EUROPEAN COMMISSION
HEALTH & FOOD SAFETY DIRECTORATE-GENERAL

Safety of the food chain
Pesticides and Biocides

SANTE/2015/10595 Rev. 4
23 September 2016

GUIDANCE DOCUMENT[1]

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 a guidance document 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.

Table of contents

1. Introduction

Articles 6 to 11 and Article 14(1) of Regulation (EC) No 396/2005[2] on Maximum Residue Levels (MRLs) for pesticides describe the procedure for applications for MRLs. Article 8(1)(g) of Regulation (EC) No 1107/2009[3] 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 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 LOQ.

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.

[2] 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.

[3] 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 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 plant protection product 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 data[4].

An application for the lowering or deletion of the existing MRL may be submitted where, for instance, consumer intake concerns are identified or because the approval of the active substance has been withdrawn.

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);

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).

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

The consumer risk assessment is first carried out by the competent authorities for the application of MRLs in Member States in the form of an Evaluation Report and then, upon request of the Commission, finalised by the European Food Safety Authority (EFSA) in the form of a Reasoned Opinion.

The Commission, who is in charge of the risk management phase, prepares a draft proposal for a Regulation to implement the MRLs in the Annexes to Regulation (EC) No 396/2005. The proposal is based on the Reasoned Opinion of EFSA and is discussed and voted at the Standing Committee on Plants, Animals, Food and Feed (PAFF) with experts from the 28 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 applicants should fill in the EU harmonised format for MRLs applications that can be found on the following webpage:

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

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 zRMS. Although the authorisation is not being sought in the zRMS' territory, the zRMS should complete the ER 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 for uses in the NEU and 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 for a decision in accordance with Article 8 subparagraphs (3) and (4).

Concerning applications for import tolerances see Chapter 3.1.

2) Compliance check

The Evaluating Member State (EMS) has to verify whether the application fulfils the requirements set under Article 7 of Regulation (EC) No 396/2005. Where the application is compliant, the EMS shall immediately forward a signed copy, either by the applicant or the

EMS on behalf of the applicant, to the Authority and the Commission in accordance with Article 8(1).

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) Informing the Commission and EFSA of the application

Member States are to submit MRL applications and Evaluation Reports to both EFSA and the Commission by using the relevant mailboxes:

EFSA: APDESK.applications@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 and informs all Member States' contact points that a new application has been received.

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.

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

The relevant EU harmonised format Evaluation reports are found on the following webpage:

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

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 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;

c) Send the supporting dossier to EFSA, when requested to do so (e.g. CD in Caddy format, send as an attachment by e-mail, upload on the EFSA-DMS).

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 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 valid 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 Article 6 proposals, 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 may consider stopping the evaluation.

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 be outlined in the reasoned opinion and will need to be addressed in a new submission.

Where MRLs are being assessed as part of the approval or renewal 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 manages to draft a proposal directly after the approval decision. In addition, the applicant may decide to narrow the MRL requests for non-representative uses in the original submission for strategic purposes.

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 is made publicly available as background document in the Register of Questions. This document is published once the consultation process with the applicant concerning any justified requests for removal of confidential information has been finalised.

http://registerofquestions.efsa.europa.eu/roqFrontend/login?

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 products[5]. Guidance documents 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

[5] 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).

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 Standing Committee. 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 proposal, which will become applicable 20 days after publication. Such proposals are trade facilitating measures and are therefore not bound to be notified to WTO via the SPS procedure. However, for the sake of transparency, those proposals 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 proposal must therefore be notified to WTO for a commenting period of 60 days. The application date of the Regulation is deferred of 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. Moreover, the Regulation provides for a transitional arrangement for products which have been produced before the modification of the MRLs and for which information shows that a high level of consumer protection is maintained.

In view of the different procedures, in most cases the Commission deals with such applications in a separate proposal. 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 Standing Committee for discussion in the A section of the agenda. 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

Where EFSA proposes to change the residue definition of the substance, the Standing Committee decides in which legal framework the matter should be addressed. In particular, the RMS should be consulted. This is carried out on a case by case basis.

12) Interservice-Service Consultation

All relevant Commission services are consulted before the proposal is put for an opinion of the Standing Committee.

13) Draft proposal on CIRCABC

In parallel, the draft proposal for a Regulation 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 proposal. Major issues should not be left for discussion on the days of the Standing Committee in view of the extent of the proposals and the limited time allocated. The Commission revises the proposal to reflect the suggestions being made.

15) Opinion of the Standing Committee

The final version of the proposal is put for a vote at the Standing Committee. The following steps are covered by the regulatory procedure with scrutiny referred to in Article 45(4).

16) Proposal 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:

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 proposal.

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

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 Pesticide Database (http://ec.europa.eu/sanco_pesticides/public/?event=activesubstance.selection), 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/plant/pesticides/legislation/docs/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 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:

http://ec.europa.eu/food/plant/pesticides/guidance_documents/mrls_en.htm.

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 notified or authorised 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 Evaluating Member State (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 plant protection product 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.

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 into 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 proposal should report the specific commodities for which the application was made and indicate whether supporting data were available.

3.2. Implementation of CXLs

In accordance with Article 5(3) of Regulation (EC) No 178/2002 of the European Parliament and of the Council[6], 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.

At regular intervals (e.g. at the end of each year), the Commission drafts a proposal to implement the Codex maximum residue limits (CXLs) adopted by the Codex Alimentarius

[6] 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).

Commission. In preparation of the Codex Committee on Pesticides Residues (CCPR), EFSA provides a Scientific report as basis for the preparation of an EU position. CXLs for which the Union did not present a reservation to CCPR, are included in the Annexes to Regulation (EC) No 396/2005 as MRLs, 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 (NAS) 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 proposals 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.

The Commission prepares a proposal 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, the EURLs are consulted at an early stage to provide inputs on the appropriate residue definition and limits of quantification (LOQs).

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

Commission Implementing Regulation (EU) No 844/2012 sets out the provisions necessary for the implementation of the renewal procedure for active substances:

http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32012R0844

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. However, where the endpoints derived in the renewal process are considerably different from the ones derived in the original approval, it may be considered to address the MRL requests under another framework such as the Article 12 review or a scientific opinion under Article 43 of Regulation (EC) No 396/2005.

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)[7] may be considered as well as current working practices in other food safety areas (e.g. for contaminants).

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 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

[7] 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, p 149.

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*.'

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 Pesticide Residue Intake Model (PRIMo) should be attached to the consumer risk assessment.

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. 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):

http://ec.europa.eu/food/plant/pesticides/guidance_documents/docs/mrl_application_form_en.doc

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.

3.7. 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 proposal to delete the existing MRLs following revocation of authorisations of plant protection products. 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.

In practice, the Commission makes use of this procedure in circumstances where all existing authorisations for plant protection products containing a specific active substance have been revoked. 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.

This is an exceptional circumstance, where the measure does not need to be based on an EFSA opinion. The EURLs are consulted on the appropriate LOQ and residue definition to be used for enforcement purposes. As the measure would affect trade, an SPS notification needs to be submitted to WTO.

5. 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:

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

6. 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 AS and PPPs:

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

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.

7 List of contact points

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

http://ec.europa.eu/food/plant/pesticides/legislation/docs/national-authorities_en.pdf

8 IT tools

8.1. 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 proposals which have been voted by the Standing Committee, but have not yet been published into the Official Journal.

http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/

8.2. PPPAMS system

The 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.

The system can be accessed through the following web-link:

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

8.3. 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

8.4. EFSA Register of Questions

The Register of Questions provides with an overview of all past and on-going EFSA assessments. All documents related to the registration of the application, the final EFSA opinion and the Evaluation report are publicly available:

http://registerofquestions.efsa.europa.eu/roqFrontend/login?

8.5. 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/

8.6. Codex Pesticides Residues in Food Online Database

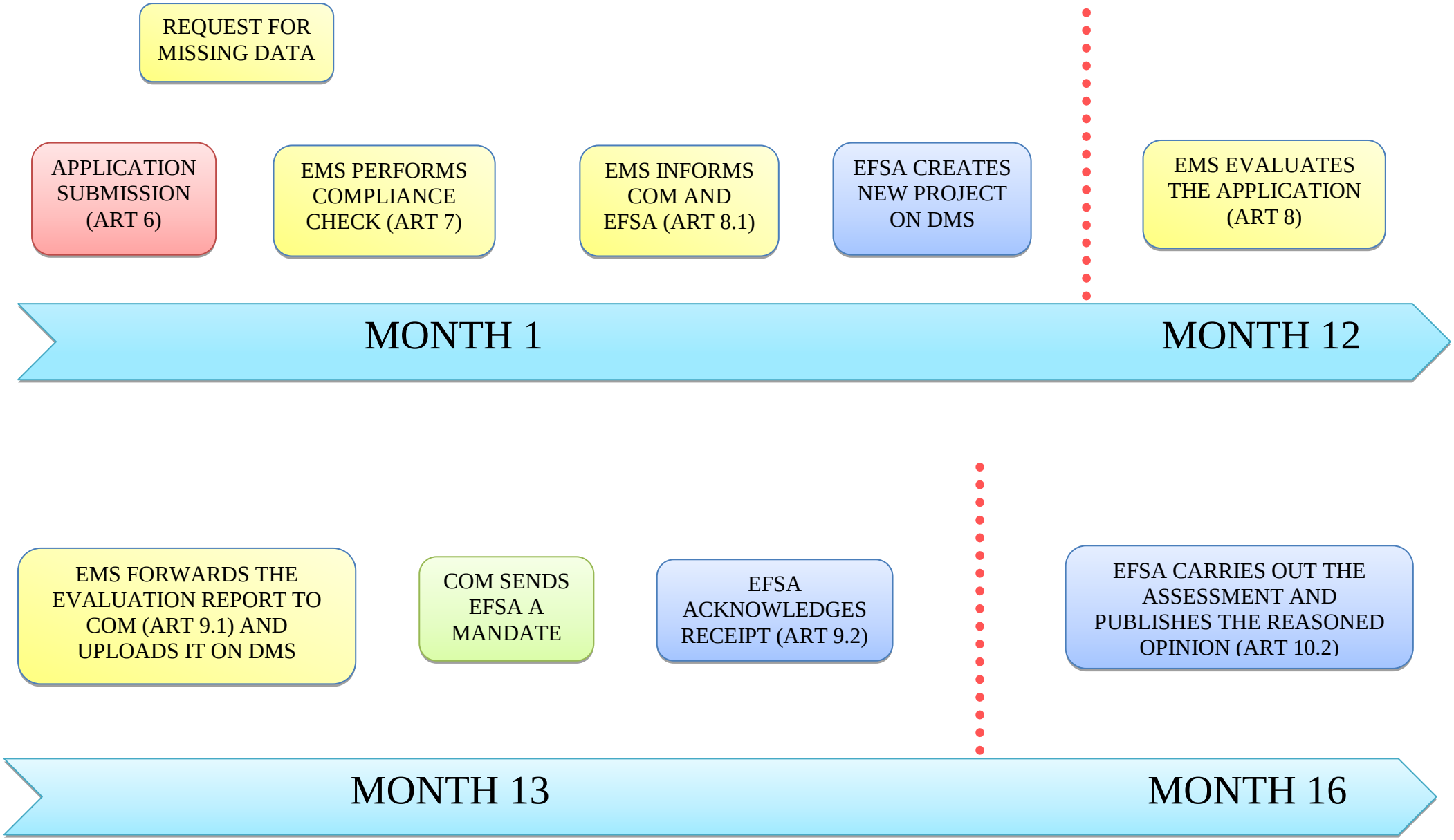
The database contains Codex Maximum Residue Limits (CXLs) for Pesticides and Extraneous Maximum Residue Limits (EMRLs) adopted by the Codex Alimentarius Commission. In the database a user can obtain information on CXLs and EMRLs for pesticide/commodity combinations. Names and definitions of commodities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

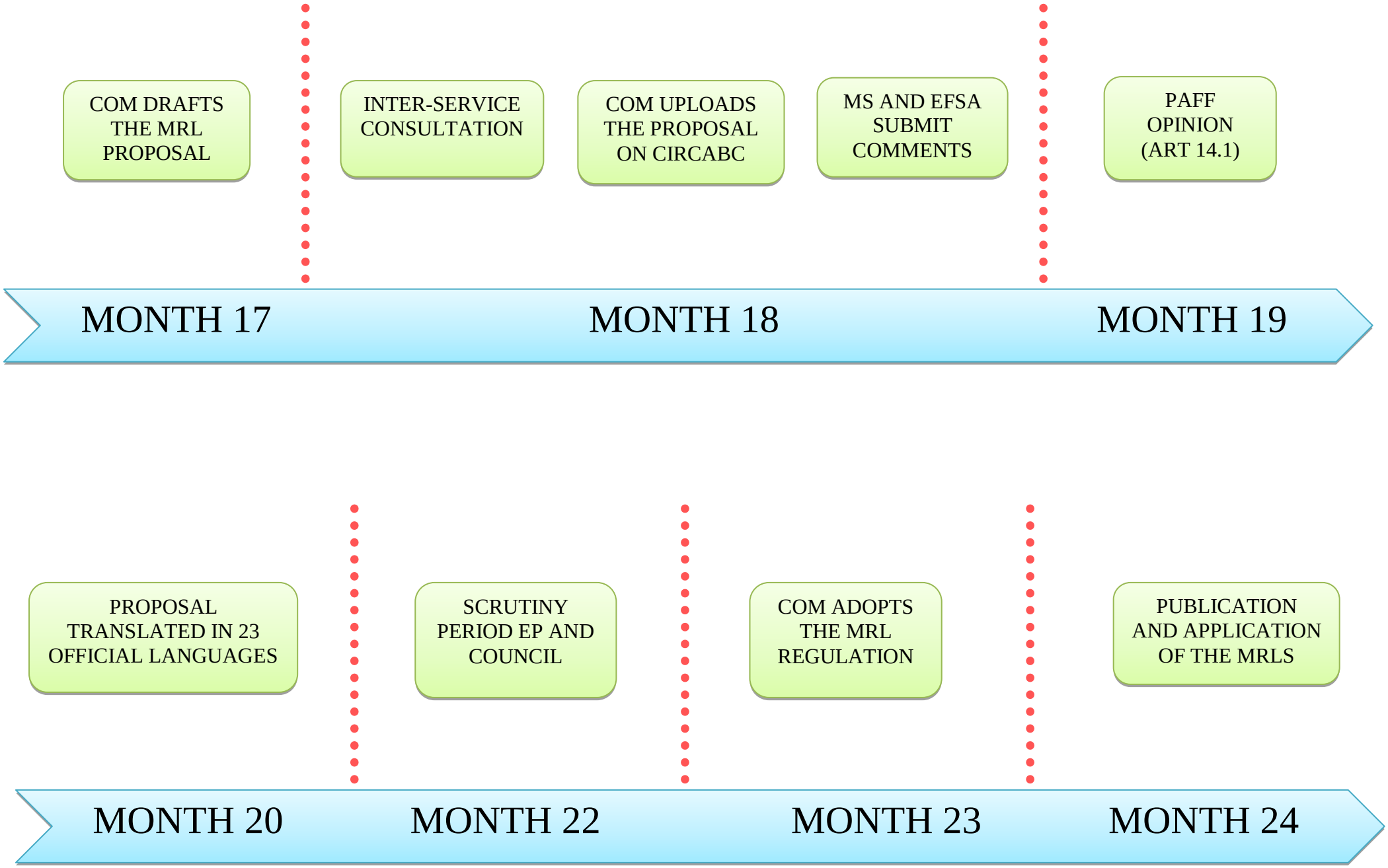
http://www.fao.org/fao-who-codexalimentarius/standards/pestres/en/

9 Abbreviations

CXL	Codex maximum residue limit
EEA	European Economic Area
EFSA	European Food Safety Authority
EMRL	Codex Extraneous Maximum Residue Limits
EMS	Evaluating Member State
FAO	Food and Agricultural Organization of the United Nations
GAP	Good agricultural practice
LOQ	Limit of quantification
MRL	Maximum residue level
NEU	Northern Europe
RMS	Rapporteur Member State
SEU	Southern Europe
SPS	Sanitary and phytosanitary (measures and agreements)
WTO	World Trade Organization
zRMS	Zonal Rapporteur Member State

ANNEX I


REQUEST FOR MISSING DATA
APPLICATION SUBMISSION (ART 6)
EMS PERFORMS COMPLIANCE CHECK (ART 7)
EMS INFORMS COM AND EFSA (ART 8.1)
EFSA CREATES NEW PROJECT ON DMS
EMS EVALUATES THE APPLICATION (ART 8)
MONTH 1
MONTH 12
EMS FORWARDS THE EVALUATION REPORT TO COM (ART 9.1) AND UPLOADS IT ON DMS
COM SENDS EFSA A MANDATE
EFSA ACKNOWLEDGES RECEIPT (ART 9.2)
EFSA CARRIES OUT THE ASSESSMENT AND PUBLISHES THE REASONED OPINION (ART 10.2)
MONTH 13
MONTH 16


COM DRAFTS THE MRL PROPOSAL
INTER-SERVICE CONSULTATION
COM UPLOADS THE PROPOSAL ON CIRCABC
MS AND EFSA SUBMIT COMMENTS
PAFF OPINION (ART 14.1)
MONTH 17
MONTH 18
MONTH 19
PROPOSAL TRANSLATED IN 23 OFFICIAL LANGUAGES
SCRUTINY PERIOD EP AND COUNCIL
COM ADOPTS THE MRL REGULATION
PUBLICATION AND APPLICATION OF THE MRLS
MONTH 20
MONTH 22
MONTH 23
MONTH 24