



MRL review under article 12 of Reg. (EC) 396/2005

Work instructions

The review of the existing maximum residue levels (MRLs) for an active substance according to Article 12 of Regulation (EC) No 396/2005, is currently performed in line with the (new) process agreed with Commission and Member States at the **Pesticide Steering Network (PSN) meeting in June 2014** and modified **at the Pesticide Steering Network meeting in November 2019**.

The process is mainly divided in three phases (see flowchart in Figure 1):

➤ First phase (steps 1 to 5)

Aim: collection of data (good agricultural practices (GAPs) and supporting data).

Actors:

- Member States (MSs), including the rapporteur member state (RMS), submitting GAPs and data supporting their national authorisations.
- RMS and MSs submitting GAPs for import tolerances and the supporting data.
- RMS identifying the most critical GAPs and preparing the evaluation report and the PROFile.
- EU Reference Laboratories for Pesticide Residues (EURLs) providing information on the availability of analytical methods for enforcement and analytical standards.
- EFSA acting as coordinator and supporting RMS and MSs.
- Main and national authorisation holders supporting MSs and RMS, if needed.

➤ Second phase (steps 6 to 7)

Aim: preparation of the draft reasoned opinion.

Actors:

- EFSA checking the completeness of the data submitted by the RMS and preparing the draft reasoned opinion.
- RMS clarifying any open points raised by EFSA during the completeness check and giving their view on the modifications performed by EFSA with respect to their original submission.
- Main authorisation holders supporting RMS, if needed.

➤ Third phase (steps 8 to 11)

Aim: finalisation and agreement on the reasoned opinion.

Actors:

- MSs (including RMS) providing comments on the draft reasoned opinion.
- EURLs providing comments and additional information on the availability of analytical methods for enforcement and analytical standard for the proposed residue definitions.
- EFSA addressing the comments received, organising an experts meeting (if needed) and finalising the output considering the comments received from RMS, MSs and EURLs.

Once finalised, the reasoned opinions are published along with all its supporting documents (evaluation reports, PROFile, PRIMo files, GAP overview file, completeness check report, Member State consultation report) on the EFSA dissemination Portal (OpenEFSA) at <https://open.efsa.europa.eu/>.

The reasoned opinion can be accessed from the section "Output" of the relevant question number page. The supporting documents can be downloaded by clicking on the "Evidences Inventory" button.



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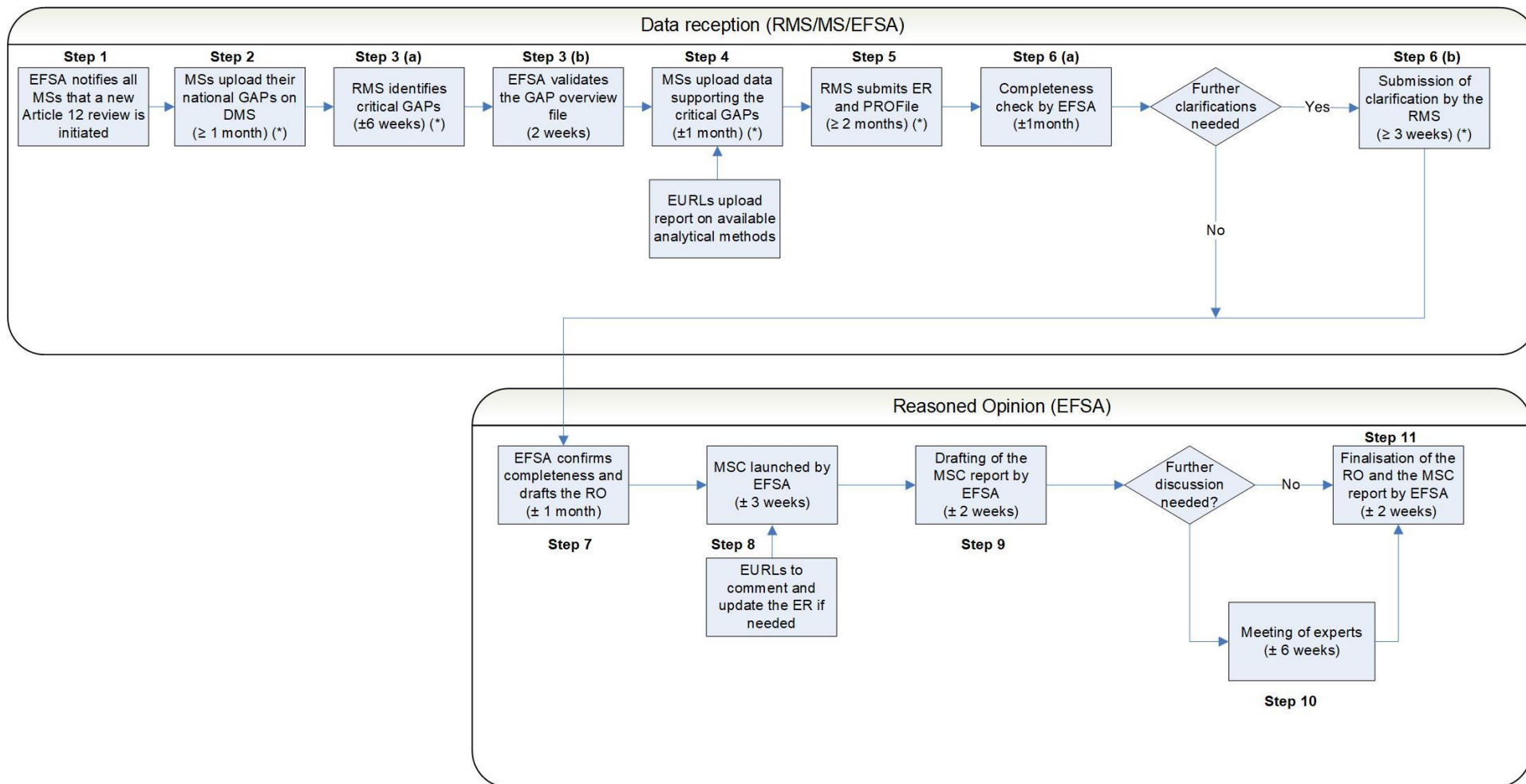
In the framework of these work instructions, each single step of the procedure is described, highlighting the timelines foreseen, the actors involved, the main tasks to be performed and the templates needed. Throughout the document, advice to complete successfully these tasks are given in green boxes, important information in red boxes and specific instructions to use the Excel tools in blue boxes. All the updated tools, templates and supporting documents (see list in Appendix A) needed to perform the MRL review will be made available on EFSA website under "Maximum residue levels" in the "Pesticides" section (<http://www.efsa.europa.eu/en/topics/topic/pesticides>).

These instructions are built on the experience gained in the last years and aim to provide clearer advice, define roles and responsibilities between MSs, RMS, EURLs and EFSA and improve transparency with stakeholders. During the whole process, MSs, RMS and EURLs are expected to follow these instructions when receiving the notification by EFSA.

At the basis of the procedure and the timelines, there is the assumption that supporting data are already available at MSs level as the uses are already authorised. It is acknowledged that, especially for very old uses, this might not be always the case. For this reason, during the process MSs can still liaise with national and main authorisation holders. It should be highlighted that EFSA cannot accept documents directly submitted by national/main authorisation holders but only data that have been independently assessed and submitted by MSs.

The timelines are designed to keep the time between the GAP collection and the drafting of the reasoned opinion as short as possible, in order to avoid that new uses and data are notified to EFSA during the consultation on the draft reasoned opinion. Nevertheless, in exceptional cases, extra time can be granted upon request and agreement with EFSA. Any delays from all sides (MSs, RMS or EFSA) should be communicated in order to allow all parties to plan the work accordingly.

This document has been revised on 1st April 2021 to reflect the implementation of the new Regulation on the transparency and sustainability of the EU risk assessment in the food chain (Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019).



(*) MSs and RMS may contact the authorisation holders at this stage

Figure 1: Flowchart of Article 12 review process.



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Step 1	Launch of a new Article 12 review	<u>Actors involved:</u> <ul style="list-style-type: none"> • Stakeholder industry representatives • RMS • EFSA as coordinator
Start of procedure		
<p>Tasks:</p> <ul style="list-style-type: none"> ➤ EFSA to notify to the stakeholder industry representatives the launch of a new Article 12 review. ➤ Interested stakeholder industry representatives to liaise with the RMS. <p>At this first stage, EFSA notifies the RMS and stakeholder industry representatives that a new Article 12 review is initiated in line with the work programme reflected in the most recent progress report (see supporting documents below).</p> <p>How to proceed:</p> <p>Stakeholder industry representatives, including non-EU authorisation holders (distribution list based on contact points received from DG SANTE) are advised to liaise with the RMS in case they wish to support the MRL review for the active substance.</p>		
<p>Supporting documents / tools:</p> <ul style="list-style-type: none"> ✓ Overview of the MRL review progress (also listing the respective RMS for the MRL reviews) under Article 12 of Regulation (EC) No 396/2005, available on EFSA website: www.efsa.europa.eu/sites/default/files/pesticides-MRL-review-progress-report.pdf 		



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Step 2  1 month	Good Agricultural Practices (GAPs) collection	Actors involved: <ul style="list-style-type: none"> • Member States, liaising with their national authorisation holder(s) if needed • RMS, liaising with main authorisation holder(s) • EFSA as coordinator
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Tasks:

- RMS and Member States to upload their national GAPs on the EFSA Document Management System (DMS).
- RMS and Member States to upload GAPs in non-EU countries for which import tolerances (IT) are authorised, after having consulted the main or national authorisation holders.

How to proceed:

- In order to assist MSs as much as possible in this process, EFSA prepared **a form for reporting GAPs** that are authorised in different MSs and countries. The template of the GAP form is available on EFSA website, and the exact name of the active substance to be reported in the GAP form, will be reported in the notification sent by EFSA. MSs should ensure that the name of the active substance is correctly reported without any unintended characters.
- **All national GAPs and ITs** should be compiled in the GAP form and **uploaded on the EFSA DMS by the given deadline**, following the naming convention given below.

- ❖ **RMS and MSs should report** only the GAPs corresponding to the **existing import tolerances** (and not the ones corresponding to existing Codex maximum residue limits (CXLs) adopted/or not yet adopted at EU level).
- ❖ Each **Member State** is responsible for reporting its own GAPs and **only clear GAPs that are reported in this format will be accepted.**
- ❖ This will be the **unique opportunity for MSs to submit GAPs.**

- MSs are also asked to clearly indicate in the GAP form **whether supporting data (residue trials) are available.** On the basis of the information provided, the RMS should be able to identify the most critical GAPs at the step 3 of the procedure.
- MSs are encouraged to follow carefully the **EXCEL GAP FORM instructions** (see blue box, page 7) and any advice described below, in order to submit clear GAPs from the beginning of the procedure, to avoid extending the process (see also **"Tips and tricks on unclear GAPs"** box on page 9).

Which GAPs should be submitted?

- ❖ GAPs currently authorised.
- ❖ GAPs that were **already positively evaluated at national level** and **expected to be authorised along the MRL review process (next 6 months)**, including GAPs that were assessed by EFSA under the Article 10 of Reg. 396/2005 **and recently legally implemented.**
- ❖ Particular attention should be given also to GAPs not recently legally implemented but assessed by EFSA in previous MRL applications. **MSs should check whether those GAPs were finally authorised at national level and be sure that they are submitted in the GAP form.** This will avoid double checking by the RMS at later stage of the procedure.
- ❖ GAPs on genetically modified crops (**tolerant to the active substance under assessment**) and conventional crops should be submitted in two different GAP forms.



Which GAPs should NOT be submitted?

- ❖ New GAPs already under assessment in the framework of Article 10 of Reg. (EC) 396/2005.
- ❖ GAPs as received by the main/national authorisation holder(s) and not reported directly by any MS.
- ❖ GAPs evaluated by the JMPR and corresponding to the existing CXLs.
- ❖ Unclear GAPs (see also "Tips and tricks" box on unclear GAPs, page 9).
- ❖ GAPs authorised according to Article 53 of Regulation (EC) 1107/2009 (emergency uses).

How to take the best advantage of existing zonal assessment?

- ❖ Report in **column W** of the GAP form, information on the zonal RMS (zRMS). The zRMS is responsible for the submission of the residue data for the zone at the step 4 of the procedure (collection of data supporting the critical GAPs).
- ❖ Report in column W of the GAP form whether data are available on CIRCABC, including a **reachable reference (e.g. link to CIRCABC)**, allowing the RMS to access and verify the data when preparing the GAP overview file.

How to simplify the identification of the most critical GAPs by the RMS at a later stage?

- ❖ **Complete the general section of the form** (i.e. country, active substance variant and type of crop).
- ❖ MSs to perform a **pre-screening of the authorised uses**, identifying the most critical GAPs and **submitting a limited number of GAPs** (if possible, a **maximum of 2-3 GAPs per crop for a geographical zone** should be submitted). This will simplify (significantly) not only the work of the RMS for the identification of the critical GAPs but also the collection of the data supporting the most critical GAP at the next step of the process.
- ❖ Make sure that **all GAPs reported** in the GAP form **are clearly reported**, meaning that all mandatory fields as listed in the "EXCEL GAP FORM instructions" (see blue box, page 7) are filled. In the GAP form, the macro button called "**validate entries**" should allow identifying any potential issues. Using this macro until having the confirmation that all GAPs are considered clear is therefore advised.
- ❖ **Do not report crops not listed into the menu of the GAP form.** If the residues in the plant commodity are linked to cross-contamination from a different use (e.g. wild fungi from use on forestry), report wild fungi as a crop and not forestry and **make use of the comment field of the GAP form** to provide the information that the residues in fungi are linked to the use on forestry. Similarly, in case the use reported is on a minor crop not listed in the dropdown menu, the MS has to select the corresponding major crop and report in the comment field of the GAP form the minor crop to which the use refers.
- ❖ **Do not report modes of applications not listed into the menu of the GAP form.** In case the application method is not listed in the dropdown menu of the GAP form, **make use of the comment field of the GAP form** to report any additional information.
- ❖ For crops on which **French GAPs** can be supported indifferently with either northern and southern residue trials, France is asked to include in the **column W** "Comment on availability of supporting data?" whether the GAP should be considered as authorised in **NEU and/or SEU**.

Supporting documents / tools:

- ✓ Template for GAPs reporting form (so called "GAP form" or "Excel GAP form"), available on [EFSA website](#) (naming convention: yyyyymmdd_[MS]_GAP_form_[active_substance].xls)



EXCEL GAP FORM instructions

(STEP 2)

Adding and deleting rows

Rows can be added using the designated button at the bottom of the GAP table. This action can be repeated as many times as needed. However, only empty rows can be deleted (also using the designated button). Hence, if the user wishes to delete rows, cell contents will have to be deleted first.

Mandatory fields

When reporting GAPs, some mandatory fields are considered by EFSA (these parameters are highlighted in a darker colour):

- *Crop common name*
- *Indoor / outdoor*
- *Application method*
- *Maximum number of applications*
- *Maximum application rate*
- *Application rate unit*
- *PHI (unless the latest growth stage at application is sufficiently specified). The absence of PHI is generally only considered acceptable if the last application is done before that the edible part is formed and therefore the BBCH at application is:*
 - *≤ BBCH 16 for leafy crops (including head and flowering brassica, stems, hops, tea, flower and herbal infusions, forage, sugar cane)*
 - *≤ BBCH 19 for root crops (including root spices, rhizome, sugar and fodder beet, chicory roots)*
 - *≤ BBCH 51 for cereals and bud/flower/aryl species*
 - *≤ BBCH 65 for the other crops*

For particular authorised GAPs, deviation from this BBCH principles might be possible and the absence of PHI when the application is done after the edible part is formed might be acceptable. In such cases, the MS must indicate, in the comment field of the GAP (**column V** of the GAP form), the justification for the deviation and the reasons to consider the GAP as clear.

Drop-down menus and associated search functions

Several fields of the GAP form are subject to drop-down menus. Nevertheless, in order to facilitate usability of this form, EFSA developed a search function for three fields:

- *Crop common name*
- *Application method*
- *Application rate unit*

This functionality allows users to ignore the drop-down menu by typing in only a part of the entry. And if the user inserts several words, the form is also able to search for the best matching entry. Here are a few examples of how this functionality can be applied.

Crop common name:

- If the user types 'app', the form will automatically return the full crop name 'Apples'.
- If the user inserts 'dry pea', the form will automatically return 'Peas (dry)'.
- If the user inserts 'tab gra', the form will automatically return 'Table grapes'.

Application method:

- If the user inserts 'foli broad', the form will automatically return 'Foliar treatment - broadcast spraying'.

Application rate unit:

- If the user inserts 'kg ha', the form will automatically return 'kg a.i./ha'.
- If the user inserts 'g kg', the form will automatically return 'g a.i./100 kg'.



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However, the functionality is not always able to find a unique match, or the user may not insert enough information to retrieve a matching entry. In that case the user will receive a message advising him to use the drop-down menu.

Validation of the entries

After the GAPs have been inserted, users can verify whether all mandatory fields have been completed (using the designated button at the bottom of the GAP table). It is highly recommended that each MS validates the GAPs in the GAP form in order to identify GAPs not clearly reported and try to report them in the best clear way, adding comments if needed to make the RMS aware of some relevant considerations.

When using this functionality, your GAPs will also be validated against the following criteria:

- **Post-harvest applications are to be considered as indoor GAPs.**
- Although **seed treatments** should be performed under indoor conditions, if the treated seeds are sown outdoor, the GAP should be reported as an outdoor use. For this reason, when a seed treatment is reported as indoor by the MS, the tool will highlight this as an inconsistency inviting the user to check whether the treated seed are really sown indoor. In case this is confirmed, the MS should include in **column W** the information that the GAP is confirmed as indoor.

Following this validation, potential issues will be highlighted in orange and users will be recommended to verify whether those entries are correct.



Tips and tricks on unclear GAPs

When one of the relevant GAP parameters (*Mandatory fields*) are missing in the GAP form, the GAP is flagged by the validation tool as **unclear**.

MSs should be aware that it is not possible to consider “unclear” GAPs in the MRL review exercise. Therefore, those **GAPs considered ‘unclear’ will be disregarded** by the RMS when preparing the GAP overview file and **there will be no further opportunity neither to clarify nor to submit new GAPs.** Nevertheless, the RMS can still decide to ask for clarification to MSs while compiling the GAP overview file (see step 3(a)), in case any doubts remain.


For this reason and to avoid extending the process, MSs should try to clarify their GAPs as much as possible before submitting to the RMS.

In order to support MSs, EFSA reported below few tips on **how to ‘clarify’ unclear GAPs:**

- ❖ Liaise with your national authorisation holder.
- ❖ Make use of the comment field of the GAP form (**column V** of the GAP form) to insert specific information on the authorised use and to provide any additional information clarifying why the missing GAP parameters are not needed and the GAP should be considered clear (keeping in mind that a no residue situation is not a sufficient reason to consider the GAP as clear).
- ❖ Check the residue trials considered at national level when authorising the use, as they might provide useful information on the missing GAP parameters.
- ❖ Try to translate as much as possible the information in the comment field into the missing GAP parameters (e.g. if in the comment field it is reported that application is done before flowering, a BBCH of 59 can be reported as growth stage at last treatment).
- ❖ In case you are dealing with **post-harvest treatment**, although a PHI is not considered relevant, a withholding period (WHP) should be reported in the GAP form under the column of the PHI. If the WHP is not defined in the GAP, the minimum interval possible (1 day) can be included in the GAP table, assuming that the treated crop is placed immediately on the market.
- ❖ If, according to the information in the comment field, you are dealing with application done after harvest during **dormancy** (as it might be for asparagus or strawberries), an indicative PHI of >100 can be included in the form, making clear in the comment field of the GAP table (**column V**) that the PHI is only indicative. This will allow the macro “automatic outcome” to work at the next step of the procedure.



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<p>Step 3 (a)</p> <p> 6 weeks</p>	<p>Identification of critical GAPs</p> <p>Compilation and submission of the GAP overview file by the RMS</p>	<p><u>Actors involved:</u></p> <ul style="list-style-type: none"> • RMS, liaising with main authorisation holder(s), if needed • EFSA supporting the RMS
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Task:

- RMS to identify the critical GAPs.

Once the collection of GAPs period with MSs for the active substance has been closed, the RMS is invited to compile all the GAPs submitted by the MSs and the import tolerances, and to identify the most critical GAPs. For this step, EFSA developed an Excel tool (namely the "**GAP overview file**") mainly designed to support the RMS in the identification of the most critical GAPs and the collection of the data at the next step of the procedure (see step 4).

It is highlighted that, at this step of the procedure, EFSA has the role to coordinate and support the RMS but the GAP grouping and the identification of the most critical uses is considered responsibility of the RMS.

How to proceed:

- EFSA informs the RMS on MSs that have reported their GAPs, and on MSs that have no authorised uses for the active substance, providing the link to the EFSA DMS folder where the GAPs forms are available.
- The RMS has to import and **collect all GAPs** reported by MSs via separate GAP forms, **into the GAP overview file** and **identify the most critical GAPs** for each crop and for each zone.
- To do so, the RMS is encouraged to follow carefully the **EXCEL GAP OVERVIEW FILE instructions** (see blue box, page 13) and **any advice described below**, in order to take the best advantage of the tool.
- RMS is asked to upload the compiled **GAP overview file** onto the EFSA DMS by the given deadline, following instructions and naming convention given.

Specific case of no uses authorised in Europe:

When, at the end of the GAPs collection, it is confirmed that no authorised uses were reported by Member States, RMS is requested to confirm whether import tolerances are currently authorised for the active substance under review.

- **If import tolerances are not** currently in place: there is no need to prepare the GAP overview file. Unless, differently agreed with risk managers, the RMS can proceed in preparing an evaluation report addressing residue definitions and analytical methods for enforcement (in plant and animal commodities) against illegal uses (see step 5). RMS is kindly requested to inform EFSA as soon as possible, in order to go ahead with the procedure.
- **If import tolerances are currently in place:** they should be compiled in the GAP overview file and the availability of supporting residue trials should also be verified.



How to deal with GAPs authorised in France?

- ❖ For the specific case of the GAPs reported by France, the GAPs that are mentioned as "N or S" in the European MRL guidance (SANCO 7525/VI/95 Rev.10.3) are by default reported both in the NEU and SEU in the GAP overview file. In order to avoid overreporting in the PROfile, the user still needs to **manually define** for which zone the GAP is relevant, using the **column W of the GAP overview file ("GAP relevant")**. The information whether the GAP should be considered as authorised in NEU or SEU as reported by France during the GAP collection, will be available under column AB "Other considerations" of the GAP overview file.

How to make the best use of the GAP overview file?

- ❖ Before reporting the GAP forms in the **GAP overview file**, please read and follow the **user instructions** carefully (see blue box, page 13).
- ❖ Import the GAPs from the individual GAP forms. When GAPs are imported, the tool performs some preliminary compatibility checks of the files, disaggregation of French GAPs, outdoor/indoor GAPs and crop groups, identification of French GAPs that need confirmation (north vs south, see also the specific point above) and identification of critical parameters that were not reported by MSs.
- ❖ GAPs for **import tolerances** should be reported in the **same GAP overview file** with the uses authorised in EU.
- ❖ GAPs on **genetically modified crops (tolerant to the active substance under assessment)** and **conventional crops** should be collected in **two different GAP overview files**.
- ❖ Only GAP forms **submitted by the MSs** should be considered in the GAP overview file. If additional GAPs that were not submitted by any MS are reported by the main authorisation holder, the RMS can verify with the relevant MSs the information provided by the authorisation holder and update the GAP overview file with the additional GAPs if confirmed by the MS.
- ❖ The RMS shall **not delete any GAP** reported by MSs in the GAP form, even if they are not clearly reported.
- ❖ RMS can still modify the GAPs reported by MSs if modifications are aimed to allow comparison among GAPs or to clarify the GAPs according to the information already available in the comment field of the GAP form. Nevertheless, in these cases the information that the GAP (e.g. unit of the application rate) has been modified should be reported in the column AB ("other considerations") of the GAP for transparency.
- ❖ Run macro **"validate entries" and make sure that no issues are identified by the tool** before running the **"automatic outcome"**.
- ❖ Before confirming that the **GAP is unclear**, the RMS has to verify whether information in the comment field of the GAP table and in column AB "other considerations" allow to clarify the conditions of use (**see also the box "Tips and tricks on unclear GAPs"**, page 9).
- ❖ There is **no need to report the GAP grouping and the data availability** (columns Y and Z) for the **unclear GAPs**. As highlighted at the first step of the procedure, unclear GAPs will not be considered further in the assessment.
- ❖ In order to allow the macro **"automatic outcome"** to work properly, **columns W, X, Y and Z** of the EFSA tool should be **completed** by the RMS. More details on how to fill these columns are provided in the **EXCEL GAP OVERVIEW FILE instructions** available in the blue box below (page 13).
- ❖ When **verifying the data availability**, the RMS is kindly requested to check not only the data considered in previous EFSA assessments and during the peer review, but also the data available in its **own national dossier** and **internal databases**, as well as in the **re-registration reports** or in the **zonal assessments** mentioned by the MSs as available on **CIRCABC**.
- ❖ **Checking and looking at the data will simplify the identification of the most critical GAPs and will also avoid asking (and receiving) a lot of data at the next step of the procedure.** The objective of this exercise is to identify (and ask for) only the trials that are really needed.
- ❖ **Data** available in the **JMPR** reports and evaluations **cannot be considered** to support **EU existing uses** and **import tolerances in place**.
- ❖ The information in columns Z and AB should be consistently reported (e.g. if according to column Z no data are available, it should not be reported in column AB that trials are available).



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The RMS is requested **to fill columns W, X, Y and Z as highlighted in the instructions**. On the other hand, in case the most critical GAP is supported by data and a possible fall-back supported by data is identified for each geographical zone, **it is not mandatory for the RMS to fill columns Y and Z** (GAP grouping and data availability) for the less critical GAPs (from rank 3 onwards). Nevertheless, **this should be flagged by the RMS in the e-mail notifying the submission of the GAP overview file**.

- RMS should **contact EFSA** during the preparation of the GAP overview file, in case any support in the compilation of the GAPs in the overview file is needed.
- RMS can decide to **contact the MSs** during the preparation of the GAP overview file, in case of any doubts on the GAPs submitted, or of any missing information that could help the ranking.

Supporting documents / tools:

- ✓ GAP forms received from MSs, uploaded on EFSA DMS
- ✓ Template of the GAP overview file, available on [EFSA website](#)
(naming convention: yyyyymmdd_GAP_overview_[active_substance].xls)



EXCEL GAP OVERVIEW FILE instructions

(STEP 3)

The GAP overview file is a single overview table of the national GAPs and import tolerances reported by MSs together with indication of the availability of supporting residues data. It is considered a supporting document produced by the RMS, with EFSA advice if needed, in order to support the identification of the critical GAPs that are retained for further consideration in the MRL review and to facilitate preparation of the ER and PROFile.

The main features of the EFSA tool include the following:

- Possibility to **manually add, delete and sort the data** (including filtering options). When GAPs are inserted/modified manually, the tool also verifies validity of the crop (no crop groups, e.g. pome fruits, allowed in this file) and validity of the different region, country and indoor/outdoor combinations to avoid inconsistencies in those data.
- **Validation of the entries** inserted by the assessor. This includes checking the following: (1) a GAP can only be reported as 'not relevant' for minor crops in France, (2) a GAP should not be reported as clear if essential GAP parameters are missing, (3) there is no need to conclude on GAP grouping and data availability for unclear GAPs.
- **Units** of the application rate are automatically **harmonised** in the overview file once GAPs are imported.
- **Automatic outcome:** for each GAP, according to the information reported, an automatic standard phrasing is generated to highlight whether the GAP is retained for assessment or whether MSs shall provide residue trials if available. For each crop and for each geographical zone, based on the data availability and the GAP grouping reported, **the tool will flag one GAP to be retained for assessment and one possible fall-back GAP** to be considered in case a risk for consumers is identified for the most critical GAP.

This form is intended to:

- (1) import and collect in one single document all the Good Agricultural Practices (GAPs), which were reported by MSs through separate "GAP forms", for a given active substance and crop type;
- (2) identify the most critical GAPs for each crop and for each geographical zone or import tolerance to be retained for the MRL review assessment;
- (3) identify the GAPs for which residue trials data should be provided by MSs in the framework of the review of Maximum Residue Levels (MRLs) under Article 12 of Regulation (EC) N° 396/2005.

General user instructions:

- First, make sure to complete the general data.
- Please note, that in order to run correctly the automatic macro, columns W, X, Y, Z should be properly completed.
- RMS is encouraged to run the "Validate entries" macro in order to verify the consistency of the data reported. Any issues notified should be solved before going further.
- Once all columns are consistently completed and data validated, the "Automatic outcome" macro can be run, to propose an outcome for each GAP.
- After the data collection, the RMS shall update the GAP overview file with the information of the data availability in order to identify the critical GAPs that should be exported to PROFile and retained for the assessment. EFSA is currently developing a new tool that will allow to export the GAP table from the GAP overview file to the PROFile. As this tool will run properly only if the GAP overview file is updated, the RMS is strongly recommended to update the GAP overview file (with information on the data availability and adjusting the ranking) after the data collection. In any case, this update is considered a good practice as the GAP overview file is a supporting document to the assessment and will be published together with the reasoned opinion.



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Collecting all the GAP forms

During the first phase of the completeness check, each MS provided at least one "GAP form.xls" (one for each "active substance/ type (conventional or GM) of crops") where their national authorisations or import tolerances are reported, if applicable. The user (RMS) is encouraged to save all these documents in one single folder, together with the GAP overview file.

For each MS, the information included in a "GAP form" can be automatically imported into the GAP overview file using the button "Import GAP" (in the worksheet Overview_GAP). When pressing this button, the user is invited to open the GAP form of interest. By default, the folder where the present document is saved will be displayed and the user can select the "GAP form" of interest. This action should be repeated for each "GAP form" that the user wishes to import in the present GAP overview file.

Although all GAPs should in principle be imported from the "GAP forms" from all Members States as mentioned above, the user can still add a GAP manually using the button "Add GAPs manually".

In order to ensure comparability of GAPs, which may have been reported either for a specific crop or for a crop group, all GAPs reported for a crop group are automatically disaggregated to the individual crops when importing the data.

Region (column D)

Based on the name of the MS, the present tool is able to identify the zone (NEU/SEU) where the GAP is authorised. Therefore, this column is completed automatically when importing the GAPs.

For the specific case of the GAPs reported by France (which may be relevant in NEU and/or SEU depending on the crop under consideration), the tool also integrates the specific rules as defined in the current guidance. The GAPs that are mentioned as "N or S" in this guidance are by default reported in the NEU and SEU in the present overview. However, the user (RMS) still has the possibility to manually define in which zone the GAP is relevant, using the column W (see below). Actually, the RMS is kindly invited to check the relevance of the French GAPs in NEU, SEU or both zones.

Similarly, when a GAP is added manually, the entries for region and country are checked against the same criteria. The user will receive an error message in case the entries are not consistent.

GAP relevant (column W)

This column must be completed by Y (yes) or N (no) and is mainly foreseen to address the issue of the French GAPs (as mentioned above). This column is completed by default when importing the GAPs, except for the French GAPs that might be authorised in either NEU or SEU. If the user (RMS) makes inappropriate changes (e.g. stating that a northern GAP is not relevant for a northern MS other than France), this will be highlighted during the validation of the entries (see validation step below). This column can be also used in case a GAP received is considered not relevant for a particular reason (e.g. foliar treatment with an herbicide at the emergence of the weeds, after harvest of an annual crop, see the example of the [GAP overview file on glyphosate](#)). Nevertheless, in these cases additional information clarifying why the GAP has to be considered as not relevant should be included in column AB (other considerations).

GAP clear (column X)

This column is automatically completed by Y (yes) or N (no) when importing the GAPs. If essential GAP parameters are missing, the cell is marked with a "N" and the missing parameters are highlighted in orange. If the user (RMS) is able to find those missing parameters (e.g. in the comment field or checking with MS if needed), column X can still be modified accordingly. According to EFSA these are the essential GAP parameters:

- (1) Crop common name
- (2) Indoor / outdoor
- (3) Application method
- (4) Maximum number of applications
- (5) Maximum application rate
- (6) Application rate unit



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(7) PHI (unless the latest growth stage at application is sufficiently specified). The absence of PHI is generally only considered acceptable if the last application is done before the edible part is formed and therefore the BBCH at application is:

- \leq BBCH 16 for leafy crops (including head and flowering brassica, stems, hops, tea, flower and herbal infusions, forage, sugar cane)
- \leq BBCH 19 for root crops (including root spices, rhizome, sugar and fodder beet, chicory roots)
- \leq BBCH 51 for cereals and bud/flower/aryl species
- \leq BBCH 65 for the other crops

Other inconsistencies may be identified if these principles are not followed:

- (1) Post-harvest applications are to be considered as indoor GAPs.
- (2) Although seed treatments should be performed under indoor conditions, if the treated seeds are sown outdoor, the GAP should be reported as an outdoor use. For this reason, when a seed treatment is reported as indoor by the MS, the tool will highlight this as an inconsistency inviting the user to check whether the treated seed are really sown indoor. The confirmation that the GAP should be considered indoor, will appear in column AB.

See also instructions for the GAP form (blue box, step2).

In specific cases, deviations from these essential parameters might be acceptable. Therefore, if the RMS considers the GAP as clear (even though there is a deviation from the essential parameters, e.g. PHI or BBCH not needed), it is required to justify the reason why, entering a comment in column AB. Then, when running the "automatic outcome", it will be possible for the RMS to modify manually the outcome of the tool and to consider this particular GAP for the assessment, if relevant.

Sort GAPs

To have a more user-friendly view, EFSA recommends running the macro "sort GAPs" before performing the GAP grouping as the tool will automatically sort the rows according the following criteria (in order of importance):

- (1) crop code
- (2) region: NEU/SEU/EU
- (3) maximum application rate
- (4) mode of application, the tool follows this logical order (from more to less critical): post-harvest, foliar, soil and seed treatment.

It is highlighted that the tool will not group nor rank the GAPs, as this is the responsibility of the user (RMS). However, once the RMS has grouped the GAPs (see below), it has the possibility to run again the macro "sort GAPs" and, for a given crop and zone, the tool will sort the rows following the GAP ranking reported by the RMS (from the most critical (1) to less critical (2, 3, etc)). In this regard, it is important to bear in mind that the ranking established by the user will always prevail over the automatic sort done by the tool.

GAP grouping (column Y)

These cells should be completed manually by the user (RMS) and, ideally, after having checked the available data. For each crop/zone, the objective is to sort the available GAPs from the most critical (1) to the less critical ones (2, 3, 4 and more). This will allow identifying the critical GAPs with the number 1 and the possible fall-back GAPs (if any) with succeeding numbers.

As a matter of consistency, the user (RMS) should not attribute a GAP grouping to the GAPs that are "not relevant" and/or "not clear". This point is checked when using the button validate entries (see validation step below).

If two GAPs have slightly different parameters but are considered similar by user, they should be marked with the same group code. However, if multiple parameters are diverging and in the absence of the data, the user cannot identify the most critical GAP, the group code should start with the same number, but a distinction should be made using a letter as follows: 1a, 1b... In any case, the less critical GAPs (group code starting from 2 onwards) should not be deleted.



Data available (column Z)

These cells should be completed manually by the user (RMS). For each GAP group, the objective is to clarify whether residue data are available to derive an MRL. It is the responsibility of the RMS to check the availability of trials supporting the GAPs reported by MSs by looking not only at the data considered in previous EFSA assessments and during the peer review, but also at data available in its own national dossier and internal databases, as well as in the re-registration reports or in the zonal assessments mentioned by the MSs as available on CIRCABC. In this column it should be reported 'Y' only in case the data are already accessible to the RMS. The aim is to invite MSs to provide further data during the next step of the completeness check only if GAPs are not (sufficiently) supported by data. In case this field is empty, the tool will automatically assume that no data are available to support the GAP.

The RMS is asked to fill columns W, X, Y and Z. On the other hand, in case the most critical GAP is supported by data and a possible fall-back is identified (and also supported by data) for each geographical zone, it is not mandatory for the RMS to fill columns Y and Z (GAP grouping and data availability) for the less critical GAPs (from rank 3 onwards).

Other considerations (column AB)

In these cells the information on the data availability as reported by the MSs under column W of the GAP form, are directly transferred when importing the GAPs. Filling this field is not mandatory and can be used by the RMS to add any considerations that might be useful, such as the source and the number of trials available (e.g. "3 trials compliant with GAP available in the RAR or GAP assessed by EFSA in an MRL application).

Concise and full view

At any step of the procedure, to have a more user-friendly view, the user (RMS) has the possibility to click on the button "concise view" and the tool will show only the essential GAP parameters (as defined above), together with the columns W, X, Y, Z and the outcome. To return to see all GAP parameters, the user can click on the button "full view". The user has the possibility to switch between full and concise view as many times as needed at any step of the procedure.

Validate entries

At each step of the procedure, the user (RMS) also has the possibility to run the macro "validate entries". This is an automatic tool to check whether the entries are sufficiently clear and consistent. The use of this macro is highly recommended, as this will alert the RMS not only about unclear GAPs, but also on inconsistencies in columns "W-Z").

When using this functionality, the GAPs will be validated as follows:

- (1) Essential GAP parameters that are still missing and the corresponding cell(s) in column X are highlighted in orange.
- (2) If "GAP groupings" are proposed (in column Y) for GAPs that are marked as "not clear" (in column X), the corresponding cells are highlighted in orange.
- (3) If data are reported as available (column Z) for GAPs that are marked as "not clear" (in column X), the corresponding cells are highlighted in orange.
- (4) If GAPs are reported as "not relevant" (in column W) for another MS than France, the corresponding cells are highlighted in orange.
- (5) In case GAPs are introduced manually by the RMS, inconsistencies in the GAP parameters are also highlighted in orange by this functionality.
- (6) Overall, this functionality will give the view, at a glance, of all inconsistencies present in the GAPs and that should be amended before running the automatic outcome.

In any case, a specific message is displayed to inform the user about potential issues identified. However, modifications are never done automatically when running this macro.



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It should be kept in mind that the GAP ranking is the responsibility of the RMS and the functionality "validate entries" will not alert about an inconsistency in the order of ranking (e.g. a GAP grouped as 1 while it should be 2).

Automatic outcome


When columns W, X, Y, Z are appropriately filled by the user (RMS) for all GAPs, the user should run the macro "automatic outcome". This macro is designed to automatically propose an outcome in column AA for each single GAP. If columns W, X, Y, Z were fulfilled in a consistent manner, the macro is able to propose an outcome for all GAPs.

In case of inconsistencies however, the macro will display a specific message to invite the user to solve the issues. Different error message may pop up depending on the type of error. In those cases, the user (RMS) is invited to solve the error himself or with the support of EFSA, if needed. If the user decides to proceed without solving the inconsistencies, the macro will not propose the outcome automatically. For GAPs where inconsistencies are identified, the column AA will be then fulfilled by the standard wording "please fix the issue first". Therefore, it is strongly recommended to follow the instructions of any eventual error message until all inconsistencies are fixed. It will allow making sure that all entries are consistent and allow automatic filling of column AA for all GAPs.

In specific cases (see "GAP clear – column X"), the user (RMS) still has the possibility to modify manually the automatic outcome proposed by the tool in order to consider/retain for assessment particular GAPs, if relevant.



PESTICIDE RESIDUES UNIT

Step 3 (b)  2 weeks	Identification of critical GAPs Validation by EFSA of the GAP overview file and final agreement	Actors involved: <ul style="list-style-type: none"> • EFSA validating the GAP overview file • RMS
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Tasks:

- EFSA to check the GAP overview file and liaise with RMS in case modification is required.
- EFSA and RMS to agree on the GAP overview file to be circulated for the next step of the procedure.

Once the period for the RMS to identify the critical GAPs for the active substance has been closed, EFSA checks and confirms within one week from the receipt of the GAP overview file, whether changes are required in the overview file or the current version can be considered the final one to be shared with MSs.

EFSA relies on the information as provided by the RMS in columns W to Z when performing the validation of the GAP overview file. When the GAP overview file is submitted with columns W, X, Y and Z not filled in, it is not possible for EFSA to validate the file without going back to the RMS, prolonging significantly the procedure.

For this reason, **EFSA will not accept GAP overview file with columns W, X, Y and Z not filled in**, unless a clear justification was provided by the RMS when notifying the submission of the file. In case an incomplete GAP overview file is received at the deadline, the RMS will be given 3 working days to complete and re-submit the file. RMS should ask support to EFSA at any time during the preparation of the GAP overview file to avoid submitting an uncomplete file.

How to proceed:

- **If no modifications are needed**, EFSA informs the RMS that the file is ready to be circulated to MSs for the next step of the procedure.
- **If modifications are needed**, EFSA revises the GAP overview file providing two versions:
 - a version where the modifications with respect to the original version submitted by the RMS are reported in red, and explanations are provided in an extra column of the GAP overview file for RMS consideration.
 - a clean version ready to be circulated to MSs, in case the RMS agrees with all the modifications proposed.

EFSA shares these two versions of the GAP overview file with the RMS for agreement, together with a request to provide a **feedback within 5 working days**; and the **e-mail of the EFSA MRL colleague** responsible for the GAP overview file.

- ➔ In case of any doubts on the comments provided, **RMS can contact directly the EFSA MRL colleague** responsible for this GAP overview file.



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Why EFSA validates the GAP overview file?

- ❖ To verify that a complete file is shared with MSs for the next step of the procedure.
- ❖ To verify that the file was properly used and the right message is included in the column "outcome".

What EFSA checks when a GAP overview file is received?

- ❖ Completeness of the file.
- ❖ Correctness of the "outcome" on the basis of the information reported.

What EFSA does NOT check when a GAP overview file is received?

- ❖ GAP grouping. As highlighted at the previous step, EFSA has the role of coordinating and supporting the RMS, but the GAP grouping and the identification of the most critical uses is considered falling under the responsibility of the RMS.


Once the GAP overview file is agreed upon, MSs will be requested in the next step (step 4) to upload data supporting the critical GAPs.

Supporting documents / tools:

- ✓ Excel GAP overview file (one file including EFSA feedback and modification proposals + one "clean" version of the file, ready to be shared), uploaded on EFSA DMS.



PESTICIDE RESIDUES UNIT

 Step 4 1 month	Collection of data supporting the critical GAPs	<u>Actors involved:</u> <ul style="list-style-type: none"> • Member States, liaising with their national authorisation holder(s) if needed • RMS • EFSA as coordinator • EURLs
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Tasks:

- Member States to check the GAP overview file and upload the data requested to support the critical GAPs.
- EURLs to upload their evaluation report on the availability of analytical methods for enforcement.

Once the RMS has compiled all GAPs reported by MSs and ITs into the GAP overview file, identified the most critical GAPs for each crop and the GAP overview file is agreed upon, MSs are requested to check whether they have to provide data supporting the critical GAPs.

This step is the unique opportunity to provide the required residue trials/supporting data to the RMS and EFSA. EFSA will no longer accept additional data on residue trials at a later stage of the MRL review.

It is expected that **MSs already have the data at their level** as the requested data support uses that are already authorised. However, if needed, it is still possible in this step for MSs to liaise with their national authorisation holders.

EFSA will only accept data which have been independently evaluated by MSs. This means that the **data supporting the critical GAPs should be reported by means of a detailed evaluation report (ER)** and that EFSA will not evaluate raw studies provided by main/national authorisation holders.

Member States should be aware that **the evaluation reports provided in the framework of the MRL review will be published as received by the Member States on EFSA website as a main supporting document** to EFSA's reasoned opinion.

- **See framework on the publication of evaluation reports, page 25.**

How to proceed:

- MSs are invited to go through the GAP overview file ("GAP overview" Excel spreadsheet) and to provide the requested information (i.e. **residue trials to support the critical GAPs**), as specified in the corresponding columns of the GAP overview file, **in the form of a detailed ER**.
- If a GAP of a MS is not retained for assessment (because covered by a more critical GAP of another MS), no residue trials are in principle needed from the MSs. **Nevertheless, this does not prevent a MS to submit residue trials to support its GAP, if considered more critical than the one identified by the RMS.** In this case, the MS can contact the RMS and provide the data supporting the concerned GAP. This information can be then considered by the RMS when revising the GAP overview file at the next step of the procedure.
- At this stage, **additional studies supporting the national authorisations** (e.g. **analytical methods, metabolism studies, storage stability studies, studies on nature and magnitude of residues in processed commodities, feeding studies...**) not submitted during the peer review or in the framework of previous MRL applications, or not already available on CIRCABC can also be submitted by MSs in the detailed ER.



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- The **zRMS is responsible** for submitting the residue data **for the zone** in an ER.
- The **templates for the evaluation report** to report the required supporting data and analytical methods is available on EFSA website. MSs and EURLs are requested to upload their evaluation report on EFSA DMS, following instructions and naming convention given.

Supporting documents / tools:

- ✓ Excel GAP overview file, compiled by RMS and agreed upon with EFSA
- ✓ Template for Member States evaluation report, available on [EFSA website](#)
(naming convention: yyyyymmdd_[MS]_additional_data_[active_substance].doc)
- ✓ Template for EURLs evaluation report, available on [EFSA website](#)
(naming convention: yyyyymmdd_EURLs_analytical_methods_[active_substance].doc)



PESTICIDE RESIDUES UNIT

 Step 5 2 months	Preparation and submission of the evaluation report and PROFile	<u>Actors involved:</u> <ul style="list-style-type: none"> RMS, liaising with main authorisation holder(s), if needed
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Tasks:

- RMS to prepare and submit an updated version of the GAP overview file, the evaluation report, the PRIMo file (not mandatory) and the PROFile to EFSA.

Once the period for collection of residue trials and supporting data with MSs is closed, the RMS is kindly requested to update the **GAP overview file** as the basis to prepare the PROFile and the evaluation report.

How to proceed:

- EFSA informs the RMS about MSs that have reported additional data, as well as about the availability of the EURLs evaluation report on the analytical methods, providing the link to the EFSA DMS folder where the evaluation reports are available.
- On the basis of all available information, the RMS is expected to **update the GAP overview file, prepare the PROFile and the supporting evaluation report.**
- The evaluation report should be drafted following the template provided and should cover all data available to support the most critical GAPs. Considering that following the completeness check, the original risk assessment is often amended by EFSA, the RMS might decide not to perform the risk assessment and not to submit the PRIMo, in case they have shortage of resources.
- RMS is asked to submit the evaluation report, PROFile and the updated GAP overview file by uploading the files on the EFSA DMS, following instructions and naming convention given.
- As the PROFile contains already the calculators for the MRLs in plants and in animals and for the dietary burdens, there is **no need for the RMS to submit these calculators separately.**

What is the PROFile?

- ❖ The Pesticide Residues Overview File (PROFile) is an **Excel file** that was designed by EFSA for collecting and **processing pesticide residue data into a database.**
- ❖ The PROFile has been developed **to support the RMS** and it should be considered the basis for drafting the evaluation report. The main reason being that it contains the **OECD calculators** used to **derive the MRLs in plant**, the **livestock dietary burden** and the **MRLs for livestock**, including all **default processing factors** applied for the calculation of the dietary burdens. **This allows the RMS to derive the MRLs for plant and livestock by using one single Excel file** and not several calculators.
- ❖ The PROFile allows the **identification of the more critical GAP** among geographical zones, and a **fall-back GAP** in case a risk for consumers is identified for the most critical use. Furthermore, if after the MRL review, the conditions of use are modified (e.g. uses are restricted to indoor applications only) or lower toxicological reference values are derived, the PROFile is very useful to identify fall-back GAPs, **allowing the risk managers to take a quick action** without necessarily lowering the MRL to the LOQ.
- ❖ Overall PROFile helps to have the full picture of the **studies available** and the **data gaps** (metabolism, analytical methods, stability, residue trials...) and should be seen as the **"residue identity card"** for the substance, where all the relevant residue data is compiled. In view of having the data as much as possible structured as database, the PROFile is the reference file where **all end points for the residue section are available in an Excel format.**



What to do before starting to prepare the PROFile?

- ❖ As the basis of the preparation of the PROFile and the ER, RMS is advised **to update the GAP overview file**, in particular by mentioning the additional data received and updating column AB (“Other considerations”) as appropriate (e.g. reporting the reference of the evaluation report where the additional studies were made available) and by modifying the GAP grouping when needed. This is expected to support the RMS in having a clear view on what has been received by MSs and **which are the most critical GAPs to be considered** in the assessment. This is particularly relevant for the future, as a new tool is currently under development allowing the RMS to export automatically the GAP table from the GAP overview file to the PROFile. To ensure that the critical GAPs to be retained for the assessment are properly exported by the new tool to the PROFile, the GAP overview file must be updated after the data collection.

What to take into consideration when preparing the PROFile and the evaluation report?

- ❖ When preparing the **PROFile (3.0)**, the RMS is invited to follow the **instructions** as detailed in the **PROFile (3.0) user guide** available on EFSA website.
- ❖ The GAPs that should be considered for the assessment, and therefore that should be included in the **PROFile**, are the **more critical GAPs** that are **supported by data** (when available). This means that in **some cases**, the **GAP** that is **finally considered** in the assessment **is not necessarily the most critical GAP** currently authorised for a crop. For this reason, it is **important to update and make available** together with the final output the **GAP overview file**.
- ❖ When filling the **comment** field of the **PROFile** for **the residue trials**, the RMS can use the “**standard sentences**” file as developed by EFSA and that will be sent by e-mail.
- ❖ In case the RMS wishes to **merge northern and southern datasets** to derive MRL and risk assessment values, the residue trial for each zone should be still **reported separately** in the PROFile (see PROFile (3.0) user guide for any further details).
- ❖ The **RMS** is invited to check the evaluation reports submitted by MSs and **compile in the evaluation report the summaries of the trials used to support the most critical GAPs**, even if already reported in an evaluation report submitted by another MS.
- ❖ The **RMS is not required to re-assess** studies that were already evaluated and submitted by other MSs, but it is kindly requested to copy and paste in the evaluation report the **studies/trials summaries** submitted by other MSs in the frame of the Art. 12 MRL review.
- ❖ **Re-registration reports and zonal assessments cannot be published as such and are not referenceable**. Therefore, the **summaries** of the studies/trials included in these reports and used to support the most critical GAPs should be **copied and pasted** by the RMS in the **evaluation report** submitted with the PROFile.
- ❖ The **RMS is invited to check whether additional data not submitted by MSs were made available by the main authorisation holder(s)** at the previous steps of the procedure and assess them in the evaluation report to be submitted with the PROFile. This is mainly intended for data other than the residue trials, that should be in principle already available at level of the MS that authorised the use.
- ❖ **Data** available in the **JMPR reports and evaluation** and used to derive the CXLs **cannot be used to support the EU GAPs and the import tolerances**. **CXLs** that were legally implemented in the EU Regulation **will be considered directly by EFSA** when drafting the reasoned opinion.
- ❖ Analytical methods provided by the EURLs cannot be used to waive the submission of analytical methods for enforcement by the authorisation holders.

→ **RMS is encouraged to contact EFSA** any time during the 2-month period if encounters any difficulties or needs EFSA advice, clarification or support with the GAP overview file or with PROFile (3.0).



At this stage, RMS may also liaise with the main authorisation holder(s) if needed, however, **it is not envisaged to share the PROFile with the main authorisation holder(s).**

RMS should be aware that **the evaluation report provided in the framework of the MRL review will be published as received on EFSA website as a main supporting document** to EFSA's reasoned opinion.

- **See also framework on the publication of evaluation reports, page 25.**

Specific case where PROFile is not required:

According to the information provided in the GAP forms, it can be that **no uses are currently authorised** for the active substance in the MSs and **no import tolerances are identified.**

In this specific case, since no EU GAPs and import tolerances are authorised and considering that the GAP overview file is intended to collect the authorised GAPs and information on the available supporting residue trials, the **GAP overview file is not considered relevant** (see also step 3(a) for more details). Similarly, a **PROFile is also not required.**

In these cases, the RMS is kindly requested to **prepare the evaluation report**, which should contain all the information allowing the identification of potential illegal uses, more in details:

- metabolism studies allowing to derive proper residue definitions in plant and animal commodities;
- analytical method for enforcement in both plant and animal commodities.

Supporting documents / tools:

- ✓ Excel GAP overview file, updated version, to be uploaded on EFSA DMS (naming convention: yyyyymmdd_GAP_overview_updated_[active_substance].doc)
- ✓ Template for evaluation report, available on [EFSA website](#) (naming convention: yyyyymmdd_[RMS]_ER_[active_substance].doc)
- ✓ Template for PROFile (3.0) available on [EFSA website](#) (naming convention: yyyyymmdd_[RMS]_PROFile_[active_substance].xls)
- ✓ PROFile (3.0) user guide, available on [EFSA website](#)
- ✓ "Standard sentences" file to be used in PROFile (3.0), attached to the e-mail



Publication of evaluation reports prepared by Member States (MSs) and Rapporteur Member State (RMS)

In accordance with Article 38 of Regulation (EC) 178/2002, as amended by Regulation (EU) 2019/1381, all the Evaluation Reports provided in the framework of the MRL review will be made proactively available by EFSA as main supporting documents to EFSA's reasoned opinions.

MSs are kindly requested to take this into account when drafting an Evaluation Report, by ensuring that it does not contain:

- **information that was awarded confidential status by the RMS pursuant to Article 7 of Regulation (EC) 1107/2009 as well as to EFSA's "practical arrangements concerning confidentiality in accordance with Articles 7(3) and 16 of Regulation (EC) No 1107/2009" in the context of applications for approval of an active substance or for an amendment to the conditions of an approval**
- **information that was awarded confidential status by EFSA pursuant to Article 16 of the above Regulation as well as to EFSA's "practical arrangements concerning confidentiality in accordance with Articles 7(3) and 16 of Regulation (EC) No 1107/2009" in the context of applications for renewal of an active substance**

information that was awarded confidential status by EFSA pursuant to Article 10 par 3 of Regulation 396/2005 and Articles 39 – 39e of Regulation 178/2002 as well as to EFSA's "practical arrangements concerning transparency and confidentiality" in the context of Authority's opinion on applications concerning maximum residue levels given that the disclosure of the above information, as proved by the applicant, might potentially harm the interests of a business operator or another legal or natural person to a significant degree pursuant to Articles 39-39e of Regulation (EC) No 178/2002. In concrete terms, this might imply by way of example not to include in the Evaluation Reports the authors' names of vertebrate studies.

Furthermore, please note that even if a document is not proactively disclosed by the Authority, EFSA is required to process requests for access to documents it holds (PAD requests) in accordance with Regulation (EC) No 1049/2001 on documents held by Union institutions, bodies or agencies (PAD Regulation). The PAD Regulation applies to all documents held by EFSA, i.e. documents which it has produced or received in all areas of its activity, including the Evaluation Reports provided by MSs in the framework of the MRL review or applications under Article 7 of the MRL regulation (Regulation (EC) No 396/2005).

Moreover, EFSA is also subject to Regulation (EC) No 1367/2006 of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies. Pursuant to Article 4(1) all environmental information, as defined in Article 2(1)(d), that is relevant to EFSA's functions and which is held by the Authority is to be made progressively available in electronic databases that are easily accessible to the public, through public telecommunication networks.



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In case EFSA receives a PAD request concerning an Evaluation Report that was submitted in the context of an MRL review and that was not proactively made available as main supporting document to EFSA's reasoned opinion, the RMS and MSs shall have the opportunity to indicate whether some information should be kept confidential and removed from the concerned document prior to its disclosure to third parties. Such confidentiality requests shall be accompanied by verifiable justifications, which will be taken into consideration by EFSA within the assessment of the merit of the concerned confidentiality request prior to the disclosure of the concerned document.

EUR-Lex links:

[Regulation \(EC\) No 178/2002](#)
[Regulation \(EC\) No 1367/2006](#)
[Regulation \(EC\) No 1049/2001](#)
[Regulation \(EC\) No 396/2005](#)
[Regulation \(EC\) No 1107/2009](#)
[Regulation \(EU\) No 2019/1381](#)




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<p>Step 6 (a)</p>  <p>1 month</p>	<p>Completeness check of the submitted Evaluation Report and PROFile</p>	<p><u>Actors involved:</u></p> <ul style="list-style-type: none"> EFSA
<p>Task:</p> <ul style="list-style-type: none"> EFSA to proceed with the completeness check of the submitted files (ER and PROFile) with the RMS. <p>Once the ER, the PROFile and the updated GAP overview file for the active substance are received from the RMS, EFSA proceeds with the completeness check of these files and ask for clarification, if needed, to the RMS (see step 6 (b)).</p> <p>In order to provide feedback to the RMS and for transparency, all EFSA's comments and proposals of amendments of the submitted PROFile are reported in the completeness check report. Depending on the outcome, RMS is then informed about the need for submission of clarifications.</p> <p>How to proceed:</p> <ul style="list-style-type: none"> EFSA notifies the RMS that the completeness check is initiated. EFSA reports all its comments in the completeness check report and amends the submitted PROFile, if necessary. The completeness check report, together with the amended PROFile and PRIMo files are shared with the RMS for its consideration. <div style="border: 1px solid green; padding: 10px; margin: 10px 0;"> <p>What EFSA does during the completeness check?</p> <ul style="list-style-type: none"> Verify that all data available in the previous assessments have been considered by the RMS. Verify that the proposed residue definitions reflect and cover the existing uses. Validate the reported residue trials (i.e. whether the reported values come from GAP compliant trials, if results from replicates were not erroneously considered, whether they are covered by the available storage stability data, whether proposed extrapolations are applicable, etc). Editorial modifications in the PROFile to simplify the consequent drafting of the reasoned opinion. Perform a preliminary risk assessment in order to verify whether there is a risk for the most critical GAPs. If so, verify whether fall-back GAPs supported by data are proposed by the RMS or are reported in the GAP overview file. Request clarification and confirmation of the fall-back GAPs (if relevant) to the RMS. <p>It is underlined that during the completeness check, EFSA will not double check that all residue trials available in each evaluation report submitted by the MSs were considered by the RMS.</p> </div>		
<p>Supporting documents / tools:</p> <ul style="list-style-type: none"> ✓ Evaluation report and PROFile submitted by the RMS ✓ Updated GAP Overview file submitted by the RMS ✓ PRIMo file(s) submitted by the RMS (not mandatory) ✓ Completeness check report, to be compiled by EFSA and to be shared with RMS 		




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<p>Step 6 (b)</p>  <p>3 weeks</p>	<p>Completeness check of the submitted Evaluation Report and PROFile – further clarification (only if needed)</p>	<p><u>Actors involved:</u></p> <ul style="list-style-type: none"> • RMS, liaising with the main authorisation holder(s), previous RMS or MSs if needed • EFSA
<p>Task:</p> <ul style="list-style-type: none"> ➤ RMS to provide further clarification, according to the completeness check report received from EFSA. <p>Once EFSA has performed the completeness check of the data provided in the ER, PROFile and GAP overview file submitted by the RMS, RMS is kindly requested to answer to EFSA’s comments and to provide any clarification if needed.</p> <p>At this step, RMS can still liaise with MSs or the main authorisation holder(s) if needed, to provide clarification or additional information (e.g. on availability of fall-back data).</p> <p>How to proceed:</p> <ul style="list-style-type: none"> • EFSA makes available on the DMS the following documentation: <ul style="list-style-type: none"> - The completeness check report which includes comments made by EFSA to the PROFile and where the RMS is invited to provide its considerations in the corresponding column of the file. - The PROFile, which could have been amended. - The PRIMo file(s), which could be indicative only considering the data available at this stage of the process. • Following the comments from EFSA and the clarifications provided, the RMS should update the supporting evaluation report, if needed. • RMS is kindly asked to upload the completed completeness check report onto EFSA DMS, following the instructions given. <p>In case no further clarifications are requested:</p> <p>The completeness check report, which contains the outcome of the completeness check undertaken by EFSA, is shared with the RMS for information only. Therefore, EFSA starts drafting the reasoned opinion, following which a Member State consultation (MSC) is launched (see steps 7 and 8).</p>		
<p>Supporting documents / tools:</p> <ul style="list-style-type: none"> ✓ Completeness check report, available on EFSA DMS, to be completed by RMS if needed ✓ Amended PROFile, available on EFSA DMS ✓ PRIMo file(s), available on EFSA DMS 		




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Step 7  1 month	Drafting of the reasoned opinion	<u>Actors involved:</u> <ul style="list-style-type: none"> • EFSA
<p><u>Task:</u></p> <ul style="list-style-type: none"> ➤ EFSA to draft the reasoned opinion. <p>Once the RMS has provided their feedback on the completeness check, EFSA finalises the completeness check report, modifies the PROFile based on the clarification received and drafts the reasoned opinion.</p> <p><u>How to proceed:</u></p> <ul style="list-style-type: none"> • EFSA notifies to all MSs that the completeness check step has been finalised, informing about the foreseen date for the Member State Consultation on the draft reasoned opinion (step 8). • EFSA prepares the draft reasoned opinion, informing MSs in case of delay. • The completeness check report is finalised following the clarifications received by the RMS, concluding on the outcome in the last column of the file. It will be published on EFSA website as a supporting document to the reasoned opinion. 		
<p><u>Supporting documents / tools:</u></p> <ul style="list-style-type: none"> ✓ Evaluation report(s) and PROFile(s) ✓ GAP overview file (updated) and PRIMo(s) ✓ Completeness check report 		




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 Step 8 3 weeks	Member State consultation	<u>Actors involved:</u> <ul style="list-style-type: none"> • Member States • RMS • EURLs • EFSA
<p>Tasks:</p> <ul style="list-style-type: none"> ➤ EFSA to launch the Member State consultation (MSC). ➤ MSs to provide comments on the draft reasoned opinion. ➤ EURLs to provide comments and update (if needed) its evaluation reports with regards availability of analytical methods and analytical standards for the proposed residue definition. <p>Once EFSA has prepared the draft reasoned opinion on the active substance based on the evaluation report as provided by the RMS and the PROfile as agreed with RMS, the draft reasoned opinion is circulated for comments, together with the following background documents:</p> <ul style="list-style-type: none"> • completeness check report, finalised following the clarifications provided by the RMS; • draft PROfile; • draft PRIMo(s); • GAP overview file (updated). <p>How to proceed:</p> <ul style="list-style-type: none"> • In the interest of transparency, MSs (including the RMS) should provide all comments on the draft reasoned opinion in a standardised format, using the commenting table provided. Track changed versions of the draft reasoned opinion cannot be accepted. • The draft reasoned opinion and its background documents are made available on the EFSA DMS. The template for commenting is available on EFSA website. MSs are requested to upload their comments in the format of the commenting table on the EFSA DMS, following instructions and naming convention given. • EURLs is invited to comment on the draft reasoned opinion, and to update its evaluation report regarding the availability of analytical methods and analytical standards for the proposed residue definition, if needed. • In case new residue definitions are proposed during the Art. 12 review procedure, this information will be clearly reported in the e-mail sent for MSC. <div style="border: 1px solid orange; padding: 10px; margin-top: 10px;"> <p>The final reasoned opinion should reflect the view of RMS, EFSA and MSs and should allow risk managers to take informed decision when legally implementing the proposed MRLs. Therefore, this consultation is mainly intended to receive feedback on the assumptions and the assessment performed by EFSA.</p> <p>A consultation on the data and authorisations to be relied upon was already performed in the framework of the data collection. EFSA will therefore not take into consideration additional data submitted in the framework of this consultation, except in exceptional cases (e.g. long time between the data call and the MSC).</p> <p>Consultation by the main authorisation holder is not foreseen. Therefore, comments as received by the main authorisation holder cannot be considered by EFSA.</p> </div>		
<p>Supporting documents / tools:</p> <ul style="list-style-type: none"> ✓ Completeness check report, finalised following the clarifications provided by the RMS ✓ Draft PROfile, draft PRIMo file(s) and draft reasoned opinion, available on DMS ✓ GAP overview file(s), available on DMS ✓ Template for commenting, available on EFSA website (naming convention: yyyyymmdd_[MS]_comment_[active_substance].doc) 		





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<p>Step 9</p>  <p>2 weeks</p>	<p>Drafting the Member State consultation report</p>	<p><u>Actors involved:</u></p> <ul style="list-style-type: none"> • EFSA
<p><u>Task:</u></p> <ul style="list-style-type: none"> ➤ EFSA to draft the Member State consultation report. <p>Once all comments from MSs are received, in the format of commenting tables, EFSA compiles and addresses them in the Member State consultation report. This report is considered a supporting document to the reasoned opinion and will be made publicly available.</p> <p>While compiling the commenting tables received, EFSA could identify one or more items that could not be concluded upon. In this case, further discussion in a pesticide MRL expert meeting will be considered necessary in order to finalise the review of the existing MRLs for the active substance.</p> <p><u>How to proceed:</u></p> <ul style="list-style-type: none"> • If a pesticide MRL expert meeting is needed: the draft MSC report, highlighting the points for further discussion with MSs experts, is made available within 2 weeks from the end of the consultation. • If no pesticide MRL expert meeting is requested, EFSA will finalise and publish the MSC report and the reasoned opinion at the same step (see Step 11). 		
<p><u>Supporting documents / tools:</u></p> <ul style="list-style-type: none"> ✓ Commenting tables provided by the MSs 		



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 Step 10 6 weeks	Optional: pesticide MRL expert meeting	<u>Actors involved:</u> <ul style="list-style-type: none"> • EFSA • Experts from MSs • RMS
<p>Task:</p> <ul style="list-style-type: none"> ➤ EFSA to organise a pesticide MRL expert meeting, if considered necessary. ➤ Experts to discuss and agree on the outcome. <p>Following the Member State consultation, if one or more unresolved issues are identified, an expert meeting should take place, in order to find agreement to finalise the review of the existing MRLs for the active substance.</p> <p>How to proceed:</p> <ul style="list-style-type: none"> • 2 weeks before the meeting, EFSA makes available the following documentation: report with points for discussion together with any relevant supporting documents. • The discussion usually takes place via teleconference. • Only MSs that provided comments on the draft reasoned opinion and the RMS are invited to participate. 		
<p>Supporting documents / tools:</p> <ul style="list-style-type: none"> ✓ Report and supporting documents to the discussion ✓ Draft Member State consultation report 		

 Step 11 2 weeks	Finalisation of the reasoned opinion	<u>Actors involved:</u> <ul style="list-style-type: none"> • EFSA
<p>Task:</p> <ul style="list-style-type: none"> ➤ EFSA to finalise the reasoned opinion. <p>Once, the MSC report has been finalised, the draft reasoned opinion (and the PROFile, if needed) are amended in order to reflect all comments received by MSs.</p>		
<p>Supporting documents / tools:</p> <ul style="list-style-type: none"> ✓ Member State consultation report, including the minutes and the main conclusions from the expert meeting if took place ✓ Final Reasoned Opinion ✓ Final PROFile ✓ Final PRIMo file(s) ✓ GAP overview file(s) 		



Abbreviations

a.i.	active ingredient
BBCH	growth stages of mono- and dicotyledonous plants
CIRCABC	Communication and Information Resource Centre for Administrations, Businesses and Citizens
cGAP	critical good agricultural practices
CXL	codex maximum residue limit
DG SANTE	DG for health and food safety
DMS	(EFSA) document management system
EFSA	European Food Safety Authority
ER	evaluation report
EURLs	EU Reference Laboratories for Pesticide Residues
GAP	good agricultural practices
GM	genetically modified
IT	import tolerance
JMPR	Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
MRL	maximum residue level
MS	member state
MSC	member state consultation
NEU	northern European Union
PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
PROFile	(EFSA) Pesticide Residues Overview File
PSN	pesticide steering network
RAR	renewal assessment report
RMS	rappporteur member state
SEU	southern European Union
WHP	withholding period
zRMS	zonal rapporteur member state



Glossary

Active substance (or active ingredient)	“active substance” is intended for the active component of a plant protection product that enable the product to perform its action against pests and plant diseases. These substances can be chemicals or micro-organisms, including viruses.
Codex maximum residue limit (CXL)	CXLs are the internationally recommended maximum residue levels of pesticides set by the Codex Alimentarius Commission (CAC). When considered safe for the consumer, these CXLs can also be taken over as MRLs in the EU legislation.
Fall-back good agricultural practice (fall-back GAP)	A fall-back GAP is a GAP that allows to derive a safe (fall-back) MRL in case a risk for consumers cannot be excluded for the most critical GAP supported by data.
Good agriculture practice (GAP)	According to Regulation 396/2005 “good agricultural practice” means the nationally recommended, authorised or registered safe use of plant protection products under actual conditions at any stage of production, storage, transport, distribution and processing of food and feed. It also implies the application, in conformity with Directive 91/414/EEC, of the principles of integrated pest control in a given climate zone, as well as using the minimum quantity of pesticides and setting MRLs/temporary MRLs at the lowest level which allows the desired effect to be obtained.
Import tolerance (IT)	According to Regulation 396/2005 an “import tolerance” is an MRL set for an imported product to meet the needs of international trade; for which the use of the active substance is not authorised in Europe for reasons other than public health reasons, or for which a different level is appropriate because the existing EU MRL was set for reasons other than public health reasons for the specific product and specific use.
Main authorisation holder	The main authorisation holder is usually the company that supported the active substance in the framework of the approval.
Most critical GAP	According to Regulation 396/2005 a “critical GAP” is the GAP, where there is more than one GAP for an active substance/product combination, which gives rise to the highest acceptable level of pesticide residue in a treated crop and is the basis for establishing the MRL.
Maximum residue level (MRL)	According to Regulation 396/2005 “maximum residue level” means the upper legal level of a concentration for a pesticide residue in or on food or feed set in accordance with this Regulation, based on good agricultural practice and the lowest consumer exposure necessary to protect vulnerable consumers.
MRL application	An MRL application is the applicant’s request to amend or set MRLs for an active substance in one or several food or animal feed.
National authorisation holder	The national authorisation holder is the company that supported the authorised uses of an active substance at national level.



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Plant protection product (PPP)	PPPs are formulations containing at least one active substance that are mainly used to keep crops healthy and prevent them from being destroyed by disease and infestation. They include herbicides, fungicides, insecticides, acaricides, plant growth regulators and repellents.
Renewal assessment report (RAR)	The RAR is the report provided by the RMS containing its scientific assessment, based on the dossier submitted by the applicant to support the renewal of an active substance.
Rapporteur member state (RMS)	The RMS is the designed EU country receiving the application, together with a dossier, for the approval of an active substance. The RMS is responsible for the initial scientific and technical evaluation of the active substance dossier, carrying out the first risk assessment. For the article 12 review of all existing MRLs, a different EU country could have been re-assigned for the assessment. The RMS appointed for respective MRL reviews can be found in the MRL review progress report published on EFSA website (see link at Step 1).
Zonal RMS (zRMS)	The "zonal rapporteur Member State" is the EU country responsible for the risk assessment of a plant protection product containing the approved active substance, in a specific zone of Europe (e.g. in the northern, central or southern zone), on behalf of the other Member States in the same zone.



Appendix A – List of relevant tools and templates

All the following documents can be downloaded via EFSA website, under “Maximum residue levels” in the “Pesticides” section: <https://www.efsa.europa.eu/en/topics/topic/pesticides>

1. Excel tools

Template for GAPs reporting form

naming convention: `yyyymmdd_[MS]_GAP_form_[active_substance].xls`
relevant for step 2, GAPs collection

Template of the GAP overview file

naming convention: `yyyymmdd_GAP_overview_[active_substance].xls`
relevant for step 3, identification of cGAP

Template for PROFile (3.0) and PROFile (3.0) user guide

naming convention: `yyyymmdd_[RMS]_PROFile_[active_substance].xls`
relevant for step 5

2. Templates for evaluation reports and commenting

Template for MSs evaluation report

naming convention: `yyyymmdd_[MS]_additional data_[active_substance].doc`
relevant for step 4

Template for EURLs evaluation report

naming convention: `yyyymmdd_EURLs_analytical methods_[active_substance].doc`
relevant for step 4

Template for RMS evaluation report

naming convention: `yyyymmdd_[RMS]_ER_[active_substance].doc`
relevant for step 5

Template for commenting

naming convention: `yyyymmdd_[MS]_comment_[active_substance].doc`
relevant for step 8