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DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY
Safety of the Food Chain
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TECHNICAL GUIDELINES¹

MRL SETTING PROCEDURE IN ACCORDANCE WITH ARTICLES 6 TO 11 OF REGULATION (EC) No 396/2005 AND ARTICLE 8 OF REGULATION (EC) No 1107/2009

¹ This document has been conceived as Technical Guidelines of the Commission Services. It does not represent the official position of the Commission. It does not intend to produce legally binding effects. Only the European Court of Justice has jurisdiction to give preliminary rulings concerning the validity and interpretation of acts of the institutions of the EU pursuant to Article 267 of the Treaty.

PREFACE

The Transparency Regulation² amended the General Food Law³ by introducing new requirements in the pre-submission phase and submission application procedure, such as:

- possibility to request for general pre-submission advice;
- obligation to notify information related to studies commissioned or carried out to support an application;
- submission of the application dossier using IUCLID format, including non-confidential version of the dossier;
- public disclosure of non-confidential version of all information submitted in support of the application and related confidentiality decision-making process;
- public consultation on submitted application dossiers.

These new requirements, as implemented by the Practical Arrangements laid down by EFSA, are reflected in the EFSA “Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances and on the MRL application procedure”: <https://www.efsa.europa.eu/en/applications/pesticides/regulationsandguidance>.

It is noted that the new provisions presented in the above-mentioned guidance apply to all MRL applications submitted as of 27 March 2021. It is therefore advised to consult the EFSA administrative guidance to gather further details on the new procedure and obligations.

The new revision of the guidance document (SANTE/2015/10595 Rev. 5.5) has been presented and discussed at the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF) - Section Pesticide Residues on 23 February 2021.

The SCoPAFF agreed that the new revision will apply to all MRL applications submitted under Regulation (EC) No 396/2005 and Regulation (EC) No 1107/2009, as of 27 March 2021. For all applications submitted before 27 March 2021, all procedural steps as described in SANTE/2015/10595 Rev. 5.4 continue to apply.

² Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC, PE/41/2019/REV/1. OJ L 231, 6.9.2019, p. 1–28.

³ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1.

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1. Introduction

Articles 6 to 11 and Article 14(1) of Regulation (EC) No 396/2005⁴ on Maximum Residue Levels (MRLs) for pesticides describe the procedure for applications for MRLs. Article 8(1)(g) of Regulation (EC) No 1107/2009⁵ on the placing of plant protection products on the market refers to, where relevant, the inclusion of a copy of the MRL application, in accordance with Article 7 of Regulation (EC) No 396/2005, in the summary dossier for the approval of an active substance. The two above pieces of legislation are relevant for the European Economic Area (EEA).

This guidance document aims at providing clarity on the various steps involved in the procedure, on the timelines and on specific circumstances related to the MRL setting process.

It is important to know that the overall procedure for setting MRLs has to be completed before an authorisation can be granted by a Member State. Any delays in the procedure of MRL setting will consequently have an impact on granting authorisation for the use of the plant protection product (PPP) at national level. It is therefore essential to establish an efficient process with defined deadlines and responsibilities to avoid unnecessary delays.

2. Current procedure for setting MRLs under Regulation (EC) No 396/2005

2.1 Annexes to Regulation (EC) No 396/2005

Annex I includes a list of all the food and feed commodities for which MRLs are set under Regulation 396/2005.

Annex II mostly contains ‘definitive’ MRLs that were previously set under EC MRL Directives following the review of active substances under Regulation (EC) No 1107/2009.

Annex IIIA contains ‘temporary’ MRLs, mostly for active substances that are awaiting a decision on the inclusion in the Annex to Commission Implementing Regulation (EU) No 540/2011 and the evaluation according to Article 12 of Regulation (EC) No 396/2005.

Annex IIIB contains ‘temporary’ MRLs for the active substances listed in Annex II in combination with the new food and feed commodities in Annex I, which were not listed before harmonisation in the respective Commission MRL Directives.

Annex IV lists active substances for which MRLs are not required.

Annex V lists those substances for which all MRLs are set at the appropriate limit of quantification (LOQ).

⁴ Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC, OJ L 70, 16.03.2005, p. 1-16.

⁵ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, OJ L 309, 24.11.2009, p. 1.

Annex VI, which has not been established yet, will report specific concentration or dilution factors for certain processing and/or mixing operations or for certain processed and/or composite products.

Annex VII lists active substance/product combinations for which Member States may authorise, further to a post-harvest treatment with a fumigant on their own territory, residue levels exceeding the existing MRL, under the condition listed in Article 18 (3) of Regulation (EC) No 396/2005.

2.2. Scope and purpose of the application

The purpose of the application is to set a new MRL, to modify an existing one, or to delete it from the Annexes to Regulation (EC) No 396/2005. This can be made in support of an authorisation request for the use of a PPP in the Union, in accordance with Regulation (EC) No 1107/2009, when any interested party or the Member State consider the modification of an MRL necessary or to facilitate international trade by means of an import tolerance request from a third country.

An application may also be submitted with a view of setting temporary MRLs, in accordance with Article 16, to include an active substance in Annex IV of Regulation (EC) No 396/2005, to amend its residue definition or to include the active substance/product combinations into Annex VII, as referred to in Article 18 (3) of Regulation (EC) No 396/2005, or to request the assessment of confirmatory data⁶.

An application for the lowering or deletion of the existing MRL may be submitted where, for instance, consumer intake concerns are identified. The need to set lower MRLs should be justified by the applicant and/or the Evaluating Member State (EMS) to avoid that resources are spent to assess applications, which do not lead to a change to the MRLs, which are already set in the EU. Ideally, the EMS should prepare a 'light' version of the Evaluation Report including the verified justification and a first intake calculation with PRIMo and send it to the Commission. This will serve as a basis for the decision whether an Article 43 review is necessary, i. e. whether a review of more than the MRL for the applied combination is necessary.

2.3. Actors involved in the process

Several actors are mentioned in the MRL setting process to which different tasks and responsibilities are assigned in Regulation (EC) No 396/2005.

The applicant is the physical entity who makes a request to a Member State to amend the Annexes to Regulation (EC) No 396/2005 concerning pesticide residues. The following parties are entitled to submit an application:

- a) A party requesting an authorisation under Regulation (EC) No 1107/2009 (Article 6(1) of Regulation (EC) No 396/2005);

⁶ See document SANTE/10235/2016, Commission Working Document on the evaluation of data submitted to confirm MRLs following the review of existing MRLs.

- b) Parties demonstrating through adequate evidence a legitimate interest in health, including organisations of civil society (Article 6(2) of Regulation (EC) No 396/2005);
- c) Parties concerned with a commercial interest such as manufacturers, growers, importers and producers of products covered by Annex I of Regulation (EC) No 396/2005 (Article 6(2) of Regulation (EC) No 396/2005);
- d) A Member State of the Union (Article 6(3) of Regulation (EC) No 396/2005);
- e) A party requesting an import tolerance (Article 6(4) of Regulation (EC) No 396/2005).

The consumer risk assessment is carried out in a two step procedure, involving the EMS who drafts an Evaluation Report and the European Food Safety Authority (EFSA) who finalises the risk assessment upon receipt of a mandate from the Commission and publishes it in form of a Reasoned Opinion.

The Commission, who is in charge of the risk management phase, prepares a draft measure for a Regulation to implement the MRLs in the Annexes to Regulation (EC) No 396/2005. The draft measure is based on the Reasoned Opinion of EFSA and is discussed and voted at the Standing Committee on Plants, Animals, Food and Feed (PAFF) - section "Pesticides Residues" with experts from Member States of the Union.

2.4. Procedural steps

1) Application submission

The requirements relating to the applications are listed under Article 7 of Regulation (EC) No 396/2005. The applicant should submit an MRL application alongside the dossier containing the supporting data using the IUCLID format through the Central Submission System indicating the Member States to which they intend to submit the application (for further details see the EFSA administrative guidance).

Applications in general should be submitted to the Member State where the authorisation is sought. The exception to this may be where the application has been or will be made under Regulation (EC) No 1107/2009 to a Member State undertaking the assessment of the core dossier as the zonal Rapporteur Member State (zRMS). Although the authorisation is not being sought in the zRMS' territory, the zRMS should complete the Evaluation Report and take the MRL forward after seeking agreement from the Member State in which the authorisation is sought.

In addition, on agreement with the Member State in which an authorisation is sought, another Member State may undertake the evaluation of the MRL application. This may be the case where the applicant seeks an authorisation for uses in Northern EU (NEU) and Southern EU (SEU) and have trials data for both as well as other core data. For the sake of efficiency, one Member State should carry out the assessment of these data and propose an MRL on the basis of the combined data set from the NEU and SEU, where appropriate. It is necessary that the Member State submits at the earliest possible stage the information via the usual pathway (EFSA-DMS and/or information exchange on zonal applications).

The Member State who receives an application either consults the EFSA Document Management System (EFSA-DMS) or coordinates with the Rapporteur Member State (RMS) about whether similar applications (for the same pesticide or the same pesticide/crop

combination) were submitted in other Member States and whether it is necessary that the RMS or another Member State evaluates the application. In case of disagreement between a Member State and the RMS, the matter is referred to the PAFF - section "Pesticides Residues" for a decision in accordance with Article 8 subparagraphs (3) and (4).

Concerning applications for import tolerances see Chapter 3.1.

2) Admissibility check

The EMS has to verify whether the application fulfils the requirements set under Article 7 of Regulation (EC) No 396/2005, including the obligations of study notifications laid down in Article 32b (2) and (3) of Regulation (EC) No 178/2002⁷. Where the application is found admissible, the EMS notifies the applicant, EFSA, the European Commission and the other Member States.

Otherwise, the EMS should ask the applicant to submit the missing data. As long as the information submitted is not in compliance with those requirements, the EMS has no obligation to draw up an Evaluation Report. If the missing data were not submitted within an appropriate period, the EMS may consider rejecting the application.

3) Queries on submitted MRL applications

Queries on submitted MRL applications may be addressed to both EFSA and the Commission by using the relevant mailboxes:

EFSA: APDESK.applications@efsa.europa.eu and pesticides.mrl@efsa.europa.eu

COM: SANTE-MRLs-applications@ec.europa.eu

4) EFSA Document Management System (DMS)

Upon receipt of the application, EFSA creates a new project in the EFSA-DMS.

5) Evaluation of the application

According to Article 8(1), the EMS has an obligation to draw up an Evaluation Report without undue delay. As a guide, the timelines as outlined in Article 37 of Regulation (EC) No 1107/2009 for product authorisations should be considered (i.e. 12 months plus 6 months in case the applicant is to submit additional data).

The EMS verifies completeness of data, carries out or verifies exposure assessments (chronic and acute) and makes recommendations on the setting of MRLs for the range of products listed in the application form. It is advisable to consult the applicant on the outcome of the assessment before sending the Evaluation Report to the Commission and EFSA.

⁷ The obligations on notifications of studies apply to any additional study requested after the submission of the application either during the admissibility check of the application by the EMS or in relation to the EMS' evaluation or EFSA's assessment, if such studies are commissioned or carried out as of 27 March 2021. Studies submitted to support an MRL application are not subject to the obligation of study notifications if they are commissioned or carried out before 27 March 2021 (see EFSA administrative guidance).

An updated application needs to be submitted, if during the detailed assessment of the application the GAPs have been modified.

A 'report generator' is available in IUCLID. The EMS can use this functionality to prepare parts of the assessment report.

6) Informing COM and EFSA of the Evaluation Report

After completion of the Evaluation Report, the Member State shall forward it to the Commission in accordance with Article 9(1) of Regulation (EC) No 396/2005. In practice, the EMS should carry out the following tasks:

- a) Upload the Evaluation Report and any relevant document, such as the Pesticide Residue Intake Model (PRIMo) and the animal burden calculator, on the EFSA-DMS;
- b) Inform EFSA and COM of the finalisation of the Evaluation Report and of the uploading via the functional mailboxes reported in step 3.

In addition, it is good practice to inform the applicant on the submission and the proposals made in the Evaluation Report.

7) COM mandate to EFSA

At regular intervals (e.g. at the beginning of each month), the Commission gathers all Evaluation Reports, which were submitted and uploaded on the EFSA-DMS together with the relevant applications. After verifying the contents, the Commission prepares a mandate formally asking EFSA to assess the MRL requests and to deliver for each Evaluation Report a Reasoned Opinion according to Article 10 of Regulation (EC) No 396/2005.

Where needed, the Commission prepares an extra mandate to address urgent requests.

8) EFSA acceptance letter

Upon receipt of the mandate, EFSA submits an acceptance letter to the Commission with the relevant EMS and the applicant(s) in copy in accordance with Article 9(2) of Regulation (EC) No 396/2005.

The time limits for EFSA to deliver an opinion are provided in Article 11 of Regulation (EC) No 396/2005. EFSA shall give its Reasoned Opinion as provided for in Article 10 as soon as possible and at the latest within three months from the date of receipt of the application.

In exceptional cases, where more detailed evaluations need to be carried out (e.g. assessment of toxicological studies not yet evaluated at EU level, amendment of residue definition, high number of MRLs requested) or where the evaluation exclusively addresses confirmatory data following the Article 12 review, the time limit laid down in the first subparagraph may be extended to six months from the date of receipt of the application.

In the acceptance letter, the deadlines for each assessment are reported. Whenever the deadline of 3 months is extended, a justification is provided.

9. Data gaps identified by EFSA

In the framework of draft measures in accordance with Article 6, EFSA should make clear recommendations as to whether it is appropriate or not to set an MRL to address a specific use. MRLs are therefore set on a permanent basis with the exception of those that fall under the circumstances reported under Article 16 (temporary MRLs).

Where data gaps are identified by EFSA, the time limit to assess the application is suspended until the additional information has been provided in accordance with Article 11(2). This process is referred to as the stop-the-clock procedure, which prevents EFSA from publishing an incomplete Reasoned Opinion that would lead to risk management difficulties. The EMS and the applicant are thus urged to provide the missing information with a view of implementing the relevant MRLs. As a guide, the EMS and applicant should provide the additional information, within 6 months in line with the timeline foreseen in Article 37 of Regulation (EC) No 1107/2009. If it becomes clear that the data cannot be generated within 6 months, the EMS is invited to ask the applicant to withdraw the application.

In cases where EFSA identifies missing information only for specific parts of the application, the applicant will be given the opportunity in the 'stop clock letter' for EFSA to take forward the uses which are fully supported and give no further consideration to the uses which are not fully supported. EFSA will publish the Reasoned Opinion and hence this will avoid delaying the MRL requests which are fully supported by data. The data gaps identified for the other MRLs will need to be addressed in a new submission.

10) EFSA risk assessment

In accordance with Article 10 of Regulation (EC) No 396/2005, EFSA assesses the applications and the Evaluation Reports and gives a Reasoned Opinion on, in particular, the risks to the consumer and where relevant to animals associated with the setting, modification or deletion of an MRL. The Reasoned Opinion is published on the EFSA Journal which is publicly available on the following website:

<http://www.efsa.europa.eu/en/publications/efsajournal>

Along with the publication of the Reasoned Opinion, the Evaluation Report and PRIMo are made publicly available as background document in the OpenEFSA Portal.

11) Decisions on applications concerning MRLs

According to Article 14(1), upon receipt of the opinion the Commission shall prepare either a regulation on the setting, modification or deletion of an MRL or reject the application without delay and at the latest within three months from the publication of the Reasoned Opinion.

In practice, in view of the internal steps involved, the Commission gathers all Reasoned Opinions, which are available in due time before the relevant PAFF. The following scenarios may occur depending on the recommendations made by EFSA in the Reasoned Opinion.

i) Increase of the existing MRL

The application will be addressed by a routine MRL measure, which will become applicable 20 days after publication. Such measures are trade facilitating measures and are therefore not bound to be notified to World Trade Organization (WTO) via the SPS procedure. However,

for the sake of transparency, those measures may be grouped in batches and notified to WTO for information only.

The overall timeline is reported in the flowchart under point 2.4.

ii) Decrease of the existing MRL

Any decrease of MRLs might lead to a trade barrier. The measure must therefore be notified to WTO for a commenting period of 60 days once the content of the draft is agreed by the relevant Commission services. The application date of the Regulation is usually deferred for 6 months to permit Member States, third countries and food business operators to prepare themselves to meet the new requirements which will result from the modification of the MRLs. On a case by case basis, if a risk requires immediate action, the period for the deferred application date could also be shortened. Moreover, the Regulation allows for a transitional arrangement for products which have been produced in the EU or imported into the EU before the modification of the MRLs provided that a high level of consumer protection is ensured.

In view of the different procedures, in most cases the Commission deals with such applications in a separate measure. This is also to avoid that applications, which lead to an increase of the MRL, are delayed by the process. Exceptions are made on a case by case basis.

Where EFSA recommends setting a lower MRL as the most critical GAP is not being used any longer, the issue should be addressed in another framework (e.g. in the context of Article 12 of Regulation (EC) No 396/2005).

iii) No change proposed by EFSA

Where a Reasoned Opinion is published without a clear recommendation to amend the existing MRL, the matter is brought to the PAFF - section "Pesticides Residues" for discussion. Prior agreement of the members of the Committee, the decision not to amend the MRL is published in the Summary Report of the meeting on the following website:

http://ec.europa.eu/food/plant/standing_committees/sc_phytopharmaceuticals/index_en.htm

iv) Amendment of the residue definition/toxicological reference values

The PAFF - section "Pesticides Residues" is responsible for establishing of new residue definitions for enforcement. This generally occurs under the framework of the Article 12 review or under the Article 43 procedure where a new residue definition is proposed in the renewal process and a need for revision has been identified as outlined in chapter 3.4. Once the draft measure is voted, the members of the PAFF - section "Pesticides Legislation" are informed on the adoption of a new residue definition for enforcement and on the lowering of MRLs. A standing point is reported in the Agenda of the PAFF for this purpose. The competent authorities are thus informed of the changes, which might affect their national authorisations.

The PAFF - section "Pesticides Legislation" is responsible for note taking of new toxicological reference values during the active substance approval/renewal process. The Commission consults EFSA to understand whether the new reference values may pose a risk to consumers in relation to the existing uses and/or MRLs. Where needed, once the reference values are endorsed, the Commission sends a mandate without undue delay to EFSA in

accordance with Article 43 of Regulation (EC) No 396/2005 to carry out a re-assessment on some or all MRLs. In that framework, Member States should be consulted to report potential fall-back GAPs that would not lead to an unacceptable risk to consumers.

As a general remark and without prejudice to the provisions of Article 14(8) of Regulation (EC) No 178/2002 (General Food Law)⁸, new residue definitions and toxicological reference values that are recommended by EFSA in Reasoned Opinions or under the framework of the peer-review, should not be considered in routine risk assessment or used for enforcement purposes until the relevant PAFF has taken formal note of them.

12) Interservice-Service Consultation

All relevant Commission services are consulted before the measure is put for an opinion of the PAFF - section "Pesticides Residues".

13) Draft measure on CIRCABC

In parallel, the draft measure is uploaded on the Communication and Information Resource Centre for Administrations, Businesses and Citizens (CIRCABC) once both the invitation and agenda of the meeting are made available.

14) Comments from Member State and EFSA

Member States and EFSA provide comments on the draft measure. Major issues should not be left for discussion on the days of the PAFF - section "Pesticides Residues" in view of the extent of the measures and the limited time allocated. The Commission revises the draft measure to reflect the suggestions being made.

15) Opinion of the PAFF

The final version of the draft measure is put for a vote at the PAFF - section "Pesticides Residues". The following steps are covered by the regulatory procedure with scrutiny referred to in Article 45(4).

16) Draft measure translation

After the voting session, the draft measure is translated in the 23 official languages. Once all versions are available, the Commission uploads it on the Comitology Register:

<http://ec.europa.eu/transparency/regcomitology/index.cfm?CLX=en>

17) Scrutiny period

The Commission submits the draft measure for scrutiny by the European Parliament and the Council. The scrutiny period lasts 2 months.

18) Adoption and publication

The Commission formally adopts the draft measure, which becomes a Commission Regulation. In the subsequent days, the legislative act is published in the Official Journal:

⁸

<http://eur-lex.europa.eu/oj/direct-access.html>

19) Application date

The MRLs usually become applicable 20 days after publication of the Regulation. Such period may be shortened in exceptional cases. This action needs however to be justified by means of a specific recital within the Regulation.

2.5. Flow charts

The indicative timeline of the MRL setting procedure in accordance with Articles 6 to 11 of Regulation (EC) No 396/2005 is reported in Annex I of this document.

3. Specific cases

3.1. Import tolerances

3.1.1. Frequently asked questions on import tolerances

Specific issues regarding the setting of MRLs following import tolerance requests in accordance with Article 6(2) and (4) of Regulation (EC) No 396/2005 are outlined below.

Who can apply for an import tolerance?

In principle, all parties mentioned in Article 6(2) of Regulation (EC) No 396/2005 can apply for an import tolerance. Due to the data requirements, especially in cases where the active substance has never been notified or authorised in the EU, it is advisable that the producer of the active substance applies for the import tolerance.

To whom should the import tolerance be addressed?

Either to the RMS for the active substance, as reported in the EU Pesticides Database (https://ec.europa.eu/food/plant/pesticides/eu-pesticides-db_en), or in case no RMS has been attributed, the application should be sent to the European Commission. In that case the Commission will designate a Member State in accordance with the procedure referred to in Article 45(2) of Regulation (EC) No 396/2005 at the request of the applicant. A contact list can be found on the following link:

http://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_legis_national-authorities_en.pdf.

As an alternative, on agreement with the RMS, another Member State can undertake the evaluation of the import tolerance. This should be communicated to PAFF - section "Pesticides Residues" in the relevant standing point in the agenda (i.e. Designation of Member States for MRL applications).

How to apply for an import tolerance?

The application form can be found on the following link:

https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_mrl_guidelines_mrl-application.pdf.

What data should be provided with an application for an import tolerance?

This depends on the knowledge of the active substance within the EU. In cases where the active substance has never been peer-reviewed in the EU, a complete dataset on toxicology, methods of analysis and residue behaviour may be required. In cases of uncertainty the RMS should be consulted.

Can an import tolerance request be made for a specific use which is not yet approved in the exporting country?

It is inappropriate to set an MRL in EU legislation, where there is no proof of an authorised use in the exporting country. Moreover, the application may lead to unnecessary work for all relevant parties.

The following information should be submitted to the EMS:

- Reference and copy of the current national legislation in the exporting country related to the MRL under consideration (including enforcement residue definition in place in the exporting country) or a clarification should be given if no MRLs are established in the exporting country;
- Evidence of the authorisation of the respective use of the PPP in the exporting country (if available, links to the national websites where such information is provided).

Where such information is not provided within the application, it is recommended that the EMS stops the assessment and informs the applicant on the missing information. If the missing data are not provided within an appropriate time period, the EMS may consider rejecting the application.

How to deal with an import tolerance request, when the residue dataset leads to an import tolerance proposal higher than the MRL in force in the exporting country?

In the framework of an import tolerance request, the MRL to be set in Regulation (EC) No 396/2005 should not exceed the one approved in the exporting country taking into account possible differences in the residue definition. Thus, even though the residue dataset leads to a higher value, the MRL should be set at an equivalent level. If the dataset leads to a considerably higher MRL than the one in the exporting country, risk management considerations may be taken to decide if the setting of a MRL at the same level as in the exporting country is appropriate, taking into account the risk that the GAP authorised in the country of origin may lead to exceedances of the MRL.

How to deal with an import tolerance request higher than the MRL in force in the exporting country? Should the request be automatically rejected?

This is a case where the applicant may anticipate the establishment of a more critical GAP within their territory. The application should be consistent with the MRL already in force in the exporting country taking into account the residue definition. If that is not the case, the application needs to be reformulated accordingly.

How to deal with import tolerance request, when the residue dataset leads to an import tolerance proposal lower than the MRL in force in the exporting country?

The Commission should propose the MRL derived by EFSA in compliance with the relevant dataset. To avoid setting an MRL which does not satisfy the agricultural requirements, when assessing the application, the EMS should clarify with the applicant whether the value derived by the EMS is sufficient to cover the GAP in the exporting country. If the difference is substantial, the applicant should provide an explanation.

How to deal with an import tolerance requested for a whole group of products in the application form where the GAP in the exporting country is defined for one product only?

This needs to be addressed on a case by case basis. It should be noted that the extrapolation rules in the exporting country may not be in line with the ones set in the EU, in view of the different grouping of crops. The applicant should clearly indicate for which individual crops, as listed in Annex I to Regulation (EC) No 396/2005, the authorisation in the exporting country is valid. The EMS should clearly indicate in the Evaluation Report which crops are covered by the import tolerance request.

How to deal with an import tolerance requested for a specific product in the application form where additional national GAPs are provided?

The MRLs should only be set on those products which are specifically indicated in the application form. If there are doubts, the EMS should consult the applicant before drafting the Evaluation Report.

How to deal with an import tolerance request concerning products with different size and/or different consumption figures (peppers vs Chili peppers) for which only one entry is foreseen in Annex I to Regulation 396/2005?

As a provisional solution, pending the relevant amendment to Annex I to Regulation (EC) No 396/2005, the setting of different MRLs for the major and minor crop may be performed by means of a footnote.

This situation may arise if an import tolerance request is made:

- for the minor crop only;
- for both the major and minor crops, but only for the minor crop data are provided; or
- for both the major and minor crops, but consumption data show there is a concern for consumers in the relation to the major crop only.

In these cases, the MRL for the major crop should be set at the LOQ, while the footnote would establish a specific MRL for the minor crop.

No footnote is necessary where an import tolerance request is made for both the major and the minor crops, but supporting data are not available for the minor crop, or where the import tolerance request is only made for the major crop.

In all cases, the recitals of the relevant draft measure should report the specific commodities for which the application was made and indicate whether supporting data were available.

3.1.2 New toxicological reference values for setting of import tolerances

There are cases where import tolerance requests are made for substances for which toxicological reference values were not agreed upon at EU level. This includes substances that were never authorised in the EU but for which import tolerance requests are made.

In such cases, the following steps should be carried out:

- The applicant submits the new toxicological data in support of the setting of new toxicological reference values;
- The EMS assesses the application containing the toxicological data and drafts an Evaluation Report;
- The Commission forwards the Evaluation Report to EFSA who is to deliver a Reasoned Opinion within 6 months;
- EFSA launches a MS consultation on the Evaluation Report with a focus on the toxicological assessment only (4 weeks);
- Following the comments received, EFSA may decide that there is a need to request additional data (stop-the-clock letter);
- Following submission of the updated Evaluation Report and taking into account the comments received, EFSA will consider the need to discuss the outstanding issues in a physical meeting or in an ad hoc TC;
- Following publication of the Reasoned Opinion, the PAFF - section "Pesticides Legislation" is responsible for taking note of the new reference values;
- Once noted, the new reference values will be considered in MRL assessments.

3.2. Implementation of CXLs

In accordance with Article 5(3) of Regulation (EC) No 178/2002 of the European Parliament and of the Council⁹, where international standards exist or their completion is imminent, they are to be taken into consideration in the development or adaptation of food law, except where such standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives of food law or where there is a scientific justification, or where they would result in a different level of protection from the one determined as appropriate in the Community. Moreover, in accordance with point (e) of Article 13 of that Regulation, the Union is to promote consistency between international technical standards and food law while ensuring that the high level of protection adopted in the Union is not reduced.

CXLs proposed by the Joint FAO/WHO Meeting for Pesticides Residues (JMPR) are thoroughly assessed by EFSA and the assessment is subsequently published in an EFSA Scientific Report. The assessment forms the basis for the position the EU takes in the annual meeting of the Codex Committee on Pesticides Residues (CCPR). After adoption of CXLs by the Codex Alimentarius Commission (CAC), the Commission drafts a measure at regular intervals (e.g. at the end of each year) to take over in Regulation (EC) No 396/2005 those Codex maximum residue limits (CXLs) for which it did not present a reservation in CCPR,

⁹ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

except where they relate to products which are not set out in Annex I to that Regulation or where they are set at a lower level than the current MRLs.

3.3. New active substances under Regulation (EC) No 1107/2009

Article 8(1)(g) of Regulation (EC) No 1107/2009 states that the summary dossier of an application for the approval of an active substance shall include, where relevant, a copy of an application for a maximum residue level as referred to in Article 7 of Regulation (EC) No 396/2005. In addition, Article 11(2) mentions that the Assessment Report prepared by the RMS shall also include a proposal to set maximum residue levels, where relevant, including a copy of the application for an MRL and/or the request for an import tolerance.

Consequently, MRLs are implemented under Regulation (EC) No 396/2005, for the representative uses and the intended uses included in the MRL application, on the basis of the recommendations reported in the EFSA Conclusion for the approval of the active substance. In any circumstances, an application form, where the intended uses and GAPS are clearly reported, should be submitted by the RMS along with the dossier to the Commission and EFSA. The drafting of a separate Reasoned Opinion for the setting of MRLs is therefore no longer required.

Where MRLs are being assessed as part of the approval of an active substance, clear recommendations should be made as regards the setting of MRLs. After the period foreseen by Article 12(3) of Regulation (EC) 1107/2009, whenever data is still missing for non-representative uses, the MRL requests should be closed. A new application needs to be submitted by the applicant who will be informed early in the procedure of the data gaps and be given the opportunity to answer before the timeline of closing the MRL requests.

A separate Reasoned Opinion will therefore address those uses that are not regarded as fully supported. By doing so, EFSA is able to finalise the Conclusion within the timeline foreseen by Regulation (EC) No 1107/2009 and the Commission can draft a measure directly after the approval decision. In addition, the applicant may decide to narrow the MRL requests for non-representative uses in the original submission.

The Commission prepares a draft measure setting MRLs or including the active substance in Annex IV to Regulation (EC) No 396/2005 as soon as the approval decision under Regulation (EC) No 1107/2009 is made. This is in view of the fact that authorisations cannot be granted until the relevant MRLs are in place. In order to achieve this objective, as soon as a draft Review Report for a new active substance is added on the Agenda of the PAFF - section "Pesticides Legislation", the Commission consults the European Union Reference Laboratories (EURLs) to provide inputs on the appropriate residue definition and LOQs. In particular, EURLs provide confirmation as to whether LOQs can be achieved by enforcement laboratories across the EU and on the validation of specific analytical methods for the various matrices. Moreover, EURLs inform the Commission on the availability of analytical standards.

3.4. Renewal of the approval of active substances under Regulation (EC) No 1107/2009

The rules governing the renewal of approval of active substances have been revised in order to align them with the provisions of the Transparency Regulation. Commission Implementing

Regulation (EU) 2020/1740 applies to active substances whose approval period ends on or after 27 March 2024, while Commission Implementing Regulation (EU) No 844/2012 continues to apply to substances whose approval period ends before 27 March 2024. Article 7(1)(i) of Regulation (EU) No 844/2012 states that the supplementary summary dossier shall include, where relevant, a copy of an application for maximum residue levels as referred to in Article 7 of Regulation (EC) No 396/2005. In addition, Article 11(2) mentions that the draft Renewal Assessment Report prepared by the RMS and the co-RMS shall also include a proposal to set maximum residue levels, where relevant.

The approach for setting MRLs for active substances that undergo the renewal process under Regulation (EC) No 1107/2009 is similar to the one described in paragraph 3.3. The Commission aims at setting the MRLs resulting from the EFSA conclusions of the peer review as soon as the renewal decision on the active substance is made. By default the MRLs are implemented based on the existing residue definition for enforcement.

However, where the endpoints derived in the renewal process are considerably different from the ones derived in the original approval and where the Article 12 review is already finalised, it may be considered to address the MRL requests separately, e.g. in a specific scientific opinion under Article 43 taking into account the extent and nature of possible concerns raised for any specific MRLs and the need for assessing the MRLs against a new residue definition for enforcement or against new toxicological reference values. Where appropriate and needed as basis for the risk management decision, the EMS and EFSA should present MRL proposals with both the existing and the newly proposed residue definition for enforcement to avoid further delays later on in the procedure.

3.5. Temporary MRLs

3.5.1 Article 16(1) of Regulation (EC) No 396/2005

MRLs may be included in Annex III to Regulation (EC) No 396/2005 on a temporary basis mainly in the following circumstances:

- in exceptional cases, in particular where pesticide residues may arise as a result of environmental or other contamination or from uses of plant protection products pursuant to Article 53 of Regulation (EC) No 1107/2009; or
- where the products concerned constitute a minor component of the diet of consumers, and do not constitute a major part of the diet of relevant subgroups, and, where relevant, of animals; or
- for honey; or
- for herbal infusions; or
- where new products, product groups and/or parts of products have been included in Annex I, and one or more Member States so request, in order to allow any scientific studies necessary for supporting an MRL to be undertaken and evaluated, provided that no unacceptable safety concerns for the consumer have been identified.

The inclusion of temporary MRLs shall be based on the opinion of EFSA, monitoring data from all Member States provided by EFSA and an assessment demonstrating that there are no

unacceptable risks to consumers or animals. In particular, as regards the setting of MRLs on the basis of monitoring data, there is no one fits all approach to determine the methodology for establishing MRLs. Risk managers should take into account the nature and circumstances of each specific case when making a decision. The approach laid down in Regulation (EU) No 283/2013 (point 6.7.2 in Part A of the Annex), the approach for spices or extraneous MRLs (EMRLs) proposed by the Food and Agriculture Organization of the United Nations (FAO)¹⁰ may be considered as well as current working practices in other food safety areas (e.g. for contaminants).

For minor crops including spices and herbal infusions it is very difficult to generate sufficient field trials. For herbal infusions in particular the source plants are sometimes cultivated in very small fields, often imported from third countries and in some cases not even cultivated at all, but collected in the wild. Due to these peculiarities, the setting of temporary MRLs based on monitoring data only may be acceptable provided that the full evaluation procedure is followed and a positive EFSA assessment obtained. To broaden the available information also monitoring data from stakeholders/associations may be considered. However, a case by case decision is needed in view of the quality and the extent of supporting data available.

The continued validity of the temporary MRLs referred to in the first four bullet points above shall be reassessed at least once every 10 years and any such MRLs shall be modified or deleted as appropriate. The maximum period of 10 years is usually set for substances that are known to be persistent in the environment. In other cases, the Commission proposes to set temporary MRLs for a period of 3-4 years and gather monitoring data during that period to study the evolution of the residue levels. In general, the temporary MRLs are reviewed after the deadline for submission of monitoring data. In specific circumstances, where for instance the use of good practices may prevent the occurring of a certain contamination, the MRL may drop automatically to the LOQ unless modified by another Regulation.

The MRLs referred to in the last bullet point shall be reassessed when the scientific studies have been completed and evaluated, but no later than four years after their inclusion in Annex III.

3.5.2 Article 18(4) of Regulation (EC) No 396/2005 following the authorisation of emergency uses according to Article 53 of Regulation (EC) No 1107/2009

A Member State may authorise the placing on the market within its territory of treated food or feed not complying with MRLs established by Regulation (EC) No 396/2005 in exceptional circumstances, and in particular following emergency authorisations granted under Article 53 of Regulation (EC) No 1107/2009, provided that such food or feed does not constitute an unacceptable risk to consumers.

Article 53 of Regulation (EC) No 1107/2009 provides a possibility: *'in special circumstances a Member State may authorise, for a period not exceeding 120 days, the placing on the market of plant protection products for limited and controlled use, where such a measure appears necessary because of a danger which cannot be controlled by any other reasonable means.'*

¹⁰ FAO, 2016. Evaluation of pesticide residues for estimation of maximum residue levels and calculation of dietary intake. FAO Plant Production and Protection Paper 224, Chapter 9, pp. 149-153.

The national authorisation of non-complying food/feed must be immediately notified to the other Member States, the Commission and EFSA together with an appropriate risk assessment. Where applicable, the PRIMo should be attached to the consumer risk assessment.

In view of the nature of these MRL applications, it cannot be expected that they always satisfy all data requirements. In view of such, EFSA should use the stop-the-clock only where necessary and may provide risk management options to address the missing data. The Commission can then either propose the setting of a temporary EU wide MRL for a specified period of time or take any other necessary measure.

3.6 Fast-track procedure by applying the EU guidelines on extrapolation of MRL

Where an application is made to set an MRL for a minor crop on the basis of an extrapolation carried out from a major crop, which was recently assessed by EFSA, a fast-track procedure may apply. This is carried out in accordance with the existing EU guidelines on extrapolation of MRL. There is thus no need for the EMS to draft a thorough Evaluation Report or for EFSA to draft an additional Reasoned Opinion. The aim is to save time and resources both at Member State and EFSA's level and avoid that such applications experience unnecessary delays.

The EMS should draft a 'light' version of the Evaluation Report including basic elements such as the MRL application, reference to the previous EFSA assessment on the major crop, the GAP table, the animal dietary burden calculator (where relevant) and the PRIMO model.

In the draft measure setting MRLs, reference to the existing Union guidelines on extrapolation must be made within the relevant recital to justify the fact that EFSA was not requested to submit a Reasoned Opinion according to Article 10 of Regulation (EC) No 396/2005.

3.7. Annex IV inclusion

Annex IV reports the list of active substances for which MRLs are not required. The general principles for the establishment and update of Annex IV are laid down in Article 5 of Regulation (EC) No 396/2005. The criteria for the inclusion of active substances into Annex IV are outlined in the relevant guidance document (SANCO/11188/2013):

https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_mrl_guidelines_sanco-2013-11188.pdf

It should be noted that the inclusion of an active substance in Annex IV does not necessarily mean a residues assessment is not required to support a product authorisation. Any new uses must fully consider the risk assessment undertaken to include the active in Annex IV. Additional information/data may be required to ensure that for the new uses residue levels will not be of a concern for consumers and/or MRLs.

3.8. Annex VII inclusion

In accordance with Article 18(3) of Regulation (EC) No 396/2005, Member States may authorise, further to a post-harvest treatment with a fumigant on their own territory, residue

levels for an active substance which exceed the existing MRL for a product where the active substance/product combinations are listed in Annex VII.

In order to include an active substance/product combination into Annex VII, an application needs to be submitted for the purpose. The MRL setting procedure outlined in Chapter 2 applies.

4. Deletion of MRLs following the revocation of authorisations of PPPs

According to Article 17 of Regulation (EC) No 396/2005, the Commission may prepare a draft measure to delete the existing MRLs following revocation of authorisations of PPPs. The deletion of the MRL consists in either setting the value to 0.01 mg/kg, as provided in Article 18(1)(b), or to the relevant LOQ.

This type of initiative does not foresee the submission on an application, Evaluation Report and Reasoned Opinion. In practice, the Commission makes use of this procedure in circumstances where all existing authorisations for PPPs containing a specific active substance have been revoked e.g. following non-approval or non-renewal. The deletion does not apply to those MRLs corresponding to CXLs based on uses in third countries or MRLs that have been specifically set as import tolerances, provided that they are acceptable with regard to consumer safety as confirmed by a full and recent EFSA risk assessment. EFSA may be asked to deliver an opinion in cases of doubt whenever needed.

The EURLs are consulted on the appropriate LOQ and residue definition to be used for enforcement purposes. In particular cases, where a high risk was identified in relation to the default value of 0.01 mg/kg, a lower LOQ may be applied specifically to the commodities of concern, provided that such low levels can be achieved by enforcement laboratories across the EU. As the measure would affect trade, an SPS notification needs to be submitted to WTO.

5. Withdrawal of MRL applications

Where an MRL application is no longer necessary or where it is clear that it will not fulfil the requirements set under Article 7 of Regulation (EC) No 396/2005 within a reasonable period, the EMS should approach the applicant requesting to withdraw the application. In cases where the EMS identifies missing information for specific parts of the application, the applicant should be requested to refine his application and take forward only the uses which are fully supported. Following the non-renewal of an active substance or a restriction of use to non-edible crops, the EMS should encourage the applicant to withdraw an MRL application where it concerns EU uses only.

For the purpose of withdrawing an MRL application, the EMS should contact the applicant and then inform both EFSA and the Commission by using the relevant mailboxes:

EFSA: APDESK.applications@efsa.europa.eu and pesticides.mrl@efsa.europa.eu

COM: SANTE-MRLs-applications@ec.europa.eu

In cases where the application was already uploaded in the EFSA Register of Questions, EFSA should close the relevant question number as a Reasoned Opinion will not be issued and send a withdrawal letter to the applicant and EMS.

6. Assessment of confirmatory data identified in the Article 12 procedure of Regulation (EC) No 396/2005

The applicable procedure is outlined in the draft Commission "Working Document on the evaluation of data submitted to confirm MRLs following the review of existing MRLs" (SANTE/10235/2016), which is uploaded on the following webpage:

https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_mrl_guidelines_sanco-10235-2016.pdf

7. Data requirements

The “new” data requirements are laid down in Commission Regulation (EU) No 283/2013:

<http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32013R0283>

The “old” data requirements are laid down in Commission Regulation (EU) No 544/2011:

<http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32011R0544>

Guidance document (SANTE/11509/2013) on the interpretation of the transitional measures for the data requirements for chemical active substances and PPPs:

https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_doss_new-data-req_rev-3.pdf

1) Application for a MRL pursuant to Article 6(1) of Regulation (EC) No 396/2005

When the application for the MRL is prepared in the context of an application for an authorisation of a PPP, the data requirements applicable for the MRL will be the same as the data requirements applicable to the respective active substance in the application for the authorisation for the PPP.

This applies also for applications done in the context of Article 6(2) and 6(3) of Regulation (EC) No 396/2005 insofar it concerns the setting or modification of a MRL for an approved active substance. In the case the substance is not approved, the new data requirements apply.

2) Application for an import tolerance pursuant to Article 6(4) of Regulation (EC) No 396/2005

In the case the substance was not approved or the approval was not renewed under Regulation (EC) No 1107/2009 the new data requirements apply.

In the case the substance was approved or the approval was renewed under Regulation (EC) No 1107/2009 the data requirements applicable to the application for import tolerance will be the same as the data requirements applicable to the application for the approval or the renewal of the approval of the active substance whatever is the latest.

3) Conflicts between Article 6 and Article 12 requirements

Article 6 applications need to comply with the data requirements that exist on the day of submission of the application to the EMS. This means that new requirements set under Article 12 would trigger the stop-the-clock procedure only if the Article 12 Regulation already entered into force at the time of submission of the Article 6 application.

Some examples are reported below for clarification purposes:

i) Article 6 application is submitted before the Article 12 review, but missing data have been identified (e.g. there is no hydrolysis study for this application)

The MRL application should be supported by sufficient data, independently of the MRL review. The data gap highlighted in the MRL review is not a new requirement and therefore a stop-the-clock should be sent to the applicant to provide the missing data as only permanent MRLs are set for new uses.

ii) Article 6 application submitted before the entry into force of the Article 12 Regulation, but endpoints changed in the MRL review

In this case the change in the endpoint is a new requirement and the applicant cannot anticipate changes in the endpoints resulting from the Article 12 review at the time of submission of the MRL application. A more flexible approach is needed to address this circumstance (e.g. temporary MRLs may be set with the same footnotes/deadlines as those reported in the Article 12 Regulation).

iii) Article 6 MRL application submitted after the entry into force of the Article 12 Regulation:

The MRL application should be fully supported by data, based on the endpoints agreed during the Article 12 review.

8 Risk assessment and guidance documents

The risk assessment is carried out in accordance with the provisions laid down in Regulation (EU) No 546/2011 on uniform principles for evaluation and authorisation of plant protection products¹¹. Guidance documents, tools and calculators relevant for the consumer risk assessment of pesticide residues can be found on the following webpage:

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

9 List of contact points

A table reporting the contact details of national authorities dealing with pesticide matters can be found on the following webpage:

https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_legis_national-authorities_en.pdf

¹¹ Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products (OJ L 155, 11.6.2011, p. 127).

10 IT tools

9.1. EU Pesticides Database

The EU Pesticides Database is a tool where all relevant information regarding active substances and their pesticide residues is stored. It also provides users with an insight on draft measures which have been voted by the PAFF - section "Pesticides Residues", but have not yet been published into the Official Journal.

https://ec.europa.eu/food/plant/pesticides/eu-pesticides-db_en

10.2. PPPAMS system

The Plant Protection Products Application Management System (PPPAMS) was developed by the European Commission to enable industry users to create applications for PPPs and submit these to Member States for evaluation. Member States then manage these applications within the system, concluding with authorisation of the PPP or refusal of the application.

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

10.3. EFSA-DMS system

The EFSA-DMS system hosts the Active Substance Assessments Workspace where all peer-review and MRL assessments can be consulted. An access to the EFSA-DMS is restricted to authorised experts from Member States, EFSA and the European Commission:

<https://dmsotds.efsa.europa.eu/otdsws/login>

10.4. EFSA Central Submission System for dossiers, prepared using the IUCLID software

<https://ecs.echa.europa.eu/cloud/home.html>

10.5. OpenEFSA portal

<https://open.efsa.europa.eu/>

10.6. EURLs DataPool

The DataPool has been created by the EU Reference Laboratories (EURLs) for Residues of Pesticides with the aim to provide pesticide residue analysts with a convenient and efficient access to information needed for proper decision-making in pesticide residue analysis.

<http://www.eurl-pesticides-datapool.eu/>

10.7. Codex Pesticides Residues in Food Online Database

The database contains CXLs for Pesticides and EMRLs adopted by the Codex Alimentarius Commission. In the database a user can obtain information on CXLs and EMRLs for pesticide/commodity combinations. Names and definitions of commodities are found in the Codex Classification of Foods and Animal Feeds.

<http://www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/pestres/pesticides/en/>

11 Abbreviations

| | |
|---------|--|
| CCPR | Codex Committee on Pesticides Residues |
| CIRCABC | Communication and Information Resource Centre for Administrations, Businesses and Citizens |
| COM | European Commission |
| CXL | Codex Maximum Residue Limit |
| DMS | EFSA Document Management System |
| EEA | European Economic Area |
| EFSA | European Food Safety Authority |
| EMRL | Codex Extraneous Maximum Residue Limits |
| EMS | Evaluating Member State |
| EURL | European Union Reference Laboratory |
| FAO | Food and Agricultural Organization of the United Nations |
| GAP | Good Agricultural Practice |
| LOQ | Limit of Quantification |
| MRL | Maximum Residue Level |
| NEU | Northern EU |
| PAFF | Standing Committee on Plants, Animals, Food and Feed |
| PPP | Plant Protection Product |
| PPPAMS | Plant Protection Products Application Management System |
| PRIMo | Pesticide Residue Intake Model |
| RMS | Rapporteur Member State |
| SEU | Southern EU |
| SPS | Sanitary and phytosanitary (measures and agreements) |
| WTO | World Trade Organization |
| zRMS | Zonal Rapporteur Member State |



