FAQ Residue of pesticides in feed

GMP+ D 3.19
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GMP+ Feed Certification scheme
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1 Introduction

GMP+ International has received questions from its participants about the requirements in the GMP+ FC scheme regarding the applicable Maximum residues level (MRLs) for pesticides in feed. Below, we have described and answered the most frequently asked questions.

The MRLs are based on EU legislation. Unfortunately, in some cases the EU legislation is unclear or the information is not complete. At the same time the authorities in the EU may have different opinions/interpretations of the legislation. Due to these reasons there are difficulties in determining the MRL for pesticides in feed products.

Despite the difficulties mentioned above and with regard to HACCP, a participant must determine - for each Critical Control Point (CCP) - the measuring values in which the safety of the product can be guaranteed. For this purpose, specific feed safety limits for undesirable substances have been established in the GMP+ Feed Certification scheme (GMP+ FC scheme). These limits are included in Appendix 1 of the GMP+ FC scheme: GMP+ BA1 Specific Feed Safety Limits. For pesticides, the limits are based on EU legislations:

- **Directive (EC) No. 2002/32**: In this directive, the forbidden/prohibited pesticides are included. This is included in part 3 of GMP+ BA1 and
- **Regulation (EC) No. 396/2005**: In this regulation, the maximum residue levels of pesticides in or on food and feed of plant and animal origin are stated. This is included in part 4 of GMP+ BA1.

  Note: The content of this legislation is integrated in the EU Pesticides database (EU PDB).

EU legislation is included in the GMP+ requirements. This means that it applies to all GMP+ participants across the globe *

Note: when national legislation is stricter than the GMP+ BA1 requirements, the GMP+ participant must respect the requirements of that legislation. GMP+ International advises to communicate with your customers about possible stricter requirements from national legislation. This way, you can take into account the requirements which your product must meet and prevent problems further down the supply chain.

Should you have any further questions or would you like to receive more information, please contact us via our contact form. If needed, this list will be expanded.

* For more information, please see our newsletter “Relationship between GMP+ FSA certification and EU legislation”
2 Questions

2.1 How to determine a pesticide MRL in feed?

In Chapter 4 of the GMP+ BA1 “Specific Feed Safety Limits” is explained how to determine a pesticide MRL in feed.

To help you determine the applicable MRL in feed, GMP+ International developed a decision tree. You can find this decision tree in this document.

Further, a couple of examples of calculations for the MRL product/pesticide combinations have been prepared and presented via the MVO website.

2.2 Which MRL is applicable on not approved/forbidden pesticides in feed products?

There are 2 options:

a. the MRL of the forbidden/prohibited pesticides are mentioned in part 3 of GMP+ BA1 Specific Feed Safety Limits. This is in accordance with Directive (EC) No. 2002/32;

b. the MRL of the unapproved pesticides can be found in EU Pesticides database. This is in accordance with Regulation (EC) No. 396/2005.

If the pesticides are not mentioned in the EU pesticides database, the default value (default MRL) of 0,01 mg/kg applies.

2.3 In which cases can ‘footnote 1’ be applied?

For a limited number of products the MRLs in Regulation (EC) No. 396/2005 are not yet applicable. This is according to the so-called “footnote 1” *.

The authorities in the EU may have different opinions/interpretations of this legislation.

➢ The recommendation to the companies is to contact the competent authorities in the regions involved to know how to apply this regulation.

* The current text of ‘footnote 1’ is: “MRLs do not apply to products or parts of the product used exclusively as ingredients for animal feed, until separate MRLs will be applicable.” This footnote is, at the time of publication of this FAQ list, under revision by the European Commission.

The new proposed text is: ‘MRLs do not apply to products or part of products that by their characteristics and nature can be used exclusively as ingredients of animal feed, until separate MRLs are set in the specific category 1200000”
2.4 Is it allowed to use processing factors (transfer factors)?

Yes, according to the legislation it is allowed but they are not determined. Until now Annex VI of Regulation 396/2005 has not yet been filled out. This annex should contains specific concentration or dilution factors for certain processing processes. But it's still empty.

For fats and oils the International Expert Committee (IEC) has adopted the MVO / FEDIOL approach.

This means the following:

- Use the processing factors in accordance with FEDIOL (where possible/applicable)
- For other products than those mentioned in the “FEDIOL paper” an own processing factor must be calculated/made. Contact your manufacturer and if needed the competent authority to carry out this calculation. Where required, it must be submitted for approval to the competent authority.
- In the absence of a calculation or the inability to apply processing factors, the MRL of the primary/basic/unprocessed product must also be used for the processed product.

GMP+ International advises to communicate with the customers about the application of processing factors.

For more information, consult the MVO website.

2.5 Relevant sources of information about pesticides

The following links to website contain information about pesticides.

- EU Pesticides database (EU PDB) (http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=homepage&language=EN)
- MVO: ‘MVO notifying requirements on Pesticides’ (https://www.mvo.nl/en-mvo-notifying-requirements-on-pesticides)
Annex 1: Decision tree

How to determine a pesticide MRL in feed

EU PDB contains MRLs for unprocessed agricultural products for food or animal feed.

EU Pesticide database (EU PDB)

Check the application of Reg. 396/2005 for your pesticide-product (A, B or C) combination

Pesticide-Product MRL a

Is the pesticide mentioned in GMP+ BA1 part 3 (Di. 2002/32/EG)

Apply the found MRL for your pesticide-product combination

GMP+ BA1 (Part 3)

No

Yes

A

Unprocessed product b

A

B

Processed Product b

B

C

Composite products

C

*Where national legislation is stricter than the EU regulations, the GMP + participant must comply with these more stringent requirements from national legislation.

<table>
<thead>
<tr>
<th>Product group</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unprocessed</td>
<td>Single unprocessed/primary/ product of vegetable or animal origin (wheat, barley, linseed, sunflower seeds, soya bean, peas, spinach)</td>
</tr>
<tr>
<td>Processed products</td>
<td>Single, treated/processed or derived product, originating from an basic product (wheat flour, semolina pellets, potato press flakes, soya flakes, soya (bean) expeller, brassed oil, pressed meal, fish meal)</td>
</tr>
<tr>
<td>Composite product</td>
<td>Composite product consisting of at least two components, being unprocessed products, processed products and/or food additives (complete feed, supplementary feed, petfood, grain mixes, premixtures)</td>
</tr>
</tbody>
</table>
A: Determination of a MRL for unprocessed products

A

Unprocessed product

Can “footnote 1” be applied?

No

MRL can be consulted in the EU PDB

Yes

EU PDB

Is the unprocessed product mentioned in the EU PDB?

Yes

The MRL for the pesticide-product combination can be found in the EU PDB

No

No MRL applies for this product

Stop

Is the pesticide mentioned in the EU PDB?

Yes

A default value applies (MRL = 0.01 mg/kg)

Stop

No

There is no MRL for your basic product yet

See FAQ list (no.2.3) for more information

Stop

Attention:

- Companies must, at all times, make a risk-based assessment of the detected pesticide content in order to ensure feed safety.
- It is possible that the country of origin does have a MRL.
- Also in the Codex Alimentarius MRLs are available of pesticide-commodity combination (http://www.fao.org/fao-who-codexalimentarius/standards/pestres/pesticides/en/)
**B: Determination of a MRL for processed products**

- **Processed product**
  - Can "footnote 1" be applied?
    - Yes: The pesticide mentioned in the EU PDB?
      - Yes: Is the unprocessed product mentioned in the EU PDB?
        - Yes: Is it possible to use processing factors? (does the production process effect the concentration/dilution of the processed product?)
          - Yes: The MRL of the unprocessed product applies
          - No: See A
        - No: A default value applies (MRL = 0.01 mg / kg)
          - Stop
      - No: No MRL applies for this product
        - Stop
    - No: There is no MRL for your basic product yet. See FAQ list (no.2.3) for more information.
  - No: EU PDB

- **Is the pesticide mentioned in the EU PDB?**
  - Yes: Is the unprocessed product mentioned in the EU PDB?
    - Yes: Use the processing factors established by FEDIOL for calculating the MRL
      - FEDIOL paper (Only for oils and fat products)
        - Yes: fat and oil products
          - Use/calculate an own processing factor (if necessary approved by the Authority) for the calculation of the MRL
        - No: See FAQ list (no. 2.4) for more information
      - No: See FAQ list (no. 2.4) for more information
    - No: No: See FAQ list (no. 2.4) for more information

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4. Processing factor = transfer factor = Concentration factor

5. The MRL of processed product is calculated on the basis of the unprocessed product

The recommendation to the companies is to contact the competent authorities in the regions involved to discuss if a processing factor can be applied.
C: Determination of a MRL for composite product

Composite product contains 2 or more unprocessed products /or processed products

Determine the MRL of the individual components

Determine the MRL in the composite product

The MRL is calculated in proportion to the MRL for the individual components:
\[ MRL_x = \left( N_1C_1 + N_2C_2 + N_3C_3 + \ldots \right) \]

\( N_i \) = % individual component

\( C_i \) = MRL individual component

Stop

> See A for the unprocessed products

> See B for the processed products