Changes in Procedures for Setting Maximum Residue Levels (MRLs) for Pesticides in the European Union (EU)

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Although the first MRL Directive was published in 1976, Community Maximum Residue Levels (MRLs) were set only for a limited number of pesticides until September 1, 2008. For some pesticides, different levels were established as national MRLs by the Member States, and for some pesticides no MRLs were set. Before September 1, 2008, there were four separate MRL Directives. The first one was published in 1976, the second and third ones were published in 1986, and the fourth one was published in 1990. Those four MRL Directives were replaced by the MRL Regulation published in 2005. The MRL Regulation did not only consolidate MRLs that appeared in the four MRL Directives, but it also established procedures and Annexes which were not included in the MRL Directives. This article summarises the provisions introduced by the MRL Regulation and the changes on the procedures for setting/modifying MRLs.

This paper is translated from R&D Report, "SUMITOMO KAGAKU", vol. 2020.

Introduction

Since the days of the European Economic Community (EEC), the European Union (EU) has recognised that differences which exist between Member States for the Maximum Residue Levels (MRLs) for pesticide residues can help to create barriers to trade.

To achieve the free movement of goods within the European Community (hereinafter, the "Community"), the EU's first MRL Directive relating to the fixing of MRLs for pesticide residues in and on fruit and vegetables was established and published in 1976. In 1986, the second MRL Directive for pesticide residues in and on cereals and the third MRL Directive for pesticide residues in and on foodstuffs of animal origin were published. These were followed in 1990 by the fourth MRL Directive on pesticide residues in and on certain products of plant origin, including fruit and vegetables. Accordingly, there were four separate MRL Directives.

However, under these Directives, Community MRLs were set for only a limited number of pesticides. For pesticides for which Community MRLs had yet to be set, some Member States had set national MRLs for some pesticide, while for some pesticides, no MRLs were set at all.

The MRL Regulation, which consolidated the four MRL Directives and set out specific procedures and details for setting or modifying MRLs, was published in 2005. Annexes containing lists of EU-harmonised MRLs and active substances (ASs) for which no MRLs are required were established by an Amendment Regulation published in 2008. For pesticide residues for which no specific MRL is set out in the Annexes to the MRL Regulation or for which ASs are not included in the list of ASs for which no MRLs are required, a default MRL of 0.01 mg/kg is applied unless different default values are fixed.

After the Community MRLs and ASs for which no MRLs are required were set in the Annexes to the MRL Regulation, evaluations for modifying the existing MRLs, setting new MRLs, and adding new ASs to the list of ASs for which no MRLs are required commenced in accordance with the procedure set out in the MRL Regulation.

Sumika Technoservice Corporation has long conducted investigations of regulatory information pertaining

to the EU's MRLs and provided support regarding the information required for setting or modifying MRLs. Based on that experience, this article provides an overview of the previous MRL Directives established for setting MRLs for pesticides as well as the MRL Regulation that replaced such Directives, and it summarises how the evaluation procedures for setting or modifying MRLs under the MRL Regulation have been established and improved.

MRL Directives and MRL evaluation under the MRL Directives

1. The early days of MRL evaluation under the MRL Directives

When MRL Regulation 396/2005[1] was published in the EU Official Journal (OJ) on March 16, 2005, the following four separate MRL Directives existed.

Directive 76/895/EEC[2] (published on December 9, 1976): Fixing of MRLs for pesticide residues in and on fruit and vegetables

Directive 86/362/EEC[3] (published on August 7, 1986): Fixing of MRLs for pesticide residues in and on cereals

Directive 86/363/EEC[4] (published on August 7, 1986): Fixing of MRLs for pesticide residues in and on foodstuffs of animal origin

Directive 90/642/EEC[5] (published on December 14, 1990): Fixing of MRLs for pesticide residues in and on certain products of plant origin, including fruit and vegetables

Each of the aforementioned four Directives consisted of the main text and Annexes I and II; Annex I contained a list of products, while Annex II contained a list of pesticide residues and MRLs.

Some products were duplicated in Directive 76/895/EEC and Directive 90/642/EEC. This is because Directive 90/642/EEC was adopted as a separate Directive with a view to transferring the MRLs set in Directive 76/895/EEC to it progressively.

Under Directive 76/895/EEC Member States may authorise the circulation within their territories of products which contain pesticide residues higher than the MRLs laid down in Annex II of the Directive (Article 3 (2)), mandatory maximum levels were to be fixed in Directive 90/642/EEC.

Due to Directive 91/414/EEC[6] concerning the placing of plant protection products (PPPs) on the market, authorisation of a PPP required MRLs in the agricultural products referred to in the authorisation have been provisionally established by the Member State and notified to the European Commission, the Commission shall consider whether the provisional MRLs are acceptable and it shall establish provisional MRLs throughout the Community (Article 4 (1) (f) of Directive 91/414/EEC). In addition, in conjunction with the approval examination of ASs under Directive 91/414/EEC, a guidance document[7] for the generation of data concerning residues and the evaluation of residue data was developed. This document provided EU guidance regarding residue trials for MRL setting, MRL calculation methods, and other matters.

Amendment Directive 97/41/EC,[8] which incorporated a mechanism provided in PPP Directive 91/414/EEC into the MRL Directives, clearly set out the evaluation procedure for MRLs.

However, prior to the amendment made by Amendment Directive 97/41/EC, modification of MRLs had been provided for by only the following brief sentences in each MRL Directive.

Directive 76/895/EEC:

The European Council, acting on a proposal from the Commission, shall adopt amendments to be made to the Annexes. In making such amendments account shall be taken of technical and scientific progress as well as of the requirements of health and agriculture (Article 5).

Directives 86/362/EEC and 86/363/EEC:

Amendments to the maximum levels set in Annex II as a result of developments in scientific or technical knowledge shall be adopted by the Council acting by a qualified majority on a proposal from the Commission (Article 10).

The Council, acting unanimously on a proposal from the Commission, shall adopt, by means of Directives, any new list of products or any new list of pesticide residues in and on the products, and their maximum values (Article 11).

Directive 90/642/EEC:

The list of pesticide residues concerned and their maximum levels shall be established by the Council, acting by a qualified majority on a proposal from the Commission (Article 1 (1)).

Amendments to the Annex as a result of developments in scientific or technical knowledge shall be adopted by the Council acting by a qualified majority on a proposal from the Commission (Article 7).

Table 1 EU MRL Amendment Directives in which certain positions were left open

Amendment Directives	Amending 86/362/EEC	Amending 86/363/EEC	Amending 90/642/EEC	Amending 76/895/EEC	Initial time limit	Extended time limit*
93/57/EEC	○	○	–	–	1998.01.01	1998.10.31
93/58/EEC	–	–	○	(Deletion)	1998.01.01	1998.10.31
94/29/EC	○	○	–	–	1999.06.30	2000.07.01
94/30/EC	–	–	○	–	1999.06.30	2000.07.01
95/38/EC	–	–	○	–	2000.07.01	–
95/39/EC	○	○	–	–	2000.07.01	–
96/32/EC	–	–	○	–	2000.04.30	2000.07.01
96/33/EC	○	○	–	–	2000.04.30	2000.07.01

○: Pesticides were added.
*: Time limits were extended by Directive 97/71/EC.

In Amendment Directive 93/57/EEC,[9] which amended Directives 86/362/EEC and 86/363/EEC, and Amendment Directive 93/58/EEC,[10] which amended Directives 76/895/EEC and 90/642/EEC, MRLs for certain pesticide crop combinations were left open (open position) for a limited time where available data were insufficient for the pesticide crop combinations to establish MRLs. A provision was introduced to establish MRLs on the basis of data provided within a specified period of time whereas establish MRLs at the appropriate limit of determination (LOD) if data was not provided. Similar Amendment Directives 94/29/EC,[11] 94/30/EC,[12] 95/38/EC,[13] 95/39/EC,[14] 96/32/EC,[15] and 96/33/EC[16] were published on several occasions as shown in **Table 1**; for some of these, the initial time limit was extended by Amendment Directive 97/71/EC.[17]

In this way, though some parts remained to be worked on, Community MRL setting of many more pesticides started.

2. MRL evaluation under the MRL Directives amended by Amendment Directive 97/41/EC

Amendment Directive 97/41/EC, which incorporated a mechanism provided in PPP Directive 91/414/EEC into the MRL Directives, revised the articles of Directives 76/895/EEC, 86/362/EEC, 86/363/EEC, and 90/642/EEC.

A reference to the provisions in Directive 91/414/EEC was incorporated into the following articles of each Directive (with the exception of Directive 76/895/EEC, in which no addition of MRLs would occur).

Directives 86/362/EEC and 86/363/EEC: Article 5 (replacement)
Directive 90/642/EEC: Article 5a (addition)

When establishing MRLs, account shall be taken of a relevant dietary intake risk assessment and of the number and quality of the data available was incorporated into the following articles of each Directive.

Directive 76/895/EEC: Article 5 (replacement)
Directives 86/362/EEC and 86/363/EEC: Article 10 (replacement)
Directive 90/642/EEC: Article 7 (replacement)

Member States of destination shall introduce arrangements for establishing MRLs for products brought into their territories from a Member State of origin, in cases where no MRLs have been established for those products was incorporated into the following articles of each Directive.

In the following articles, the conciliation procedure to be invoked when no Community MRL has been established for a product, when a product which satisfies the MRLs applied by its Member State of origin contains pesticide residue levels in excess of MRLs accepted in the Member State of destination, and when either the Member State of destination has introduced new MRLs or has altered MRLs which differ substantially from the corresponding levels established by other Member States was also incorporated. Such conciliation procedures include submitting a proposal aimed at establishing a temporary MRL by the Commission.

These articles provided that in such a proposal, the Commission shall take into account of existing technical and scientific knowledge on the matter and in particular data submitted by the Member States with an interest, especially the toxicological assessment and estimated acceptable daily intake (ADI), good agricultural practices (GAP) and the trial data which the Member States of origin used to establish the MRL.

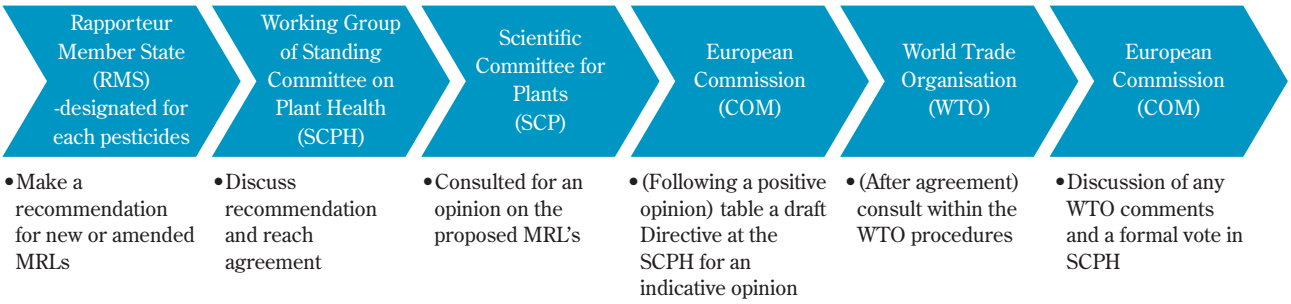


Fig. 1 Scheme of procedures for setting and reviewing MRLs

Directive 76/895/EEC:
Article 5a (addition)
Directives 86/362/EEC and 86/363/EEC:
Article 5a (replacement of Article 5)
Directive 90/642/EEC:
Article 5b (addition)

After certain provisions were amended by Amendment Directive 97/41/EC, the European Commission developed the "Programme of work on pesticide maximum residue levels (MRL's)." [18]

The programme of work describes the procedures for setting and reviewing MRLs. **Fig. 1** shows a simplified scheme for the procedures.

The programme of work also describes the following 11 situations identified where MRLs need to be fixed, and timetables are given for some of the situations. In the following 11 situations, reviewing of MRLs which were fixed on a temporary basis for acephate, methamidophos, and vinclozolin in accordance with Amendment Directive 98/82/EC is included as one of the situations.[19]

- Open positions: Amendments of existing MRLs with "open positions" incorporated by past Amendment Directives
- Pre-prepared pesticides: Re-examination of pesticides for which MRL proposals had been prepared but which were not finally included in Amendment Directives
- New ASs: Approval of ASs and subsequent Article 4 (1) (f) of Directive 91/414/EEC notifications by which MRLs may be set
- Existing ASs: Amendment of MRLs following approval, withdrawal of uses, or non-approval
- Revision of Directive 76/895/EEC: Continuing re-evaluation of MRLs fixed in the Annexes to Directive 76/895/EEC
- Cases of concern: Amendment of existing or setting of new MRLs for pesticides where a concern that residues may pose a risk to human health is informed
- Conciliation procedure: Setting of temporary MRLs after conciliation procedure is invoked in situations where no Community MRLs exist and where differences in national MRLs give rise to a dispute
- Safeguard clause: Amendment of MRLs where the procedures in the safeguard clauses are triggered
- New or changed use: Amendment of MRLs following assessment of information and studies of a newly authorised use or changed use
- Import tolerance (IT): Setting or amendment of MRLs where an IT is requested
- Vinclozolin, methamidophos and acephate: Reviewing of temporary MRLs

Due to the programme of work, the frequency of amendments to the MRL Directives increased compared to the period before the introduction of the programmes.

MRL evaluation under the MRL Directives continued until the evaluation of MRLs in accordance with MRL Regulation 396/2005 began.

MRL Regulation and MRL evaluation under the MRL Regulation

1. Structure of MRL Regulation 396/2005

MRL Regulation 396/2005 was published in the OJ on March 16, 2005; it came into force on April 5, 2005.

From the date referred to in the second paragraph of Article 50 (September 1, 2008, which was 6 months from the publication of Amendment Regulation 149/2008,[20] the last of the Regulations establishing Annexes I–IV, in the OJ on March 1, 2008), MRL Directives 76/895/EEC, 86/362/EEC, 86/363/EEC, and 90/642/EEC were repealed and replaced by MRL Regulation 396/2005.

Regulation 396/2005 consists of the chapters listed

in **Table 2** and the Annexes listed in **Table 3**. Annexes corresponding to Annexes I and II also existed under the MRL Directives, and some of the content established by the MRL Directives is contained in Annexes I and II of Regulation 396/2005. Annexes III to VII are newly established by Regulation 396/2005.

Annexes II, III, and V list specific MRLs. Annex IV lists ASs for which no MRLs are required. The default value of 0.01 mg/kg shall be applied to products listed in Annex I for which no specific MRL is set out in Annexes II or III, or for ASs not listed in Annex IV, unless different default values are fixed for an AS taking into account the routine analytical methods available, and set out in Annex V (Article 18 (1) (b)).

It was provided that Chapters II, III, and V shall apply as from 6 months from the publication of the last of the Regulations establishing Annexes I, II, III, and IV (Article 50).

Although Regulation 396/2005 specified a time limit to establish Annexes I, II, III, and IV, Annexes II, III, and IV were established nearly 2 years after the date referred to in the Regulation (April 5, 2006) as shown in **Table 3**.

Annex I provided a list of products for which harmonised MRLs shall apply in accordance with the provisions of Article 4. In addition to products for which MRLs under MRL Directives existed and other products for which national MRLs existed, other products

Table 2 Chapters provided in Regulation 396/2005

Chapter	Title	Articles
I	Subject matter, scope and definitions	1–5
II*	Procedure for applications for MRLs	6–17
III*	MRLs applicable to products of plant and animal origin	18–20
IV	Special provisions relating to the incorporation of existing MRLs into this Regulation	21–25
V*	Official controls, reports and sanctions	26–34
VI	Emergency measures	35
VII	Support measures relating to harmonized pesticide MRLs	36–37
VIII	Coordination of applications for MRLs	38–42
IX	Implementation	43–47
X	Final provisions	48–50

*: These Chapters apply as from 6 months from the publication of the last of the Regulations establishing Annexes I, II, III and IV.

Table 3 Annexes to Regulation 396/2005

Annex (to be first established within)		Title (first established by)
Annex I (2005.07.05 - 3 months from EIF (2005.04.05) - Art.4(2))		Products of plant and animal origin referred to in Article 2(1) (Regulation 178/2006 (2006.02.02))
Annex II (2006.04.05 - 12 months from EIF (2005.04.05) - Art.21(2))		MRLs formerly defined under Directives 86/362/EEC, 86/363/EEC and 90/642/EEC, referred to in Article 21(1) (Regulation 149/2008 (2008.03.01))
Annex III (2006.04.05 - 12 months from EIF (2005.04.05) - Art.22(2))		Temporary MRLs referred to in Articles 16(1) and 22(1) (Regulation 149/2008 (2008.03.01))
	Part A	Temporary MRLs for substances without MRLs under Directives 86/362/EEC, 86/363/EEC and 90/642/EEC
	Part B	Temporary MRLs for products not defined in Annexes I of Directives 86/362/EEC, 86/363/EEC and 90/642/EEC
Annex IV (2006.04.05 - 12 months from EIF (2005.04.05) - Art.5(2))		List of active substances of plant protection products evaluated under Directive 91/414/EEC for which no MRLs are required, referred to in Article 5(1) (Regulation 149/2008 (2008.03.01))
Annex V (No time limit)		List of default values, as referred to in Article 18(1)(b) (Regulation 899/2012 (2012.10.06))
Annex VI (No time limit)		(Not established yet)
Annex VII (No time limit)		Active substance/product combinations, as referred to in Article 18(3) (Regulation 260/2008 (2008.03.19))

for which it was appropriate to apply harmonised MRLs were included in Annex I. Annex I was established by Amendment Regulation 178/2006[21] published in the OJ on February 2, 2006 and came into force on February 22, 2006.

Annexes II, III, and IV were established by Amendment Regulation 149/2008 published in the OJ on March 1, 2008 and came into force on September 1, 2008, 6 months after their publication in the OJ. Amendment Regulation 839/2008,[22] which partially amended Annexes II, III, and IV established by Amendment Regulation 149/2008, was published in the OJ on August 30, 2008. This amendment was made to add the following to Annexes II to IV: harmonised MRLs under the MRL Directives that had not been listed in Annex II established by Amendment Regulation 149/2008, national MRLs that had not been listed in Annex III, and additional ASs for which certain Member States requested to include in Annex IV, list of ASs for which no MRLs are required. Accordingly, the Regulation applied from September 1, 2008, the same date that Amendment Regulation 149/2008 came into force.

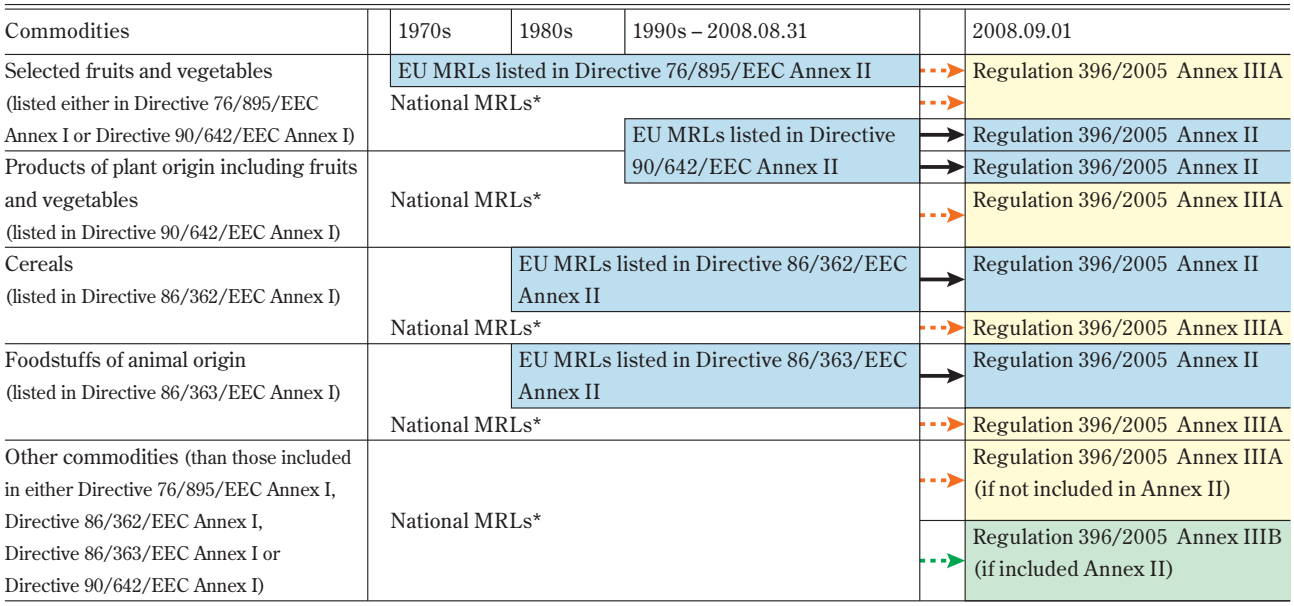
In Annex II, MRLs provided for under Directives 86/362/EEC, 86/363/EEC, and 90/642/EEC were incorporated in accordance with the provisions of Article 21 (1).

Annex III was divided into Parts A and B.

In Part A of Annex III, remaining MRLs in Annex II of Directive 76/895/EEC and the temporary MRLs that take into account the national MRLs for ASs for which decisions on approval or non-approval had not yet been taken under PPP Directive 91/414/EEC were listed, unless already listed in Annex II, in accordance with the provisions of Article 22 (1). With regard to the national MRLs, where an AS for which a decision on approval or non-approval had not yet been taken under PPP Directive 91/414/EEC and where a Member State had set, by the date of entry into force of Annex I (February 22, 2006) at the latest, a national MRL for the AS for a product or had decided that no MRL was required for the AS, the Member State concerned should notify the Commission of the national MRL, or the fact that no MRL was required for the AS in accordance with the provisions of Article 23.

In Part B of Annex III, temporary MRLs for new products for which no MRLs had been set in Directives 86/362/EEC, 86/363/EEC, or 90/642/EEC with pesticide residues listed in Annex II were listed in accordance with the provisions of Article 16 (1) (f).

Fig. 2 shows how the MRLs set by the MRL Directives and the national MRLs were transferred to Annexes II and III of the MRL Regulation.



*: Regarding the national MRLs notified by Member States, MRLs which do not present an unacceptable risk to consumers were set as temporary MRLs in Annex III.
→: Incorporated in accordance with Art.21(1)
⇢: Incorporated in accordance with Art.22(1) and taking into account EFSA Opinion.
⇢: Incorporated in accordance with Art.16(1)(f) and taking into account EFSA Opinion.

Fig. 2 EU MRLs fixed by MRL Directives and National MRLs transferred to EU MRLs under Regulation 396/2005

In Annex IV, the ASs evaluated under PPP Directive 91/414/EEC for which no MRL are required were listed in accordance with the provisions of Article 5 (1).

In accordance with the provisions of Article 24, the European Food Safety Authority (EFSA) provided a Reasoned Opinion (RO) on potential risks to consumer health arising from temporary MRLs that may be included in Annex III and ASs that may be included in Annex IV.

The EFSA carried out the risk assessment of proposed temporary MRLs and recommended MRLs which did not present an unacceptable risk to consumers as temporary MRLs in an RO.[23), 24)] As for ASs for which no MRL are required, the EFSA recommended ASs that would not present an unacceptable risk, associated with the use of the ASs according to the authorised uses, to consumers without setting MRL in an RO.[25)] The MRLs to be listed in Annex III and the ASs to be included in Annex IV were set on the basis of these ROs.

In Annex V, if no specific MRLs were set out for products in Annex II or III, or for ASs not listed in Annex IV, default values fixed for ASs taking into account the routine analytical method available were listed in accordance with the provisions of Article 18 (1) (b). For non-approved ASs in the EU for which MRLs specially set as ITs, etc. do not exist and approved ASs which are not applied to products for which MRL is required and cause no residue to such products as a result of authorised use, MRLs were set in Annex V. Annex V was first established by Amendment Regulation 899/2012.[26)] Where all existing authorisation of PPPs have been revoked following non-approval of ASs, the MRLs set out for those ASs in Annex II or III are to be deleted in accordance with the provisions of Article 17. For ASs for which MRLs corresponding to Codex MRLs (CXLs) based on uses in third countries or those specially set as ITs do not exist, all MRLs were reduced to the relevant LOD, and such default values were fixed and listed in Annex V in accordance with the provisions of Article 18 (1) (b).

In Annex VI, specific concentration or dilution factors for certain processing and/or mixing operations or for certain processed and/or composite products are to be included in accordance with the provisions of Article 20 (2). At present, however, Annex VI has not yet been established.

In Annex VII, AS/product combinations for which, further to post-harvest treatment with a fumigant, residue levels for an AS may be authorised even when those levels exceed the MRLs specified in Annex II or III for product provided that the products are not intended for immediate consumption and cannot be made available to the end user or consumer until the residues no longer exceed MRLs specified in Annex II or III were listed in accordance with the provisions of Article 18 (3). Annex VII was established by Amendment Regulation 260/2008.[27)]

2. MRL evaluation under MRL Regulation 396/2005

MRL Regulation 396/2005 contains more articles with provisions on evaluation procedures than the MRL Directives. In addition, the EFSA began participating in evaluations that require risk assessment. The articles of the Regulation describe an assessment of the risks of the acute reference dose (ARfD) being exceeded, which the articles of the MRL Directives did not describe. The assessment of risks of ADI or ARfD being exceeded as a result of the modification of the MRL; the contribution to the intake due to the residues in the product for which MRLs were requested (Article 10 (1) (c)) is included in an RO.

Chapter II, in which the procedure for applications for MRLs is described, was one of the chapters that were to apply as from 6 months from the publication of the last of the Regulations establishing Annexes I, II, III, and IV. For this reason, MRL evaluations in accordance with the provisions of Regulation 396/2005 started from September 1, 2008, which was 6 months after the March 1, 2008 on which Amendment Regulation 149/2008 establishing Annexes II, III, and IV was published in the OJ.

In current cases of evaluations on the setting/modification of MRLs, there are cases for which procedures are not clearly described in Regulation 396/2005 since they were to be handled after the publication of Regulation 396/2005. Procedures including those for such cases are described in the technical guidelines entitled "Technical Guidelines – 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." [28)] The following explanation was prepared based on information from the sources including this technical guidelines.

As a result of the MRL evaluation, an Amendment Regulation to Regulation 396/2005 is to be prepared. However, since the setting of the date of application of

new MRLs differs depending on whether the existing MRLs will be increased or decreased, in most cases Amendment Regulations increasing existing MRLs and those decreasing the existing MRLs are to be prepared separately.

An Amendment Regulation increasing the existing MRLs comes into force and will become applicable 20 days after publication in the OJ.

For an Amendment Regulation decreasing the existing MRLs, the European Commission must submit to the World Trade Organization (WTO) a notification according to the WTO Agreement on the application of Sanitary and Phytosanitary measures (SPS Agreement) once the content of the Amendment Regulation draft is agreed. An Amendment Regulation usually becomes applicable 6 months after the effective date (usually 20 days after publication in the OJ). However, if a risk requires immediate action, the period for the deferred application date could be shortened. The Regulation allows for a transitional arrangement for products which have been produced in the EU or imported into the EU before the date of application, provided that a high level of consumer protection is ensured. In the case of assessment of existing MRLs, mentioned later, the EFSA may recommend setting lower MRLs as the most critical GAP (cGAP), when in accordance with which applications are made the highest residues may reasonably arise, is not being used any longer.

(1) Evaluations requiring MRL applications

Under the MRL Directives, setting of harmonised MRLs began with a notification from each Member State to the European Commission. Under MRL Regulation 396/2005, however, it begins with submission of an application from a party that requesting authorisation for the use of a PPP or another interested party.

The MRL application form[29] currently in use lists the following nine cases as the purposes of MRL application (a single application may correspond multiple purposes).

- Set specific MRL(s) (new AS not mentioned in Annex II/III/IV of Regulation 396/2005)
- Set specific MRL(s) (changing current MRL listed in Annex II or III of Regulation 396/2005)
- Set IT(s) (new AS not mentioned in Annex II/III/IV of Regulation 396/2005)
- Set IT(s) (changing current MRL listed in Annex II or III of Regulation 396/2005)
- Delete MRL(s)
- Include an AS in Annex IV
- Amend existing residue definition
- Include of AS/product combinations into Annex VII as referred to in Article 18 (3) of Regulation 396/2005
- Evaluation of MRL confirmatory data following review according to Article 12 of Regulation 396/2005

(i) MRL (including IT) setting/modification application

As a result of amendments to the provisions of Article 4 (1) (f) of PPP Directive 91/414/EEC by MRL Regulation 396/2005, the MRLs for agricultural products affected by the use referred to in the authorisation have been set or modified by Regulation 396/2005 where appropriate (Article 48 (2)).

The following provision also exists in PPP Regulation 1107/2009[30] as the condition for authorisation. For plants or plant products to be used as feed or food, where appropriate, the MRLs for the agricultural products affected by the use referred to in the authorisation have been set or modified in accordance with MRL Regulation 396/2005 (Article 29 (1) (i) of Regulation 1107/2009).

MRL Regulation 396/2005 provides that where a Member State envisages granting an authorisation or provisional authorisation for the use of a PPP in accordance with PPP Directive 91/414/EEC, that Member State shall consider whether, as a result of such use, an existing MRL set out in Annex II or III needs to be modified, whether it is necessary to set a new MRL, or whether the AS should be included in Annex IV. The Regulation also provides that the Member State shall require the party requesting the authorisation to submit an MRL application if necessary (Article 6).

If MRLs need to be modified for the purpose other than authorisation, such as setting ITs or other purposes, interested parties or Member States may submit an MRL application. Under Regulation 396/2005 the following parties are entitled to submit an MRL application. According to the applicant, the Member State to which an application is to be submitted is designated.

- A party requesting an authorisation shall submit an application to a Member State which envisages granting an authorisation for the use of a PPP (Article 6 (1)).

- Parties that demonstrating, through adequate evidence, a legitimate interest in health, including civil society organisations, may submit an application to a Member State (Article 6 (2)).
- Commercially interested parties such as manufacturers, growers, importers and producers of products covered by Annex I may submit an application to a Member State (Article 6 (2)).
- Where a Member State considers that the setting, modification, or deletion of an MRL is necessary, that Member State may compile and evaluate an application (Article 6 (3)).
- Applications for ITs shall be submitted to Rapporteur Member States (RMS) designated pursuant to PPP Directive 91/414/EEC or, if no such RMS has been designated, applications shall be made to Member States designated by the Commission (Article 6 (4)).

An application for the lowering or deletion of the existing MRLs may be submitted where consumer intake concerns are identified. In this case, the need to set lower MRLs should be justified by the applicant and/or Member State.

In the case of applications for ITs, the following evidence pertaining to authorised use in the exporting country should be submitted.

- Reference and copy of the current national legislation in the exporting country related to the MRL under consideration (including the residue definition), or a clarification if no MRLs are established in the exporting country.
- Evidence of the authorisation of the respective use of the PPP in the exporting country

With regard to inclusion of ASs in Annex IV, the criteria are outlined in the "Guidance document on criteria for the inclusion of active substances into Annex IV of Regulation (EC) No 396/2005." [31] The inclusion of an AS in Annex IV does not necessarily mean that a residue assessment is not required to support a PPP authorisation. 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.

An application for inclusion of AS/product combinations into Annex VII needs to be submitted if, for an AS/product combination that has not been listed in Annex VII, the residue level for the AS in the product that underwent post-harvest treatment with a fumigant is to exceed the existing MRL. If an AS/product combination is included in Annex VII, Member States may authorise the use of a PPP even if the residue level of the AS in the product exceeds the existing MRL.

A Member State to which an MRL application is submitted shall draw up an evaluation report (ER) as the Evaluating Member State (EMS) (Article 8 (1)). However, evaluation of the application may be carried out by the RMS by way of derogation (Article 8 (3)), or where a Member State encounters difficulties in evaluating an application or in order to avoid duplication of work, it may be decided in accordance with the procedure referred to in Article 45(2) which Member State shall evaluate particular applications (Article 8 (4)).

In addition, under PPP Regulation 1107/2009, an application for authorisation shall be examined by a Member State in the zones (groups of Member States, each Member State belongs to one of three zones, namely North, Central, and South) concerned in advance of the evaluation by the other Member States within the same zone to which the application for authorisation is submitted. Therefore, the application may be evaluated by a Member State other than the one in which the authorisation is sought (Article 35 of Regulation 1107/2009).

The EFSA assesses the applications and ERs, and gives an RO on (Article 10 (1)). Upon receipt of the RO of the EFSA, a Regulation on the setting, modification, or deletion of an MRL, or a Decision rejecting the application shall be prepared by the Commission (Article 14 (1)). However, 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, the EMS should draft a light version of ER, and in the Amendment Regulation to setting MRLs, reference to the existing guidelines on extrapolation are made in the relevant recital to justify the fact that EFSA was not requested to submit an RO.

Where an MRL application is included in the dossier for AS approval or renewal of AS approval, the MRL application is evaluated in a similar way. As described below, where relevant, an MRL application is included in the dossier submitted for approval or renewal of approval, and a proposal on MRLs is included in the assessment report prepared by the RMS.

Application for AS approval - PPP Regulation 1107/2009:

The summary dossier of an application for AS approval shall include, where relevant, a copy of

an MRL application (Article 8 (1) (g) of Regulation 1107/2009).

The Draft Assessment Report (DAR) prepared by the RMS shall include, where relevant, a proposal to set MRLs (Article 11 (2) of Regulation 1107/2009).

Application for renewal of AS approval – Renewal Regulation 844/2012:[32)]

The supplementary summary dossier for renewal of AS approval shall include, where relevant, a copy of an MRL application (Article 7 (1) (i) of Regulation 844/2012).

The draft Renewal Assessment Report (RAR) prepared by the RMS shall include, where relevant, a proposal to set MRLs (Article 11 (2) (d) of Regulation 844/2012).

Although there are no clearly defined provisions in the aforementioned Regulations, evaluation of MRLs by EFSA is included in the EFSA Conclusion for AS approval/approval renewal instead of an RO of EFSA on an MRL application, and an MRL Amendment Regulation is to be prepared based on the recommendations in the Conclusion.

However, in case of renewal of approval, where the endpoints derived in the renewal process are considerably different from the ones derived in the original approval, and where assessment of existing MRLs, mentioned later is already finalised, it may be considered to address the MRL requests separately, in a specific scientific opinion of the EFSA under Article 43 of MRL Regulation 396/2005 taking into account the extent and nature of possible concerns raised for any specific MRLs and need for assessing the MRLs against new residue definition or against new toxicological reference values. Where appropriate and needed as a basis for the risk management decision the EMS and EFSA should present MRL proposals with both the existing and newly proposed residue definition.

Fig. 3 shows a simplified scheme for the procedures.

(ii) Submission of MRL confirmatory data identified in the assessment of existing MRLs

In the assessment of existing MRLs mentioned later, the EFSA derives tentative MRLs that are not fully supported by data but for which no risk to consumers could be identified, and lists the data required to confirm those MRLs. Such data for which the due date for submission is set out by an Amendment Regulation based on the RO of EFSA is referred to as confirmatory data. In PPP Regulation 1107/2009 there is a provision (Article 6 (f) of Regulation 1107/2009) regarding submission of confirmatory information for approval as the approval condition. To avoid confusion, confirmatory data concerning MRLs is herein referred to as MRL confirmatory data.

Although submission of MRL confirmatory data which confirm temporary MRLs may not lead to setting or modification of MRLs, an MRL application is submitted as in the case of application for MRL setting/modification. The Member State to which the application is submitted is basically the Member State which prepared the ER in the course of the assessment of existing MRLs, namely the RMS of evaluation for approval.

Where MRL confirmatory data and new use data are inherently linked, MRL confirmatory data may be

*1: Where MRLs are being assessed as part of the approval/renewal of approval of an active substance, an MRL application is submitted as a part of the dossier.
*2: In case of IT, RMS for the active substance. In case no RMS has been attributed, the Commission will designate a Member State.
*3: Where MRLs are being assessed as part of the approval/renewal of approval of an active substance, evaluation of MRLs is included in the Draft Assessment Report(DAR)/Draft Renewal Assessment Report (RAR).
*4: Where MRLs are being assessed as part of the approval/renewal of approval of an active substance, evaluation of MRLs by EFSA is included in EFSA Conclusion.
*5: If a decrease of the existing MRL is proposed, an Amendment Regulation draft is notified to the WTO for a commenting period of 60 days.
*6: Where MRLs are being assessed as part of the approval/renewal of approval is made of an active substance, the Commission can prepare an Amendment Regulation draft as soon as the approval/renewal of approval decision is made.

Fig. 3 Scheme of procedures for setting and modifying MRLs by submitting an MRL application

submitted in the context of an MRL application for MRL setting/modification.

When an MRL application is submitted, the EMS prepares an ER, the EFSA prepares an RO, and the Commission prepares an MRL Amendment Regulation based on the RO of the EFSA. Even when no MRLs are set or modified, the footnotes added to the temporary MRLs are deleted, where relevant, by the Amendment Regulation based on the submitted and assessed MRL confirmatory data.

In some situations, the evaluation of MRL confirmatory data takes place within the renewal of AS approval assessment. In this case, the assessment by the Member State is reported in the RAR instead of the ER, the assessment by the EFSA is reported in the EFSA Conclusion for approval renewal instead of an RO of the EFSA, and the Commission may prepare an MRL Amendment Regulation based on the assessment made by the EFSA. The "Commission Working Document on the evaluation of data submitted to confirm MRLs following the review of existing MRLs,"[33] which outlines the applicable procedure for the evaluation of MRL confirmatory data, includes specificities for AS in the renewal of approval process as well as general procedure.

(iii) MRL applications submitted by a Member State following the authorisation of emergency uses

The provision on authorisation of emergency uses in Article 8 (4) in PPP Directive 91/414 EEC has been taken over by Article 53 of PPP Regulation 1107/2009. Following the authorisation of emergency uses, the Member State concerned shall immediately inform the other Member States and the Commission of the measure taken, providing detailed information about the situation and any measures taken to ensure consumer safety (Article 53 (1) of Regulation 1107/2009); the Commission may ask the EFSA for an opinion, or for scientific or technical assistance (Article 53 (2) of Regulation 1107/2009).

Where pesticide residues may arise from uses of PPPs authorised as emergency uses (Article 16 (1) (a)), temporary MRLs to be included in Annex III may be set by an Amendment Regulation (Article 16 (1)).

A Member State may authorise the placing on the market within its territory of treated food or feed not complying with the existing MRLs, provided that such food or feed does not constitute an unacceptable risk from the emergency uses. Such authorisation shall immediately be notified of the other Member States, the Commission, and the EFSA, together with an appropriate risk assessment with a view to setting a temporary MRL for a specified period or taking any other necessary measure in relation to such products (Article 18 (4)).

Based on the above provisions, a Member State shall submit an MRL application, the EFSA shall conduct risk assessment, and the Commission can then either propose the setting of a temporary MRL for a specified period of time or take other necessary measures based on the assessment made by the EFSA. When temporary MRLs are to be set, an MRL Amendment Regulation shall be prepared.

(2) Evaluations without MRL applications

The following evaluations proceed without MRL applications.

(i) Assessment of existing MRLs

The EFSA shall, within a period of 12 months from the date of approval or non-approval of an AS under PPP Directive 91/414/EEC after the entry into force of the articles related to evaluation of MRLs under Regulation 396/2005, submit an RO based on the relevant assessment report prepared under Directive 91/414/EEC (Article 12 (1)). In this RO, the EFSA submits its opinion on the following matters, in particular, for the AS.

- Existing MRLs for that AS set out in Annex II or III (Article 12 (1) (a))
- The necessity of setting new MRLs for that AS, or its inclusion in Annex IV (Article 12 (1) (b))
- Specific processing factors that may be needed for that AS (Article 12 (1) (c))
- MRLs which the Commission may consider including in Annex II and/or III and on those MRLs which may be deleted related to that AS (Article 12 (1) (d))

For ASs approved under PPP Directive 91/414/EEC before the entry into force of the articles related to evaluation of MRLs under Regulation 396/2005, the RO referred to in Article 12 (1) shall be delivered by the EFSA within 12 months of the entry into force of the articles related to evaluation under Regulation 396/2005.

Although Regulation 396/2005 provides only the aforementioned description, the RMS of evaluation for approval engages in preparation of the ER and collecting authorised GAPs of each Member States without

MRL application. For this reason, there are many ASs for which the EFSA has not yet complete ROs even though the time limit set out in Regulation 396/2005 exceeded considerably.

Regarding ASs for which evaluation for approval started after the date of application of PPP Regulation 1107/2009 (June 14, 2011), the EFSA has already assessed MRLs in the course of the evaluation for approval , therefore no assessment of existing MRLs is conducted following approval.

In the assessment of existing MRLs, there are many cases in which EFSA recommends setting lower MRLs or deletion of MRLs in the RO of the EFSA. In some cases, a new residue definition is proposed. In addition, even when MRLs are not deleted, to the MRLs which the EFSA recommends to retain as tentative MRLs EFSA lists the data required to submit to confirm those MRLs.

The progress of assessment of existing MRLs has been delayed significantly from the initial plan, and 115 cases of assessment have yet to be completed according to the "Overview of the MRL review progress under Article 12 of Regulation (EC) No 396/2005"[34] dated February 14, 2020. For some ASs, assessment is to be conducted in parallel with the evaluation for renewal of approval.

However, the provisions in Article 12 do not include assessment of existing MRLs for ASs, of which date of non-approval under PPP Directive 91/414/EEC is before the entry into force of the articles related to evaluation of MRLs under Regulation 396/2005. For some MRLs for these ASs, MRLs have been amended as needed based on the risk assessment conducted in accordance with the provisions in Article 43 mentioned later. There are also some ASs for which all MRLs have been reduced to the relevant the LOD following the revocation of authorisations of PPPs mentioned later, and included in Annex V since no MRLs corresponding to CXLs based on the uses in third countries or no MRLs specially set as ITs exist.

(ii) Implementation of CXLs into harmonised MRLs

Article 5 (3) of the General Food Law (GFL) Regulation 178/2002[35] provides that where international standards exist or their completion is imminent, they shall be taken into consideration in the development or adaptation of food law, except where such standards or the relevant parts would be an ineffective or inappropriate means for the fulfillment 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. In accordance with the provision in Article 13 (e), the EU shall promote consistency between international technical standards and food law while ensuring that the high level of protection adopted in the Community is not reduced. In accordance with these provisions, CXLs proposed by the Joint Food and Agriculture Organization of the United Nations (FAO) /World Health Organization (WHO) Meeting on Pesticide Residues (JMPR) are assessed by the 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 European Commission prepares an Amendment Regulation to take over in harmonised MRLs those CXLs for which the European Commission did not present a reservation in the CCPR, except where they relate to products which are not set out in Annex I or where they are set at a lower level than the current MRLs.

The European Commission presents a reservation for CXLs for which risk to consumers in the EU is identified, or consumer safety is not confirmed by EFSA risk assessment.

(iii) Inclusion of temporary MRLs based on monitoring data and the RO of EFSA

Temporary MRLs may be included in Annex III based on monitoring data and the RO of EFSA mainly in the following circumstances presented in Article 16 (1) (a)–(f). Article 16 (1) (e) is not currently applicable because PPP Regulation 1107/2009 has no provision on essential uses of PPPs containing non-approved ASs under PPP Directive 91/414/EEC.

- In exceptional cases, in particular those where pesticide residues may arise as a result of environmental or other contamination or from uses of PPPs pursuant to Article 8 (4) of PPP Directive 91/414/EEC (Article 16 (1) (a))
- 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 (Article 16 (1) (b))
- For honey (Article 16 (1) (c))
- For herbal infusions (Article 16 (1) (d))

- 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 (Article 16 (1) (f))

In the aforementioned circumstances, the inclusion of temporary MRLs shall be based on the RO of EFSA, monitoring data, and an assessment demonstrating that there are no unacceptable risks to consumers or animals.

The continued validity of the temporary MRLs referred to in Article 16 (1) (a)–(d) 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 Article 16 (1) (f) shall be reassessed when the scientific studies have been completed and evaluated, but no later than 4 years after their inclusion in Annex III.

(iv) Risk assessment in accordance with Article 43

In accordance with the provisions of Article 43, the European Commission or the Member States may request from the EFSA a scientific opinion on any measure related to the assessment of risks.

As a result of an evaluation for renewal of AS approval or review of AS approval (including evaluation of confirmatory information for approval), once new toxicological reference values are endorsed, the Commission sends a mandate to EFSA to carry out a re-assessment on some or all MRLs where needed in accordance with the provisions of Article 43 to understand whether the new reference values may pose a risk to consumers in relation to the existing uses and/or MRLs. In that framework, Member States should be consulted to report potential fall-back GAPs that would not lead to an unacceptable risks to consumers.

In practice, even in cases other than those in which new toxicological reference values are endorsed in the renewal or review of approval process, the EFSA is requested to carry out risk assessment, and MRLs are amended based on the RO of the EFSA when new information has become available which indicates that concerns of consumer protection may be raised in relation to the existing MRLs.

For example, the European Commission requested EFSA to carry out risk assessment on the MRLs for ASs which may have concern about risk because the EFSA had not conducted risk assessment for MRLs transferred to Annex II from MRL Directives 86/362/EEC, 86/363/EEC, and 90/642/EEC before their transfer, and the MRLs were amended by Amendment Regulation 1097/2009[36] based on the RO of the EFSA.

(v) Deletion of MRLs following revocation of authorisations of PPPs

In accordance with the provisions of Article 17, amendments to Annex II or III needed to delete an MRL following the revocation of an existing authorisation for PPP may be adopted without seeking the RO of the EFSA (Article 17). The deletion of the MRL consists either setting the value to 0.01 mg/kg or to the relevant limit of quantitation (LOQ).

In practice, the Commission makes use of such deletions in circumstances where all existing authorisations for PPPs containing a specific AS have been revoked following non-approval or non-renewal of the AS. In addition, deletion of MRLs may occur where whole or part of authorisations for PPPs have been revoked, for example when conditions of approval of AS is restricted to uses only on non-edible crops by amendment to the conditions of approval or when approved AS becomes non-approved AS without evaluation following withdrawal from the evaluation for renewal of approval.

This deletion does not apply to those MRLs corresponding to CXLs based on uses in third countries or MRLs that have been specifically set as ITs, provided that they are acceptable with regard to consumer safety as confirmed by a full and recent EFSA risk assessment. In cases of doubt regarding the safety of CXLs and/or ITs, whenever needed, the EFSA may be asked to deliver an RO.

If MRLs exist for the ASs of which component in residue definition is the same or similar as that of a particular non-approved or non-renewed AS, an adjustment shall be made so that MRLs derived from the uses of such AS are not deleted.

Conclusion

The current EU practices for setting/modifying MRLs has been formulated by trial and error. For this reason, the system is complicated. Setting of MRLs following the approval of AS is now carried out more

efficiently. However, existing MRLs may be modified or deleted following non-renewal or withdrawal of AS approval, amendment to the conditions of AS approval, or change of toxicological reference values as a result of examination of existing AS, or evaluation for renewal of AS approval or review of AS approval.

It is necessary to understand the cases in which MRLs are set, modified, and deleted, and take necessary procedures as soon as possible if such cases can be foreseen. We will be glad if this article is of assistance in dealing with such work. In the section 'Reference', the links to the referenced documents are also provided, as far as they are currently available, so that the details can be confirmed with the contents of the source document.

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The following is a link to the latest version '1607/VI/97 rev.2' dated 1999.06.10
https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_mrl_guidelines_foreword.pdf (Ref. 2020/3/27).
In the above document, document numbers and titles of Appendix A-I, which are components of the whole document and contain the content of guidelines, are listed. Due to space limitations, links to Appendix A-I are not provided here.
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