		Corresponding PROFile entry		Information for users who want to update a previous dietary burden calculation considering the OECD calculator (using PROFile 3.0)			
OECD Feed Crop	**OECD Feed Commodity**	**RAC code**	**Default PF**	**New feed item?**	**Related to a crop previously considered?**	**New default PF?**	**Conclusion**
Corn, pop	grain	500030	N/A	No	N/A	N/A	No change of the input values is expected.
Cotton	undelinted seed	401090	N/A	No	N/A	N/A	No change of the input values is expected.
Cowpea	seed	300010	N/A	No	N/A	N/A	No change of the input values is expected.
Lupin	seed	300040	N/A	No	N/A	N/A	No change of the input values is expected.
Millet	grain	500040	N/A	Yes	Yes (millet grain)	N/A	If GAP on millet grain was authorised, the relevant residue trials were already reported and are now taken into consideration in the livestock DB.
Oat	grain	500050	N/A	No	N/A	N/A	No change of the input values is expected.
Pea (Field pea)	seed (dry)	300030	N/A	No	N/A	N/A	No change of the input values is expected.
Rye	grain	500070	N/A	No	N/A	N/A	No change of the input values is expected.
Sorghum	grain	500080	N/A	Yes	Yes (sorghum)	N/A	If GAP on sorghum grain was authorised, the relevant residue trials were already reported and are now taken into consideration in the livestock DB.
Soybean	seed	401070	N/A	No	N/A	N/A	No change of the input values is expected.
Triticale	grain	500090	N/A	No	N/A	N/A	No change of the input values is expected.
Wheat	grain	500090	N/A	No	N/A	N/A	No change of the input values is expected.

Feed items considered in the OECD calculator		Corresponding PROFile entry		Information for users who want to update a previous dietary burden calculation considering the OECD calculator (using PROFile 3.0)			
OECD Feed Crop	**OECD Feed Commodity**	**RAC code**	**Default PF**	**New feed item?**	**Related to a crop previously considered?**	**New default PF?**	**Conclusion**
4 - By-products							
Apple	pomace, wet	130010	5.0	No	N/A	Yes	New default PF of 5 (previously 2.5) might change the input value.
Beet, sugar	dried pulp	900010	18.0	Yes	Yes (sugar beets)	Yes	If GAP on sugar beets was authorised, the relevant residue trials were already reported and are now taken into consideration in the livestock DB. Additional processing studies might be available and useful.
Beet, sugar	ensiled pulp	900010	3.0	Yes	Yes (sugar beets)	Yes	If GAP on sugar beets was authorised, the relevant residue trials were already reported and are now taken into consideration in the livestock DB. Additional processing studies might be available and useful.
Beet, sugar	molasses	900010	28.0	Yes	Yes (sugar beets)	Yes	If GAP on sugar beets was authorised, the relevant residue trials were already reported and are now taken into consideration in the livestock DB. Additional processing studies might be available and useful.

Feed items considered in the OECD calculator		Corresponding PROFile entry		Information for users who want to update a previous dietary burden calculation considering the OECD calculator (using PROFile 3.0)			
OECD Feed Crop	**OECD Feed Commodity**	**RAC code**	**Default PF**	**New feed item?**	**Related to a crop previously considered?**	**New default PF?**	**Conclusion**
Brewer's grain	dried	500010	3.3	Yes	Yes (barley grain)	Yes	If GAP on barley grain was authorised, the relevant residue trials were already reported and are now taken into consideration in the livestock DB. Additional processing studies might be available and useful.
Canola (Rape seed)	meal	401060	2.0	No	N/A	No	No change of the input values is expected.
Grapefruits	dried pulp	110010	10.0	Yes	Yes (grapefruits)	Yes	If GAP on grapefruits was authorised, the relevant residue trials were already reported and are now taken into consideration in the livestock DB. Additional processing studies might be available and useful.
Oranges	dried pulp	110020	10.0	Yes	Yes (oranges)	Yes	If GAP on oranges was authorised, the relevant residue trials were already reported and are now taken into consideration in the livestock DB. Additional processing studies might be available and useful.
Lemons	dried pulp	110030	10.0	Yes	Yes (lemons)	Yes	If GAP on lemons was authorised, the relevant residue trials were already reported and are now taken into consideration in the livestock DB. Additional processing studies might be available and useful.

Feed items considered in the OECD calculator		Corresponding PROFile entry		Information for users who want to update a previous dietary burden calculation considering the OECD calculator (using PROFile 3.0)			
OECD Feed Crop	**OECD Feed Commodity**	**RAC code**	**Default PF**	**New feed item?**	**Related to a crop previously considered?**	**New default PF?**	**Conclusion**
Limes	dried pulp	110040	10.0	Yes	Yes (limes)	Yes	If GAP on limes was authorised, the relevant residue trials were already reported and are now taken into consideration in the livestock DB. Additional processing studies might be available and useful.
Mandarins	dried pulp	110050	10.0	Yes	Yes (mandarins)	Yes	If GAP on mandarins was authorised, the relevant residue trials were already reported and are now taken into consideration in the livestock DB. Additional processing studies might be available and useful.
Coconut	meal	120050	1.5	Yes	Yes (coconuts)	Yes	If GAP on coconuts was authorised, the relevant residue trials were already reported and are now taken into consideration in the livestock DB. Additional processing studies might be available and useful.
Corn, field	milled by-pdts	500030	1.0	Yes	Yes (maize grain)	Yes	If GAP on maize grain was authorised, the relevant residue trials were already reported and are now taken into consideration in the livestock DB. Additional processing studies might be available and useful.
Corn, field	hominy meal	500030	6.0	Yes	Yes (maize grain)	Yes	If GAP on maize grain was authorised, the relevant residue trials were already reported and are now taken into consideration in the livestock DB. Additional processing studies might be available and useful.

Feed items considered in the OECD calculator		Corresponding PROFile entry		Information for users who want to update a previous dietary burden calculation considering the OECD calculator (using PROFile 3.0)			
OECD Feed Crop	**OECD Feed Commodity**	**RAC code**	**Default PF**	**New feed item?**	**Related to a crop previously considered?**	**New default PF?**	**Conclusion**
Corn, field	distiller's grain (dry)	500030	3.3	Yes	Yes (maize grain)	Yes	If GAP on maize grain was authorised, the relevant residue trials were already reported and are now taken into consideration in the livestock DB. Additional processing studies might be available and useful.
Corn, field	gluten feed	500030	2.5	Yes	Yes (maize grain)	Yes	If GAP on maize grain was authorised, the relevant residue trials were already reported and are now taken into consideration in the livestock DB. Additional processing studies might be available and useful.
Corn, field	gluten, meal	500030	1.0	Yes	Yes (maize grain)	Yes	If GAP on maize grain was authorised, the relevant residue trials were already reported and are now taken into consideration in the livestock DB. Additional processing studies might be available and useful.
Cotton	meal	401090	1.3	No	N/A	No	No change of the input values is expected.
Flaxseed/ Linseed	meal	401010	2.0	No	N/A	No	No change of the input values is expected.
Lupin seed	meal	300040	1.1	Yes	Yes (lupin seed)	Yes	If GAP on lupins seed was authorised, the relevant residue trials were already reported and are now taken into consideration in the livestock DB. Additional processing studies might be available and useful.

Feed items considered in the OECD calculator		Corresponding PROFile entry		Information for users who want to update a previous dietary burden calculation considering the OECD calculator (using PROFile 3.0)			
OECD Feed Crop	**OECD Feed Commodity**	**RAC code**	**Default PF**	**New feed item?**	**Related to a crop previously considered?**	**New default PF?**	**Conclusion**
Palm (hearts)	kernel meal	402020	2.0	Yes	Yes (palm hearts)	Yes	If GAP on palm hearts was authorised, the relevant residue trials were already reported and are now taken into consideration in the livestock DB. Additional processing studies might be available and useful.
Peanut	meal	401020	2.0	No	N/A	No	No change of the input values is expected.
Potato	process waste	211000	20.0	Yes	Yes (potatoes)	Yes	If GAP on potatoes was authorised, the relevant residue trials were already reported and are now taken into consideration in the livestock DB. Additional processing studies might be available and useful.
Potato	dried pulp	211000	38.0	Yes	Yes (potatoes)	Yes	If GAP on potatoes was authorised, the relevant residue trials were already reported and are now taken into consideration in the livestock DB. Additional processing studies might be available and useful.
Rape	meal	401060	2.0	No	N/A	No	No change of the input values is expected.
Rice	bran/pollard	500060	10.0	Yes	Yes (rice grain)	Yes	If GAP on rice grain was authorised, the relevant residue trials were already reported and are now taken into consideration in the livestock DB. Additional processing studies might be available and useful.

Feed items considered in the OECD calculator		Corresponding PROFile entry		Information for users who want to update a previous dietary burden calculation considering the OECD calculator (using PROFile 3.0)			
OECD Feed Crop	**OECD Feed Commodity**	**RAC code**	**Default PF**	**New feed item?**	**Related to a crop previously considered?**	**New default PF?**	**Conclusion**
Safflower	meal	401110	2.0	Yes	Yes (safflower)	Yes	If GAP on safflower was authorised, the relevant residue trials were already reported and are now taken into consideration in the livestock DB. Additional processing studies might be available and useful.
Soybean	meal	401070	1.3	No	N/A	No	No change of the input values is expected.
Soybean	hulls	401070	13.0	Yes	Yes (soyabean)	Yes	If GAP on soyabean was authorised, the relevant residue trials were already reported and are now taken into consideration in the livestock DB. Additional processing studies might be available and useful.
Sugarcane	molasses	900020	32.0	Yes	Yes (sucarcane)	Yes	If GAP on sugarcane was authorised, the relevant residue trials were already reported and are now taken into consideration in the livestock DB. Additional processing studies might be available and useful.
Sunflower	meal	401050	2.0	No	N/A	No	No change of the input values is expected.
Wheat	distiller's grain (dry)	500090	3.3	Yes	Yes (wheat grain)	Yes	If GAP on wheat grain was authorised, the relevant residue trials were already reported and are now taken into consideration in the livestock DB. Additional processing studies might be available and useful.

Feed items considered in the OECD calculator		Corresponding PROFile entry		Information for users who want to update a previous dietary burden calculation considering the OECD calculator (using PROFile 3.0)			
OECD Feed Crop	**OECD Feed Commodity**	**RAC code**	**Default PF**	**New feed item?**	**Related to a crop previously considered?**	**New default PF?**	**Conclusion**
Wheat gluten	meal	500090	1.8	Yes	Yes (wheat grain)	Yes	If GAP on wheat grain was authorised, the relevant residue trials were already reported and are now taken into consideration in the livestock DB. Additional processing studies might be available and useful.
Wheat	milled by-products	500090	7.0	Yes	Yes (wheat grain)	Yes	If GAP on wheat grain was authorised, the relevant residue trials were already reported and are now taken into consideration in the livestock DB. Additional processing studies might be available and useful.

APPENDIX 3 – DEFAULT PROCESSING FACTORS

APPENDIX 3.1 – FORAGE FEED COMMODITIES

For forage commodities, EFSA derived default PFs on the basis of dry matter contents in raw agricultural commodities (RAC) and processed commodities (PC), assuming the most conservative scenario where residues are all concentrated into the dry matter. Default processing factors (Default PF) are therefore derived according to the following ratio:

$$DefaultPF = \frac{Dry\ matter\ (PC)}{Dry\ matter\ (RAC)}$$

For the percentage of dry matter in raw agricultural commodities (DM RAC %) and in processed commodities (DM PC %), EFSA referred to the OECD guidance 73 on residues in livestock where all these feed commodities are described **[1]**.

Commodities		DM RAC (%)	DM PC (%)	Default PF
Alfalfa	hay (fodder)	35	89	2.5
Alfalfa	meal	35	89	2.5
Alfalfa	silage	35	40	1.1
Barley	silage	30	40	1.3
Clover	hay	30	89	3
Clover	silage	30	30	1
Cowpea	hay	30	86	2.9
Grass	hay	25	88	3.5
Grass	silage	25	40	1.6
Lespedeza	hay	22	88	4
Oat	hay	30	90	3
Pea	hay (hay or fodder)	25	88	3.5
Pea	silage	25	40	1.6
Sorghum, grain	silage	35	21	0.6
Soybean	hay (fodder)	56	85	1.5
Soybean	silage	56	30	0.5
Trefoil	hay	30	85	2.8
Triticale	hay	30	88	2.9
Vetch	hay	30	85	2.8
Wheat	hay (fodder dry)	25	88	3.5

APPENDIX 3.2 – PROCESSED FEED COMMODITIES

For processed commodities other than forage, EFSA derived default processing factors (default PF) based on the theoretical yield factor of the corresponding processes, assuming the most conservative scenario where residues fully concentrate into the processed commodity (or by-product) under consideration. Default processing factors are therefore derived according to the following ratio:

$$Default\ PF = \frac{1}{Theoritical\ yield\ \ factor} = \frac{1}{mass\ PC \Big/ mass\ RAC} = \frac{mass\ RAC}{mass\ PC}$$

Based on the description of the processed feed commodities provided in the OECD guidance 73 on residues in livestock **[1]**, and taking into account a wide range of other sources (see appendix 3.3), EFSA made further investigation to estimate the theoretical mass balances for each of the relevant process. This allowed deriving theoretical yield factors, from which the following default process factors (PF) are derived.

Although several sources were considered by EFSA, it is highlighted that this first attempt to derive default PFs may need to be completed later on by further research on this matter. Meanwhile, users should keep in mind that these default PFs represent the worst case situation where no studies are available and that there is always the possibility to lower these processing factors based on processing studies or even to waive the use of these default PFs if sufficient argumentation is provided.

Commodities		Yield factor	Default PF	Justification
Apple	pomace, wet	0.2	5	Several sources **[2, 3, 4]** indicate that apples may yield between 60 and 80 % of raw juice depending on the pressing technique. According to the old guidance document for calculation of the livestock dietary burden, the DM content for apple pomace was defined at approximately 20 %. Also considering that DM content of fresh apples ranges between 15 and 20 % and DM content of apple juice amounts to approximately 12 %, a juice yield of 60 % (and a pomace yield of 40 %) was considered to be the most realistic. Hence a default processing factor of 2.5 was estimated. Under the new OECD guidance however **[1]**, the DM content for wet pomace is defined as 40 % and in order to obtain this DM, content a yield of 80 % juice and 20 % pomace is considered more realistic. This is also consistent with the more modern techniques used nowadays for industrial processing. Hence a default processing factor of 5 is now proposed.
Beet, sugar	dried pulp	0.055	18	According to a sugar beet pulp producer **[5]**, 1 ton of sugar beets yields 178 kg of wet pulp (28 % DM) or 55 kg of dry pulp (90 % DM). These figures are also confirmed by a report prepared by a consultant **[6]**. In this paper, several sources were considered and the default yields of 230 kg for wet pulp (21 % DM) and 56 kg of dry pulp (90 % DM) were calculated. Hence the yield factor for dry sugar beet pulp is estimated at 0.055.
Beet, sugar	ensiled pulp	0.33	3	Ensiled sugar beet pulp was assumed to be the wet sugar beet pulp used for subsequent ensilaging. Considering that OECD defines the ensiled sugar beet pulp with a DM content of 15 % **[1]**, the above reported yields were corrected for DM content. Hence the yield factor for ensiled sugar beet pulp is estimate at 0.33.
Beet, sugar	molasses	0.036	28	Blonk Consultants prepared a report for the Dutch Sugar Union. This consultant considered several sources and concluded on default yields of 36 kg for sugar beet molasses **[6]**. This value could not be confirmed by another report. However, the validity of other yield factors derived by this consultant for other sugar beet by-products was cross-checked from different sources. Therefore, the results proposed by this consultant are deemed reliable for sugar beet molasses. Hence the yield factor for dry sugar beet molasses is estimated at 0.036.

Commodities		Yield factor	Default PF	Justification
Brewer's grain	dried	0.3	3.3	Two independent sources were identified indicating that 1 tonne of dry malt is necessary to produce approximately 300 kg of dry brewer's grain **[7, 8]**. Considering that this process is similar to the process for distiller's grain and that dry malt corresponds approximately to the same amount of raw barley, a yield factor of 0.3 is considered realistic for dry brewer's grain.
Canola (Rape seed)	meal	0.5	2	Based on the oil contents reported in the OECD guidance document for processed commodities (38-44 %) **[1],** canola (rapeseed) is classified as oilseed with high oil content (approx. 50 %). Hence the yield for the meal is estimated at 0.5.
Citrus	dried pulp	0.1	10	According to Feedipedia **[9]**, fresh citrus pulp is the solid residue that remains after fresh fruits are squeezed for their juice. It amounts to 50-70 % of the fresh weight of the original fruit. This pulp is subsequently subject to a drying process where the water content of citrus pulp decreases from about 80 % to 11 % water. Assuming the worst case situation where the fresh citrus pulp amounts to 50 % of the fresh weight of the original fruit, 1 ton of oranges would yield approximately 110 kg of dried pulp. A different source of FAO also depicts a detailed mass balance of orange juice processing where 1 ton of oranges yields approximately 80 kg of dried orange pulp **[10]**. An approximate yield factor of 0.1 is therefore considered realistic for dried citrus pulp.
Coconut	meal	0.65	1.5	EFSA consulted food composition data bases from EU Member States that are available in English and that can be freely consulted online **[11]**. It includes databases from the following Member States: CZ, DK, EE, FI, FR, SK, ES, SE and UK. Data regarding the fat content of fresh coconut was available in 6 databases (EE, FR, SK, ES, SE and UK) and fat content ranges from 33.5 to 36 %. Hence the yield factor for coconut meal is estimated at 0.65.

Commodities		Yield factor	Default PF	Justification
Corn, field	milled by-pdts	1	1	This fraction is not defined in detail in the OECD guidance but it may contain grits, meal or flour obtained during the dry milling process. These by-products are considered similar to grits, meal and flour for human consumption but with different quality standards. Such fractions mainly originate from the endosperm after removal of the outer layers (see also hominy meal) and concentration of residues in this feed item is not expected. Hence a default processing factor of 1 is applied.
Corn, field	hominy meal	0.17	6	According to the OECD guidance, this fraction is a mixture of corn bran, germ, and part of starchy portion of corn kernels, following dry milling **[1]**. Although this fraction may contain part of the starchy portion (endosperm), it was assumed by EFSA that this fraction is mainly composed of the outer layers of the kernel and the germ. Several sources were identified indicating that fractions of the corn kernel other than the endosperm, may account for 16-18 % of the whole kernel weight **[12, 13]**. EFSA therefore estimated an approximate yield factor of 0.17 for hominy meal.
Corn, field	gluten feed	0.4	2.5	According to several sources of information, corn gluten feed results from wet milling and contains mainly bran and steep water liquor **[14]**. In some cases it may also contain the germ meal (obtained after extraction of the germ oil). EFSA retrieved a report from Blonk Consultants that reviews several sources of information on the wet milling process **[15]**, concluding on a default yield of 175 kg gluten feed (90 % DM) from 1 ton of corn. However, the OECD guidance document defines the DM content of gluten feed at 40 %, probably referring to the gluten feed before the final drying process **[1]**. Hence, correcting the yield for dry matter content, a yield factor of 0.4 is estimated for gluten feed. This information could not be verified by another source, but it is highlighted that the fractions included in the hominy meal are similar to the fractions included in the gluten feed, the main difference being linked to the process itself (dry versus wet milling). Considering the same fractions for hominy meal and correcting them for DM content (to account for the water added in the wet milling process), a similar yield is obtained. The estimate of Blonk Consultants is therefore considered reliable.

Commodities		Yield factor	Default PF	Justification
Corn, field	gluten, meal	1	1	According to several sources of information, corn gluten meal results from wet milling and contains the remainder of the endosperm after extraction of the starch **[16]**. Considering that this fraction no longer contains the outer layers of the kernel and that it has a lower DM content that the raw commodity, it is considered unlikely for residues to concentrate in this fraction. Hence a default processing factor of 1 is applied.
Cotton	meal	0.8	1.3	Based on the oil contents reported in the OECD guidance document for processed commodities (18-26 %) **[1]**, cotton seed is classified as oilseed with high oil content (approx. 20 %). Hence the yield for the meal is estimated at 0.8.
Distiller's grain	dried	0.3	3.3	According to a dried destiller's grain producer **[17]**, 1 ton of wheat grain yields 400 kg of dried destiller's grain. However, several other sources were identified which indicated yield factors of 0.3 for dry distiller's grain, regardless whether the grain was originating from corn or wheat grain **[18, 19, 20]**. These yield factors also referred to the yield factors considered in the production of biofuels. Hence, biofuel industry being the main producer of distiller's grain worldwide, a yield factor of 0.3 was considered to be the most relevant for dry distiller's grain.
Flaxseed/Linseed	meal	0.5	2	Based on the oil contents reported in the OECD guidance document for processed commodities (46 %) **[1]**, flaxseed/linseed is classified as oilseed with high oil content (approx. 50 %). Hence the yield for the meal is estimated at 0.5.
Lupin seed	Meal	0.9	1.1	EFSA consulted food composition data bases from EU Member States that are available in English and that can be freely consulted online **[11]**. It includes databases from the following Member States: CZ, DK, EE, FI, FR, SK, ES, SE and UK. However, data regarding the fat content of lupin was only available in the Spanish database: 9.74 % **[21]**. Hence the yield factor for lupin meal is estimated at 0.9.
Palm (hearts)	kernel meal	0.5	2	According to Feedipedia **[22]**, palm kernels yield approximately 50 % of oil and meal each. This also corresponds to the fat content reported for palm kernels by Kok S. et al. (2011) **[23]**. Hence the yield factor for palm kernel meal is estimated at 0.5.

Commodities		Yield factor	Default PF	Justification
Peanut	Meal	0.5	2	EFSA consulted food composition data bases from EU Member States that are available in English and that can be freely consulted online **[11]**. It includes databases from the following Member States: CZ, DK, EE, FI, FR, SK, ES, SE and UK. Data regarding the fat content of fresh peanut was available in 8 databases (CZ, EE, FI, FR, SK, ES, SE and UK) and fat content ranges from 43 to 48.8 %. Hence the yield factor for peanut meal is estimated at 0.5.
Potato	process waste	0.05	20	According to the OECD guidance, "potatoes wastes" correspond to wet peel released during the peeling process **[1]**. The efficiency of peeling processes for potatoes has been improved over the years. Moreover, the peeling loss also depends on the size of the raw product and there are a wide range of varieties of potatoes. From the different sources, there are indications that the peeling loss ranges from 5 % to 20 % **[24, 25]**. Therefore, a worst case scenario would be to consider a theoretical PF coming from the most efficient technologies (5 % peeling loss), giving a PF of 20.
Potato	dried pulp	0.026	38	The process of potatoes "wet milling" involves the extraction of the fibres (or potatoes pulp) in order to release starch. From 1000 kg of potatoes, 140 kg of fibres (at 16.5 % DM) can be extracted **[15]**. These fibres are then dried up to 88 % DM before being fed to animals as "potatoes dried pulp". Therefore, the mass of "potatoes dried pulp" that can be produced from 1000 kg of potatoes is 140 x 16.5/88 = 26 kg. This estimate is confirmed by another source where it is indicated that 1000 kg of potatoes can yield 33 kg of dried pulp **[26]**. Consequently, considering a worst case situation where residues concentrate in this by-product, the theoretical process factor for potato dried pulp is estimated at 38.
Rape	Meal	0.5	2	Based on the oil contents reported in the OECD guidance document for processed commodities (38-44 %) **[1],** rapeseed is classified as oilseed with high oil content (approx. 50 %). Hence the yield for the meal is estimated at 0.5.

Commodities		Yield factor	Default PF	Justification
Rice	bran/pollard	0.1	10	According to the rice knowledge bank **[27]**, most rice varieties are composed of roughly 20 % rice hull or husk, 11 % bran layers, and 69 % starchy endosperm, also referred to as the total milled rice. In an ideal milling process this will result in the following fractions: 20 % husk, 8−12 % bran (depending on the milling degree) and 68−72 % milled rice or white rice (depending on the variety). Total milled rice contains whole grains or head rice, and brokens. The by-products in rice milling are rice hull, rice germ and bran layers, and fine brokens. Similar values for bran yield were reported on feedipedia **[28]** and by an independent consultant (Blonk) **[29]**. A yield of 10 % rice bran is therefore considered realistic.
Safflower	Meal	0.5	2	Based on the oil contents reported in the OECD guidance document for processed commodities (25-40 %) **[1],** safflower is classified as oilseed with high oil content (approx. 50 %). Hence the yield for the meal is estimated at 0.5.
Soybean	Meal	0.8	1.3	Based on the oil contents reported in the OECD guidance document for processed commodities (13-24 %) **[1],** soybean is classified as oilseed with low oil content (approx. 20 %). Hence the yield for the meal is estimated at 0.8.
Soybean	Hulls	0.08	13	According to FAO's AGRICULTURAL SERVICES BULLETIN No. 97, hulls account for approximately 8 % of the soybean seed weight **[30]**. This is also confirmed by a report from Blonk Consultant where different by-products from soybean were investigated **[7]**.
Sugarcane	Molasses	0.031	32	Blonk Consultants prepared a report for the Dutch Sugar Union **[6]**. This consultant considered several sources and concluded on default yields of 31 kg for sugar cane molasses. This value could not be confirmed by another report. However, the validity of other yield factors derived by this consultant for other processed items was cross-checked from different sources. Therefore, the results proposed by this consultant are deemed reliable for sugarcane molasses. Hence the yield factor for sugarcane molasses is estimated at 0.031.
Sunflower	Meal	0.5	2	Based on the oil contents reported in the OECD guidance document for processed commodities (19-48 %) **[1],** sunflower is classified as oilseed with high oil content (approx. 50 %). Hence the yield for the meal is estimated at 0.5.

Commodities		Yield factor	Default PF	Justification
Wheat gluten	Meal	0.55	1.8	This feed item was not defined in the OECD guidance. According to several sources, this feed item seems to be composed of wheat bran, mixed with liquid by-products from starch extraction **[31, 32]**. EFSA retrieved a report from Blonk Consultants **[15]** that reviews several sources of information on the wet milling process, concluding on a default yield of approximately 250 kg (sum of gluten feed and bran, 90 % DM) from 1 ton of wheat. However, the OECD guidance document defines the DM content of gluten feed at 40 %, probably referring to the gluten meal before the final drying process **[1]**. Hence, correcting the yield for dry matter content, a yield factor of 0.55 is estimated for gluten feed.
Wheat	milled by-products	0.15	7	According to the OECD guidance, this fraction is a mixture of bran, shorts and middlings obtained through dry milling **[1]**. Although this fraction may contain part of the starchy portion (endosperm), it was assumed by EFSA that it mainly corresponds to the bran, outer layers of the grain. Several sources were identified indicating that outer layers of the wheat grain (bran), may account for 12-17 % of the whole grain weight **[33, 34]**. EFSA therefore estimated an approximate yield factor of 0.15 for bran and other milled by-products.

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APPENDIX 4 – MRL CALCULATIONS IN LIVESTOCK

- Transfer factor ("TF"): Calculation by interpolation between 0 (zero) and the closest feeding levels. Such a calculation is always possible provided that quantifiable residues are reported. However, if the estimated intake is between the feeding levels, the other methodologies (interpolation and linear regression) are much more reliable and the TF methodology is not deemed relevant.
- Interpolation ("Interpol"): Calculation by interpolation between the two closest feeding levels. Such a calculation is only possible if the estimated intake is within the range of the feeding levels.
- Linear regression ("Regress"): Calculation based on the linear regression using data available at each feeding level (equation as 'y = ax + b'). Such a calculation is only possible if estimated intakes are within 30 % of the extreme feeding levels. The relevance of this calculation is also linked to the R^2 (coefficient of determination for the linear regression) which should be minimum 0.9; this indicator is reported in the PROFile. In any case, proposal derived from the linear regression should be taken cautiously.
- PROFile 3.0 makes the calculations following each relevant methodology and results are reported in the column named "summary calculation". If different methodologies are applicable and relevant, the highest value resulting from the different approaches is automatically reported in the cell "proposed STMR/HR". Applicable methodologies vary depending on the estimated intake (DB) compared to the feeding levels (DL), as reported in the following table:

	DB<0.7*DL1	**0.7*DL1<DB<DL1**	**DL1 <DB<DL2**	**DL2 <DB<DL3**	**DL3 <DB<1.3*DL3**	**DB>1.3*DL3**
TF	TF1	TF1	No	No	TF3	TF3
Interplol	No	No	Interpol DL1-DL2	Interpol DL2-DL3	No	No
Regress.	No	Yes (if R^2>0.9)	Yes (if R^2>0.9)	Yes (if R^2>0.9)	Yes (if R^2>0.9)	No
Proposed HR/SMTR	TF1	Max (TF1, Regress.)	Max (Interpol DL1-L2, Regress.)	Max (Interpol DL2-DL3, Regress.)	Max (TF3, Regress.)	TF3

ABBREVIATIONS

BBCH-scale	Biologische Bundesanstalt, Bundessortenamt and CHemical industry – The BBCH-scale is a system for uniform coding of phenologically similar growth stages of all mono- and dicotyledonous plant species.
bw	body weight
CF	Conversion Factor
cGAP	critical Good Agricultural Practice
CXL	Codex maximum Residue Limit
DB	Dietary burden
DL	Dose level
DM	Dry matter
DT90	Time required for a given chemical to obtain by natural degradation in soil 10 % of the amount initially present in that soil.
EU	European Union
GAP	Good Agricultural Practice
HR	Highest Residue
Interpol.	Interpolation
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
Log Po/w	Logarithm of the octanol-water partition coefficient.
LOQ	Limit of Quantification
MRL	Maximum Residue Level
MS	Member State
NEU	Northern Europe
OECD	Organization for Economic Cooperation and Development
PC	Processed commodity
PF	Processing Factor
PHI	Pre-Harvest Interval
RA	Risk Assessment
RAC	Raw Agricultural Commodity
Rber	Calculated Residue Value – Method to calculate the MRL of a given residue data set, using a distribution-free parameter (quantile). This method does not assume a normal distribution for the measured residue values (see also Document SANCO 7039/VI/95).
Regress.	Linear regression
RD	Residue Definition

RL	Residue Level
Rmax	Maximum Residue Value – Method to calculate the MRL of a given residue data set, assuming a normal distribution for the measured residue values (see also Document SANCO 7039/VI/95).
SEU	Southern Europe
STMR	Supervised Trials Median Residue
TF	Transfer factor