

Guideline

# Residue Monitoring Fruit, Vegetables, Potatoes



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**Note:** *The Guideline Residue Monitoring Fruit, Vegetables, Potatoes is written in German and translated into English. In case of discrepancies between the translation and the German version, the German original is valid.*

# 1 Fundamentals

All scheme participants are obliged to comply with the legal requirements regarding maximum levels and approved active substances/pesticides of each respective production country and country of intended use (**Regulation (EC) No. 396/2005** and/or equivalent provisions). On request, the agricultural/horticultural business must be able to provide proof of the approval of the active substances used for each culture in the country of use.

The Residue Monitoring in the QS scheme refers to fresh unprocessed/unprepared fruit, vegetables and potatoes and serves the purpose of controlling food products regarding compliance with the maximum legal levels/limit values for

- Active substances of plant protection products/post-harvest treatments and their relevant metabolites
- Pollutants
- Heavy metals
- Nitrate

In addition to this, evidence of not authorised active substances and their metabolites according to the residue definition is checked for the specific crop. A further objective is to identify the causes of possible exceedances of maximum residue levels and detections of unauthorised active substances and avoid them in future by taking suitable measures within the QS scheme.

This guideline outlines the controls and provides specifications for the implementation of Residue Monitoring to ensure constant surveillance on all stages of the QS scheme and to aid laboratories and samplers. The residue situation is monitored through regular product checks and directly by QS within the scope of the constant internal control system.

## 1.1 Scope

The Guideline Residue Monitoring applies to scheme participants who acquire certification in line with the following standards:

- Production Fruit, Vegetables, Potatoes, QS-GAP
- Wholesale Fruit, Vegetables, Potatoes
- Preparation/ Processing Fruit, Vegetables, Potatoes
- Food Retail/ FR Storage Fruit, Vegetables, Potatoes

The Guideline Residue Monitoring also applies to the following companies/organisations:

- Producer businesses which participate in the QS scheme on the basis of approved standards
- Laboratories
- Sampling institutes (samplers)
- Coordinators who organise sampling on the Production stage

## 1.2 Responsibilities

When implementing residue monitoring, the scheme participants/coordinators are responsible for ensuring that the sample related data and/or analysis results are entered into the database ([www.qs-plattform.de](http://www.qs-plattform.de)). Analysis results obtained or transferred in other ways are not accepted. A sample can only be used once to make up the targeted number of samples. For all samples, only one sample related data set and one analytical result per physical sample is allowed. Scheme participants must comply at all times with the requirements of the QS scheme and always be in a position to demonstrate compliance with said QS requirements. It must ensure that, in addition to the requirements of this guideline and other applicable QS requirements (for example: guideline coordinators agriculture/production, guideline production/QS-GAP, guideline wholesale, guideline preparation/processing, guideline food retail fruit, vegetables, potatoes), the legal provisions that apply in the country in which the products were produced as well as the country in which they are marketed by the scheme participant are fulfilled.

### Producers/coordinators

Implementation of Residue Monitoring for producer businesses is the responsibility of the coordinator who is also responsible for checking whether the analysis results of the samples were entered into the QS database by the laboratory.

The possibility exists of commissioning third parties (producers' organisations, labs etc.) with the implementation of Residue Monitoring.

### **Stage wholesale (incl. food retail storage), preparation/processing**

The implementation of residue monitoring for wholesalers/ preparation and processing companies/ food retail storage facilities is the responsibility of each respective scheme participant. The scheme participants are also responsible for checking whether the analysis results of the samples were entered into the QS database by the laboratory.

The possibility exists of commissioning third parties (producers' organisations, labs etc.) with the implementation of Residue Monitoring.

#### **Samplers**

The samplers are responsible for all stages in the sampling process, including the packaging and forwarding of the sample(s) to the lab.

#### **Laboratories**

The laboratories are responsible for the analysis of the samples and are obliged to enter all results correctly into the QS database.

If individual analytical methods are subcontracted to another QS-approved lab, responsibility for the correctness of these results and the entry thereof into the database lies with the commissioning lab.

## **2 Database**

The analysis results entered in the QS database serve among other things as the basis for the review of the control plan.

The scheme participants/coordinators/laboratories can evaluate their analysis results in the QS database via the evaluation tools it contains. In addition to this, anonymised evaluations can be made by QS with the inclusion of all entered test results.

Only the scheme participants/coordinators and QS have access to the stored sample data of a particular scheme participant/coordinator. It is possible to release analysis results to other scheme participants.

User manuals, supporting documents and format templates for implementing Residue Monitoring in the database can be found on the website under the "Support" tab.

## **3 Control Plan**

The control plan contains the risk groups and countries of risk origin of the products from which the number of mandatory samples to be drawn on the stages wholesale (incl. food retail storage) and preparation/processing and the minimum test methods to be applied are calculated. The risk classification and/or number of samples for a certain product can be changed at short notice if necessary. In order to adjust the data to the current residue situation in the QS scheme, the risk groups and countries of origin are revised at least once a year by a panel of experts (scientific advisory body). The analysis results of the previous year, the national report "Pesticide Residues" and the results of other national and international monitoring systems are used for this purpose.

Each valid control plan has to be implemented.

⇒ Appendix 10.1 Control Plan

## **4 Total Number of Annual Samples**

### **4.1 Production stage**

Product samples have to be drawn and analysed every year in 35% of fruit and vegetable-producing businesses and 5% of potato-growing businesses. The businesses are selected at random by the QS database. The selected businesses are displayed to the coordinator in the QS database as so-called sampling orders. Sampling and analysis for the selected businesses have to be conducted within one year in line with the provisions of this guideline. The culture to be sampled should be selected here from the cultures certified in the producer business with referral to the risk classification of the control plan.

If there is an increase in the number of complaints (MRL exceeded or detection of unauthorised active substances) among the producers of a single coordinator, QS can increase the number of samples to be drawn by the coordinator.

## 4.2 Stage wholesale (incl. food retail storage), preparation/processing

The required number of samples is calculated per product and year on the basis of the weight of the produce procured as QS produce. This applies irrespective of whether the goods are marked with the QS certification mark or not. Evidence must be produced that the required number of samples were drawn for a period of 12 months. The samples should be distributed on the basis of risk and seasonal occurrence. An individual sampling plan should be drawn up here for each business.

The provisions listed in the control plan should be regarded as minimum requirements. More frequent analysis can be necessary in certain circumstances within the scope of corporate due diligence and legal requirements. Each business must ascertain and determine this in its in-house risk analysis. Additional samples as well as samples of non-QS goods can be entered into the QS database as so-called "voluntary samples". All samples entered must be identifiable to the supplier and/or producer on the basis of corresponding documents (e.g. delivery notes).

⇒ 9.2 Terms and Definitions: voluntary sample

## 5 Sampling requirements

Sampling is to be conducted and documented in accordance with **Directive 2002/63/EC establishing Community methods of sampling for the official control of pesticide residues in and on products of plant and animal origin** as well as the explanations of **"the manual monitoring" of the Federal Office of Consumer Protection and Food Safety (BVL)** or analogous national documents. To satisfy the requirements of mandatory sampling, only fruit, vegetables and food potatoes ready for harvesting or marketing may be sampled. In addition to this, "follow-up samples", "voluntary samples", "release samples", "pre-harvest samples" may be drawn and entered into the QS database.

⇒ 9.2 Terms and Definitions: mandatory sample, follow-up sample, voluntary sample, release sample, pre-harvest sample

When sampling to determine the nitrate level in vegetable products, the product-specific requirements outlined in Appendix 10.5 must be complied with.

⇒ Annex 10.5 Nitrate determination: Specifications for sampling procedure and sample preparation

### 5.1 Stage production

Sampling is organised by the coordinator. Sampling by the producer, a staff member or a third party/organisation commissioned by the producer is not permitted. Samples are taken in agricultural/horticultural businesses (field/storage facility) in the presence and/or with the consent of the director of the business. Alternatively, the sample can be taken after delivery to a buyer's premises (e.g. wholesale, producer's organisation).

Different varieties of a crop/culture (e.g. coloured lettuce) can be sampled as a compound sample. Prerequisite for this is, that all products originate from the same field, had the same treatment regarding plant protection products and that the same maximum residue levels apply. These aspects must be ensured and documented at sampling.

### 5.2 Stage wholesale (incl. food retail storage), preparation/processing

Sampling is organised by the scheme participant. Sampling by the producer of the goods or an employee of the producer's company is not permitted.

### 5.3 Sampler

Sampling can be carried out by in-house samplers (except at the production level), coordinator and commissioned experts. The sampler must be proficient. The scheme participant/coordinator has to ensure the proficiency or has to be verified once to the scheme participant. The proof of the expert knowledge can be documented by participation in a corresponding training (internal/external).

### 5.4 Entries into the database

For all samples, only one sample related data set and one analytical result per physical sample is allowed. The sample related data must be entered before the end of the laboratory analysis. The entry deadline of maximum 10 days after the sample was drawn must be complied with here.

## 5.5 Sampling protocol

The sampler must keep records (in line with Appendix 10.2) of the type and origin of the batch, the FVP/WS number and/or QS ID, the owner, supplier or conveyor, as well as the date, time and place of sampling and all other relevant information. The responsible person in each business or the producer and the sampler sign the sampling protocol to confirm that the samples were taken properly by the sampler. Every deviation from the prescribed sampling method has to be recorded. A signed copy of this protocol must accompany every laboratory sample while one additional copy goes to the owner of the batch or his/her representative. The original remains with the sampler.

⇒ Annex 10.2 Sampling protocol

## 5.6 Packaging and consignment of samples

The sample must be packed in such a way that damage, negative external influences and contamination are ruled out. The container must be properly marked/labelled (sample number, type of product) and the sample delivered to the laboratory without delay. It must not be allowed to rot during transport, i.e. fresh samples should be kept refrigerated, frozen samples frozen.

# 6 Laboratories

To guarantee that the quality of analysis results between laboratories is kept at a uniformly high level, only QS-approved laboratories may be commissioned to conduct analyses. Applications for QS approval for residue monitoring should be made directly to QS (Appendix 10.3 Data sheet for laboratories when applying for QS approval).

## 6.1 Prerequisites for QS approval

The prerequisite for QS approval is presentation of the below-listed documents along with successful completion of a QS laboratory performance assessment. The documentation is verified by QS.

### 6.1.1 Documentary evidence

#### Accreditation

The laboratories must have accreditation in line with **EN ISO/IEC 17025**, as amended, for the examination area of Chemicals (Plant Protection Products) in Foods. QS prescribes a methodical accreditation for all test methods that are obligatory in line with the control plan.

The following test methods must be used in the laboratory to gain QS approval:

- Multi-methods with
  - Detection module GC (incl. selective detectors and/or GC-MS(/MS)-coupling))
  - Detection module LC-MS/MS (e.g. DFG S 19, contained in **EN 12393-1, 2 and 3** and /or QuECHERS; contained in **prEN 15662:2018-07**)
- This also includes active substances quantified after appropriate **modification of the multi-method** in line with the **analytical observations report** (EU Reference Laboratory for Single Residue Methods) e.g. for dithianon, fenbutatin oxide, phenoxycarboxylic acids (as free acids), matrine. These active substances can also be quantified by a single method. Subcontracting is not permitted.
- Dithiocarbamates

Other single, group and special methods mentioned in the control plan can be subcontracted.

⇒ Appendix 10.1 Control Plan

Laboratories need to be proficient in all the methods listed in the data sheet for the approval of laboratories or need to allocate the methods to a QS approved laboratory via a subcontract. The QS requirements regarding the subcontracting need to be incorporated. This applies also to the maintenance of the recognition.

If individual test methods have been implemented but not yet listed in the laboratory's accreditation certificate, preliminary approval can be declared. The prerequisite for this is the accreditation of the test method within the next 12 months.

Validation documentation has to be submitted for the methods applied for in accordance with the SANTE document in its currently valid version. The documentation must at least cover the documents listed in the data sheet. Additional paperwork and documents must be submitted to QS if necessary.

⇒ Appendix 10.3 Data sheet for the approval of laboratories

### Minimum requirements for the test spectrum of a multi-method

The laboratory must provide a list of all active substances with quantification limits for the area of Fruit, Vegetables, Potatoes which can be verified by the laboratory. The list should be subdivided in line with the detection modules used (e.g. GC-ECD, GC-FPD, GC-MS(/MS), LC-MS/MS). This also includes active substances quantified after an appropriate modification of the multi-method (in line with EURL publications).

When using the multi-method, all compounds mentioned in the residue definition of Regulation No. 396/2005 (including esters, conjugates, etc.) must be analysed, if they can be detected by the multi-method. If the multi-method covers active substances (parent substances) with a complex residue definition and findings are made, an appropriate special method for the precise determination of the metabolites must be used in order to satisfy **Regulation (EC) No. 396/2005**. The finding of the special method should be listed in the report.

### Subcontracting

The option exists of subcontracting the analysis of the test methods listed in the control plan to another QS-approved laboratory. Subcontracts can only be awarded to laboratories which have QS approval for the use of the test method in question. Subcontracts are subject to approval, for which the following documents must be submitted:

- Name of the commissioned laboratory
- Agreement between the laboratories on the subcontract, including details of the parameters to be analysed

Each test method can only be subcontracted to one laboratory. If there is a change to the awarding of a subcontract for a test method or if the subcontracting is cancelled because the laboratory is able to control the method itself, QS must be notified to this effect without any request to do so. The subcontract must be fulfilled by the commissioned laboratory and may not be passed on to a third laboratory.

It is the responsibility of the commissioned laboratory to enter the analysis results into the QS database.

In the scope of the laboratory performance assessment the subcontracted test methods have to be delivered to the subcontracted laboratory previously approved by QS. The sample has to be marked as test material in the scope of the laboratory performance assessment and tested for the subcontracted test methods only. The analysis has to be carried out within the period prescribed in the test. Results of the subcontracted analysis have to be transmitted to QS by the laboratory participating in the laboratory performance assessment.

### Laboratory suitability tests

Participation in external laboratory suitability tests within the last year prior to application is the pre-requisite for QS approval for every analysis method. Evidence must be provided by means of the corresponding documents. If a laboratory has not yet participated, a declaration of intent regarding the planned laboratory suitability test (including the organiser) must be presented.

⇒ Appendix 10.3 Explanation of documents to be submitted

If there are no results of a laboratory suitability test for a particular analysis method as no tests of this kind are offered for them in the required matrix, the decision on the approval of a comparable laboratory suitability test lies with QS.

### 6.1.2 QS laboratory performance assessments

To acquire QS approval, laboratories in the approval process whose document check was positive must provide proof of their competence in a performance assessment organised by QS before approval is granted. Successful participation in a laboratory performance assessment is mandatory a maximum of one year after completion of a document check, otherwise proof of successful participation in a more recent performance assessment must be produced before QS approval can be granted.

Laboratories in the approval process which participated unsuccessfully in a QS laboratory performance assessment twice in succession must pass two consecutive laboratory performance assessments to obtain QS approval. If a laboratory has failed the performance assessment three times in succession, QS reserves the right to suspend the approval process for 12 months.

Voluntary participation in a QS laboratory performance assessment is possible on request for laboratories which are not in the process of obtaining QS approval and which are not approved by QS. There is no legal right of participation in a laboratory performance assessment.



### 6.1.3 Validity of the approval procedure

If the required documents are not submitted by the laboratory within 12 months of the request by QS, the approval procedure is cancelled. If there is still interest in participating in the QS scheme, a new approval procedure begins upon application, which includes a renewed document check as well as renewed successful participation in a laboratory performance assessment.

## 6.2 Maintenance of QS approval

Annual participation in laboratory performance assessments and suitability tests organised by QS is required among other things for the retention of QS approval.

### 6.2.1 QS laboratory performance assessment

All laboratories with QS approval are obliged to participate in laboratory performance assessments organised by QS at least once a year. The participating laboratories are evaluated with a points system.

Participation in an additional QS laboratory performance assessment is obligatory if

- the previous QS laboratory performance assessment was failed
- the laboratory did not score the minimum number of required points

In the scope of the laboratory performance assessment the subcontracted test methods have to be delivered to the subcontracted laboratory previously approved by QS. The sample has to be marked as test material in the scope of the laboratory performance assessment and tested for the subcontracted test methods only. The analysis has to be carried out within the period prescribed in the test. Results of the subcontracted analysis have to be transmitted to QS by the laboratory participating in the laboratory performance assessment.

⇒ Appendix 10.4 Evaluation Criteria for Laboratory Performance Assessment

### 6.2.2 Laboratory suitability tests

Proof of regular participation in other laboratory suitability tests in the field of plant protection products and for approved individual methods in the fruit, vegetables, potatoes matrix must be provided to QS as follows:

- Annual list of laboratory suitability tests scheduled for the current calendar year (by 15 March of the current year)
- Annual list (no later than 15 March of the following year) of the suitability tests taken the previous year with results and, where appropriate, measures taken.

The obligatory QS laboratory performance assessment is not counted in here. Voluntary participation outside the obligatory QS laboratory performance assessment can be taken into account.

## 6.3 Loss of QS approval

If a laboratory loses its approval, existing orders can be worked off and the results entered into the QS database for a maximum of two weeks from the date approval was lost. A new application for approval is possible after six months at the earliest.

The application for renewed approval is subject to:

- a renewed document check
- a successful participation in a QS laboratory performance assessment (after application for renewed QS approval)
- the performance of a laboratory audit conducted by QS at the expense of the laboratory.

Applications for renewed approval must be submitted no later than 12 months after the loss of approval. After that, the reacquisition of approval is only possible via a new application.

⇒ Appendix 10.3 Data entry form for laboratories

⇒ 6.1.1 Documentary evidence

⇒ 6.1.2 QS laboratory performance assessment

⇒ Appendix 10.4 Evaluation Criteria for Laboratory Performance Assessment

## 6.4 Processing/preparation/analysis of samples

Only samples marked as QS samples on the accompanying sampling protocol or which are listed as such in the QS database are to be tested by the laboratories as QS samples. The principal shall be advised to provide sufficient sample material (in accordance with Directive 2002/63/EC) for the commissioned scope of investigation.

The processing and preparation of samples for analysis for plant protection product residues must be in accordance with **Annex 1 of Regulation (EC) No. 396/2005**, as amended. If one result indicates that the maximum residue level (measured value = actual value) has been exceeded, the result must be confirmed by a second examination of the newly prepared sample using a validated method (confirmatory method). Alternatively, if the principal wishes, this examination can be assigned to a second QS-recognized laboratory. If specifications are made by EU reference laboratories with regard to the confirmation method, these must be taken into account.

A portion (min. 200 g) of every analysis sample (homogenate) must be retained by the laboratory in frozen state for at least three months after analysis has ended.

The defined specifications for the preparation of samples, use of individual samples, compilation of collective samples/ homogenate and storage must be complied with when determining the nitrate level in vegetable products.

⇒ Appendix 10.5 Nitrate Quantification: Provisions for the sampling method and processing of samples

The analysis results must be available within 10 working days of the receipt of the samples.

## 6.5 Calculation of the degree of exploitation of the acute reference dose (ARfD)

The laboratory is obliged to list in all analysis reports the degree of exploitation of the acute reference dose (ARfD) for every active substance for which an ARfD exists. The calculation of the degree of exploitation of the ARfD is based on the ARfD published in the EU Pesticides Database and on the current EFSA PRIMo model. The degree of exploitation of the ARfD must be entered into the database (as a numerical value separated by commas).

## 6.6 Basis for evaluation of analysis results

The decisive factor when evaluating the measured values in the QS scheme is the actual value, i.e. the measured value without consideration of an analytical measuring uncertainty (e.g. of  $\pm 50$  percent with active substances of the multi-method). If the actual value is above the legally established maximum residue level, this is assessed as an exceedance of the maximum residue level.

## 6.7 Obligation to enter results into the database

All sample related data records on hand at the laboratory must be processed by the laboratory and entered correctly into the QS database for completion within the specified deadlines. For all samples, only one sample related data set and one analytical result per physical sample is allowed. The following deadlines apply to the entering of results:

- The sample must be completed in the QS database no later than 10 working days after receipt of the sample.
- The analysis results have to be entered into the QS database alongside the corresponding sample number within three working days of the end of the analysis.
- Complaints as defined by the QS definition (exceedance of the maximum residue level and/or detection of unauthorised active substances) which are established by the laboratory must be entered immediately into the QS database by the next working day after the end of the analysis.
- If a data record has to be reset or unblocked in the QS database, the laboratory must complete it again in the database within three working days after resetting/unblocking or retransmission to the laboratory.

⇒ 9.2 Terms and Definitions: Complaints

### Remarks field, laboratory related data

The remarks field for the laboratory related data should be used for:

- evaluation/assessment of the sample with regard to its marketability in line with applicable legal regulations
- evaluation/assessment of the sample with regard to unauthorised active substances (if conducted by the laboratory).
- entering the name of the sampler if the laboratory offers entry of sample related data as a service but did not draw the sample

- the description of abnormalities and peculiarities

### Entry of results into the database

When entering results, there are three other options in addition to the numerical value of the finding (number with a comma):

- "<BG" (means LQ) for findings below the quantification limit
- "n.n." = not detected. This entry is preassigned automatically by the database for all active substances consigned in the laboratory profile with the selected method.
- "n.a." = not analysed. This option should be used if no analysis was made for certain active substances with a consigned method.

## 6.8 Reporting in the original report

The original report of the analysis entered in the QS Database must contain at least following information:

- Information about sample and sampling (e.g. sample size, condition and if necessary picture)
- Sample receipt date and investigation period
- All tested active substances and metabolites as well as the appropriate limit of determination (substance spectrum incl. date and version number); information transmission (e.g. annex to the analytical report, link to the website) is left to the laboratory)
- Analytical method
- Subcontracting (if necessary)

For positive findings:

- Summary of the proven substances and metabolites
- Residue monitoring and their maximum levels of active substances, metabolites and conversion rate in accordance with currently valid regulations; the regulations should be named, e.g. regulation (EG) Nr. 396/2005, regulation (EU) Nr. 2023/915, German maximum residue levels
- Reference to recent changes to maximum levels, if relevant
- Percentage utilization of the maximum level in accordance with the residue definition
- Acute reference dose (ARfD) with source (e.g. EU Pesticide Database)
- Utilization of the ARfD stating the model used for calculation (PRIMO of EFSA)
- Evaluation of the marketability according to regulation (EG) 396/2005

For the QS laboratory performance assessment:

- Assigned test methods (in the accompanying laboratory data)
- Evaluation of the test results in accordance with the current legal requirements, according to the specification of QS without consideration of an extended measurement uncertainty

## 6.9 Access authorisation and perusal of documents

QS reserves the right to either check compliance with the accreditation requirements and regulations within the scope of a laboratory audit by itself or have them checked by a commissioned person/organisation. The laboratory is obliged to grant QS or a person/organisation commissioned by QS access to all documentation relating to its activities within QS Residue Monitoring.

In addition to this, QS or authorised third parties can commission analyses from the laboratory. If necessary, this can also be done with regard to concealed samples.

# 7 Exceedances/Not authorized active substances

Legal reporting requirements must be complied with in the event of complaints. QS must also be notified of complaints by the scheme participant/coordinator/laboratory. Findings of  $\leq 0.01$  mg/kg are not taken into account, provided that the legal maximum residue level are not lower. If the laboratory reports findings to the third decimal place, these are rounded off in the evaluation.

The customer has the option of having the result of a noncompliant sample checked by a further QS-recognized laboratory by means of an examination of the homogenate.

Evidence that originates from treated or processed goods can lead to complaints if the reason for the complaint can be traced back to the affected component of the raw material used.

Evidence from samples, which were taken out of QS residue monitoring, can lead to complaints or be regarded as release samples, in case they are handled and analysed in line with QS requirements. Samples from the official surveillance will be accepted similarly.

## 7.1 Stage production

After a complaint has been ascertained, the producer is suspended from the further marketing of the culture in question in the QS scheme. The coordinator must ensure that the producer is informed without delay.

Once the producer/coordinator has been notified of a complaint by QS, a case-specific consultancy has to be undertaken within four weeks by the official plant protection or advisory service or by a person/organisation authorised in Germany in line with **Art. 10 of the Plant Protection Law**. The consultation is to be documented based on a consultancy protocol specified by QS and proven to QS (Annex 10.6). For Producers who are certified according to the guidelines "QS Production Fruit, Vegetables, Potatoes" or "QS-GAP Production Fruit, Vegetables, Potatoes" the proof is provided in the next regular audit. Outside of Germany, similarly qualified consultancy services are to be used. If consultancy cannot be arranged within this deadline, evidence must be produced that a consultancy appointment has been arranged within two weeks of notification of the complaint. Once consultancy has taken place, evidence thereof must be submitted to QS within one week at the latest.

⇒ Annex 10.6 consultancy protocol

QS decides depending on the complaint whether sanction proceedings are to be initiated or not. The producer has the possibility to submit a written statement on the complaint to QS via his coordinator.

Additional documents can be requested in the course of the sanction proceedings (**Sanction Procedure, Appendix 5.1 of the Guideline General Regulations**).

As an alternative to the initiation of a sanction procedure, QS may impose, in case of complaints (in particular detection of non-authorized active substances) additional sampling (follow-up sample) by the coordinator within 12 months depending on the company size:

- Producers up to 25 ha of the claimed crop: 1 sample
- Producers between 25 and 50 ha of the claimed crop: 2 samples
- Producers larger than 50 ha of the claimed crop: 3 samples

release samples are not accepted for this purpose.

⇒ 9.2 Terms and definitions follow-up sample

## 7.2 Stage wholesale, preparation/processing

Compliance with maximum residue levels with regard to operating equipment (e.g. post-harvest treatment, cleaning agents, Biocides) is the responsibility of the scheme participant.

Once a complaint has been established, any existing goods from the same batch that may still be in stock on the company's premises are suspended from further marketing in the QS scheme. The scheme participant has the option of submitting a written statement about the complaint to QS. It is then up to QS to decide whether sanction proceedings are to be initiated or not.

If the cause of an exceedance of a maximum level or limit value and/or the use of an unauthorised or unapproved active substance is found to lie with the agricultural/horticultural business, the measures outlined in 7.1, above apply.

## 7.3 Stage food retail

A corrective actions report, in which the measures to be taken and procedures to be followed in the event of an exceedance are defined, must be on hand and available for presentation at all times.

## 7.4 Unblocking/regaining eligibility to deliver into the QS scheme

For a business to regain eligibility of delivery after a complaint, a sample from the same culture without any complaint (a so-called "release sample") must be presented to QS along with the analysis report. The sample must be drawn after the defective sample. The sampled product must come from the same field/greenhouse like the complained product. If no more goods from the affected field/greenhouse is available, the field/greenhouse that is harvested next, must be sampled. If the release sample is drawn at a producer business, neutral sampling must be organised by the coordinator.

An additional sample imposed on the producer (follow-up sample) (see chapter 7.1) cannot serve as a release sample.

If the producer is blocked and the objected crop is no longer available at the producer and will not be marketed in the current cultivation period (at least in the next four months), the producer can regain the eligibility to deliver into the QS scheme. In this case, the producer confirms the unavailability of the crop.

## 8 Approval of Monitoring Programmes Other than QS

For the approval of other monitoring programmes by QS, evidence of the comparability of the control system with the requirements of the QS Guideline for Residue Monitoring must be produced. QS reaches a decision on approval in its committees in each individual instance.

## 9 Definitions

### 9.1 Explanation of symbols

References to related documents are highlighted in **bold type**.

Notes are marked with **Note:** *italic text*.

References to other chapters in the guideline are marked with ⇒.

### 9.2 Terms and definitions

- Working days  
The days Monday to Friday are regarded as working days in the QS scheme.
- Acute reference dose ARfD
  - With active substances for which no ARfD exist or are required, "n.e." = not required/non-existent should be entered in the entry field.
  - If an active substance has been assigned an ARfD, the degree to which the ARfD has been exploited should be given (numerical value with decimal point) and not the legally assigned value.
- Complaint
  - Evidence of not authorised active substances and their metabolites according to the residue definition for the crop in the country of origin
  - Evidence of the maximal legal levels being exceeded
  - The actual value is taken into account in the QS scheme, i.e. the measured value without consideration of the measuring uncertainty of  $\pm 50$  percent
  - Findings  $\leq 0.01$  mg/kg are not taken into account if the corresponding maximum residue level is higher than 0.01 mg/kg
- Compound sample  
A compound sample as defined by QS is the representative overall sample. To this end, samples from different places in a lot/batch are combined into an overall sample. In this regard, a "compound sample" should not be seen as the mixing of different products, products from different lots/batches or from different producers into an overall sample. The results of samples of this kind are not approved in the QS scheme as they have no relevant meaning for the individual product.
- Incremental sample  
A quantity of material taken from a single place in the lot or subplot. It may be a single lettuce or spinach head, or handful of baby leaf, or one bag of cut leaves
- Sample type  
The following sample types can be selected in the QS database:
  - The "mandatory sample" serves to fulfill the sample target specified by QS. The obligatory examination methods result from the QS control plan. Additional methods can be added. Samples are taken solely from products that are ready for harvest or sale, from QS goods that have been purchased or requested (test sample).

- The "follow-up sample" results from a complaint. The obligatory examination methods result from the QS control plan. Additional methods can be added. Only products ready for harvest or sale are sampled.
- A "release sample" is taken after a complaint. It can be used by the scheme participant to regain his/her eligibility to deliver the noncompliant product into the QS scheme.
- The "voluntary sample" does not count as one of the mandatory samples that a company has to draw in line with the control plan. The extent of the commissioned method can be selected as desired. Only products ready for harvest or sale are sampled.  
The "pre-harvest sample" does not count as one of the mandatory samples that a company has to draw in line with the control plan. This type of sample is always evaluated by QS as a sample from products which are not ready for harvest and/or sale. It can be used to estimate the residue situation in a product.

A list of general terms and definitions can be found in the **Guideline General Regulations**.

## 10 Annexes

### **10.1 Control plan**

### **10.2 Sampling Report**

### **10.3 Registration form for laboratories**

### **10.4 Evaluation Criteria for Laboratory Performance Assessment**

### **10.5 Nitrate Quantification: Provisions for the sampling method and processing of samples**

### **10.6 Consultancy protocol**

All annexes are published separately as excerpts.

Guideline  
**Residue Monitoring**  
**Fruit, Vegetables, Potatoes**

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