**FoodDrinkEurope views on Transitional Periods when lowering Maximum Residue Limits (MRLs) for Pesticide Residues in Food**

*Interested and/or submitted comments: COCERAL, CropLife Europe, Europatat, Euroseeds, FEFAC, FERM, FRUCOM, PROFEL, Starch Europe, FEDIOL, ECA*

Background

Regulation (EC) No 396/2005 lays down maximum residue levels (MRLs) for pesticides in or on food and feed of plant and animal origin in the European Union. The question of residues and the possible setting of MRLs has to be clarified before granting any authorisation of plant protection products in Europe as well as for allowing imported goods on the Union's market. According to the European legislation on plant protection products (PPP), approval of active substances for PPP must be renewed periodically and on request. When an active substance is not renewed and all its national authorisations have been revoked, -MRLs supporting those revoked national authorisations are lowered accordingly. Article 49 contains provisions for the applicability of transitional measures. Whereas Article 49 (1) refers to the first introduction of Reg. (EC) No 396/2005, Article 49 (2) refers to the amending regulations due mainly to MRL changes. It says: *"Where necessary to allow for the normal marketing, processing and consumption of products, further transitional measures may be laid down (…)".* It also states that those measures have to be designed *"without the prejudice to the obligation to ensure a high level of consumer protection".*

When Reg (EC) No 396/2005 was introduced, article 12 defined that existing MRLs had to be reviewed. The first step in this review of existing MRLs is a collection of all authorized uses, followed, in most cases but not always, by a risk assessment of EFSA to evaluate existing MRLs for the need to support current uses and give proposals to MRL changes.

MRLs for pesticide residues are recommended to be lowered in the following cases:

- a pesticide (active substance) is no longer permitted in the EU,
- a pesticide (active substance) is no longer used in the EU, either for a specific application (one specific crop) or for crops in general,
- pesticide residues may lead to a health risk for consumers, either for a specific application (one specific crop) or for crops in general

Current approach when lowering MRLs

For amending regulations when lowering MRLs there are currently two options which are used by the European Commission:

- When the "old" MRL does not present a health risk for consumers: Option 1: Recital (x) and (y)

Recital (y): A reasonable period should be allowed to elapse before the modified MRLs become applicable in order 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.

-> A deferral period will be granted before the new MRLs will become valid (usually 6 months) after the entry into force of the new MRL regulation (20 days after publication). Although also providing a certain transition time, a "deferred application" of MRLs is something different from "transitional periods" from a legal point of view.

Recital (x): In order to allow for the normal marketing, processing and consumption of products, this Regulation should provide 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.

-> Regulation (EC) No 396/2005 as it stood before being amended by this Regulation shall continue to apply to products which were produced in the Union or imported into the Union before the date the new MRLs apply (usually Article 2 of the amending regulation).

In this case, products which have been produced or imported before the new MRLs apply can be marketed and processed until end of shelf life.

- When the “old” MRL may present a health risk for consumers: Option 2: Recital (y)

  Recital (y): A reasonable period should be allowed to elapse before the modified MRLs become applicable in order 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.

  -> A deferral period will be granted before the new MRLs will become valid (usually 6 months).

  In this case, the new MRLs become directly applicable after the end of the deferral period of the amending regulation. This is true for raw materials, ingredients and end-products independent of their shelf life. Products lawfully produced or imported before become non-compliant when they do not meet the new MRLs.

<u>Problems that arise from the current approach</u>

When active substances are not renewed in the EU, national authorisations are revoked and agricultural practices in the EU will have to be adjusted accordingly. Third Countries must also adapt their agricultural practices to the new MRLs, especially when there is no Codex MRL (CXL) which has been considered acceptable by the EU or an import tolerance for the specific pesticide-commodity combination is missing.

For most crops there is only one harvest per year. At the time of application, the use of the plant protection product has been a legal and compliant use. Where MRL changes occur post-application, farmers may be unable to export that crop, potentially threatening the livelihoods of farmers, causing food waste, and reducing the availability of fresh products and compliant raw materials.

When active substances are banned that are effective against EU priority pests (link), without there being an effective alternative, the EU territory and food supply chain risk being confronted with big losses in the agricultural production sector, and consequently in the food industry as a big customer of that sector. On request of the EU Commission[1]), EFSA's monthly Plant Health newsletter (link) is aiming at identifying the relevant information on plant pests that might be of concern for the EU and therefore may require consideration by risk assessors and risk managers.

For many commodities, first processing steps (e.g. drying, washing, cutting, freezing) are undertaken in the country where the crop is cultivated. These raw materials are often also stored in this country and sold to the food chain partners on demand to guarantee the supply of consumers with food over the whole year. A part of these raw materials, they stay in the country of cultivation until the next harvest. In addition, in the case of third countries, considerable time can elapse between the production of raw materials, ingredients and end-products in conformity with EU practices and their transport to the EU for processing and marketing.

When – besides the deferral period (as defined in the MRL amending regulation) - no transitional periods are granted for products which have been lawfully produced or imported into the EU before the new MRLs apply (Option 2) these products do not meet the new MRLs and they will have to be discarded according to the current procedure of the European Commission and Member States. Food commodities can have a very long shelf-life, due to, e.g. by freezing, drying, or processing. Dried ingredients can be stored for years (e.g. tea, herbs) before they are marketed or used as ingredients for end-products. Deep-frozen, canned, and dried end-products again can have a shelf-life of several years. Thus, it is not reasonable to expect all these products and stocks to be sold (or exported) within the given deferral period (usually 6 months) which is often too short for farmers and supply chain to adapt. Consequently, big quantities of processed ingredients and end-products would need to be destroyed.

It is to be noted that apart from the lowering of MRLs, when unexpected findings occur (e.g. the residue definition has changed or it turns out that the pesticide is a multiple source substance) the lack of transitional periods allowing food business operators to adapt to the new requirements can also be extremely critical.

A non-exhaustive list of cases and the consequences thereafter is included in Annex. Proper transitional periods are therefore an important parameter for realising the EU's goal to fight food waste. We think that discarding already produced food is neither an appropriate nor

[1] European Commission – Directorate General for Health and Food Safety, Request to provide a scientific and technical assistance on a horizon scanning exercise in view to crisis preparedness on plant health for the EU territory (M-2017-0012, EFSA-Q-2017-00037)

proportionate measure in legislation. It is only justified when a concrete food product definitely presents a health risk for the consumer. If not, in the EU the principle should be followed that food which has been lawfully produced, should not be wasted.

Effective risk management requires ensuring a high level of consumer protection whilst examining its consequences including economic damage to food operators and its contribution to food waste. The food industry considers that the policy currently favoured by the Commission does not always deliver a proportionate response; as working with the MRLs as residues levels and not taking into account the real residues levels in the food (which are often (much) lower than the MRL), in certain cases, it overstates the risk to consumers during the transition period and underestimates the practical implications resulting from the realities of the food supply chain.

Therefore, the food and drink industry requests to have transitional measures for all lawfully produced foodstuffs which allow the marketing and further processing until end of shelf life of the corresponding products when MRLs for pesticides residues are lowered. We believe a compromise should be made to on one hand ensure a high level of consumer protection and on the other hand minimise damage to the food supply chain and help avoid destroying valuable food products.

Moving forward: A pragmatic approach towards transitional measures

We recognise that the food chain is complex (e.g. crop cycles, product shelf-life) and this complexity requires more sophisticated risk management measures then currently presented. Nevertheless, it is imperative that the Commission in its role as risk manager fully assesses all possible consequences of any measure in accordance with the principle of proportionality.

In many cases it is not proportionate to reject transitional periods. To date, neither the residue levels found in the food product itself (which are often considerably lower than the established MRLs as demonstrated in the extensive EU monitoring programs) are considered in risk management actions nor if the product in question is safe from a toxicological point of view. Instead, it should be possible to continue to place food on the market that has already been produced and to use and process it until the end of its shelf-life, provided it is safe i.e. the exposure from residues in a concrete product does not exceed the toxicological reference levels. To estimate if the short-term consumption of a food is safe, a threshold level could be calculated, either by EFSA or with the help of the EFSA PRIMo model, that corresponds to a residue level that does not exceed the ARfD (i.e. is slightly lower than the ARfD).

## Annex: Non-exhaustive list of examples where transitional measures were not granted for some commodities

**Thiabendazol** Reg. (EU) 2017/1164

No transitional measures except the deferral period of 6 months for: mangoes (MRL 5 mg/kg -> 0,01* mg/kg) and cultivated fungi (MRL 10 mg/kg -> 0,01* mg/kg). With the same Reg., some MRLs were even raised, e.g. for citrus fruit from 5 mg/kg to 7 mg/kg and for bananas from 5 mg/kg to 6 mg/kg. Although MRLs were also lowered for e.g. apples and pears (each 5 mg/kg -> 4 mg/kg) and sweet potatoes (MRL 15 mg/kg -> 0,01* mg/kg) for those commodities transitional measures until shelf life were granted.

With the same Regulation, also some MRLs for Acrinathrin were changed.

**Acrinathrin** Reg. (EU) 2017/1164

No transitional measures except the deferral period of 6 months for: bananas (MRL 0,5 mg/kg -> 0,02* mg/kg), pepper (MRL 0,2 mg/kg -> 0,02* mg/kg), peaches (MRL 0,2 mg/kg -> 0,02* mg/kg), apricots (MRL 0,3 mg/kg -> 0,02* mg/kg), melons and watermelons.

Reported problems in pepper because of the lack of transitional periods. With the regulation, also e.g. the MRL for tomatoes was lowered (from 0,1 mg/kg to 0,02* mg/kg), but for tomatoes transitional measures until shelf life were granted.

**Prochloraz** Reg. (EU) 2020/192

No transitional measures except the deferral period of 6 months for: citrus fruit (MRL 10 mg/kg -> 0,03* mg/kg), bananas (MRL 0,05* mg/kg -> 0,03* mg/kg), mangoes (MRL 5 mg/kg -> 0,03* mg/kg), pineapple (MRL 5 mg/kg -> 0,03* mg/kg), kiwis (MRL 0,05* mg/kg -> 0,03* mg/kg) (and bovine liver).

On the other hand, several MRLs were raised (e.g. lychees, passion fruit, pomegranates from 0,05* mg/kg to 7 mg/kg each).

**Imazalil** Reg. (EU) 2019/1582

No transitional measures except the deferral period of 6 months for: grapefruits (MRL 5 mg/kg -> 4 mg/kg), oranges (MRL 5 mg/kg -> 4 mg/kg), apples (MRL 2 mg/kg -> 0,01* mg/kg), pears (MRL 2 mg/kg -> 0,01* mg/kg), medlars (MRL 5 mg/kg -> 0,01* mg/kg), bananas (MRL 2 mg/kg -> 0,01* mg/kg), potatoes (MRL 3 mg/kg -> 0,01* mg/kg) (and bovine liver).

Big problem reported for bananas and the lowering of the MRL is only related to the fact that no fall back GAP in the EU was found (not surprising for a tropical fruit). For grapefruits and oranges, fall back GAPs were found in the EU, thus, a reduction of the MRL to the LOQ could be avoided. With the regulation, also some MRLs were raised (e.g. strawberries from 0,05* mg/kg to 2 mg/kg).