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WG 04-05/11/2025

WG 05-06/06/2025



**Guidance document for the evaluation of homogeneity of feed and the cross-contamination**

**PURPOSE OF THIS DOCUMENT**

To identify clear criteria for the competent authorities in the Member States to evaluate the methods used by Feed Business Operators (e.g. use of micro-tracers, sampling methods, etc.) to ensure the appropriate homogeneity of feed and to assess and control cross-contamination.

**NOTE**

This document is an evolving document and will be updated to take account of experiences and information from the Member States, from competent authorities, feed businesses operators and the Commission’s Health and Food Audits and Analysis Directorate.

**WARNING**

The content of this document reflects the views of the European Commission and, as such, is not legally binding. It does not create any new legal provisions, nor rights or obligations, nor does it seek to cover all provisions on the evaluation of homogeneity of feed and the cross-contamination in an exhaustive manner. Only the Court of Justice of the European Union is competent to interpret European law authoritatively. The views expressed in this Notice cannot prejudge the position that the European Commission might take before the Court of Justice of the European Union and national courts.

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# 1. INTRODUCTION

Regulation (EC) No 183/2005 laying down requirements for feed hygiene[[1]](#footnote-2) (also known as the Feed Hygiene Regulation, hereafter ‘FeHR’) has applied since 1 January 2006. It lays down general hygiene requirements to be followed by feed businesses operators at all stages of the feed chain.

Regulation (EU) 2019/4 on the manufacture, placing on the market and use of medicated feed[[2]](#footnote-3) has applied since 28 January 2022. It lays down specific provisions regarding medicated feed and intermediate products, which apply in addition to other Union legislation on feed.

Since the adoption of the FeHR, Member States have developed control and verification systems, procedures and work documents for the implementation of the FeHR.

The Commission’s Health and Food Safety Directorate General carried out a series of audits in all Member States. Based on the outcome of those feed audits, Directorate F of DG SANTE drafted the “Overview report hazards and management of risks in the feed Sector”[[3]](#footnote-4) which highlighted a number of areas where competent authorities face challenges in either understanding or complying with the relevant legal requirements, among others, homogeneity of feed and the management of cross-contamination, especially related to feed additives and veterinary medicinal products.

Some Member States have raised the issue of the verification of feed establishments in relation to the obligation of the feed business operators to ensure homogeneity and avoid cross-contamination (whether the establishments are registered or approved, as it is relevant to both types of establishments). Hence, competent authorities need a guidance on criteria to evaluate the measures put in place by the feed business operators in this regard.

While homogeneity and cross-contamination are separate concepts, the approach for their determination is based on common general principles and requirements, including the necessity to recourse to tracers and applying similar sampling procedures. Guidance on these common elements is provided in part 3 of this document, while parts 4 and 5 focus on the specificties of homogeneity testing and cross-contamination respectively, notably with regards to the method of measurement and number of analytical determinations on the one hand, and to the interpretation of results and acceptability criteria on the other hand.

The guidance document does not take into account possible national rules laid down to ensure the achievement of the objectives of the FeHR and Regulation 2019/4.

Feed business operators are responsible for the safety of feed, and for the implementation of own control plans and measures based on the hazard analysis and control of critical points (HACCP) within the business under their control. Therefore, feed business operators are responsible for determining and implementing the necessary measures to guarantee the compliance of feed placed on the market in relation to homogeneity and cross-contamination.

The purpose of this guidance document is to assist national competent authorities with the evaluation of the methods and measures implemented by feed business operators regarding the FeHRand Regulation (EU) 2019/4, with a view to contributing to an effective and consistent implementation across Member States. Consequently, the guidance document provides information on the achievable homogeneity and the avoidance of cross-contamination of [in?] the facilities manufacturing feed.

# 2. DEFINITIONS

## 2.1. Legal definitions

**'Feed hygiene'**[[4]](#footnote-5)means the measures and conditions necessary to control hazards and to ensure fitness for animal consumption of a feed, taking into account its intended use;

**'Feed' (or 'feedingstuff')**[[5]](#footnote-6)means any substance or product, including additives, whetherprocessed, partially processed or unprocessed, intended to be used for oral feeding to animals;

**'Feed business'**[[6]](#footnote-7)means any undertaking whether for profit or not and whether public or private, carrying out any operation of production, manufacture, processing, storage, transport or distribution of feed including any producer producing, processing or storing feed for feeding to animals on his own holding;

**'Feed business operator'**[[7]](#footnote-8) (hereafter ‘FBO’), for the purposes of the FeHR, means the natural or legal person responsible for ensuring that the requirements of Regulation (EC) No 183/2005 are met within the feed business under their control;

**'Establishment'**[[8]](#footnote-9) means any unit of a feed business;

**'Competent authority'**[[9]](#footnote-10) means the authority of a Member State or of a third country designated to carry out official controls;

**'Feed additives'**[[10]](#footnote-11)means substances, micro-organisms or preparations, other than feed material and premixtures, which are intentionally added to feed or water in order to perform, in particular, one or more of the functions mentioned in Article 5(3) (of Regulation (EC) No 1831/2003[[11]](#footnote-12));

**'Premixtures'[[12]](#footnote-13)** means mixtures of feed additives or mixtures of one or more feed additives with feed materials or water used as carriers, not intended for direct feeding to animals;

**'Coccidiostats' and 'histomonostats'**[[13]](#footnote-14) means substances contained in authorised feed additives and intended to kill or inhibit protozoa;

**'Veterinary medicinal products'[[14]](#footnote-15)** (hereafter ‘VMP’) means any substance or combination of substances which fulfils at least one of the following conditions:

1. it is presented as having properties for treating or preventing disease in animals;
2. its purpose is to be used in, or administered to, animals with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action;
3. its purpose is to be used in animals with a view to make a medical diagnosis;
4. its purpose is to be used for euthanasia of animals;

**'Feed materials'[[15]](#footnote-16)** means products of vegetable or animal origin, whose principal purpose is to meet animals’ nutritional needs, in their natural state, fresh or preserved, and products derived from the industrial processing thereof, and organic or inorganic substances, whether or not containing feed additives, which are intended for use in oral animal-feeding either directly as such, or after processing, or in the preparation of compound feed, or as carrier of premixtures;

**'Compound feed'[[16]](#footnote-17)** means a mixture of at least two feed materials, whether or not containing feed additives, for oral animal-feeding in the form of complete or complementary feed;

**'Medicated feed'[[17]](#footnote-18)** means a feed, which is ready to be directly fed to animals without further processing, consisting of a homogenous mixture of one or more VMP or intermediate products with feed materials or compound feed;

**‘Intermediate product’[[18]](#footnote-19)** means a feed, which is not ready to be directly fed to animals without further processing, consisting of a homogenous mixture of one or more VMP with feed materials or compound feed, exclusively intended to be used for the manufacture of medicated feed;

**'Batch'[[19]](#footnote-20)** means an identifiable quantity of feed determined to have common characteristics, such as origin, variety, type of packaging, packer, consignor or labelling, and, in the case of a production process, a unit of production from a single plant using uniform production parameters or a number of such units, when produced in continuous order and stored together.

Some of these definitions only apply for the purposes of the legal act in which they were made.

## 2.2. Other definitions

For the purpose of this guidance document, the following terms have the following meanings:

**'Cross-contamination'** means contamination of a non-target feed with an active substance, or unintended transfer to a non-target feed of a contaminant or component, originating mainly from the previous use of the facilities or equipment;[[20]](#footnote-21)

**'Homogeneity'** means the uniform dispersion of all ingredients in the same mixture, including those of lower inclusion;

**'HACCP system'** means a system which identifies, evaluates, and controls hazards which are significant for feed safety, in accordance with the principles laid down in Article 6(2) of Regulation (EC) No 183/2005;

‘**HACCP plan**’ means documentation or set of documents, prepared in accordance with the principles of HACCP, to ensure control of significant hazards in the feed business;

**‘Tracer’** means asubstance/product added or present in a feed, which is measured in order to determine the compliance with certain criteria of homogeneity and/or cross-contamination;

**‘Mix’** means a quantity of mixed feed that fits inside the mixer. A batch can correspond to one or more mixes;

**‘Manufacturing line’** means the whole technical system which includes the process stages of dosing and mixing (mixers including upstream and downstream feeders).

**‘Flushing’** meansa cleaning procedure of the manufacturing line of feed, part of the manufacturing line or a specific equipment, between two batches in regular production, consisting in passing a feed grade product through the manufacturing line for a determined number of times.

**‘Recovery rate’** (for the purpose of this guidance, the result of the following calculation, expressed in %) means tracer concentration of all analysed samples during a homogeneity test[[21]](#footnote-22), divided by the expected concentration.

with: *RR* = recovery rate

*m* = mean tracer concentration of all analysed samples during a homogeneity test

*C* = expected concentration

**‘Macro-ingredient’** means an ingredient present in the final product in large amount.

**‘Micro-ingredient’** means an ingredient present in the final product in minute amount.

**‘Verification’** means the application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure is or has been operating as intended.

# 3. GENERAL PRINCIPLES AND REQUIREMENTS

## 3.1. Relevant legal provisions

### 3.1.1. Relevant legal provisions on homogeneity

Article 5(2) of the FeHR lays down that FBOs (other than those referred to in Article 5(1)), shall comply with the provisions in Annex II to the FeHR, where relevant for the operations carried out. Requirements with a specific relevance for homogeneity are set out in point 3 of the Section “Facilities and Equipment” of the Annex II to the FeHR:

|  |  |
| --- | --- |
| *Annex II to FeHR, Section “Facilities and Equipment”* | *3.*  *Facilities and equipment to be used for mixing and/or manufacturing operations shall undergo appropriate and regular checks, in accordance with written procedures pre-established by the manufacturer for the products.*   1. *All scales and metering devices used in the manufacture of feeds shall be appropriate for the range of weights or volumes to be measured and shall be tested for accuracy regularly.* 2. *All mixers used in the manufacture of feeds shall be appropriate for the range of weights or volumes being mixed and shall be capable of manufacturing suitable homogeneous mixtures and homogeneous dilutions. Operators shall demonstrate the effectiveness of mixers with regard to homogeneity*. |

Additional specific requirements with relevance for homogeneity are set out in Article 6(1) and Article 4(1) in conjunction with Section 4, point 2. of Annex I of Regulation (EU) 2019/4 on medicated feed:

|  |  |
| --- | --- |
| Regulation (EU) 2019/4 | Provision(s) |
| Article 4 | *1. Feed business operators shall manufacture, store, transport and place on the market medicated feed and intermediate products in compliance with Annex I.* |
| Article 6 | *1.*  *Feed business operators manufacturing medicated feed or intermediate products shall ensure that the veterinary medicinal product is homogeneously dispersed in the medicated feed and in the intermediate product.* |
| Annex I, Section 4, point 2. | 1. *Specific regular own checks as well as stability tests shall ensure compliance with the homogeneity criteria as laid down in accordance with Article 6(2), the maximum levels of cross-contamination for active substance in non-target feed as laid down in accordance with Article 7(2) and the minimum storage life of the medicated feed and the intermediate products.* |

### 3.1.2. Relevant legal provisions on cross-contamination

Article 5(2) of the FeHR lays down that FBOs (other than those referred to in Article 5(1)), shall comply with the provisions in Annex II to the FeHR, where relevant for the operations carried out. Requirements with a specific relevance for cross-contamination are set out in points 2.(b) of Section “Facilities and Equipment”, point 3. of Section “Production”, and points 1. and 3. of Section “Storage and Transport” of Annex II to the FeHR:

|  |  |
| --- | --- |
| *Annex II to FeHR, Section* | *Provision(s)* |
| *Facilities and Equipment* | *2. The lay-out, design, construction and size of the facilities and equipment shall:*  *(a) (…)*  *(b)*  *be such as to minimise the risk of error and to avoid contamination, cross-contamination and any adverse effects generally on the safety and quality of the products.* |
| *Production* | *3.* *Technical or organisational measures must be taken to avoid or minimise, as necessary, any cross-contamination and errors. There must be sufficient and appropriate means of carrying out checks in the course of manufacture.* |
| *Storage and Transport* | *1.* *Processed feeds shall be separated from unprocessed feed materials and additives, in order to avoid any cross-contamination of the processed feed; proper packaging materials shall be used.*  *3. Feeds shall be stored and transported in such a way as to be easily identifiable, in order to avoid any confusion or cross-contamination and to prevent deterioration.* |

Additional specific requirements with relevance for cross-contamination are set out in Article 7(1) and Sections 1, 3, 4, 5 and 8 of Annex I to Regulation (EU) 2019/4 on medicated feed:

|  |  |
| --- | --- |
| Regulation (EU) 2019/4 | Provision(s) |
| Article 7 | *1.*  *Feed business operators manufacturing, storing, transporting or placing on the market medicated feed or intermediate products shall apply measures in accordance with Article 4 to avoid cross-contamination.* |
| Annex I, Section 1(1) | 1. *… Cleaning plans shall be introduced and be drawn up in writing, in order to ensure that any contamination, including cross-contamination is minimised.* |
| Annex I, Section 3(2) | 1. *Medicated feed and intermediate products shall be stored separately from any other feed in order to avoid any cross-contamination.* |
| Annex I, Section 4(2) | 1. *Specific regular own checks as well as stability tests shall ensure compliance with the homogeneity criteria as laid down in accordance with Article 6(2), the maximum levels of cross-contamination for active substance in non-target feed as laid down in accordance with Article 7(2) and the minimum storage life of the medicated feed and the intermediate products.* |
| Annex I, Section 5(4) | 1. *Containers in vehicles used for the transport of medicated feed or intermediate products shall be cleaned after each use to avoid any risk of cross-contamination.* |
| Annex I, Section 8(2) | 1. *… Vehicles used for the manufacture of medicated feed shall be cleaned after each use for the manufacture of medicated feed to avoid any risk of cross-contamination.* |

## 3.2. Criteria for the documentary verification by the competent authorities of an operator’s homogeneity and cross-contamination testing

Tests on homogeneity and cross-contamination, performed by all FBOs carrying out operations other than those referred to in Article 5(1) of the FeHR as part of their own controls[[22]](#footnote-23), should be based on pre-established descriptions and written procedures at least with regards to:

1. The main different processes utilised to manufacture feed throughout the entire manufacturing line;
2. Identification and justification of the mixing volume and mixing time used for the tests;
3. The particle size of the different components of the feed to be tested, which can be determined through analytical methods and/or by screening using sieves and mills, and the specifications of raw materials and other ingredients (feed additives, premixtures and/or VMP) added without prior milling;
4. Frequency of homogeneity and cross-contamination tests;
5. The phase of the production process where homogeneity and cross-contamination is determined (mixing, storing, etc.);
6. Identification and justification of the tracer which is going to be used (particle size, added quantity, point of inclusion, any required premixing, use of multiple tracers, etc.);
7. Identification and justification of the sampling procedure, including number and size of samples, points of the line (sampling point) where homogeneity and cross contamination are evaluated, duly identified in a manufacturing flow diagram and returns, with reference to the equipment to be used;
8. Pre-defined criteria for the maximum permissible tolerances for homogeneity and cross-contamination and its justification;
9. Interpretation of results;
10. Description of measures to be applied in the event of non-compliance (either because there is a legal requirement[[23]](#footnote-24), or it is a requirement set by the FBOs themselves);
11. Description of the cleaning procedure of the equipment and facilities between batches (flushing charge with description of the nature and quantity of flushing material or other procedures) where applicable;
12. Destination of the cleaning product (flushing charge or other procedures);
13. Preventive measures (forbidden manufacturing sequences, separation of lines of production, flushing…);
14. The laboratory, with analytical ability, where the samples will be sent.

In accordance with Article 15 of Regulation (EU) 2017/625[[24]](#footnote-25), the FBOs must provide upon request the relevant documentation on the above-mentioned aspects for official control purposes.

### 3.2.1. Tracers

The use of a tracer is necessary to carry out tests for the determination of homogeneity and cross-contamination. A tracer can be selected and used based on the following criteria:

* It should be used by the FBOs according to their established written procedures;
* It should be safe[[25]](#footnote-26) for workers handling the feed, for the animals which the feed is intended for (to be taken into account: the safety of the chosen trace element for the animal species, the levels of inclusion, the possible limitations of use for certain species) and for humans in general;
* It may be incorporated with a carrier (or as a premixture)[[26]](#footnote-27);
* It should be derived from a single source. As a general rule, it should not be present in any of the other ingredients included in the feed to be tested in order to avoid inaccurate results due to the background levels present (background noise);
* It should be a micro-ingredient[[27]](#footnote-28);
* It should be incorporated at sufficient quantity in order to avoid high variations in results and:
  + **In the case of control on homogeneity**, the tracer should be chosen considering that the added quantity should allow for a sufficient detection by the analytical method with an adequate measurement uncertainty.
  + **In the case of control on cross-contamination**, and given the tracer’s detection limit, the added quantity of tracer and the analytical method used should allow for a sufficient detection, for example in the case of coccidiostats/histomonostats a minimum transfer of 0,5%;
* Analytical methods meeting the provisions laid down in point 3.2.4. are available;
* It should be stable with respect to the manufacturing process between the place of its incorporation and the place of sampling.

The following types of tracers can be considered:

a) **Feed additives and VMPs**

* **Trace elements**. The most commonly chosen trace elements for homogeneity test are cobalt and manganese. However, other trace elements can also be used. Where more than one source of the trace element contributes to its presence in the feed (e.g. also from feed materials) the result can be influenced by the background levels. For this reason, the choice of trace elements as tracer for cross-contamination tests should be carefully considered and properly justified.
* **Colouring agents** (authorised feed additives).
* **Coccidiostats/histomonostats and active substances contained in VMPs** authorised for the purpose of the manufacture of medicated feed, provided that sufficiently sensitive analytical methods can be implemented, and the proper handling of the batches including the tracer is described in the HACCP plan.

b) **Microtracers** consisting of metallic particles, such as elemental iron particles coated with a dye, retrieved by magnetic separation, for homogeneity or cross-contamination tests. In case of use of magnetic tracers, attention should be paid to the possible use of magnets to protect the equipment.

Tracers can be pre-mixed with feed materials (in the same way as the usual production process) before adding them to the mix. The tracer can be added to the mixer at the same time and location as a "hand added" vitamin or VMP. Alternately, a tracer can be incorporated in a premixture (?) and added to feed via a computerized micro-ingredient addition system if it is the usual way to add VMPs or feed additives.

**Note**: Analytical constituents such as crude protein, crude fat, crude ash, crude fibre, etc. should not be used as tracers, as they do not reflect homogeneous distribution of micro-ingredients.

### 3.2.2. Frequency for homogeneity testing and cross-contamination testing

a) General principles

Tests for the determination of homogeneity and cross-contamination should always be performed at the beginning of the activity, and later upon any noticeable change in the production technique or equipment, occurrence of repeated deviations found during homogeneity and cross-contamination testing or in case of non-compliances (official controls, complaints from the customers).

Tests for the determination of cross-contamination should not be performed without prior determination of homogeneity, given that tests for cross-contamination cannot be interpreted without the recovery rate or when the mix does not meet the homogeneity requirements as referred to in point 3.1.1.

Moreover, FBOs should define their own frequency of homogeneity and cross contamination tests on the basis of a risk assessment linked to the products and the activity carried out (including the type of feed produced, e.g.: compound feed, premixtures), the production technique and the results of the past checks in the feed mill. In addition, requirements set out by feed quality/safety schemes or other voluntary certifications may be taken into account where appropriate.

The frequency should be set according to the above-mentioned risk assessment of the FBO. However:

* the general recommended minimum frequency of tests for the determination of homogeneity and cross-contamination is once every 2 years;
* for manufacturers of feed which are approved to use coccidiostats/histomonostats and manufacturers of intermediate products and/or medicated feed, it is usually recommended to perform a determination of homogeneity and cross-contamination at least once a year for each manufacturing line used for that production.

Results of the tests for the determination of homogeneity and cross-contamination must be kept available and provided by the FBOs to the competent authorities upon request in accordance with Article 15 of Regulation (EU) 2017/625.

b) Additional considerations on tests for the determination of cross-contamination

Competent authorities may consider facilitating the implementation of the above general principles in relation to the determination of cross-contamination in the case of very simple manufacturing lines such as those used in mobile or on-farm mixers, consisting only of one mixer, provided that all of the following conditions are met:

* the mixer is a very simple device where residues can be checked visually and removed manually (e.g. with a vacuum cleaner or with a broom);
* the manufacturing line is not used to produce medicated feed of feed containing coccidiostats/histomonostats;
* the cleaning procedure is described in the HACCP plan.

### 3.2.3. Sampling for the tests

The sampling method implemented by the FBOs should:

* enable operators to take samples reliably, rapidly and safely;
* facilitate the collection of samples that are representative of the product flow/of one mix;
* facilitate the collection of samples of the desired size;
* provide a result that resembles as closely as possible, the result that would be obtained during a usual feed production;
* be representative of all the types of feed with different characteristics (e.g. pellets, mineral, meals, mash, etc.) manufactured by the feed business;
* cover all of the facilities including all manufacturing lines involved in the process.

#### 3.2.3.1. Sampling point

The sampling point should be decided, taking into account the efficiency of the test and the safety of the FBO. For example:

* **Homogeneity**: At the exit of the mixer, and/or at other sampling points, downstream from the mixer, where appropriate and duly justified (e.g. to better reflect the homogeneity of the final product delivered to the customers).
* **Cross-contamination**: The point of bagging, at the time of loading bulk feed for its exit from the manufacturing line, etc.

In order to investigate the cross-contamination linked to specific portions of the manufacturing line, FBOs may decide to do additional cross-contamination tests, for example at the exit of the mixer or pelleting machine and, in the case of marketing bagged feed, at the point where this bagging is carried out.

#### 3.2.3.2. Sample size

The sample size should be sufficient in order to comply with laboratory requirements.

#### 3.2.3.3. Number of samples

The number of samples depends on the type of test (homogeneity or cross contamination) carried out, see point 4.2 and point 5.2 respectively.

#### 3.2.3.4. Organisation of sampling

Before initiating a test for the determination of homogeneity and cross-contamination, it is recommended to rinse the manufacturing line with a material that will not modify the product nor interfere with the test.

Regardless of the chosen tracer, the sampling frequency should be set up taking into account the time needed to empty the mixer or move the mixed product on to the next manufacturing stage, before beginning the next mixing process. In cases where sampling takes place at the very end of the manufacturing line, for example at loading of the truck through a silo, the time to empty the silo and the time to load a truck should be taken into account, so that only one mix was stored in the silo, etc.

This could be done, for instance, carrying out a calculation taking into account, not only the time required to empty the mixer, but also the number of samples to be collected.

The sampling exercise should be distributed evenly over the emptying/discharging time, and the first sample should be collected after a period of time "T" after the start of the discharging of the mixer, and the following samples should be taken after every period of time “T”, where:

Example: if it takes 5 minutes to empty the mixer, and 5 samples are required a sample should be taken every 50 seconds:

Depending on the tracer used, the common procedure technique for homogeneity and cross-contamination testing should be based on the production of the following batches:

|  |  |  |
| --- | --- | --- |
| **Manufacturing procedure for homogeneity and cross-contamination testing** | | |
| **Name of the mix** | **Composition of the mix** | **Test to be performed** |
| Mix A0 (\*) | Standard feed without tracer | Natural content of the tracer |
| Mix A/A’ (\*\*) | Standard feed with tracer | Homogeneity and content of the tracer |
| Mix B | Standard feed without tracer | Cross-contamination test |
| Mix C | Standard feed without tracer | Cross contamination test: measure of decrease in cross-contamination and measure of flushing efficacy |

(\*) Only in case trace elements or colouring agents are used as tracers.

(\*\*) It is recommended to prepare two mixes (A and A’) with tracer to ensure that the final Mix A’ contains the tracer in sufficient amount for the subsequent tests.

### 3.2.4. Analytical methods

Tracers should be analysed by appropriate and applicable methods of analysis fulfilling the following criteria with good results for the intended use:

1. accuracy (trueness and precision),
2. applicability (matrix and concentration range),
3. limit of detection,
4. limit of quantification,
5. precision,
6. repeatability,
7. reproducibility,
8. recovery,
9. selectivity,
10. sensitivity,
11. linearity,
12. measurement uncertainty,
13. other criteria that may be selected as required.

The analytical methods vary depending on the chosen tracer and may also differ for a given tracer, depending on the objective of the testing (homogeneity vs. cross-contamination).

For trace elements, the atomic absorption spectroscopy (AAS), inductively coupled plasma mass spectrometry (ICP-MS) and inductively coupled plasma atomic emission spectrometry (ICP-AES) are the most commonly used methods, while for feed additives and pharmacologically active substances, the preferred method is high performance liquid chromatography possibly coupled with mass spectrometry (HPLC or HPLC-MS).

For microtracers, a magnetic separator is usually used to remove particles from the samples. These particles are able to develop coloured spots on a given surface (mostly paper) if they are in contact with alcoholic solutions. The spots are then counted noting the total. Microtracers can also be analysed by colorimetry.

For colouring agents and coccidiostats/histomonostats and other feed additives, the analytical method laid down in the authorisation act of the feed additive should be used.

In case VMP with antimicrobial active substances are used as tracers [produced? *- what do you mean here?*], the analytical methods laid down in the Annex to Commission Delegated Regulation (EU) 2024/1229[[28]](#footnote-29) may be considered as an option, taking into account their limit of quantification.

# 4. HOMOGENEITY TESTING

This specific chapter on tests for the determination of homogeneity must be considered in addition to Chapter 3. It provides elements to the competent authorities for the verification of an operator’s homogeneity testing.

## 4.1. Objective

The aim of the homogeneity testing is to check the efficacy of the mixer (or where appropriate of the manufacturing line/establishment), e.g. the capability to ensure an adequate dispersion of micro-ingredients, feed additives and VMP across appropriate mix sizes and considering the mixing time. Its aim is not to check the compliance of a specific final product regarding the homogenous distribution of all of its different components.

Homogeneity must be effective in order to ensure that all incorporated components (notably dietary nutrients, feed additives and VMP in the case of medicated feed or intermediate products) are equally dispersed and in the proper proportion in the whole mix.

Tests for the determination of homogeneity should be considered as an integral part of the equipment requirements and good manufacturing practices of each establishment responsible for the manufacture of feed. Therefore, the FBOs must demonstrate that they have equipment and processes suitable and effective to obtain homogeneous mixtures.

For this purpose, the tests can be carried out using tracers such as trace elements, colouring agents, coccidiostats/histomonostats, VMP or micro-tracers. The demonstration of homogeneity of these tracers in the finished product means that the macro-ingredients added in larger amounts would also be homogeneously distributed. On the contrary, the homogeneous distribution of a macro-ingredient does not necessarily imply the homogeneous distribution of micro-ingredients.

## 4.2. Method of measurement and number of analytical determinations

The following mixes should be considered:

* Mix A0: mix of standard feed not supplemented with the tracer. Only necessary if trace elements or colouring agents are used as tracers, with a view to measure their natural content in the feed, unless the trace elements or colouring agent used as tracer is from a single source and not significantly present in any other ingredient. At least 4 samples should be collected inside or out of the mixer. The trace element (e.g. cobalt or manganese) or colouring agent content intrinsic to the feed should be determined;
* Mix A: mix of feed (with similar composition to Mix A0 where appropriate) supplemented with the tracer in order to ensure its uniform distribution. Applied in all methods, whichever tracer is added. At least 10 samples should be collected at the established sampling point to ensure sufficient accuracy of the calculation. The sampling should be distributed over the emptying/discharging time, and the first sample should be collected after a period of time "T" after the start of the discharging of Mix A. Sampling continues until there is a considerable decrease in flow. The content of the tracer added to the feed is determined in the 10 samples. In the case of trace elements (e.g. cobalt or manganese) as a tracer, the moisture content should also be determined.

mixer

Period of time "T"

Start of the discharging/unloading of Mix A

Sample A1

Sample A2

T

For the calculation of “T”, please refer to point 3.2.3.4.

When checking the mixing process, samples need to be taken as close to the mixer discharge as possible and at predetermined and regular intervals throughout the mix and put into sequentially numbered containers. The whole set of individual samples should be sent for separate analysis.

## 4.3. Interpretation of results and acceptability criteria

Interpretation of the data should look at variation between samples and may also look at average recovery. In addition, homogeneity results should not be interpreted for each determination in isolation, but the evolution of the results of the determinations performed over time should also be considered.

A target maximum percent coefficient of variation (CV) and recovery rate (RR) should be established, taking into account the analyte, type of feed (e.g. premixture vs. other types of feed), the target levels and background values. In most cases, a target CV of 5% (7 % in case of colouring agents) and a target RR of 70 to 110% (80 to 110% in case of VMPs) should be achievable according to current technology.

The CV is expressed as the ratio of the standard deviation divided by the mean, expressed in percentages.

It is calculated based on the individual results of the tracer in each sample taken, according to:

*CV* =

with: *CV* = coefficient of variation

*s* = standard deviation

= the mean of the values in samples with tracer

Where “s” is calculated according to:

*s* =

with: *s* = standard deviation

Σ = sum of

= value in a given sample with tracer (corrected by deducting the intrinsic content determined in the Mix A0, if applicable)

= the mean of the values *xi* in samples with tracer

*n* = number of analyses

Suggested interpretation of the coefficient interpretation (CV) and possible follow-up:

* CV equal to or less than 5%: acceptable.
* CV in the 5-10% range: still considered acceptable, but calling for improvements.
* CV above 10%: corrective actions should be implemented, for example, readjusting mixing time, checking the added quantity of tracer, additional maintenance of the mixing equipment, etc.

The results of the homogeneity tests performed with the representative products should be considered as reflecting the general performance of the mixer (and where appropriate of the manufacturing line/establishment).

In addition to the written procedures, all the details of the tests should be kept available and provided by the FBOs to the competent authorities upon request[[29]](#footnote-30).

# **CROSS-CONTAMINATION TESTING**

This specific chapter on tests for the determination of cross-contamination must be considered in addition to Chapter 3. It provides elements to the competent authorities for the verification of an operator’s cross-contamination testing.

## 5.1. Objective

The objective of the cross-contamination testing is to determine the intrinsic cross-contamination factor of the manufacturing line, in order to take measures to ensure that the feed placed on the market complies with the legislation (for example maximum levels laid down in Directive 2002/32/EC for coccidiostats/histomonostats).

FBOs usually produce several types of feed in the same premises, with various types of feed being produced in the same manufacturing line one after the other.

In practice, the cross-contamination of traces of one batch to the next is technically unavoidable, because residues from the previous production are still in the line when the next batch is being manufactured. On lines where the ingredients for the next batch are lined up while the current batch is being produced, there is also a possibility of cross-contamination of the current batch by the ingredients of the next batch. Other sources of cross-contamination are also possible (e.g. storage, transport, etc.)

The FBOs must adopt measures to reduce these occurrences in order to keep the cross-contamination at the lowest possible level and to comply with the legal limits (where applicable).

Therefore, tests for the determination of cross-contamination should be considered as an integral part of the HACCP system implemented at each feed establishment. Consequently, the FBOs, and in particular those who manufacture:

* medicated feed and intermediate products,
* feed containing feed additives with a maximum allowed content, or feed additives authorised for certain species and not for others, including coccidiostats/histomonostats,
* feed containing other products of concern for which it is important to manage cross-contaminations: GMOs, feed materials of animal origin such as processed animal protein (PAP), etc.

must consider all the risks related to their production process, especially when using certain feed additives, premixtures and VMP.

Any other possible activity carried out in the premises of the feed business should always be taken into account when assessing cross-contamination.

Cross-contamination may occur at any point on the manufacturing line, and each part of the line may contribute to the total level of cross-contamination, that is plant-specific.

Several factors may influence the level of cross-contamination of a substance in a feed mill: the facilities themselves (the equipment of the facilities), the substance itself, the staff (skills, training and experience), the production technique, the type of feed and its formulation, and the measures that are taken to control cross-contamination.

The plant itself and the equipment have a big impact on the level of cross-contamination. For instance, a poor degree of maintenance or calibration, dead corners along the line, inadequate micro-ingredients adding points into the mixer, insufficient emptying of the mixer, incorrect or return flows, the type of elevators, dust hang-up on walls and top, leaking gates or valves influence substantially the level of cross-contamination of the feed mill.

Usually, the highest level of cross-contamination occurs in the first sample of the mix immediately following the batch formulated with the ingredient of concern. The level of cross-contamination can also change as the feed passes through the feed mill, from the mixer to the surge bin, to the bucket elevator, to holding bins above the pellet mill, through the pellet mill, through the pellet cooler and holding bins before loading onto trucks for delivery.

The test should normally be conducted taking into account the average conditions of the production process. In some cases, it can also be useful to conduct the test in the most unfavourable conditions for cross-contamination (e.g. sticky substances, feed in meal form, small batches, bigger batches than usual, long manufacturing lines; etc.), in order to test the worst-case conditions. The test should be conducted to have information related to products actually used or produced in the facility.

It is important that the next batches take the same route through the feed mill as the initial mix formulated with the tracer (Mix A), including flushing mix, if any.

## 5.2. Method of measurement and number of analytical determinations

The following mixes should be considered:

* Mix A0: mix of standard feed not supplemented with the tracer. Only necessary if trace elements or colouring agents are used as tracers, with a view to measure their natural content in the feed. At least samples should be collected inside or out of the mixer. The trace element (e.g. cobalt or manganese) or colouring agent content intrinsic to the feed should be determined.
* Mix A/A’: feed with tracer (with similar composition to Mix A0 where appropriate) – as mentioned in point 3.2.3, it is recommended to prepare two mixes (A and A’) with tracer to ensure that the final Mix A’ contains the tracer in sufficient amount for the subsequent tests.
* Mix B: standard feed, with no tracer added.
* Mix C, D, etc: additional mixes of standard feed, with no tracer added, as necessary, in particular for the lines used for the production of medicated feed with antimicrobial active substances in order to ensure compliance with the maximum levels of cross-contamination laid down in the Annex to Implementing Regulation 2024/1229.

The feed samples taken for the purposes of testing for cross-contamination can be sampled after mixing for the homogeneity test.

The sampling should be distributed over the emptying/discharging time of each mix, and the first sample should be collected when the discharging of the final mix with the tracer (Mix A or Mix A’) arrives at the sampling point. Sampling continues until there is a considerable decrease in flow during the same period of time. The content of the tracer added to the feed is determined in the different samples (and corrected by deducting the intrinsic content determined in the Mix A0, if applicable).

For all mixes, a sufficient number of samples should be collected at the established sampling point. The resulting samples may be pooled in different groups for analysis, as detailed in the following practical example:

* Take and pool several samples from the final mix with tracer (Mix A or Mix A’, = base level), preferably right after the mixer; analytical result = base level.

NB: when combining cross-contamination and homogeneity testing, the mean value determined in the 10 (or more) samples taken in the Mix A with tracer, referred to in point 4.2, may be retained as base level.

* Take 30 samples from each mix without tracer (Mix B and possible Mix C, D, etc.).

For each mix without tracer, the 30 samples are pooled in 3 groups: the 2 first samples (= head level) (in each mix they contain the main part of the tracer), the 6 last samples (= tail level), and the remaining 22 samples (= body level).

For each mix, the samples of the 3 pooled groups are sent to be analysed separately, resulting in 3 separate analytical results: head level, body level and tail level.



Emptying / discharging timeline

Head level

Pool the 2 sampleses

Body level

Pool the 22 samples

Tail level

Pool the 6 samples



The sampling point should be as close as possible to the end of the line, preferably at loading point or bagging. In case multiple mixes are blended in a finished product silo, the sampling point should be at the discharge into that silo.

In addition to the written procedures, all the details of the tests should be kept available and provided by the FBOs to the competent authorities upon request.

## 5.3. Interpretation of results and acceptability criteria

The cross-contamination rate is calculated as a percentage of the concentration in the first mix (Mix B) manufactured with no tracer added (cross-contamination level), divided by the concentration of the tracer (analytically detected) in the final mix containing the tracer (Mix A or Mix A’). It is an indicator of the performance of the feed mill regarding the cross-contamination. Additional information can be obtained if the cross-contamination rate is calculated for the second mix (Mix C) and for the subsequent mixes (Mix D, etc.) with no tracer added.

Calculation of the cross-contamination rate of each mix, based on the practical example with pooling of the samples provided in point 5.2:

Suggested interpretation of the cross-contamination rate and possible follow-up:

* If the cross-contamination rate of the Mix B is equal to or less than 5%, and, where a Mix C and a Mix D are considered, the rate of the Mix C is equal to or less than 3% and the rate of the Mix D is equal to or less than 1%, the system can be considered in proper operational condition;
* If the cross-contamination rate of the Mix B is higher than 5%, and/or, where applicable, the rate of the Mix C is higher than 3% and/or the rate of the Mix D is higher than 1%, the operator should carry-out a revision and maintenance of the equipment (including substitution if required) and tests should be repeated afterwards, notwithstanding the implementation of preventive measures as necessary (e.g. flushing).

NB: a big deviation between the added amount of the tracer and the one analytically detected in mix A is a clear indication that the manufacturing line is not functioning properly, because a consistent part of the tracer remains in the equipment, instead of being incorporated into the feed.

## 5.4. Preventive actions by FBOs - FAQs

***What can be done to minimize the cross-contamination level?***

* **General information**

The FBOs should adopt every possible measure in order to keep the level of residues as low as possible and respect the maximum limits, where applicable, taking into account the application of good manufacturing practice and the “as low as reasonably achievable (ALARA) principle”.

In particular, in cases where the cross-contamination rate does not provide assurance that the following criteria will be met:

* Maximum admissible levels for coccidiostats/histomonostats in feed for non-target animal species, as established by Directive 2002/32/EC;
* Maximum levels of cross-contamination of antimicrobial active substances in non-target feed laid down in Delegated Regulation (EU) 2024/1229.

Preventive actions must be implemented by the FBOs to ensure that the above criteria can be systematically respected. This must be done without prejudice to the application of Article 20 of Regulation (EC) No 178/2002 to batches already produced, where necessary.

The preventive actions should take into account the result of the cross-contamination tests and should be adapted, on a case-by-case basis, to the nature of the specific production (for example: stickiness of the active substance, different size of the mix, abrasion, etc.).

* **Prevention by flushing**

Where necessary, depending on the results of the tests, all or some parts of the equipment involved in the process should be flushed after the production of a feed containing a substance which could lead to cross-contamination (hereafter “the active substance”), in order to reduce cross-contamination between batches.

Flushing is the most cost-effective measure to be implemented when the installation features and other procedures in place do not allow to contain the cross-contamination level. It should be done using a specified amount (usually not less than 1/3 of the mixer capacity depending on its capacity) of grains, compound feed or other suitable feed grade material, for a specified time proven to purge the system adequately. The FBOs should demonstrate the efficacy of their flushing procedures, which should also be described in the HACCP plan. It is critical that the flushing material take the same route through the feed mill as the initial mix formulated with the active substance, e.g. a VMP.

Generally, one big mix is better for cleaning the line than smaller mixes adding up to the same quantity.

After use, the flushing material should be identified, managed and stored in such a way to not affect the safety of the feed produced by the FBOs.

1. In case of active substances other than antimicrobials, coccidiostats/histomonostats and antiparasitics, the flushing material could be:
2. as the best practice, added to the feed that has just been produced with the same active substance, provided that the dosage of the active substance in the final feed complies with the legislation, and taking into account the permitted tolerances (Annex IV, part B to Regulation (EC) 767/2009, or Annex IV to Regulation (EU) 2019/4);
3. or destroyed;
4. or used for a technical purpose out of the feed chain (biogas production, composting, fuel, etc.), if the active substance is compatible with the technical purpose, from a technological point of view, and safe;
5. or stored and used in the production of a future batch of feed containing the same substance, provided that the dosage of the substance in the final feed complies with the legislation, and taking into account the permitted tolerances (Annex IV, part B to Regulation (EC) No 767/2009, or Annex IV to Regulation (EU) 2019/4);
6. or used for the production of non-target feed, provided that such non-target feed complies, where applicable, with the maximum levels of undesirable substances laid down in Annex I to Directive 2002/32/EC.

If the flushing material is added to the production of compatible feed (options i., iv. and v. described above), the operator should make sure that the labelled declarations are not affected by this addition.

If the cross-contamination is linked mainly to a portion of the line/machine (premix dosing bin, pelleting machine), a micro-flushing can be used to clean only this portion of the line. In this case, the flushing material can be added to the batch of feed containing the active substance.

Regardless of the measures adopted, the feed producers must guarantee the homogeneity and the correct dosage of the substances in the produced feed.

1. In case the active substance is an antimicrobial, a coccidiostat/histomonostat or an antiparasitic:
   * If the flushing material is used only once, all options listed in the above paragraph a) apply. However, the use of the flushing material for the production of non-target feed (option v.) should be considered the least preferred option in the context of the global effort to reduce the threat of anti-microbial resistance (AMR) and, if applied, the non-target feed must comply with:
   * the specific maximum levels of cross-contamination laid down in Article 2 of Delegated Regulation (EU) 2024/1229, or
   * the maximum levels of undesirable substances laid down in Section VII of Annex I to Directive 2002/32/EC.
   * If the flushing material is used more than once, it should be properly destroyed after the last use for flushing and the following specific recommendations are made:

* it should be used after the production of batches of feed, or intermediate products, containing the same active substance, and
* it should not be introduced in the line before the point of addition of the active substance (mixer or pre-pelleting machine), to prevent a contamination of the head of the line.

NB1: depending on the specific VMP or coccidiostat feed additive added to the feed, several active substances may need to be considered simultaneously for the application of these recommendations.

NB2: flushing may also be applied to processing, storage or transport facilities, as necessary, following the same recommendations.

* **Prevention by actions on the machines/equipment**

Cleaning and maintenance of the mixer, conveying system, pellet cooler, storage space and sack-off bin or delivery truck between runs to remove residual feed, is recommended when the flushing is not sufficient to contain cross-contamination. Cleaning of mixers is often necessary where liquid/sticky ingredients (e.g. molasses or fat) are added to the mixer.

The cleaning should be planned and performed in accordance with written procedures pre-established by the FBOs. Moreover, the plant and the equipment should undergo regular checks according to scheduled maintenance plans, keeping the corresponding records.

In the case of a new feed mill, this should be designed and built with a view to prevent and reduce cross-contamination problems by: avoiding as much as possible long internal transport and dead corners along the line, installing ground wires, choosing mixers with complete cleanout, dedicating a small bin to flushing material, remodelling the boot of elevators, preferring bucket elevators or chain conveyors instead of screws, adjusting ribbons or paddles, installing plastic “wipers” on ribbons, installing air sweep jets for cleaning the mixer, etc...

.The use of a separate manufacturing line for feed containing certain substances, e.g. for the production of medicated feed or feed with coccidiostats/histomonostats, or even dedicated weekly production, helps to limit cross-contamination problems for these substances. Cross-contamination of non-target feed, or of feed for non-target species in case of feed with coccidiostats/histomonostats, produced on this line should be further managed with the sequence of production and flushing, if appropriate.

In case of manufacturing medicated feed, “end of line techniques” limit cross-contamination problems.

* **Prevention by actions on the active substances and their addition**

Some measures can be adopted to reduce the residues of the active substances inside the machineries and keep the line as clean as possible.

Regarding VMP, intermediate products or coccidiostats/histomonostats, FBOs should aim to select active substances that are non-dusty and in granular form. If added to the mixer, the addition of the active substances should be carried out when the mixer is half full in order to lower the dust.

The dust should be kept low, by allowing more time for it to clear the system. The dust should be collected after the production and be disposed of.

Where feasible, the active substances should be added as close as possible to the end of the line, for example in pre-pelleting, after extrusion, or in a specific mixing truck, provided that homogeneity is assured.

***Influence of the sequence of production?***

Sequencing (or scheduling) of production does not allow for a reduction of cross-contamination but can contribute to manage cross-contamination in order to ensure compliance with the requirements set out in the legislation and prevent any adverse impact on animal or public health or to specifically avoid the contamination of specific batches of production, for example for commercial reasons.

The FBOs should establish their own rules for drawing up production schedules derived from the HACCP plan taking into account the outcome of the cross-contamination testing performed in the premises, the characteristics of the substances (e.g. on adhesive strength, dusting potential, electrostatic properties and the size and density of the particles) and the species for which they are authorised. In addition, attention should be paid to the risk for animal and public health, with the adoption, where required, of scheduling exclusions (e.g. no production of horse feed after a batch of feed containing ionophores). This task should be conducted by the “qualified person responsible for quality control”[[30]](#footnote-31). FBOs should not manage the cross-contamination issues by sending all the contaminated material to less sensitive animals without taking any other measures to decrease the level of cross-contamination.

In order to establish these schedules, the FBOs should define, for each substance considered at-risk according to the HACCP plan, the number of batches to be produced between a batch containing a given active substance (coccidiostat and histomonostat, VMP or other) and a batch for a non-target species or for the target species during the withdrawal period and afterwards for continuous food producing animals (dairy cows, laying hens). This defined number of batches should take into account the rate of cross-contamination of the plant, the flushing efficacy, the physical characteristics of the substance and the level of risk for animal (e.g. sensitive species) and public health.

***How can the verification of the compliance of the product with the legal requirements be carried out by the FBOs?***

An internal sampling plan[[31]](#footnote-32) on finished feed should be established in the HACCP plan and performed by the FBOs, on a risk basis, in order to verify the effectiveness of the measures put in place for managing cross-contamination and to ensure the compliance of the feed put on the market. The sampling plan should be based on the following principles:

1. In the batch of non-target feed placed on the market, the real content of residues of active substance due to cross-contamination should be evaluated.
2. The residues due to cross-contamination are usually non-uniformly distributed through the feed. Therefore, and based on the relevant provisions of Commission Regulation (EC) No 152/2009[[32]](#footnote-33), it is recommended that at least 18 incremental samples (keeping in mind that the number of samples depends on the size of the tested batch - minimum size 100 g), should be taken as close as possible to the loading of the finished feed. The incremental samples should be mixed together and homogenised to form an aggregated sample of at least 4 kg from which derive 2 final samples of 500 g to be analysed.
3. In case several mixes (usually “head”, “body” and “tail” mixes) of the same batch are produced, samples should be representative of the batch. Samples may be pooled if they belong to the same batch.
4. In case of a not satisfying result in a batch made up of several mixes, it could be also appropriate to later investigate the rate of cross-contamination taking into account the head, body and tail of the whole batch. The number of incremental samples can be determined taking into account the size of the whole batch and Commission Regulation (EC) No 152/2009; the incremental samples can be pooled to form several aggregated samples, at least one for each part of the batch: head, body and tail. Two final samples from each aggregate sample should be analysed to determine separately the level of cross- contamination of the beginning, the middle and the end of the batch. This procedure can be applied during packaging of the final product in bags, or during the loading of the final product in a tank truck (in bulk).

# ANNEX

**Non-exhaustive list of available documents on homogeneity and cross-contamination in animal nutrition**

**Developed by feed manufacturers’ organisations in the Union**

**1. The European Feed Manufacturers' Federation (FEFAC)**

European Feed Manufacturers' Guide – EFMC - <https://fefac.eu/resources/good-practices/european-feed-manufacturers-guide-efmc/>

**2. BELGIUM**

OVOCOM – Document AT-08 - Cross-contamination (v0.15 - 080121) - <https://www.ovocom.be/s/certificatie/certificaten/fca-documenten?language=en_US>

**3. FRANCE**

OQUALIM – Annexes 3 and 4 of the guide of good practice [*guide des bonnes pratiques d’hygiene de la nutrition animale (GBPNA)*] - <http://www.oqualim.com/>

**Others**

**1. Report of the Joint FAO/WHO expert meeting on carryover in feed and transfer from feed to food of unavoidable and unintended residues of approved veterinary drug**

<http://www.fao.org/documents/card/en/c/ca6296en>

**2. ICCF Guidance Document #03: Homogeneity Testing of Feed Ingredients, September 2020**

<https://iccffeed.org/wp-content/uploads/ICCF-GL_03-Homogeneity-Testing-Step7.pdf>

**3. The FAMI-QS Code of Practice version 6 / REV. 4 – 2018-10-02**

<https://fami-qs.org/wp-content/uploads/2022/02/FAMI-QS_Code_of_Practice_V6_Rev4.pdf>

1. Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene (OJ L 35, 8.2.2005, p.1, ELI: http://data.europa.eu/eli/reg/2005/183/oj). [↑](#footnote-ref-2)
2. Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC (OJ L 4, 7.01.2019, p. 1, ELI: http://data.europa.eu/eli/reg/2019/4/oj). [↑](#footnote-ref-3)
3. DG(SANTE)2016-8965, https://ec.europa.eu/food/audits-analysis/overview/details/100. [↑](#footnote-ref-4)
4. Article 3(a) of Regulation (EC) No 183/2005. [↑](#footnote-ref-5)
5. Article 3(4) of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1, ELI: http://data.europa.eu/eli/reg/2002/178/oj). [↑](#footnote-ref-6)
6. Article 3(5) of Regulation (EC) No 178/2002. [↑](#footnote-ref-7)
7. Article 3(b) of Regulation (EC) No 183/2005. [↑](#footnote-ref-8)
8. Article 3(d) of Regulation (EC) No 183/2005. [↑](#footnote-ref-9)
9. Article 3(e) of Regulation (EC) No 183/2005. [↑](#footnote-ref-10)
10. Article 2(2)(a) of Regulation (EC) No 1831/2003. [↑](#footnote-ref-11)
11. Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29, ELI: http://data.europa.eu/eli/reg/2003/1831/oj). [↑](#footnote-ref-12)
12. Article 2(2)(e) of Regulation (EC) No 1831/2003. [↑](#footnote-ref-13)
13. Article 2(2)(k) of Regulation (EC) No 1831/2003. [↑](#footnote-ref-14)
14. Article 4(1) of Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43, ELI: http://data.europa.eu/eli/reg/2019/6/oj). [↑](#footnote-ref-15)
15. Article 3(2)(g) of Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC (OJ L 229, 1.9.2009, p.1, ELI: http://data.europa.eu/eli/reg/2009/767/oj). [↑](#footnote-ref-16)
16. Article 3(2)(h) of Regulation (EC) No 767/2009. [↑](#footnote-ref-17)
17. Article 3(2)(a) of Regulation (EU) 2019/4. [↑](#footnote-ref-18)
18. Article 3(2)(b) of Regulation (EU) 2019/4. [↑](#footnote-ref-19)
19. Annex II, Section “Definitions”, to the FeHR. [↑](#footnote-ref-20)
20. Please note that the definition of cross contamination used for the purpose of this document differs from the one laid down in article 3(2)(d) of Rregulation 2019/4. [↑](#footnote-ref-21)
21. As detailed in point 4. HOMOGENEITY TESTING, homogeneity tests aim at checking the efficacy of mixers, e.g. their capability to ensure an adequate dispersion of micro-ingredients, feed additives and VMP across appropriate mix sizes and considering the mixing time. [↑](#footnote-ref-22)
22. As a consequence of the obligations laid down in Article 5(2) in conjunction with Annex II, point 3(b) of Section “Facilities and equipment” and point 3 of Section “Quality control”, Article 6 and Article 7 of the FeHR. [↑](#footnote-ref-23)
23. Such as, for example, when exceeding the cross contamination levels set in delegated Regulation 2024/1229, or when exceeding the maximum content authorised for a given feed additive in a compound feed. [↑](#footnote-ref-24)
24. Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/ EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95, 07/04/2017, p. 1, ELI: http://data.europa.eu/eli/reg/2017/625/oj). [↑](#footnote-ref-25)
25. Tracers fall into the definition of “products intended for animal feed” of Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed (OJ L 140, 30/05/2002 p. 10, ELI: http://data.europa.eu/eli/dir/2002/32/oj). Accordingly, they must be “*sound, genuine and of merchantable quality and therefore when correctly used do not represent any danger to human health, animal health or to the environment or could adversely affect livestock production*.” In particular, iron particles used as tracers are subject to a maximum content in arsenic. [↑](#footnote-ref-26)
26. In the case of being incorporated with a carrier (or as a premixture), the mix of the tracer and the carrier should be homogenous. [↑](#footnote-ref-27)
27. Materials such as Na or Ca minerals may be considered micro-ingredients and used as tracers, provided they are added in minute amount and all other criteria for tracers are met. [↑](#footnote-ref-28)
28. Commission Delegated Regulation (EU) 2024/1229 of 20 February 2024 supplementing Regulation (EU) 2019/4 of the European Parliament and of the Council by establishing specific maximum levels of cross-contamination of antimicrobial active substances in non-target feed and methods of analysis for these substances in feed (OJ L, 2024/1229, 30.4.2024, ELI: http://data.europa.eu/eli/reg\_del/2024/1229/oj). [↑](#footnote-ref-29)
29. In accordance with the provisions laid down in Article 7, point 1(a) of the FeHR and in point 2(a) of Section “Record keeping” of Annex II thereto, as well as Section 6 of Annex 1 to Regulation 2019/4. [↑](#footnote-ref-30)
30. As referred to in point 1 of Section “Quality control” to the FeHR. [↑](#footnote-ref-31)
31. As foreseen in Section “Quality Control” of Annex II to the FeHR and Section 4 “Quality Control” of Annex I to Regulation (EU) No 2019/4. [↑](#footnote-ref-32)
32. Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed (OJ L 54, 26.2.2009, p. 1, ELI: http://data.europa.eu/eli/reg/2009/152/oj). [↑](#footnote-ref-33)