

Deletion of MRLs for substances that are not approved under the PPP Regulation An assessment of the Commission's current practice in the light of EU law*

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I. Terms of reference

I have been instructed by PAN-Europe, Foodwatch and the Veblen Institute to examine the following questions.

1. Is the European Commission's practice of setting Maximum Residues Limits (the 'MRLs') based on Codex values (the 'CXL') or import tolerance requests for 'cut off' pesticides banned within the EU (building on its technical guidelines) compliant with EU law? Specifically, does this practice align with the 'cut-off' criteria established under Regulation (EC) No 1107/2009 (the 'PPP Regulation') for substances deemed hazardous to human health (Annex II, points 3.6.2 to 3.6.5)?
2. Within the existing EU and international framework including Article 17 of Regulation 396/2005 (the 'MRL Regulation'), could the European Commission lower to the Limit of Quantification (LOQ) MRLs based on Codex values as well as previously established import tolerances for EU-banned substances:
 - a. Falling under the 'cut off' criteria for humans of the PPP Regulation (i.e. CMRs and endocrine-disrupting substances mentioned in points 3.6.2 to 3.6.5 of Annex II)?
 - b. Which have been banned because of public health concerns (other than the above-mentioned 'cut off' criteria) or for environmental reasons ('cut off' set out under point 3.7 and in 3.8.2 of Annex II and others such as toxicity to bees)?
3. For each, if yes, under which specific conditions could the Commission take such actions, considering that the current technical guidance document foresees the deletion of all MRLs but those established under CXL or via import tolerance request - as long as EFSA has concluded the levels are safe for consumers? Could the Commission delete/withdraw previously established import tolerances if an EFSA opinion establishing a 'safe threshold' of exposure exists and constitutes the most recent scientific opinion delivered by an EU agency?

* **Disclaimer:** The assessment performed in this study does not take into account the potential constraints stemming from international trade law, including WTO law.

4. If a zero-tolerance approach to MRLs for EU-banned substances is not feasible under the current framework, what specific regulatory amendments would be necessary to allow for such an approach?
5. Considering the specific case of carbendazim, thiophanate-methyl and cyproconazole, is the European Commission's decision to maintain existing MRLs, despite EFSA identifying risks for consumers and the European Parliament objecting to related Commission Regulations, compliant with Articles 1 and 14 of Regulation 396/2005?

II. Legal background

Annex II of the PPP Regulation sets out a number of 'cut-off' or 'hazard-based' criteria. Active substances that meet such criteria cannot be approved, irrespective of any consideration regarding the level of risk.

Some of these criteria relate to health (mutagenicity 1A/1B (3.6.2), carcinogenicity 1A/1B (3.6.3), reproductive toxicity 1A/1B (3.6.4), endocrine disruption (3.6.5)), while others relate to the environment (persistent organic pollutant (POP) (3.7.1), persistent, bioaccumulative and toxic (PBT) (3.7.2), very persistent and very bioaccumulative (vPvB) (3.7.3), endocrine disruption (3.8.2)).

For most of the health-related criteria¹, the prohibition to approve an active substance is subject to one exception, that relates to situations of 'negligible exposure'. A substance that meets such criteria can nevertheless be approved where it is intended to be used in a PPP that: (i) is used in closed systems or in other conditions excluding contact with humans and (ii) where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with Article 18(1)(b) of the MRL Regulation. This default value (usually set at 0.01 mg/kg, but subject to variation depending on the substance (see Annex V of the MRL Regulation)) corresponds to the limit of quantification (LOQ)².

It follows from the above that substances fulfilling one or several cut-off criteria cannot be approved (or re-approved), marketed and used on the EU territory, regardless of the concrete risk that their use entails for human health or the environment. Even under the "negligible exposure scenario", the residues on the substance cannot exceed the LOQ.

For the sake of completeness, it should be added that active substances that do not meet the cut-off criteria can nevertheless be considered harmful for human or animal health or as having an unacceptable effect on the environment following a risk-based assessment. The Commission can therefore decide not to (re-)approve them, whether for

¹ The only exception is the mutagenicity criterion.

² The Commission' technical guidelines confirm this: "Annex V lists those substances for which all MRLs are set at the appropriate limit of quantification (LOQ)."

health reasons (neurotoxicity, immunotoxicity, etc.) or for environmental reasons (toxicity for bees or other non-target arthropods, aquatic organisms, etc.).

III. The Commission's position

According to the Commission's [guidelines](#), the non-(re-) approval of a substance does not automatically trigger the deletion of the MRL (i.e., its lowering to the LOQ): *'The deletion does not apply to those MRLs corresponding to CXLs based on uses in third countries or MRLs that have been specifically set as import tolerances, provided that they are acceptable with regard to consumer safety as confirmed by a full and recent EFSA risk assessment. EFSA may be asked to deliver an opinion in cases of doubt whenever needed.'*

IV. Critical assessment of the Commission's position

1) Setting MRLs for substances not-(re)approved for human or animal health reasons

The Commission's view that import tolerances (IT) and CXLs could be used to avoid the deletion of a MRL following the non-(re)approval of an active substance based on health considerations **is highly questionable from an EU law perspective**. It is hardly compatible with (a) the definition of ITs and CXLs; (b) the procedure organised by Article 17 MRL Regulation; (c) the principle of regulatory alignment between the MRL legislation and the pesticides regulation; and (d) the non-discrimination principle.

(a) ITs and CXLs cannot be used to introduce different levels of public health protection

Article 3(2)(g) of the MRL Regulation defines IT as *'an MRL set for imported products to meet the needs of international trade where:*

- *the use of the active substance in a plant protection product on a given product is not authorised in the Community for reasons other than public health reasons for the specific product and specific use; or*
- *a different level is appropriate because the existing Community MRL was set for reasons other than public health reasons for the specific product and specific use;'* (emphasis added)

It appears clearly from this definition that an IT **cannot be granted as regards substances that are not approved in the EU for public health reasons**.

As regards CXLs based on uses in third countries, Article 14(2) of the MRL Regulation only states that they must be *'taken into account'*, among many other factors, in decisions on applications concerning MRLs. There is therefore no obligation to align the EU requirements with such international standards. Even more to the point, Article 5(3) of the General Food Law Regulation no. 178/2002 provides that international standards must **not** be taken into consideration where such standards *'would be an (...)*

inappropriate means for the fulfilment of the legitimate objectives of food law (...) or where they would result in a different level of protection from the one determined as appropriate in the Community' (emphasis added). **CXLs can therefore not be applied to substances that are banned in the EU for health reasons** as this would not only undermine the objectives of food law, but it would also create a dual standard, i.e. it would result in creating a different level of protection for imported products than the one set within the EU as per the PPP Regulation.

This conclusion is borne out by recital 26 of the preamble to the MRL Regulation: *'For food and feed produced outside the Community, different agricultural practices as regards the use of plant protection products may be legally applied, sometimes resulting in pesticide residues differing from those resulting from uses legally applied in the Community. It is therefore appropriate that MRLs are set for imported products that take these uses and the resulting residues into account provided that the safety of the products can be demonstrated using the same criteria as for domestic produce.'* (emphasis added).

Through this recital that the legislator made it clear that imported products must be subject to the same health-related criteria as those applicable to EU-grown products as far as pesticides residues are concerned. This passage dispels any remaining doubt regarding the applicability of the hazard-based approach to imported products. If cut-off criteria apply to the use of pesticide in the EU, it should also apply to the use of pesticides on imported products.

(b) The automatic procedure of Article 17 MRL Regulation ITs and CXLs cannot be used to introduce different levels of public health protection

Article 17 of the MRL Regulation provides that *'amendments to Annexes II or III needed to delete an MRL following the revocation of an existing authorisation for a plant protection product may be adopted without seeking the opinion of the Authority.'* It appears from the wording of this provision (*'following'*) that the deletion of an MRL is the normal and automatic consequence of a decision not to (re-)approve an active substance within the EU. The fact that an opinion of the Authority is not necessary for such a deletion confirms this finding.

The General Court reached the same conclusion in *Delfifruit / Commission*³:

the objective of Article 17 of Regulation No 396/2005 is to enable the Commission to remove, as soon as possible, the MRLs for that active substance, in particular with the aim of protecting human health and consumers from the intake of unauthorised pesticide residues, in accordance with recitals 5 and 22 of that regulation. The exemption from an EFSA opinion laid down in that provision is explained by the fact that, since that authority has already had the opportunity to take a position on the concerns for human health linked to exposure to an active substance in the procedure which culminated in the non-renewal of the approval of such a substance, it would be superfluous to refer the matter to it once again to deliver a new opinion on that substance in the context of the procedure for the removal of the MRLs, unless, before the adoption of a regulation removing the MRLs, reliable and new scientific elements show a significant evolution of

³ Judgment of 13 July 2022, *Delifruit v. Commission*, T-629/20, EU:T:2022:448 (emphasis added).

scientific knowledge since the position taken by EFSA on that substance. (para. 43, emphasis added).

In other words, contrary to what the Commission's guidelines seem to suggest, Article 17 of the MRL Regulation makes the deletion of an MRL the (quasi-) automatic consequence of a decision not to (re-)approve an active substance based on health protection grounds. This deletion should not be conditional upon any prior assessment by EFSA (deemed 'superfluous' by the General Court) unless there are '*reliable and new scientific elements show a significant evolution of scientific knowledge*' since EFSA delivered its opinion as part of the (re-)approval procedure.

While it is true that Article 14 of the MRL Regulation provides that an EFSA opinion must be issued '*within one year from the date of the inclusion or non-inclusion of an active substance in Annex I to Directive 91/414/EC*' (emphasis added), this provision must be understood in the context of the time. Under Directive 91/414/EC, the approval of an active substance was not subject to a prior risk assessment by EFSA (which was only created in 2002 by the General Food Law Regulation). Therefore, the MRL procedure was the only opportunity for an EU independent agency to intervene in the process. Since EFSA acquired a central role in the assessment of active substances under the PPP Regulation, and since ECHA (created in 2007 by the REACH Regulation) started classifying substances based on hazards, the provision of an additional opinion under the MRL procedure may often seem superfluous, especially when the substance was classified as meeting cut-off criteria.

Furthermore, recital 22 to the MRL Regulation's preamble states that '*where uses of pesticides are not authorised at Community level, MRLs should be set at an appropriately low level to protect the consumer from the intake of unauthorised or excessive levels of pesticides residues*'. In other words, MRLs for unauthorised PPPs / non-approved substances should be set at such a low level that they prevent any intake of such PPPs or substances (i.e., LOQ). While the expression '*unauthorised or excessive levels*' may seem ambiguous (implying that unauthorised but not excessive levels could be accepted), other linguistic versions tend to support the view that the two adjectives refer to distinct situations. Therefore, the most sensible interpretation of this recital is that, while the MRL for substances that have been banned in the EU for public health reasons should be set at the LOQ, MRLs for substances for which only certain uses have been accepted must not be set at an excessive level.

(c) The requirements of the MRL Regulation are aligned with those of the PPP Regulation

It appears clearly from the MRL Regulation that it was designed to align with the regulatory regime applicable to the marketing of PPPs within the EU⁴. At the time the MRL Regulation

⁴ See in particular recital 12 of the MRL Regulation: 'Directive 91/414/EEC lays down basic rules with respect to the use and placing on the market of plant protection products. In particular the use of those products should have no harmful effects on humans or on animals. Pesticide residues resulting from uses of plant protection products may have harmful effects on the health of consumers. It is therefore appropriate that rules for MRLs

was adopted, this regime was laid down in Directive 91/414. This Directive was entirely based on risk, not hazard assessment⁵. However, when that Directive was replaced by the PPP Regulation, the hazard-based assessment introduced by that Regulation was implicitly carried over to the MRL Regulation.

Admittedly, recital 47 of the PPP Regulation states that it applies ‘*without prejudice*’ to the MRL Regulation, meaning that the entry into force of the PPP Regulation is not meant to alter the content of the MRL Regulation. However, no provision of the MRL Regulation excludes a hazard-based approach. Therefore, the transposition of such an approach to pesticide residues on imported products cannot be said to alter the content of the MRL Regulation.

In that connection, it must be reminded that the Commission has already deleted MRLs of active substances on the ground that they met certain cut-off criteria, based on a statement made by EFSA during the procedure for the renewal of such substances⁶. In the abovementioned *Delifruit / Commission* ruling, the General Court confirmed the validity of the Commission’s decision⁷, and confirmed that in principle MRLs could only be set as regards PPPs that could be authorized in the EU:

42 (...) it should be noted that the establishment of an MRL for an active substance is inherently linked to the approval of that substance, on the basis of which marketing authorisations for plant protection products are granted. In particular, an MRL for an active substance, other than the default value provided for in Article 18(1)(b) of Regulation No 396/2005, is justified, in principle, only if plant protection products containing that substance are intended to be placed on the market (see, by analogy, judgments of 8 January 2002, *France v Monsanto and Commission*, C-248/99 P, EU:C:2002:1, paragraph 80 (...))

(d) *The principle of non-discrimination*

Finally, allowing the setting of MRLs for active substances that cannot be used on EU grown products would run counter to the principle of non-discrimination. This general principle of EU constitutional law ‘*requires comparable situations not to be treated differently and different situations not to be treated in the same way, unless such*

for products intended for human consumption be defined that are linked to the authorisation for use of plant protection products as defined under Directive 91/414/EEC’.

⁵ See judgment of 9 September 2011, *Dow AgroSciences Lts and others / Commission*, case T-475/07, EU:T:2011:445, para. 156; judgment of 19 November 2009, *Denka International / Commission*, case T-334/07, EU:T:2009:453, paras 112-118.

⁶ Commission Regulation (EU) 2020/1085 of 23 July 2020 amending Annexes II and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for chlorpyrifos and chlorpyrifos-methyl in or on certain products

⁷ Judgment of 13 July 2022, *Delifruit v. Commision*, T-629/20, EU:T:2022:448.

*treatment is objectively justified*⁸. Besides, any measure based on the precautionary principle – which lies at the heart of the PPP Regulation and of the hazard-based approach to specific endpoints – must be objective and non-discriminatory⁹.

When it refuses to delete a MRL for EU-banned substances, the Commission treats differently EU farmers and their third-country competitors. Furthermore, this difference of treatment does not seem to rest on any objective justification. The only plausible justification would relate to the need to comply with WTO/GATT/SPS requirements. However, an assessment of the merits of such a justification falls beyond the scope of this opinion.

2) Setting MRLs for substances not-(re)approved for environmental reasons

The view expressed by the Commission in its Guidelines seems more convincing as regards substances banned for environmental reasons. It must be noted that the MRL Regulation is only concerned with **consumer protection**, and therefore only with human (and animal) **health**. This is because MRLs govern the marketing of agricultural **products** in the EU, and not the **use** of active substances and PPPs in agricultural practices. This use is regulated by the PPP Regulation for EU-grown products and by third-country regulations for imported goods.

There is however one precedent in which MRLs have been lowered to the LOQ based on environmental concerns. In 2023, following the non-reapproval of certain types of neonicotinoids (clothianidin and thiametoxam), the Commission has decided to delete the MRL for such substances given their toxicity for bees¹⁰. Interestingly, the Commission put forward two lines of reasoning to justify this decision.

First, the decline in pollinators would be detrimental to health because it would threaten food security and increase the risk of non-contagious diseases by reducing the availability of vegetal food (fruits, nuts, vegetables). Through that line of reasoning, the Commission tried to establish a link between the protection of bees and consumer protection, so as to make it with fit with the primary goal of the MRL Regulation.

Second, the Commission timidly (and somewhat implicitly) argued that MRL can also be used to protect the environment. In support of that proposition, the Commission harked back to Article 5(1) of the General Food Regulation. According to that provision, food law (including the MRL Regulation) *'shall pursue one or more of the general objectives of a high level of protection of human life and health and the protection of consumers' interests, including fair practices in food trade, taking into account, where appropriate,*

⁸ Judgment of 6 June 2019, *P. M. and Others*, C-264/18, EU:C:2019:472, para. 28 and the case-law cited

⁹ See e.g. judgment of 17 March 2016, *Zoofachhandel Züpke / Commission* T-817/14, EU:T:2016:157, para. 51

¹⁰ Commission Regulation (EU) 2023/334 of 2 February 2023, amending Annexes II and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for clothianidin and thiamethoxam in or on certain products.

the protection of animal health and welfare, plant health and the environment’ (emphasis added).

Whether either line of reasoning would hold in court remains to be seen. Currently, this regulation is heavily contested by third countries on the ground that its extraterritorial reach would be incompatible with WTO law.

In any event, it is interesting to note that the regulation expressly acknowledges the possibility of granting import tolerance (IT), albeit under strict conditions. Given the definition of IT set forth in the MRL Regulation (see above), ITs could indeed be granted as regards MRLs that have been set on environmental (as opposed to health) grounds. The same goes for CXLs. As far as the non-discrimination principles is concerned, it could be convincingly argued that EU producers and third-country farmers are objectively not in the same situation as regards agricultural practices (as they operate in different jurisdictions) so that the difference in treatment ensuing from disparate levels of environmental protection between the EU and third-countries is not illegal.

The only argument that could, on the face of it, support the view that MRL should be deleted as regards substances banned in the EU for environmental motives, is Article 17 of the MRL Regulation. As explained above, this provision seems to make the deletion of an MRL the automatic and logical consequence of any decision not to approve an active substance in the EU, irrespective of the reason underlying that decision. However, even if Article 17 was interpreted as covering non-approvals based on environmental considerations, it would still not preclude the grant of ITs, which are precisely meant to act as a derogatory regime.

Admittedly, one could argue that the legal divide between ‘health’ and ‘environment’ is artificial and at odds with the ‘one health’ narrative advocated by the Commission. The Court of Justice itself has recognized *‘the close link between the protection of the environment and that of human health, (...) it not being possible to achieve a high level of protection of human health without a high level of environmental protection, in accordance with the principle of sustainable development’*¹¹. In that regard, it could probably be easily demonstrated, from a scientific perspective, that the environment-related cut-off criteria (POPs, PBT, vPvB) are also of direct concern for human health.

However, even assuming that this is correct, the fact remains that the impact on health caused by environment degradation is usually local: it is hard to argue, for instance, that the contamination of groundwater in Brazil will have an impact on the health of European consumers. Therefore, such an impact probably remains outside the scope of the MRL Regulation as it currently stands. While the justification advanced by the Commission to support the deletion of MRLs for certain neonicotinoids tries to circumvent this limitation, its compatibility with EU law (not to mention with international trade law) remains questionable.

¹¹ Judgment of 25 June 2024, *Ilva*, C-626/22, EU:C:2024:542, para. 72.

V. Answer to the questions asked

1. *Is the European Commission's practice of setting Maximum Residues Limits (the 'MRLs') based on Codex values (the 'CXL') or import tolerance requests for 'cut off' pesticides banned within the EU (building on its technical guidelines) compliant with EU law? Specifically, does this practice align with the 'cut-off' criteria established under Regulation (EC) No 1107/2009 (the 'PPP Regulation') for substances deemed hazardous to human health (Annex II, points 3.6.2 to 3.6.5)?*

Answer: No, there are good grounds to argue that this practice is not compliant with EU law as it ignores (1) the definition of IT and CXL; (2) Article 17 of the MRL Regulation; (3) the principle of regulatory equivalence between the PPP Regulation and the MRL Regulation; (4) the non-discrimination principle.

2. *Within the existing EU and international framework including Article 17 of Regulation 396/2005 (the 'MRL Regulation'), could the European Commission lower to the Limit of Quantification (LOQ) MRLs based on Codex values as well as previously established import tolerances for EU-banned substances:*

- a. *Falling under the 'cut off' criteria for humans of the PPP Regulation (i.e. CMRs and endocrine-disrupting substances mentioned in points 3.6.2 to 3.6.5 of Annex II)?*

Answer: it certainly could (it already did it for chlorpyrifos and chlorpyrifos-methyl) but it probably also should, as a matter of EU law. However, this opinion does not cover the question of the compatibility of such a practice with international trade law.

- b. *Which have been banned because of public health concerns (other than the above-mentioned 'cut off' criteria) or for environmental reasons ('cut off' set out under point 3.7 and in 3.8.2 of Annex II and others such as toxicity to bees)?*

Answer: For public health concerns, yes. It could and probably also should as a matter of EU law. For environmental reasons (whether or not cut-off), it probably could not, based on EU law. It should be reminded that this opinion does not cover the question of the compatibility of such a practice with international trade law.

3. *For each, if yes, under which specific conditions could the Commission take such actions, considering that the current technical guidance document foresees the deletion of all MRLs but those established under CXL or via import tolerance request - as long as EFSA has concluded the levels are safe for consumers?*

Answer: The Commission should not follow (and should amend) its guidance on this point as it seems incompatible with EU law.

Could the Commission delete/withdraw previously established import tolerances if an EFSA opinion establishing a 'safe threshold' of exposure exists and constitutes the most recent scientific opinion delivered by an EU agency?

Answer: Yes but it could be politically difficult for the Commission to ignore an opinion that it requested itself. In fact, the Commission should consider, based on Article 17 of the MRL Regulation, that it does not need to request an EFSA opinion on MRLs for substances banned based on cut-off criteria.

4. *If a zero-tolerance approach to MRLs for EU-banned substances is not feasible under the current framework, what specific regulatory amendments would be necessary to allow for such an approach?*

Answer: A zero-tolerance approach is feasible and arguably compulsory under the current framework as regards EU-banned substances for **public health reasons**. The MRL Regulation could however be clarified in that respect to dispel any remaining doubt. While there are many ways to achieve such an objective, a straightforward approach would probably consist in adding a provision at the end of Chapter 1 (Subject-matter, scope and definition) that would provide that *'Only default values can be set for substances that have not been approved under Regulation 1107/2009 on the ground of their harmful effect on human or animal health, unless reliable and new scientific elements show a significant evolution of scientific knowledge since the risk assessment was last performed under Regulation 1107/2009'*. To ensure consistency, a provision should be inserted in the PPP Regulation to the effect that the grant of an MRL to a substance banned in the EU for public health reasons should trigger a review of the non-approval regulation.

In order to extend this regime to EU-banned substances on **environmental grounds** (which, arguably, are currently not covered), the same provision could simply read: *'Only default values can be set for substances that have not been approved under Regulation 1107/2009 unless reliable and new scientific elements show a significant evolution of scientific knowledge since the risk assessment was last performed under Regulation 1107/2009'*. However, such an extension would probably render the whole IT regime useless. It would therefore require deleting any reference to import tolerances in the MRL Regulation. A major caveat is that such an extension might run counter to international trade law principles and might therefore be declared invalid by the ECJ.

Either way, Article 15 would also need to be revised to clarify that, whenever a substance is banned in the EU for public health (and potentially environmental) reasons, the Commission must immediately delete the MRLs regulating to that substance. The opinion of EFSA can only be requested if reliable and new scientific elements show a significant evolution of scientific knowledge.

5. *Considering the specific case of carbendazim, thiophanate-methyl and cyproconazole, is the European Commission's decision to maintain existing MRLs, despite EFSA identifying risks for consumers and the European Parliament objecting to related Commission Regulations, compliant with Articles 1 and 14 of Regulation 396/2005?*

Answer: This decision is arguably not compatible with EU law (article 3 and 17 MRL Regulation and the non-discrimination principle) given that these three substances are no longer approved in the EU and meet one or several health-related cut-off criteria:

- Carbendazim is classified as reprotoxic 1B and mutagenic 1B;
- Thophanate-methyl is identified by EFSA as an endocrine disruptor of relevance to humans (in addition to having carbendazim as one of its main metabolites)
- Cyproconazole is classified as reprotoxic 1B;

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* *