Requirements for laboratories participating in the HDE Trade Services GmbH Fruitmonitoring scheme

As of: 13th May, 2020

1. Accreditation

1.1. Laboratories must be accredited according to ISO/IEC 17025 in the relevant field for any work commissioned.

1.2. The methods used must be covered by the scope of accreditation and the accreditation must relate to products examined as part of the Fruitmonitoring scheme (fruit and vegetable monitoring of HDE Trade Service GmbH; in the following short: HTS).

1.3. Subcontracts may only be issued under the Fruitmonitoring scheme to laboratories that are accredited for the required tests.
All subcontracted laboratories must be named. Subcontracted laboratories also need to be contract partners of HTS.
In the scope of investigations, which is reported and approved in the Fruitmonitoring database, it is obligatory that for every parameter that is marked as being analysed by subcontracted laboratories the complete company name of the subcontracted laboratory must be entered in the comment field of the respective parameter.

2. Technical equipment

The analysis must be carried out according to current standardised methods or relevant validated multi methods using state-of-the-art technology.

3. Competence of the laboratory – minimum requirements for the test range

3.1. A-laboratories

A-laboratories must be able to analyse at least 80% of the minimum (standard) range of the listed substances in fresh fruit and vegetables. The analysis of these substances and all other substances specified in the laboratory's standard pesticide screening scope must be carried out for every standard pesticide analysis.

HTS may expand the minimum range by adding new substances. A-laboratories must ensure within 3 months that they can continue to analyse 80% of the substances based on the expanded standard scope of analysis (preferably by including the recently added substances). If this is not the case, the laboratory will be downgraded to a level B after 3 months. This only applies if new substances are added to the standard parameter list and therefore the laboratory loses the A status (because it does not cover at least 80% of the standard parameters anymore). It is not mandatory to add the new substances, but it must be ensured that the laboratory does not lose the A status after the addition of the new substances.

3.2. B-laboratories

B-laboratories must be able to analyse at least 50% of the minimum (standard) range of the listed substances in fresh fruit and vegetables. The analysis of these substances and all other substances specified in the laboratory's standard pesticide screening scope must be carried out for every standard pesticide analysis.

In addition, a continuous development and improvement process is required to ensure, among others, that the laboratory can demonstrate within 24 months after the start of the cooperation (date on which the contract was concluded) that it has increased the list of substances it is capable of analysing by at least 20% in relation to the minimum range (standard).
After 48 months at the latest, the minimum analysis range must include at least 80% of the listed substances in fresh fruit and vegetables.

3.3. C-laboratories

C-laboratories do not carry out any pesticide analyses themselves, they only undertake additional examinations (e.g. mycotoxins, preservatives, nicotine, authenticity of

variety, heavy metals, GMOs, origin analyses, microbiological analyses).

3.4. Scope of investigations
Laboratories must enter a new, current scope of investigations in the Fruitmonitoring database within a maximum of 12 months. An approved scope of investigations, that is an active scope of investigations, must not be older than 12 months based on the date in the field “Valid from”.
This serves to ensure that the approved scope of investigations is always up-to-date and in line with the status of the laboratory.

3.5. The Fruitmonitoring reporting limits shall be observed.
The Fruitmonitoring reporting limit (short: FM reporting limit) is the lowest concentration of the mass of an analyte that can be validated with an acceptable level of accuracy using the complete analytical method. The FM reporting limit shall be attained by all Fruitmonitoring approved laboratories.

The reporting limit is the term that is used in the SANCO document 12495/2011 METHOD VALIDATION AND QUALITY CONTROL PROCEDURES FOR PESTICIDE RESIDUES ANALYSIS IN FOOD AND FEED and that should be familiar to every accredited laboratory.
The FM reporting limit was defined via laboratory comparison by Fruitmonitoring (HTS).

3.6. All results where both maximum levels and ARfD values are exceeded must be verified.

4. Proficiency test

Participation in round robin tests / interlaboratory tests

4.1. A- and B-laboratories participate at least twice per calendar year in qualified round robin tests / interlaboratory tests (e.g. FAPAS, QS, LVU, etc.) in the field of “Pesticides in Fruit & Vegetables”, provided these are available in the international market. All

parameters to be analysed as part of the round robin tests, for which the laboratory is accredited and which are specified in the Fruitmonitoring scope of analysis, must be determined.

In addition, the laboratories participate in regular round robin tests (at least once per calendar year) based on one of the other parameters (additional examinations) specified in the Fruitmonitoring scope. The round robin test must include a different additional parameter ever year, depending on availability.

The laboratory presents to HTS for review the results of the round robin tests, the resulting measures and the laboratory data obtained during the measures implemented.

The interlaboratory tests must satisfy the principles of the ISO/IEC Guide 43:1997, Part 1.

4.2. C-laboratories regularly take part (at least once per calendar year) in professional round robin tests / interlaboratory tests on additional analyses, which the laboratory itself carries out.
The laboratory presents to HTS for review the results of the round robin tests, the resulting measures and the laboratory data obtained during the measures implemented.
The interlaboratory tests must satisfy the principles of the ISO/IEC Guide 43:1997, Part 1.

4.3. To demonstrate the consistent quality of the tests performed within a laboratory, the laboratory must keep a record of the actual measurement uncertainty determined as part of the method validation according to ISO/IEC 17025, and communicate this to HTS upon request.

5. Test reports and handling samples

5.1. As soon as the laboratory receives a Fruitmonitoring sample, this must be logged on the Fruitmonitoring system no later than the next working day, and the key data (laboratory sample number, entered for retailer, client, lot number, product, type of

analysis, date of sample receipt, analysis order) must be registered. The laboratory is obliged to enter this and all other sample data correctly and truthfully.
Samples that are not registered in the Fruitmonitoring database within the allowed time limit will be locked automatically by the system.
Locked sample datasets must be reported to the Fruitmonitoring team (HTS) immediately indicating the reason for the late registration by e-mail. Locked sample datasets that are not reported will be cancelled with costs as sanction cases because of late registration.

5.2. Commissioned examinations of standard pesticide analyses must be carried out within a maximum of 5 working days after the sample is received and completed with a report.

5.3. The analysis certificates are produced in the national language and in English and/or German if requested by the client.

5.4. If the maximum residual levels are defined in the EU-VO for a sum parameter, the results must show both the measured values of the sum and the individual parameters.

If it is not possible to record all individual parameters analytically, the sum of the individual parameters actually determined analytically must be shown for the sum parameter. The comment field must contain a note stating that not all individual parameters of the sum parameter were determined.

5.5. The analysis results must refer to the statutory maximum limits and, if existent, to the ARfD values. The statutory maximum limits and, if existent, the ARfD values and the exhaustion of the ARfD values must be entered into the results recording in the database and must be part of the analysis report.

The laboratories perform their calculation and evaluation based on EU guidelines. The exhaustion of ARfD values is calculated in accordance with the provisions of the European Food Safety Authority (EFSA) or the German Federal Institute for Risk Assessment (BfR) or the World Health Organization (WHO).

5.6. If the laboratory has been commissioned to take samples, these must be taken separately for each batch. A representative quantity of the batch must be selected in accordance with the 2002/63/EC Directive.

5.7. Digital pictures of the sample showing legibly at least all identification elements must be taken (including all outer packaging) and attached to the corresponding sample dataset in the Fruitmonitoring database. The pictures show the product clearly identifiable as well as the labels. For data protection reasons it is not permitted if persons are depicted on the pictures uploaded to a sample dataset.

5.8. There must be enough homogenate to make at least three equal-sized portions. Two portions must be kept as retained samples for at least three months.

5.9. The refrigeration chain must be observed during the storage and transportation of the homogenate. Any nonconformity must be recorded in the test report.

6. Information system

The laboratory sets up an IT interface to the Fruitmonitoring database or enables a direct input into the Fruitmonitoring portal to ensure that the results of the analyses can be entered into the database immediately after these results have been validated.

HTS specifies the interface once if possible. However, subsequent changes to this specification may be required. Such changes should only be made where strictly necessary and carried out by HTS in such a way that any costs incurred by the laboratories are minimised.

The examination results of the standard pesticide analyses and/or individual tests must be entered and transferred into the Fruitmonitoring database within 8 calendar days counting from the day of sample receipt. The results of the additional examinations (e.g. mycotoxins, preservatives, nicotine, authenticity of variety, heavy metals, GMOs, origin analyses, microbiological analyses) must be entered and transferred into the Fruitmonitoring database within 21 calendar days counting from the day of sample receipt.

When taking samples to determine the best-before date, the day of the microbial

preparation is used as a start date for the analysis, and the 21-calendar-day period commences from this date.

Any exceptions must be justified and approved by HTS before exceeding the time limit. Findings with a red evaluation must be transferred to the Fruitmonitoring database as soon as the test report has been created.

7. Cancellation of samples

Samples that are registered in the Fruitmonitoring database must be transferred within the specified time limits. Only in exceptional cases samples can be cancelled. The relevant retailer and/or HTS decides on the cancellation. The cancellation must be requested in writing at HTS (info@fruitmonitoring.com) before the time limit is exceeded.

In the following cases, sample datasets can be cancelled with costs (EUR 5,00 plus the respectively valid VAT if applicable) by HTS:

- For data entry errors in Fruitmonitoring, e.g.
    - Missing or incorrectly rated evaluation areas
    - Missing or incorrect parameter entries in the results recording
    - Missing or incorrect maximum quantities and/or guidance values and/or critical values and/or ARfD values and/or ARfD utilization
    - Wrong dates (e.g. sample receipt, test report)
    - Wrong or missing information in the field "Investigation Order"
    - Wrong statement in the field "Kind Of Sample Examination”
    - Wrong selection and/or entry in the field "Organic product"
    - Wrong statement in the field "Plant protection products of the FM-standard list not detectable (standard investigation)"
    - Missing or incorrect information in the field "Brand"
    - Missing or incorrect information in the field "Lot number"
    - Wrong information in the field "Client" and/or “Supplier to retailer”
    - Wrong selection in the field "Product"
    - Wrong selection in the field "Country of origin"
    - Wrong information in the field “sample number”

- Missing or incorrect test report
- Missing or indistinct or illegible photo(s) of the analysed sample and the associated labels or marking elements
- When creating new sample datasets due to a previously incorrectly registered laboratory internal sample number.
- In case of overdue sample transfers (These samples are also considered as sanction cases, see Appendix 2 in the framework contract.)
- Multiple created sample datasets
- Accidentally or mistakenly created sample datasets
- Belatedly registered samples that the affected retailer does not allow to be entered and/or transferred into the Fruitmonitoring database. (These samples are also considered as sanction cases, see Appendix 2 in the framework contract.)
- Sample datasets without entered date in the field “date of sample receipt laboratory” will be cancelled with costs as of the 9th day counted from the date of the creation of the sample dataset. These sample datasets are considered sanction cases because of overdue transfers.
- Sample datasets without any entered investigation order will be cancelled with costs as of the 9th day counted from the date of the creation of the sample dataset. These sample datasets are considered sanction cases because of overdue transfers.