TOPIC 12 – OFFICIAL CONTROLS

Subject N° 19: Official control of residues and environmental contaminants

Content

1. Residue Control

1.1. Risk analysis

FAO/WHO has published a guideline[1] to help national authorities improve their food control system. In this publication, the objective of monitoring and the use of risk analysis are outlined:

The objective of reduced risk can be achieved most effectively by the principle of prevention throughout the production, processing and marketing chain. To achieve maximum consumer protection it is essential that safety and quality be built into food products from production through to consumption. This calls for a comprehensive and integrated "from farm to fork" approach in which the producer, processor, transporter, vendor, and consumer all play a vital role in ensuring food safety and quality.

The Codex Alimentarius Commission defines risk analysis as a process composed of three components:

- **Risk assessment** – a scientifically based process consisting of the following steps: (i) hazard identification; (ii) hazard characterization; (iii) exposure assessment; and (iv) risk characterization;
- **Risk management** – the process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options;
- **Risk communication** – the interactive exchange of information and opinions throughout the risk analysis process concerning hazards and risks, risk related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.

Risk analysis must be the foundation on which food control policy and consumer protection measures are based. While not all countries may have sufficient scientific resources, capabilities, or data to carry out risk assessments, it may not even be necessary in all cases to generate local data for this purpose. Instead countries should make full use of the international data and expertise as well as data from other countries that are consistent with internationally accepted approaches. Risk assessments carried out at the international level by JECFA, JMPR, and other expert bodies are particularly useful. Developing countries should take a pragmatic approach and develop a cadre of scientists to interpret such data and assessments, and to use this information for the development of national food control programmes.

[1] ftp://ftp.fao.org/docrep/fao/009/a0601e/a0601e00.pdf

1.2. Objectives of residue control programmes

Residue control programmes are generally implemented to achieve one of two objectives:

- either to assess the compliance of consumable products on the market with rules and regulations;
- or to provide information that can be used in the process of evaluating the exposure of the population to the compounds investigated.

Or the residue programmes may aim to combine these two objectives.

Assessment of compliance includes testing for forbidden substances, unauthorised use of authorised substances as well as testing for compliance with established limits (e.g. maximum residue limits/levels, action levels, target levels) for the concentration of substances in the object of investigation.

Before planning a residue control programme, the objectives to be met must be clearly defined, since these objectives define which type of samples should be taken, the sampling strategies that should be used, where samples should be taken and how the sampling should be done.

Example 1:
Objective: provide information for exposure calculations
Type of sample: commodity with high consumption and/or high average concentration
Sample matrix: part eaten
Where to sample: where consumer buys the commodity
Sampling strategy: objective

Example 2:
Objective: control for illegal use of a forbidden veterinary drug
Type of sample: animal where a relevant use for drugs exists, or feed, water, etc., if relevant
Sample matrix analysed: organ where residue can be found in highest concentration
Where to sample: where illegal use can be suspected
Sampling strategy: selective or suspect

1.3. Sampling programme

1.3.1. Sampling strategies

The sampling strategy used for the sampling programme can have direct influence on the results achieved in a surveillance programme.

The "sampling strategy" can be defined as the approach used to select the units of the target population subject to controls: businesses, animals, foodstuffs, etc. It is worth noting that the comparability and interpretation of the results relies on the sampling strategy but as well on other parameters like the analysis methods, analysis matrices, preparation of samples, methods of calculation of the results, etc. (Eurostat – Typology of sampling strategies[2]):

- **Objective sampling**
  Strategy based on the selection of a random sample from a population on which the data are reported. It includes also other random samplings as “stratified” in subpopulations and sampling with proportional criterion, multistage sampling, etc.;
- **Selective sampling**
  Strategy based on the selection of a random sample from a subpopulation (or more frequently from subpopulations) of a population on which the data are reported. The subpopulations are determined on a risk basis or not. The sampling from each subpopulation is not proportional: the sample size is proportionally bigger for instance in subpopulations considered at high risk;
- **Suspect sampling**
  Selection of an individual product or establishment in order to confirm or reject a suspicion of non-conformity. It's not a random sampling. The data reported refer themselves to suspect units of the population.

1.3.2. Where to sample

The place of sampling can be critical for the legal use of an analytical result e.g.:

- when testing for compliance of pesticide residues in food with MRLs, the samples must be taken after the lot/consignment has entered the market, not on farm;
- when testing for forbidden veterinary drugs, the sampling can be done at the farm or later in the production chain as long as the origin of the animal and absence of cross-contamination can be trusted.

1.3.3. How to sample

The sampling techniques used are paramount to the analytical results that can be achieved.

For official sampling, sampling must be done in adherence to procedures laid down in legislation.

[2] https://circabc.europa.eu/sd/d/2fc47bd9-237a-4c79-93e0-6a4665cf3591/201_Typology_sampling_strategies.pdf

Guidelines could be designed in a tiered approach with general guidelines resting at the sampling institution and specific guidelines being distributed by the requesting laboratory together with the request for samples.

Guidelines should be detailed and targeted to the specific sampling situation in order to provide all necessary information for carrying out the sampling as well as packing, storing and transportation of samples and readily available for the relevant personnel (i.e. inspectors and sampling officers) in the local language.

For some substances and/or matrices, specific information on sampling must be available – including specifications for the type of packing, requirements for storage before transportation and time limits and conditions for transportation. Such information could be provided by the laboratory responsible for requesting the samples.

Inspectors and sampling officers should have a clear knowledge of the purpose of sampling, including the sampling strategies to be used. Depending on the actual organisation, this information could be part of a sampling guideline; general knowledge about sampling strategies, etc., could be subjects for training of sampling personnel.

1.4. Data management

Data collection and maintenance is an important task of any monitoring programme and a fundamental component of risk assessment.

Data collected during sampling and analysis should be stored either manually or electronically in such a way that data will not be compromised by either tampering or loss.

For enforcement, the most important information (apart from the analytical result) is the data needed to identify the sample and the responsible producer, while for monitoring and exposure programmes, a clear and systematic description of the sample type becomes more important. For mixed programmes, care must be exercised to gather and store both types of data.

The data structure should be tailored to the actual situation; if the data system must store data from many different chemical domains, a general structure may be useful. The EFSA standard sample description includes a list of standardised data elements (items describing characteristics of samples or analytical results such as country of origin, product, analytical method, limit of detection, result, etc.), controlled terminologies and validation rules to enhance data quality. These can be used to describe analytical samples for evaluation purposes[3].

1.5. National and international databases with residue data

[3] http://www.efsa.europa.eu/en/efsajournal/pub/1457.htm

The EFSA Journal[4] is an open-access, online scientific journal that publishes the scientific outputs of the European Food Safety Authority. EFSA's various output types are devoted to the field of risk assessment in relation to food and feed and include nutrition, animal health and welfare, plant health and plant protection, e.g. the European Union Report on Pesticide Residues in Food[5].

Also the United States Department of Agriculture publishes annual summaries of their Pesticide Data Program[6].

The World Health organization (WHO) homepage information on chemical risks in food[7] can give information, for example, on POPs and melamine. Since 1976, WHO has implemented the Global Environment Monitoring System - Food Contamination Monitoring and Assessment Programme (GEMS/Food)[8], which has informed governments, the Codex Alimentarius Commission and other relevant institutions, as well as the public, on levels and trends of contaminants in food, their contribution to total human exposure, and significance with regard to public health and trade. The programme was implemented by the WHO in cooperation with a network of more than 30 WHO Collaborating Centres and recognized national institutions located all around the world.

1.6. Rapid Alert System for Food and Feed and exchange of information

The EU Rapid Alert System for Food and Feed (RASFF)[9] is used to provide food and feed control authorities with an effective tool to exchange information on measures taken responding to serious risks detected in relation to food or feed. This exchange of information helps authorities to act more rapidly and in a coordinated manner in response to a health threat caused by food or feed. Whenever an EU member state has any information relating to the existence of a serious direct or indirect risk to human health deriving from food or feed, this information is immediately notified to the RASFF. RASFF notifications usually report on risks identified in food, feed or food contact materials that are placed on the market in the notifying country or detained at an EU point of entry at the border. The notifying country reports on the risks it has identified, the product and its traceability and the measures taken.

According to the seriousness of the risks identified and the distribution of the product on the market, the RASFF notification is classified as alert, information or border rejection notification. A "border rejection notification" concerns a consignment of food, feed or food contact material that was refused entry into the EU for reason of a risk to human health and also to animal health or to the environment if it concerns feed.

The contamination of food by chemical hazards is a worldwide public health concern and is a leading cause of trade problems internationally. Contamination may occur through environmental

[4] http://www.efsa.europa.eu/en/publications/efsajournal.htm
[5] http://www.efsa.europa.eu/en/efsajournal/pub/2430.htm
[6] http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5091055
[7] http://www.who.int/foodsafety/chem/en/
[8] http://www.who.int/foodsafety/chem/gems/en/
[9] http://ec.europa.eu/rasff

pollution of the air, water and soil, such as the case with toxic metals, PCBs and dioxins, or through the intentional use of various chemicals, such as pesticides, animal drugs and other agrochemicals.

2. Residues of veterinary drugs

Food-producing animals may be treated with medicines to prevent or cure disease. This can leave residues in the food products from the animals. The legislation on residues of veterinary medicinal products used in food producing animals should provide for a scientific evaluation before respective products are authorised. If necessary, maximum residue limits (MRLs) must be established and in some cases the use of substances prohibited, in order that proper use of authorised substances do not leave residues that are compromising consumer safety.

The description in the present manual of controls with residues of veterinary drugs in food products of animal origin will be described with reference to EU legislation. Special focus will be on the surveillance system that must be in place to ensure fulfilment of EU export requirements for animals and products of animal origin.

2.1. Legislation concerning residue controls

With regards to food safety, article 11 of Regulation (EC) No 178/2002 require that “food and feed imported into the community for placing on the market within the Community shall comply with the relevant requirements of food law or conditions recognised by the Community to be at least equivalent thereto or, where a specific agreement exists between the Community and the exporting country, with requirements contained therein”.

The present manual is widely based on legislation and practices required for or implemented by EU Member States. According to the legislation cited above, an exporting country can implement the EU requirements otherwise as long as this implementation is equivalent with the EU requirements.

Several legal acts should be taken into consideration, when the national residue control plan (NRCP) is prepared and implemented for export of animals and products of animal origin to EU. All of this legislation is publicly available and can be accessed via the European Commission's EUR-Lex website[10].

EU countries must monitor food of animal origin for the presence of residues and draw up respective residue monitoring plans. How these plans need to be designed and implemented is outlined in the following legislation:

- Regulation (EC) No 178/2002/EC[11] – general principles and requirements of food law
- Directive 96/23/EC[12] – sampling frequency and level, controlled substances for each food

[10] http://eur-lex.europa.eu/en/index.htm
[11] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32002R0178:EN:NOT
[12] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31996L0023:EN:NOT

- Decision 97/747/EC[13] – rules for milk, eggs, honey, rabbits and game meat
- Decision 98/179/EC[14] – official sampling and treatment of samples
- Decision 2005/34/EC[15] – standards for testing residues in products of animal origin imported from non-EU countries

Presently, the requirements for residue control in the Member States are regulated by the rather stiff prescriptions in Directive 96/23/EC. This legislation includes requirements for control of pesticide residues (either authorised for use as veterinary drugs or present as contaminants from feed...) and environmental contaminants.

It seems very likely, however, that future regulations[16] will be more flexible, putting more weight on a risk based sampling program laid down by the member state, while still maintaining a core of coordinated control for the whole EU. Such change in legislation could also influence the requirements for residue control in countries, exporting food of animal origin to the EU.

2.2. Planning and implementing residue control

The task of setting up and implementing the national residue control should be assigned to a central public department or body. This institution should draw up the plan and coordinate the activities of central and regional departments involved in the implementation of the plan, including inspections, sampling, analysis, reporting and follow-up activities.

The following sections describe the elements necessary for the implementation of the residue plan. Section 2.3 describes how to set up a national residue control plan (NRCP).

2.2.1. Sampling strategy

The residue control plan should be aimed at detecting all illegal treatment (i.e. use of unauthorized substances or products or misuse of substances authorized for other use or purposes) and controlling the compliance with the maximum residue limits (MRLs) for residues of veterinary drugs. The control plan should also be aimed at surveying and revealing the reasons for residues in food of animal origin.

To optimise the control of residue levels, the sampling should be targeted at detecting the presence and highest levels of those substances that the samples are to be analysed for. This implies that the sampling may not be representative for food on the market – and may include matrices not included in the diet of the consumer, e.g. offal, urine, feed and water.

The sampling must be unforeseen, unexpected and effected at no fixed time and on no particular day of the week. Sampling shall be carried out in variable intervals spread over the whole year. In this context it has to be considered that a number of substances are administered only in particular seasons.

[13] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31997D0747:EN:NOT
[14] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998D0179:EN:NOT
[15] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32005D0034:EN:NOT
[16] Presently (2012), it seems that such changes will not be implemented before 2016.

Some examples of criteria for targeted sampling on farm and on primary processing establishment (i.e. slaughter houses) are given in the Annex to Commission Decision 98/179 (CD 98/179):

Figure 1: On farm targeted sampling (Annex to CD 98/179)

2.3.2. On farm targeted sampling

2.3.2.1. Criteria for the selection of targeted sample

Farms for on farm sampling can be chosen using local knowledge or any other relevant information such as type of fattening system, breed and sex of animal. The inspector then makes an assessment of all the stock on the farm to select those animals to be sampled. In making this assessment the following criteria should be applied *inter alia:*

— indication of use of pharmacological active substances,

— secondary sexual characteristics,

— behavioural changes,

— the same level of development in a group of animals of different breed/categories,

— animals with good conformation and little fat.

2.3.2.2. Type of targeted sample to be collected

For the detection of pharmacological active substances the corresponding suitable samples are taken according to the provisions in the residue control plan.

Figure 1: Targeted sampling at e.g. slaughterhouse (Annex to CD 98/179)

2.3.3. Targeted sampling at primary processing establishments

2.3.3.1. Criteria for the selection

In making their assessment on the animal carcases and/or the animal products to be sampled the inspector should apply the following criteria *inter alia:*

— sex, age, species, and farming system,

— information about the producer,

— indication of use of pharmacological active substances,

— common practice with regards to the administration of particular pharmacological active substances in the respective farm production system.

When taking the samples, efforts should be made to avoid multiple sampling from one producer.

2.3.3.2. Type of samples collected

For the detection of pharmacological active substances the corresponding suitable samples are taken according to the provisions in the residue control plan.

In addition to the sampling defined by the NRCP, samples for follow-up investigations must be foreseen in budgets for sampling institutions and laboratories, and procedures for such follow-up actions should be laid down.

2.2.2. Substances to monitor

The present legislation in the EU (Directive 96/23, Annex I) classifies residues in two main categories.

Group A contains most of the substances which are prohibited from use in food producing animals in EU. Group B contains residues of many pharmacologically active substances which may be authorized for use in food producing animals in the EU. It also includes pesticides and chemical contaminants. Some overlapping exists; i.e. Group B also includes some substances without approved use (e.g. while all corticosteroids belong to group B2f, only a few – e.g. betamethasone, dexamethasone, methylprednisolone, prednisolone – may have an authorised use).

GROUP A – Substances having anabolic effect and unauthorised substances

(1) Stilbenes, stilbene derivatives, and their salts and esters

(2) Antithyroid agents

(3) Steroids

(4) Resorcylic acid lactones including zeranol

(5) Beta-agonists

(6) Compounds included in Table 2 in Regulation (EU) No 37/2010 (including later amendments) on pharmacologically active substances and their classification

GROUP B – Veterinary drugs[17] and contaminants

(1) Antibacterial substances, including sulphonamides, quinolones

(2) Other veterinary drugs

- (a) Anthelmintics
- (b) Anticoccidials, including nitroimidazoles
- (c) Carbamates and pyrethroids
- (d) Sedatives
- (e) Non-steroidal anti-inflammatory drugs (NSAIDs)
- (f) Other pharmacologically active substances

(3) Other substances and environmental contaminants

- (g) Organochlorine compounds including PCBs
- (h) Organophosphorus compounds
- (i) Chemical elements
- (j) Mycotoxins
- (k) Dyes
- (l) Others

[17] Including unlicensed substances which could be used for veterinary purposes

Annex II to Directive 96/23 lists for each commodity which Group A and Group B subgroups must be monitored for in the respective commodities (Figure 3**Error! Reference source not found.**). However, this table has been elaborated into the table shown in Annex 1, which shown the present requirements for an acceptable plan.

Figure 2: Annex II from Directive 96/23

ANNEX II

RESIDUE OR SUBSTANCE GROUP TO BE DETECTED BY TYPE OF ANIMAL, THEIR FEEDINGSTUFFS, INCLUDING DRINKING WATER, AND PRIMARY ANIMAL PRODUCTS

Type of animal, feedingstuffs or animal products Substance groups	Bovine, ovine, caprine, porcine, equine animals	Poultry	Aquaculture animals	Milk	Eggs	Rabbit meat and the meat of wild(*) game and farmed game	Honey
A 1	X	X	X			X	
2	X	X				X	
3	X	X	X			X	
4	X	X				X	
5	X	X				X	
6	X	X	X	X	X	X	
B 1	X	X	X	X	X	X	X
2a	X	X	X	X		X	
b	X	X			X	X	
c	X	X				X	X
d	X						
e	X	X		X		X	
f							
3a	X	X	X	X	X	X	X
b	X			X			X
c	X	X	X	X		X	X
d	X	X	X	X			
e			X				
f							

(*) Only chemical elements are relevant where wild game is concerned.

Substances in Group A are of greatest concern to the EU as they are either banned or restricted. Non-EU countries must monitor compounds in Group A1 - A6 in the relevant commodities. If testing for the relevant substances is not in the residue monitoring plan, it may not be approved and the country would not be eligible to export these commodities to the EU.

There are several other substances banned in animal production in the EU not currently listed in Group A e.g. malachite green (for treatment of fungal disease in fish) and several growth promoting antibiotic substances banned from animal feeding stuffs in the EU because of known chemical risks e.g. olaquindox, carbadox, nifursol. If such substances are authorised in a non-EU country, particularly in livestock production for the EU market, it should consider analytical and/or other control strategies to offer equivalent guarantees to those of EU legislation, which bans their use. If an exporting country authorises the use of certain steroid hormones or beta-agonists for growth promotion or the use of stilbenes, thyrostats or estradiol, their residues control plan can only be approved if there is a 'split system' in place, which guarantees that animals (or their products) for export to the EU have not been treated at any time during their rearing.

In respect of the group B substances, the NRCP should contain those substances which are likely to be used in the livestock production system. The choice of substances tested should be justified with a documented risk-based approach.

Tools for such risk-based approach could include:

- Information on available prescription medicine for animals;
- Data collection system of frequently used veterinary medicine products;
- Information on available relevant medicine from other sources (e.g. non-prescription, internet and other illegal imports);
- Residue control results from previous year(s);
- Recommendations from scientific and administrational bodies (WHO/FAO, EU-RLs[18] and FVO[19]);
- Residue control results from countries with comparable production conditions;
- RASFFs[20] (especially for import control).

In addition to the calculated minimum number of samples in each subgroup, the remaining number of required samples should be allocated according to the experience and background information of the country.

Methods for misuse of substances for growth promotion or prevention of illness is not static, but should be expected to change. Thus, strategies for sampling should be laid down by specialist with knowledge of the possibilities for misuse as well as symptoms and effects of such not prescribed use.

2.2.3. Sampling methods

Sampling for control of residues of veterinary drugs and certain other compounds in animals and animal products must follow the prescriptions laid down in CD 98/179.

Guidelines equivalent to these should be readily available for the relevant personnel (i.e. inspectors and sampling officers) in the local language.

[18] EU Reference Laboratories - http://ec.europa.eu/food/food/controls/reference_laboratories/index_en.htm
[19] EU Commission's Food and Veterinary Office - http://ec.europa.eu/food/fvo/index_en.cfm
[20] Rapid Alert System for Food and Feed - http://ec.europa.eu/food/food/rapidalert/index_en.htm

Statistics on sampling should be reviewed by persons responsible at a central level in order to verify that samples adhere to the aims and prescriptions for the NRCP. Results from such reviews could be communicated to representatives of institutions participating in the NRCP (e.g. competent authority, national reference laboratory, regional laboratories and sampling institutions).

2.2.4. Analytical methodology

Analysis of samples analysed to fulfil the NRCP shall be carried out exclusively by laboratories approved for official residue control by the competent authority. These laboratories must have an accreditation system in place and must prove their competence by regular and successful participation in adequate proficiency testing schemes.

Only those analytical techniques, for which it can be demonstrated in a documented traceable manner that they are validated and have a false compliant rate of < 5% (β-error)[21] at the level of interest, shall be used for screening purposes in conformity with Directive 96/23. In the case of a suspected non-compliant result, this result shall be confirmed by a confirmatory method.

Confirmatory methods for organic residues or contaminants shall provide information on the chemical structure of the analyte. Consequently, methods based only on chromatographic analysis without the use of spectrometric detection are not suitable on their own for use as confirmatory methods. However, if a single technique lacks sufficient specificity, the desired specificity could be achieved by analytical procedures consisting of suitable combinations of clean-up, chromatographic separation(s) and spectrometric detection.

For group A substances, all positive findings must be confirmed using the reference method criteria laid down in accordance with measures implemented by the Commission – i.e. for residues of veterinary medicines in accordance to Commission Decision 2002/657 (CD 2002/657).

There is no requirement for specific method procedures ("standard methods", "reference methods"). Instead, criteria for performance of analytical methods and interpretation of results are laid down in CD 2002/657. For some areas (e.g. pesticides) where other specific rules have been laid down in Community legislation, CD 2002/657 does not apply.

Documents from the EU Reference Laboratories (EU-RLs) give some guidelines for implementation of CD 2002/657 and for validation of screening methods.

Even when a fully validated "reference method" is transferred and implemented, the laboratory must carry out their own validation. However, some of the gained experience from the initial validation may be transferred to the new laboratory provided that this information is available and documented during the initial validation (examples of issues that can be transferred in some cases: stability of reagents, standard solutions and sample extracts; some tests of robustness). The guidelines from the EU-RLs give further guidance on validation of transferred screening methods.

[21] I.e. the rate of false negative results must be below 5% for samples having a concentration at the level of interest.

2.2.5. Reporting

CD 98/179 lists the information that must, at least, be present in the sampling report and the information that must be available to the analytical staff. This information should be extended as needed with other information necessary to identify the sample and its origin as well as all information necessary for the proper follow-up procedure. The information must be stored and not accessible to unauthorised persons.

1. Sampling report

A report shall be produced and signed after each sampling procedure. The inspector collects at least the following data in the sampling report:

- address of the competent authorities;
- name of the inspector or identification code;
- official code number of the sample;
- sampling date;
- name and address of the owner or the person having charge of the animals or the animal products;
- name and address of the animal's farm of origin (when sampling on farm);
- registration number of the establishment-slaughterhouse number;
- animal or product identification;
- animal species;
- sample matrix;
- medication within the last four weeks before sampling (when sampling on farm);
- substance or substance groups for examination;
- particular remarks.

All information relevant for the interpretation of the analytical results must be collected. This can include sex, age and weight of the animal tested.

Copies of the report are to be foreseen depending on the sampling procedure. The sampling report and its copies shall be signed at least by the inspector; in case of on-farm sampling, the farmer or his deputy may be invited to sign the original sampling report.

The original of the sampling report remains at the competent authority, which has to guarantee that unauthorised persons cannot access this original report.

If necessary, the farmer or the owner of the establishment may be informed of the sampling undertaken.

2. Sampling report to the laboratory

The laboratory report established by the competent authorities must contain at least the following information:

- address of the competent authorities;
- name of inspector or identification code;

- official code number of the sample;
- sampling date;
- animal species;
- sample matrix;
- substances or substance groups for examination;
- particular remarks.

This report is handed over to the routine laboratory together with the samples.

Guidelines available to the sampling officer should specify what information should be collected and how it should be transferred to relevant institutions.

The specific origin of the samples must not be known to the analytical staff until the analytical report has been completed and signed, but provided that proper procedures for restriction of access to the detailed sample information can be established, the full information on the sample could be available to the institution doing the actual analysis.

2.2.6. Follow-up

Every case of non-compliant analytical results must be assessed by follow-up investigations. Procedures that enable immediate information exchange about non-compliant cases between laboratories, central administration, regional/local inspectors should be in place.

Measures vary depending on whether the finding indicates illegal treatment or non-compliance with residue levels of authorised substances.

In any case, the cause of the finding must be clarified through investigations:

- concerning the business operator or animal keeper;
- concerning the veterinary practitioner;
- concerning other parties, for instance, suppliers of feed.

At the same time, recall of contaminated product must be ensured.

Kind and scope of controls must be documented. A system of traceability for animals and products, as well as samples, must be in place.

Investigations concerning the business operator or animal keeper should include, at least:

- the identity of the animal(s) in question;
- tracing the animals to farm level in case the samples are collected at slaughterhouse;
- a review of the use of veterinary drugs, including a check of the drugs present on the farm, with regard to the kind of drugs used; the amount of drugs used; the origin of drugs used;
- in case of authorised veterinary drugs:
    - adherence to the rules of defined waiting periods must be assessed;
    - receipts proving sales of drugs, and other relevant documentation;
    - prescriptions by the veterinarian;
    - prescriptions of feeding drugs;
    - a review of the animal keeper’s documentation if relevant.

Investigations concerning veterinary practitioners:

- checks of the documents to be kept according to national legislation;
- purchase and use of drugs containing substances listed in Table 2 of Regulation (EU) No 37/2010;
- signs of use of drugs which are not allowed in animals intended for food production.

If follow-up investigations at the producer, farm or the veterinary practitioner produce signs that substances which may be used as veterinary drugs have been used, and have been bought from other farms or establishments, these farms and establishments must be inspected also.

When the laboratory has reported a residue finding, the competent food control or veterinary office shall take follow-up samples. The approach and amount of sampling should depend on the kind of residue found.

This follow-up sampling should be aimed to identifying the sources of contamination, possibly by taking additional samples of feed, drinking water, or other potential sources.

In case of confirmed non-compliant animals/products, measures must be taken to assure that the non-compliant animal/product does not reach the market.

The following actions – depending on circumstance and national legislation – could be taken in non-compliant cases:

- confiscating the feeding stuff or products;
- recall and destruction of the products;
- slaughtering the animals; products from such animals are prohibited for use in human consumption;
- determine restrictions for the circulation of products from the particular farm/establishment;
- determine the measures, which must be carried out for reducing of exceeded MRLs;
- oblige owner to improve self-control system in the establishment and ensure mandatory sampling on residues;
- tightened control of particular farm/establishment;
- ensure official control for every lot intended for export.

2.3. Setting up a national residue control plan (NRCP)

The following section describes the necessary actions to fulfil EU requirements for a national residue control plan.

An approved residue monitoring plan is one of the prerequisites for export to the EU. EU animal and public health conditions must also be satisfied[22].

The plan will only have to cover those animal species from which products will be exported to EU, and those establishments that are involved in producing these foods.

[22] Further guidance on this subject can be found at http://ec.europa.eu/food/international/trade/index_en.htm.

In order to export food of animal origin to the EU, one of two prerequisites must be fulfilled:

- either all producers of such products must fulfil the requirements for residue control;
- or a strict scheme for registration and control of export approved establishments must be in place ('split system').

2.3.1. Initial residue control plan

The initial national residue control plan from a non-EU country must give details on the structure and legal background of the systems involved in the residue control.

The initial plan must include (where applicable) information on:

- The competent authority/authorities responsible for residue controls in all commodities included in the residue monitoring plan:
  - Contact details (name and address of the central competent authority);
  - Structure of the competent authority e.g. the levels involved (central, regional, local) and the personnel resources allocated for residues controls;
  - Role of the central competent authority e.g. drawing up the residue monitoring plan, co-ordinating and supervising residue control activities at different levels (central, regional, etc.), collection of data (e.g. results of monitoring), evaluation of data (e.g. was sampling carried out in accordance with the plan), application of corrective measures if required, submission of annual data to the Commission etc.
- The residue monitoring plan (and results from the previous year):
  - Existing (groups of) commodities which can currently be exported to EU and plans for expanding or restricting this list, which commodities that are included in the plan, and for which commodities results from the previous year's residue monitoring have been provided;
  - Information on the legal basis of the residue monitoring plan;
  - Information on whether the plan is based on Council Directive 96/23/EC or on an equivalent standard (e.g. Codex Alimentarius). If an equivalent standard has been used, this should be described;
  - Information on how the planned number of samples have been derived, in particular whether a 'split system' for animal production is in place;
  - Indicate whether all groups of residues are included in the plan for each of the relevant commodities (as listed in Annex I to Council Directive 96/23/EC). If not, explain on what basis substance groups have been excluded from the plan;
  - The list of substances to be detected, the matrices to be tested, and the screening and confirmatory methods used, the analytical limits of detection and action levels / national tolerances (to determine non-compliant results) should be clearly laid out in the plan;
  - Indicate whether there are any national tolerances or Maximum Residue Limits/Levels (MRLs) which do not correspond with EU MRLs;
  - For residues of substances which are unauthorised or illegal in the non-EU country, indicate what action limits are applied and the rationale for setting these. When those limits exist, information on whether they are consistent with EU minimum required performance limits (MRPLs) where applicable;

- Information on which type of services/personnel are involved in official sampling, and whether sampling is carried out only by officials or if third parties are involved;
- Description of the sampling strategies used;
- Explain any discrepancies in the number of samples planned versus the number of samples analysed;
- Briefly describe the measures taken – administrative, penal, professional and procedural (reinforcement of monitoring on the farms concerned) – for the non-compliant results detected during the implementation of previous year's plan.

- Laboratory Network:
  - Name(s) and address(es) of all laboratories involved in official residue testing;
  - Information on the level of competence of the National Reference Laboratory (if one has been established in the country), as well as the routine laboratories, particularly as regards the implementation of quality assurance in accordance with ISO 17025:2005, including the identity of the accrediting body (if applicable);
  - Information on the performance of the laboratories regarding their participation in relevant proficiency testing schemes.
- Authorisation and use of pharmacologically active and other substances in food producing animals:
  Information on whether
  - stilbenes or thyrostats;
  - hormones and beta-agonists;
  - substances which are included in Table 2 of the Annex to Commission Regulation (EU) No 37/2010 (e.g. chloramphenicol, nitrofurans and nitroimidazoles);
  - substances which are expressly prohibited from in-feed administration to food producing animals in the EU (e.g. carbadox, olaquindox, nifursol, etc.);
  - antibiotics for the treatment of certain diseases in honey bees;
  - dyes such as malachite green and crystal violet;

  are authorised for use in food producing animals at any stage of production. Depending on the substance, additional information must be given.

Templates and further details for reporting such information is available on the internet[23]. A copy has been included in Annex 2.

2.3.2. Subsequent (annual) residue control plans

1. Description of the regulatory systems

Non-EU countries are not required to send a detailed description of their regulatory systems every year. Only relevant updates or changes to the system need to be communicated to the European Commission. For non-EU countries with a well-established regulatory system, details of which were sent with the initial plan, subsequent communication with the European Commission would normally include:

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23 http://ec.europa.eu/food/food/chemicalsafety/residues/docs/table_1_information_required_for_tc_residue_control_programmes_20032012_en.pdf

- the (prospective) residue control plan;
- results of the previous year's plan, details of its implementation i.e. numbers of samples taken compared to the number planned and the measures taken for non-compliant ('positive') results. This is evidence of how the plan was implemented and an indicator of the competent authorities' performance.

2. The (prospective) residue control plan

The NRCP must provide information on which kind of samples that are planned for each of the categories of animal species (as listed in Annex 1) which are currently being exported to the EU (or which the country wishes to export to EU).

The plan must describe which substance groups are covered in the analytical scope, and for each substance give detailed information on the number of samples analysed and provide information on the performance of the methods used, including method principle for both screening and confirmatory methods, detection capability (CCβ)[24] for screening methods, decision limit (CCα)[25] for confirmatory methods as well as the level of action[26].

The number of samples within each species group and substance group are laid down in Directive 96/23 as a function of the size of the annual production for each species group. These sampling requirements are summarised in Figure 4.

Figure 3: Summary of sampling requirements by commodity/species

[24] If the concentration level in the sample is at CCβ, then the probability that the analytical result will be at or above CCα is 95% (for β = 5%).
CD 2002/657: detection capability (CCβ) means the smallest content of the substance that may be detected, identified and/or quantified in a sample with an error probability of β. In the case of substances for which no permitted limit has been established, the detection capability is the lowest concentration at which a method is able to detect truly contaminated samples with a statistical certainty of 1 – β. In the case of substances with an established permitted limit, this means that the detection capability is the concentration at which the method is able to detect permitted limit concentrations with a statistical certainty of 1 – β.
[25] CD 2002/657: decision limit (CCα) means the limit at and above which it can be concluded with an error probability of α that a sample is non-compliant.
[26] Level of action: concentration above which a result is deemed non-compliant

Species	Commodity	Frequency
Bovine	Meat	0.4 % of the animals slaughtered the previous year
Bovine/ Ovine/Caprine	Milk	One per 15.000 tonnes of annual production - minimum 300 samples
Porcine	Meat	0.05% of the animals slaughtered the previous year
Caprine, Ovine	Meat	0.05 % of the animals slaughtered the previous year older than 3 months
Equine	Meat	No frequency or minimum number of samples established
Poultry	Meat	One per 200 tonnes of annual production (deadweight)
	Eggs	One per 1.000 tonnes of annual production for human consumption - minimum 200 samples
Rabbit	Meat	10 per 300 tonnes of annual production (deadweight) for the first 3.000 tonnes + 1 sample for every 300 tonnes thereafter
Farmed & wild game	Meat	At least 100 samples
Farmed fin fish	Meat	One per 100 tonnes of annual production (deadweight)
Bees	Honey	10 per 300 tonnes of annual production for human consumption for the first 3.000 tonnes + 1 sample for every 300 tonnes thereafter

Source: http://ec.europa.eu/food/food/chemicalsafety/residues/docs/requirements_non_eu.pdf

Templates for reporting such information are available[27]. The minimum numbers of samples under EU rules are automatically updated, when the production data are entered. Details of the analytes, materials to be tested, screening and confirmatory analytical methods, etc., can be entered.

When reporting the plan, care must be exercised in distinguishing between number of samples and number of analysis.

As an example, if the plan has indicated that 12 samples of horses are to be analysed for substances in subgroup B1 (stilbenes) and 12 samples of horses are to be analysed for substances in subgroup B2 (antithyroids), a total of 24 samples must be taken – even when each sample is analysed for both subgroups B1 and B2.

This must be reflected in reporting the plan as well as the results.

[27] http://ec.europa.eu/food/food/chemicalsafety/residues/plantemplate.xls

The templates presented on the web[28] for reporting the plan or the results are not well suited to report such information.

One possible solution for the example above (when only samples of 12 horses are planned to be taken) could be to report in the template that 12 horses are planned to be analysed for substances in group B1 and to add a note, stating that the 12 samples of horses reported for subgroup B1 also will be analysed for substances in subgroup B2 (and including information on the substances analysed for). These 12 horses should then NOT be reported in the template under subgroup B2. Alternatively could be reported that 6 horses were to be analysed for substances in group B1, and 6 horses were to be analysed for substances in group B2 (supplementary information could be added in notes).

2.4. Special rules for certain commodities

In addition to the general rules described above, special rules exists for export of horses (and products of horses), casings and honey.

These rules are described in “Imports of animals and food of animal origin from non-EU countries. Manual on residue requirements for non-EU countries exporting to the EU”[29].

2.5. Reporting results from the annual monitoring programme

Results from the annual monitoring programme must be reported to the EU Commission on an annual basis. Templates for reporting such information are available[30]. When reporting the results, care must be exercised in distinguishing between number of samples and number of analysis, see remarks in section 2.3.2 (Subsequent (annual) residue control plans).

2.6. Systems and procedures for approval and registration for VMPs

In the EU, a company can market a veterinary medicinal product only after a marketing authorization has been issued by an EU member state or by the EU Commission through EMA[31]. Before the EU member state or the EU Commission issues a marketing authorization, the company must submit a marketing authorization application, called the “dossier”. The dossier includes data from studies showing the product’s quality, safety, and efficacy.

The legislation on residues of veterinary medicinal products used in food producing animals provides for a scientific evaluation before respective products are authorised. The objectives of marketing authorisation are to ensure that the product is safe for the consumer of food derived from treated animals, the animal itself, those handling the product, and the environment. If

[28] Plan: http://ec.europa.eu/food/food/chemicalsafety/residues/plantemplate.xls
Results: http://ec.europa.eu/food/food/chemicalsafety/residues/resultstemplate.xls
[29] http://ec.europa.eu/food/food/chemicalsafety/residues/docs/requirements_non_eu.pdf
[30] http://ec.europa.eu/food/food/chemicalsafety/residues/resultstemplate.xls
[31] European Medicines Agency - http://www.ema.europa.eu/ema/index.jsp

necessary, maximum residue limits (MRLs) are established and in some cases the use of substances is prohibited.

For an animal drug, the EMA Committee for Medicinal Products for Veterinary Use (CVMP) is responsible for the scientific evaluation. In the CVMP, experts from all EU Member States are seated. The Rapporteur, or lead reviewer on the dossier, prepares an overview of the committee's scientific evaluation, called the CVMP Assessment Report.

The CVMP Assessment Report:

- summarizes the data submitted by the company on the product's quality, safety, and efficacy;
- explains the assessment done by the CVMP to support the committee's recommendation to the EU Commission to issue a marketing authorization; and
- is the basis for the European Public Assessment Report (EPAR) published on EMA's website.

3. Pesticide residues

Pesticides cover a wide range of very different chemical substances. Pesticides are toxic compounds that are deliberately spread in nature, precisely because of their toxic properties. Pesticides are therefore different from the other chemicals used in the modern society. Since the toxicity of pesticides is not necessarily specific to the organisms it must fight, contaminants or residues in food may cause harm humans.

Pesticides are mainly used to prevent pests in the production of fruit, vegetables and cereals. Additionally, small quantities are used in the production of meat, to fight insects in stables and on animals, and – with less relevance to food – also wood preservatives. There exist different types of pesticides, depending on the pests to be controlled; insecticides, herbicides, fungicides and plant growth regulators. Around thousand active substances are produced and used worldwide. As a consequence of the use of pesticides, it is possible to identify residues in a large number of food products.

The description in the present manual of controls with pesticide residues in foods will be described with reference mainly to EU legislations.

3.1. Legislation concerning residue controls

In many countries, there is national legislation regulation on which pesticides are authorized. Many countries also have national legislation on the maximum amounts of pesticide residues in different food commodities. Such upper limits are also referred to as Maximum Residue Levels (MRLs) or tolerances (in the United States). In countries with no national legislation, the MRLs set by the Codex system are often used. MRLs are normally set for raw agricultural commodities (RAC), for example, banana with peel, lettuce, and apples.

The Codex Alimentarius Commission (CAC) is an international body that aims to protect the health of consumers, ensure fair trade practices in the food trade, and promote coordination of all food standards work undertaken by international governmental and nongovernmental organizations. CAC also set MRLs, which are indicative and not statutory. The Codex MRLs are to be used as guidance on acceptable levels when there is no other legislation in place; for example in countries without their own national MRLs or they can be used if national MRLs have not been set for a particular compound.

MRLs set by Codex are evaluated and negotiated through a stepwise procedure. Initially, the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) considers recognized use patterns of good agricultural practice (GAP) and evaluates the fate of residues, animal and plant metabolism data, and analytical methodology as well as residue data from supervised trials conducted according to GAP. Based on these data, MRLs are proposed for individual pesticides. Toxicologists evaluate

the toxicological data related to the pesticides and propose acceptable daily intakes (ADI) and acute reference doses (ARfD). The toxicological data originate from animal studies and include both studies on the short-term and long-term effects. The ADI is a measure of the amount of specific substance (in this case, a pesticide) in foods and drinks that can be consumed over a lifetime without any appreciable health risk. ADIs are expressed as milligram/kilogram body weight/day. The ARfD of a substance (here pesticide) is an estimate of the amount of the substance in food or drinks, normally expressed on a body weight basis, that can be ingested during a period of 24 hours or less without appreciable health risks to the consumer on the basis of all known facts at the time of the evaluation. ARfD apply only to pesticides that cause acute effects, e.g. phosphorus pesticides that are cholinesterase inhibitors.

The Codex Committee on Pesticide Residues (CCPR) considers at their annual meetings the MRLs proposed by the JMPR. CCPR is an intergovernmental meeting with the prime objective to reach agreement on proposed MRLs. The MRLs are discussed in an eight-step procedure and after the final step, the CCPR recommends MRLs to CAC for adoption as Codex MRLs. To protect the health of the consumers, the intake calculated using the proposed MRLs is compared with the ADI or the ARfD and if the calculated intake exceeds one of these two values the MRL cannot be accepted.

Often, when national MRLs are set, an evaluation is performed on a national level, that in many ways are similar to the evaluation performed by JMPR. Some countries also set their own ADIs or ARfDs. As part of the evaluation of pesticides within the European Union (EU), ADIs and ARfDs are set on the EU level which then applies in all Member States. These values can differ from the values set by Codex.

Food and feed imported into the community should comply with EU or equivalent requirements for food safety in the EU (see 2.1. Legislation concerning residue controls).

The present manual is widely based on legislation and practices required for or implemented by EU Member States.

The Member States within the EU set harmonized EU MRLs for pesticides. All harmonized legislation can be found on the website of the EU Commission[32]. In April 2005, new legislation (Regulation (EC) No 396/2005) entered into force in which only harmonized EU MRLs can be set and all national legislation are turned into EU legislation.

Attention should be paid to the EU Commission Regulation No 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin as some compounds has dual use and can be used both as pesticide and as a veterinary drug.

EU countries must monitor food for the presence of pesticide residues and draw up respective residue monitoring plans. How these plans need to be designed and implemented is outlined in the following legislation:

- Regulation (EC) No 178/2002 – general principles and requirements of food law;

[32] http://ec.europa.eu/sanco_pesticides/public/index.cfm

- Regulation (EC) No 396/2005 and amendments – Pesticides MRLs in/on food and feed of plant and animal origin and Commission implementing rules;
- Regulations amending Annexes II and III to Regulation (EC) No 396/2005 – amendments from 2008 to 2011[33];
- Commission Regulation (EC) No 178/2006 – food and feed to which pesticide MRLs apply;
- Commission Regulation (EU) No 600/2010 – additions and modification of examples of related varieties or other products to which the same MRL applies;
- 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 and repealing Directive 79/700/EEC;
- EU multi-annual control programmes, Commission Implementing Regulation (EU) No 788/2012 of 31 August 2012 concerning a coordinated multiannual control programme of the Union for 2013, 2014 and 2015 to ensure compliance with maximum residue levels of pesticides and to assess the consumer exposure to pesticide residues in and on food of plant and animal origin.

Codex[34], EU[35] and many countries publish their MRLs on their website, e.g. United States[36], Australia[37], Japan[38], and South Africa[39]. In New Zealand[40], and the United States[41], authorities have compiled information about legislation and MRLs worldwide. Other countries do not have their own legislation and MRLs published on websites but the information can be gathered by contacting the relevant authorities. For countries that have published MRLs on websites, be aware that addresses changes and the most recent legislation is not yet published.

3.2. Planning and implementing residue control

The task of setting up and implementing the national residue control should be assigned to a central public department or body. This institution should draw up the plan and coordinate the activities of central and regional departments involved in the implementation of the plan, including inspections, sampling, analysis, reporting and follow-up activities.

The following sections describe the elements necessary for the implementation of the residue plan.

3.2.1. Sampling strategy

The residue control plan should be aimed at controlling food on the market (domestically produced as well as imported) to check compliance with statutory limits, e.g. MRLs or monitor the intake of pesticides. Normally, the two purposes are combined.

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[33] http://ec.europa.eu/food/plant/plant_protection_products/legislation/max_residue_levels_en.htm
[34] http://www.codexalimentarius.net/pestres/data/index.html?lang=en
[35] http://ec.europa.eu/sanco_pesticides/public/index.cfm
[36] http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&sid=bd32aab1f2263d189c2ea7ae45c321e9&tpl=/ecfrbrowse/Title40/40cfr180_main_02.tpl
[37] http://www.apvma.gov.au/residues/standard.php#tables
[38] http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/MRLs-p
[39] http://www.doh.gov.za/healthtopics.php?t=Food%20Control&c=Legislation
[40] http://www.foodsafety.govt.nz/industry/sectors/plant-products/pesticide-mrl/worldwide.htm
[41] http://www.fas.usda.gov/htp/MRL.asp

Consequently, the sampling plan should include samples that are allocated according to the consumption pattern of commodities in the country and samples that are allocated according to the frequency of findings e.g. for the last five years. In addition, a maximum and minimum of samples should be set on each included commodity, e.g. 100 and 10.

Likewise, the relative allocation of the samples between domestically produced commodities and imported commodities should be based on supplies on the market and expected residues as known from examinations from previous years.

The examinations cover food commodities from domestic production, from other Member States and from non-EU countries. The samples are taken randomly. Additionally, check sampling can be performed in cases where high levels of pesticide residues may be expected. Such examinations will be instigated by violations of regulations, e.g. MRLs, and they normally cover a single pesticide in one commodity from a specific area or country.

To cover all the different commodities consumed in the country, a rolling programme can be implemented. An example of this is the EU coordinated multi-annual control programmes, (Commission Implementing Regulation (EU) No 788/2012[42]), which the Member States should fulfil in addition to their national control programme. Thirty to forty foodstuffs constitute the major components of the diet in the Union. Since pesticide uses show significant changes over a period of three years, pesticides should be monitored in those foodstuffs over a series of three-year cycles to allow consumer exposure and the application of Union legislation to be assessed. The rolling programme is:

Year 1: Beans with pod (fresh or frozen), carrots, cucumbers, oranges or mandarins, pears, potatoes, rice, spinach (fresh or frozen) and wheat flour.

Year 2: Aubergines, bananas, cauliflower or broccoli, table grapes, orange juice, peas without pod (fresh or frozen), peppers (sweet), wheat and virgin olive oil (oil processing factor = 5, taking into account an olive oil production standard yield of 20% of the olive harvest).

Year 3: Apples, head cabbage, leek, lettuce, peaches including nectarines and similar hybrids; rye or oats, strawberries, tomatoes and wine (red or white) made from grapes.

3.2.2. Pesticides to monitor

In principle, all pesticides used worldwide should be monitored (around 1000). However, this is probably not done by any laboratory due to state of art in the analysis. For domestically produced foods, the pesticides approved in the country should be analysed for and if suspicion on use of not approved or illegal pesticides, these compounds should be added to the analytical scope.

For the imported food, it is even more difficult to decide which pesticides to be monitored as the pesticides use in the exporting countries is most likely not know. Consequently, global information

[42] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:235:0008:0027:EN:PDF

on pesticide residue findings can be examined e.g. via reports (e.g. EU reports[43]), scientific articles on monitoring or databases like Pesticides-Online[44].

EU multi-annual control programmes[45] includes a list in Annex 1 of approximately 200 pesticides that all Member states must analyse for in the coordinated programme. However, some Member States analyse up to 800 pesticides.

3.2.3. Sampling methods

Sampling for control of pesticide residues must follow the prescriptions laid down in Commission Directive 2002/63/EC or CAC/GL 33 – recommended method of sampling for the determination of pesticide residues for compliance with MRLs.

Guidelines equivalent to these should be readily available for the relevant personnel (i.e. inspectors and sampling officers) in the local language.

In many cases, there will be a need to obtain samples over a 12-month period to take account of seasonal variations.

Statistics on sampling should be reviewed by persons responsible at a central level in order to verify that samples adhere to the aims and prescriptions for the NRCP. Results from such reviews could be communicated to representatives of institutions participating in the NRCP (e.g. competent authority, national reference laboratory, regional laboratories and sampling institutions).

3.2.4. Sampling point

Samples should be representative of the supply chain. It could be retail outlets (supermarkets, local shops, market stalls, and farm shops), wholesale outlets, points of entry (Border Inspection Point e.g. ports and airports) and manufacturers (processing industries).

[43] http://www.efsa.europa.eu/en/efsajournal/pub/2430.htm
[44] http://www.pesticides-online.com
[45] http://ec.europa.eu/food/plant/plant_protection_products/max_residue_levels/eu_multi-annual_control_programme_en.htm

4. Organic contaminants

Environmental contaminants are chemicals that accidentally or deliberately enter the environment and are often a result of human activities. They are undesirable, harmful substances, which can be found at trace level in foodstuffs. They are not present in food due to a deliberate action, but as they are present in the environment in which the food is grown, harvested, transported, stored, packaged, processed, and consumed. They may end up as food contaminates which can be a thread to consumer safety.

Environmental contaminants are in this chapter regarded as persistent organic pollutants (POPs), which is defined as “chemical substances that persist in the environment, bio-accumulate through the food chain, and pose a risk of causing adverse effects to human health and the environment”. Stockholm Convention on Persistent Organic Pollutants is an international environmental treaty, signed in 2001, which aims to eliminate or restrict the production and use of persistent organic pollutants, including a number of organochlorine pesticides such as DDT, aldrin, chlordane and heptachlor, polychlorinated biphenyls (PCBs), polychlorinated dibenzo-o-dioxins (“dioxins”) and polychlorinated dibenzofurans (“furans”). Most of the POPs can be found in food items, as a common characteristic for the compounds is fat solubility, which allow them to accumulate through the food chain and biomagnified in higher species. Therefore, the most important human food intake sources for the POPs are fatty foods including fish, meat, eggs and dairy products.

Dioxins and furans are the common names for a group of chemicals that are formed during combustion processes such as waste incineration, power generation, metal production, and fuel burning. These compounds are found in small amounts in the air, water and soil. As a result of their chemical persistence and presence in the environment, they also enter the food chain. Human exposure to dioxins and furans is mainly through the diet.

Polychlorinated Biphenyls (PCBs) are man-made chemicals that are banned from manufacture in many countries. They are very persistent and can be transported over long distances. As a result, they are found throughout the environment. Humans are still exposed to small amounts of PCBs, primarily through foods.

Organochlorine pesticides are a number of pesticides which has previously been used as pesticides, but today banned in many countries due to the persistency and toxicology. They are generally fat soluble and can accumulate in the food chain, human exposure is therefore mainly through foods. However, if still used, there is the possibility of direct exposure.

Polycyclic aromatic hydrocarbons (PAHs) are one of the most widespread organic pollutants. In addition to their presence in fossil fuels they are also formed by incomplete combustion of carbon-containing fuels such as wood, coal, diesel, fat, tobacco, and incense. PAHs are lipophilic and are therefore present in fatty foods as a consequence of environmental contamination or they can be found, for example, on the surface of smoked food due to the smoking process.

Considering the huge variety of chemical agents and the complexity of conceivable contamination pathways, operators must conduct a precise evaluation of chemical risks of the product, evaluate

the risk of environmental contaminants in the feed, considering the production processes, machinery used, technical agents used, etc., to determine the possible origin and probability of contamination, and to take appropriate action as needed to reduce or prevent such risks. As an example, fruit and vegetables can be exposed to contamination from hydrocarbons from the exhaust during transport or different types of oils from machinery used either in the production or during transport and precautions should be taken in order to avoid contamination of the food.

In EU general principles and requirements of food law, Article 14, the requirements for food safety are the following: “food shall not be placed on the market if it is unsafe and food shall be deemed to be unsafe if it is considered to be injurious to health or unfit for human consumption”.

In determining whether any food is unsafe, regard shall be had:

- to the normal conditions of use of the food by the consumer and at each stage of production, processing and distribution; and
- to the information provided to the consumer, including information on the label, or other information generally available to the consumer concerning the avoidance of specific adverse health effects from a particular food or category of foods.

In determining whether any food is injurious to health, regard shall be had:

- not only to the probable immediate and/or short-term and/or long-term effects of that food on the health of a person consuming it, but also on subsequent generations;
- to the probable cumulative toxic effects;
- to the particular health sensitivities of a specific category of consumers where the food is intended for that category of consumers.

Authorities and food producers must therefore take measures to ensure the foods, both by monitoring and control of the products during the production chain, but also by on-going protection of feed, food production, manufacturing, packaging and transport to ensure there is no risk of contamination of the final product. In determining whether any food is unfit for human consumption, regard shall be had to whether the food is unacceptable for human consumption according to its intended use, for reasons of contamination, whether by extraneous matter or otherwise, or through putrefaction, deterioration or decay.

Authorities as well as food manufacturers and companies dealing with foods should pay attention to the general food laws description: when any unsafe food is part of a batch, lot or consignment of food of the same class or description, then it shall be presumed that all the food in that batch, lot or consignment is also unsafe and therefore not be placed on the marked. Food that complies with specific provisions for food safety shall be deemed to be safe insofar as the aspects covered by the specific provisions are concerned. Conformity of a food with specific provisions applicable to that food shall not bar the competent authorities from taking appropriate measures to impose restrictions on it being placed on the market or to require its withdrawal from the market where there are reasons to suspect that, despite such conformity, the food is unsafe. Where there are no specific provisions, food shall be deemed to be safe when it conforms to the specific provisions of national food law of the Member State in whose territory the food is marketed and the food shall be in compliment with that.

Food contaminants are substances that may be present in certain foodstuffs due to environmental contamination, cultivation practices or production processes. If present above certain levels, these substances can pose a threat to human health. EU rules ensure that food placed on the market is safe to eat and does not contain contaminants at levels which could threaten human health:

- Maximum levels are set for the contaminants of greatest concern to EU consumers, either due to their toxicity or their potential prevalence in the food chain. These include aflatoxins, heavy metals (such as lead and mercury), dioxins and nitrates.
- The levels are set on the basis of scientific advice provided by the European Food Safety Authority (EFSA). Member State authorities are responsible for sampling food products, to ensure that they comply with the legislation.
- For imported foodstuffs, the country of origin is responsible for compliance with EU legislation, and this is controlled at EU borders and on the market.

The EU promotes best practice among all those involved in the production, storage and delivery of food to ensure that contaminant levels are kept to a minimum.

A number of countries and international organisations have set MRL or maximum values for the presence of environmental contaminants in foods. For pesticides, the most important for international trade are the values set in the Codex Alimentarius[46] and the European Union MRL values[47]. The MRL value to be taken into consideration is always the value applied on the market of destination.

When discussing environmental contaminants in food, attention should be drawn to the sources of the contaminants into the foods and in that perspective, one of the major factors is the presence of environmental contaminants in feed. The overall objectives for official control of feeding stuffs are:

- to avoid that feed causes problems with food safety;
- to keep food and feed producers to their obligations to ensure human and animal health and the environment in regard to their products;
- to create good conditions for fair trade with feed.

The authorities should inspect food business operators as well as performing direct analytical control of the foods from the companies. The purposes of the analytical chemical control are to monitor, control and survey the levels of environmental contaminants in the different food items, including:

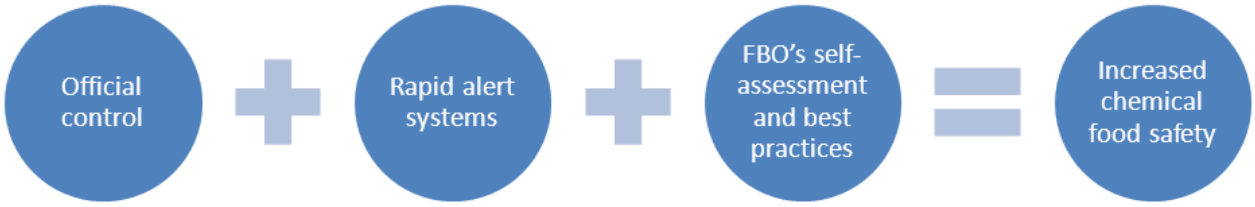
- control imposed under EU rules or Codex Alimentarius rules;
- EU recommendations to conduct surveys for selected chemical contaminants in various food categories;
- control of products with EU import restrictions. These are, for example, aflatoxins, heavy metals, melamine, pesticide residues or dioxins as regulated, for example, in Commission regulation No 258/2010 imposing special conditions on the imports of guar gum originating

[46] http://www.codexalimentarius.net/pestres/data/index.html?lang=en
[47] http://ec.europa.eu/sanco_pesticides/public/index.cfm

in or consigned from India due to contamination risks by pentachlorophenol and dioxins and similar regulations.

To obtain maximum chemical food safety and avoid environmental contaminants in foods, several factors should be included in the food system. The official authorities should inspect the food business operators and perform the official control. Input to both the official authorities and the food business operators should be information about food contaminants and arising problems in foods as for example a rapid alert system described in a later chapter. The food business operators (FBOs) should perform self-assessment including required documentation from sub suppliers concerning the absence of environmental contaminants. The FBOs should furthermore use best practices in the entire food production line.

Figure 5: Factors that contribute to increased chemical food safety



4.1. Legislation concerning environmental contaminants and residue controls

The European Union (EU) has strictly regulated controls on the use of veterinary drugs and pesticides and guidelines for controlling of residues and contaminants. These are found, for example, in Council Directive 96/23/EC for animal products and their products with detailed procedures for EU Member States to set up national monitoring plans, including details on sampling procedures. Furthermore, the EU Commission implemented regulation No 788/2012 concerning a coordinated multiannual control programme for 2013, 2014 and 2015 to ensure compliance with maximum residue levels of pesticides, including the organochlorine pesticides and to assess the consumer exposure to these compounds in and on food of plant and animal origin, which all Member States are obliged to follow.

Commission Regulation No 1881/2006 setting maximum levels for certain contaminants in foodstuffs and Commission Regulation No 835/2011 amending Regulation (EC) No 1881/2006 as regards maximum levels for polycyclic aromatic hydrocarbons in foodstuffs, are setting maximum levels for polycyclic aromatic hydrocarbons (PAHs), more specific for benzo(a)pyrene and for the sum of benzo(a)pyrene, benz(a)anthracene, benzo(b)fluoranthene and chrysene. Maximum levels for dioxin are included in Commission Regulation No 1881/2006 and Commission Regulation No 420/2011 amending Regulation No 1881/2006 setting maximum levels for certain contaminants in foodstuffs for both the sum of dioxins and the sum of dioxins and dioxin-like PCBs. Furthermore, in Commission Regulation No 1259/2011 amending Regulation (EC) No 1881/2006 as regards maximum levels for dioxins, dioxin-like PCBs and non-dioxin-like PCBs in foodstuffs, maximum

levels are set for the indicator PCBs as the sum of PCB-28, 52, 101, 138, 153 and 180. In addition to these maximum levels, Commission recommendation of 23 August 2011 on the reduction of the presence of dioxins, furans and PCBs in feed and food, introduces action levels in order to stimulate a pro-active approach to reduce the presence of dioxins and dioxin-like PCBs in food.

4.2. Legislation concerning sampling and performance of analytical method

In Commission Regulation No 333/2007 laying down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs, the legislation for the sampling and official control are described for the compounds mentioned. Similar, Commission Regulation No 252/2012 laying down methods of sampling and analysis for the official control of levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in certain foodstuffs.

4.3. Planning and implementing residue control

Planning and implementing official chemical control in food and feed shall be carried out by the national competent authority. Some aspects of the control, e.g. chemical analyses, can be outsourced to private analytical laboratories but the final quality control and responsibility lies with the competent authority.

A food control system must be developed and implemented in a transparent manner. The confidence of consumers in the safety and quality of the food supply depends on their perception of the integrity and effectiveness of food control operations and activities (FAO/WHO).

The number of chemical compounds belonging to the group of organic environmental contaminants is large. National and international legislation for control and sampling are established for a small number of compounds but for the majority of compounds, the analytical control must be carried out based on the current available scientific knowledge.

The overall structure for planning of chemical analytical control can be described by four steps (modified from US FDA 2011). In figure 6, the four steps are shown:

1) Understand the potential hazard
2) Identify critical points for control
3) Develop a control strategy
4) Publishing of control results.

Figure 6: Developing and planning of chemical control

1. Understand the potential hazard

The starting point for all activity regarding chemical control in food and feed is to understand the potential hazard on human health posed by a specific chemical compound or group of compounds with similar properties. Information of toxicology, sources of the environmental contamination, potential species related and process-related hazard is important issues to consider. Accumulation in certain tissues of the animal and possible changes in concentration due to processing is relevant to take into account as well (e.g. extraction of fish oil will increase the content of fat soluble compounds on fresh weight basis). When all aspects have been considered, it must be determined whether the potential hazard is significant or not. The evaluation can be used for prioritising the control between different potential hazards.

2. Identify critical point for control

From a food safety point of view, it is essential to look at the entire production process when conducting analytical control. Even if maximum limits have been set for the food item to be eaten and therefore samples for control purposes have to been taken accordingly, it can be of value to take additional samples earlier in the production chain. For aquaculture fish, the feed is often more relevant to monitor than the fish itself because the feed in many cases is the only source of the contaminants. The feed can be manufactured and sold to several farms and thus, it is much more efficient from an economic as well as a food safety point of view to carry out control or monitoring on the feed.

3. Develop a control strategy

Every action of chemical control must be carried out on the basis of some kind of tolerance levels. It can be maximum limits from international or national legislation or ad hoc tolerance levels. Ad hoc tolerance levels can be set from evaluation of TDI (tolerable daily intake) and food consumption figures or other scientific advice. Sampling procedures and frequency of testing must

be specified. Corrective actions must be established and they can be adjusted in relation to the purpose of the programme: whether it is official control or monitoring and survey. Emergency procedures can be established for dealing with particular hazards (e.g. recall of products). A part of the control strategy can be a check of the food business operator's self-assessment results.

4. Publishing of control results

Publishing of control results will increase the public awareness of potential food hazards for food business operators and maintaining consumer confidence in the food system. The origin of the control samples can be made anonymous depending on the actual situation.

5. Inorganic contaminants

The amount of metals in food and feed depends upon the natural content and the conditions under which food and feed are produced and processed. Some metals have nutritional functions and are essential to the health. But others such as lead, cadmium and mercury have no nutritional relevance and can cause serious illnesses (Table 1).

Table 1: Elements commonly monitored in food (Capar and Szefer, 2011)

Element	Primary purpose
Aluminium (Al)	Toxicity
Arsenic (As)	Toxicity
Boron (B)	Nutrition
Cadmium (Cd)	Toxicity
Calcium (Ca)	Nutrition
Chromium (Cr)	Nutrition/toxicity
Copper (Cu)	Nutrition
Fluorine (F)	Nutrition/toxicity
Iodine (I)	Nutrition/toxicity
Iron (Fe)	Nutrition
Lead (Pb)	Toxicity
Magnesium (Mg)	Nutrition
Manganese (Mn)	Nutrition
Mercury (Hg)	Toxicity
Molybdenum (Mo)	Nutrition
Nickel (Ni)	Toxicity
Phosphorus (P)	Nutrition
Potassium (K)	Nutrition
Selenium (Se)	Nutrition/toxicity
Sodium (Na)	Nutrition
Tin (Sn)	Toxicity
Zinc (Zn)	Nutrition

5.1. Legislation concerning residue controls

5.1.1. Food

To reduce the risk to human health associated with a high heavy metal content in food and feed, maximum allowed limits in several commodities have been laid down in the European legislation.

In certain foods maximum levels for the heavy metals, cadmium, lead and mercury and inorganic tin (Table 2) have been established by Commission Regulation (EC) No 1881/2006[48]. The methods of sampling and analysis for the official control of the maximum levels of these metals are described in Commission Regulation (EC) No 333/2007. Surveillance for residues of chemical elements in foods of animal origin is also specified in Council Directive 96/23/EC (subcategory B3c).

Table 2: Examples of maximum levels (ML) in certain foods established in Commission Regulation (EC) No 1881/2006

Foodstuffs	Maximum levels (mg/kg wet weight)
Lead	
Meat (excluding offal) of bovine animals, sheep, pig and poultry	0.10
Muscle meat of fish	0.30
Bivalve molluscs	1.5
Food supplements	3.0
Cadmium	
Meat (excluding offal) of bovine animals, sheep, pig and poultry	0.050
Muscle meat of the following fish: bullet tuna (*Auxis* species)	0.20
Bivalve molluscs	1.0
Bran, germ, wheat and rice	0.20
Mercury	
Food supplements	0.10
Muscle meat of the following fish: - eel (*Anguilla* species) - mullet (*Mullus* species)	1.0

[48] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:02006R1881-20100701:EN:NOT

- redfish (*Sebastes marinus*, *S. mentella*, *S. viviparus*) - shark (all species) - swordfish (*Xiphias gladius*) - tuna (*Thunnus* species, *Euthynnus* species, *Katsuwonus pelamis*)	
Tin (inorganic)	
Canned foods other than beverages	200
Canned beverages, including fruit juices and vegetable juices	100
Canned baby foods and processed cereal-based foods for infants and young children, excluding dried and powdered products	50

5.1.2. Feed

Directive 2002/32/EC[49] contains maximum limits for heavy metals including arsenic, lead, mercury and cadmium in certain feed materials, feed additives and feeding stuffs (Table 3). It prohibits the dilution of contaminated feed materials.

Table 3: Examples of maximum levels (ML) in certain feeds established in EU Directive 2002/32/EC

Products intended for animal feed	**Maximum content in mg/kg (ppm) relative to a feeding stuff with a moisture content of 12%**
Lead	
Complete feed	5
Complementary feed with the exception of:	10
- mineral feed	15
Cadmium	
Feed materials of vegetable origin	1
Mercury	
Feed materials with the exception of:	0.1
- fish, other aquatic animals and products derived thereof	0.5
- calcium carbonate; calcium and magnesium	0.3

[49] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32002L0032:EN:NOT

carbonate	
Compound feed with the exception of:	0.1
- mineral feed	0.2
- compound feed for fish	0.2
- compound feed for dogs, cats and fur animals	0.3
Arsenic	
Complete feed with the exception of:	2
- complete feed for fish and fur animals	10*
- complete feed for pet animals containing fish, other aquatic animals and products derived thereof and/or seaweed meal and feed materials derived from seaweed	10*

* Upon request of the competent authorities, the responsible operator must perform an analysis to demonstrate that the content of inorganic arsenic is lower than 2 mg/kg.

5.2. Legislation concerning sampling

In the EU, the sampling of foodstuff for the official control of the levels of lead, cadmium, mercury and inorganic tin shall follow Commission Regulation (EC) No 333/2007[50]. Careful sampling can be time consuming since it is important that the analysed samples are representative of the original bulk product. All procedures used for acquisition, reduction and preservation of the sample may affect the reliability of the analytical result. For the sampling of foodstuffs intended for metal analysis, it is important to pay special attention to avoid contamination and analyte loss during handling and transport to the laboratory.

5.2.1. General sampling requirements

The general provisions include sampling by authorised personnel and separate sampling of each lot or sublot which is to be examined. A quantity of sample material (incremental sample) shall be taken at various places distributed throughout the lot or sublot. An aggregate sample shall be made up by combining the incremental samples. Samples for enforcement, defence and referee purposes shall be taken from the homogenised aggregate sample. Each sample shall be placed in a clean, inert container. All necessary precautions shall be taken to avoid any changes affecting the levels of contaminants and analytical determination or in other ways make the samples unrepresentative. Each sample taken for official use shall be sealed and labelled at the place of sampling. A sample record shall be kept permitting each lot or sublot to be identified unambiguously (lot number, date and place of sampling) together with any additional information

[50] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32007R0333:EN:NOT

likely to be of assistance to the analyst. Any departure from the sampling procedure shall be noted in the sample record (Commission Regulation (EC) No 333/2007).

5.2.2. Sampling methods

Large lots shall be divided into sublots on condition that the sublot may be separated physically. For products traded in bulk consignments (e.g. cereals), Table 4 shall apply. For other products, Table 5 shall apply.

Table 4: Subdivision of lots into sublots for products traded in bulk consignments

Lot weight (ton)	Weight or number of sublots
≥ 1 500	500 tonnes
> 300 and < 1 500	3 sublots
≥ 100 and ≤ 300	100 tonnes
< 100	—

Table 5: Subdivision of lots into sublots for other products

Lot weight (ton)	Weight or number of sublots
≥ 15	15 to 30 tonnes
< 15	—

Table 6: Minimum number of incremental samples to be taken from the lot or sublot

Weight or volume of lot/sublot (in kg or litre)	Minimum number of incremental samples to be taken
< 100	3
≥ 50 and ≤ 500	5
> 500	10

Table 7: Number of packages or units (incremental samples) which shall be taken to form the aggregate sample if the lot or sublot consists of individual packages or units

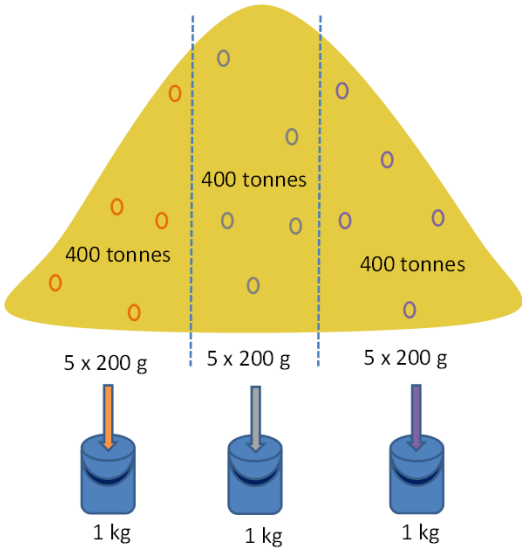
Number of packages or units to be taken	Number of packages or units to be taken
≤ 25	at least one package or unit
26 to 100	about 5%, at least two packages or units
> 100	about 5%, at maximum 10 packages or units

The minimum number of incremental samples to be taken from the lot or sublot to form the aggregate sample is specified in Table 6 (bulk) and Table 7 (individual packages or units). Figure 7 illustrates sampling of 1200 tonnes bulk product. Since the weight of the lot is not always an exact multiple of the weight of the sublots, the weight of the sublot may exceed the mentioned weight by a maximum of 20%. If it is a bulk liquid product, the lot or sublot shall be thoroughly mixed. Then, a homogeneous distribution of contaminants is assumed within a given lot or sublot and it is therefore sufficient to take three incremental samples from a lot or sublot to form the aggregate sample.

The weight of an incremental sample shall be at least 100 grams or 100 millilitres, resulting in an aggregate sample of at least about 1 kg or 1 litre except where it is not possible e.g. when the sample consists of 1 package or unit.

When received in the laboratory, the complete aggregate sample shall be finely ground and thoroughly mixed using a process that has been demonstrated to achieve complete homogenization (Commission Regulation (EC) No 333/2007).

Figure 7: Sampling of 1200 tonnes bulk product (e.g. cereal) divided into 3 sublots of 400 tonnes. Each sublot is sampled 5 times by 200 g increment sample to form 1 aggregate sample which is taken for analysis.



5.2.3. Analytical methods for official control

For determination of e.g. lead in wine, a specific analytical method for the official control should be applied (Commission Regulation (EC) No 2676/90). However, if no specific methods are prescribed by the EU, any validated method can be applied if the selected method meets specific performance criteria on detection and quantification limit, precision, recovery and specificity (Table 8). CEN, ISO and AOAC have published several official methods for the determination of heavy metals in feed and food. These standards provide both general and specific instruction for trace element analysis (Table 9).

Table 8: Performance criteria for methods of analysis for lead, cadmium, mercury and inorganic tin (Commission Regulation (EC) No 333/2007 amended by Commission Regulation (EU) No 836/2011[51] of 19 August 2011)

Parameter	Criterion		
Applicability	Foods specified in Regulation (EC) No 1881/2006		
Specificity	Free from matrix or spectral interferences		
Repeatability (RSD_r)	$HORRAT_r$ less than 2		
Reproducibility (RSD_R)	$HORRAT_R$ less than 2		
Recovery	If an extraction step is applied in the analytical method, the analytical result shall be corrected for recovery. In this case, the level of recovery must be reported. In case no extraction step is applied in the analytical method (e.g. in case of metals), the result may be reported uncorrected for recovery if evidence is provided by ideally making use of suitable certified reference material that the certified concentration allowing for the measurement uncertainty is achieved (i.e. high accuracy of the measurement), and thus that the method is not biased. In case the result is reported uncorrected for recovery, this shall be mentioned.		
	Inorganic tin	Lead, cadmium, mercury	
		ML[52] is < 0.100 mg/kg	ML is ≥ 0.100 mg/kg
LOD	≤ 5 mg/kg	≤ one fifth of the ML	≤ one tenth of the ML
LOQ	≤ 10 mg/kg	≤ two fifths of the ML	≤ one fifth of the ML

Table 9: Examples of CEN, ISO and AOAC standards

CEN - **EN 13804:2002** Foodstuffs - Determination of trace elements - Performance criteria, general considerations and sample preparation
CEN/TS 15506:2007 Foodstuffs - Determination of trace elements - Determination of tin in fruit and vegetables preserved in cans by flame atomic absorption spectrometry (AAS)
CEN - **EN 16278:2012** Animal feeding stuffs - Determination of inorganic arsenic by hydride generation atomic absorption spectrometry (HG-ASS) after microwave extraction and separation by solid phase extraction (SPE)
AOAC - **990.04** Mercury (Methyl) in seafood by liquid chromatography-atomic absorption spectroscopy (LC-AAS)
ISO/TS 6733:2006 Milk and milk products - Determination of lead content - Graphite furnace atomic absorption spectrometric method

[51] http://eur-lex.europa.eu/Notice.do?val=583712:cs&lang=en&list=583712:cs,&pos=1&page=1&nbl=1&pgs=10&hwords=
[52] Maximum limit

5.3. Planning and implementing residue control

In live animals and animal products, metals are regulated by Council Directive 96/23/EC (chemical elements, subcategory B3c). The directive establishes the frequencies and level of sampling and the groups of substances to be controlled for each food commodity. Surveillance should be aimed particularly at controlling and monitoring the metal contamination. The EU Member States should draft a national residue monitoring plan. The control plan is aimed at monitoring of environmental contaminants and at surveying and revealing the reasons for residue hazards in foods of animal origin. Sampling must be unforeseen, unexpected and effected at no fixed time and on no particular day of the week. Normally targeted sampling (selecting products with known or suspected contamination) should be applied.

Commission Decision 97/747/EC provides further rules for certain animal products: milk, eggs, honey, rabbits and game meat. Commission Decision 98/179/EC lays down detailed rules for official sampling procedures and official treatment of samples until they reach the laboratory responsible for analysis.

The number of samples needed for control of compliance with Commission Regulation (EC) No 1881/2006 has not been specified. It is only described in general terms that *foodstuffs shall not be placed on the market if they contain a contaminant level exceeding the maximum level (ML)*.

6. References and literature

6.1. Papers, reports, articles and books

Capar S.G. and Szefer P. (2011). Determination and Speciation of Trace Elements in Foods: Methods of Analysis of Food Components and Additives, Second Edition, Editor Ötles S., p. 165-210

CRL guidance paper (7 December 2007). CRLs view on state of the art analytical methods for national residue control plans http://www.bvl.bund.de/SharedDocs/Downloads/09_Untersuchungen/EURL_Empfehlungen_Konzentrationsauswahl_Methodenvalierungen.pdf?__blob=publicationFile&v=2

EU factsheet Food Contaminants, January 2008. Health and Consumer Protection Directorate-General http://ec.europa.eu/dgs/health_consumer/press/fs_contaminants_final_web.pdf

Eurostat – Typology of sampling strategies (Doc. ESTAT/F5/ES/201) https://circabc.europa.eu/sd/d/2fc47bd9-237a-4c79-93e0-6a4665cf3591/201_Typology_sampling_strategies.pdf

FAO/WHO: Assuring food safety and quality: Guidelines for Strengthening National Food Control Systems. 76 pp. ftp://ftp.fao.org/docrep/fao/009/a0601e/a0601e00.pdf

Guidelines for the validation of screening methods for residues of veterinary medicines (initial validation and transfer). Community reference laboratories residues (CRLs). 20/1/2010 http://ec.europa.eu/food/food/chemicalsafety/residues/Guideline_Validation_Screening_en.pdf

Imports of animals and food of animal origin from non-EU countries. Manual on residue requirements for non-EU countries exporting to the EU http://ec.europa.eu/food/food/chemicalsafety/residues/docs/requirements_non_eu.pdf

Pesticide Data Program, Annual Summary, Calendar Year 2009. USDA http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5091055

Residues of Veterinary Medicinal Products - Control and Monitoring http://ec.europa.eu/food/food/chemicalsafety/residues/control_en.print.htm

Standard sample description for food and feed. EFSA Journal 2010; 8(1):1457 [54 pp.] http://www.efsa.europa.eu/en/efsajournal/pub/1457.htm

The 2009 European Union Report on Pesticide Residues in Food. EFSA Journal 2011;9(11):2430 [225 pp.] http://www.efsa.europa.eu/en/efsajournal/pub/2430.htm

Recommended Methods of Sampling for Pesticide Residues for the Determination of Compliance with MRLs. Codex Alimentarius document CAC/GL 33-1999 http://www.codexalimentarius.org/download/standards/361/CXG_033e.pdf

US Food and Drug Administration, 2011. Fish and fishery products hazards and control guidance. Fourth Edition April 2011, 468 pp. http://www.fda.gov/food/guidancecomplianceregulatoryinformation/guidancedocuments/seafood/fishandfisheriesproductshazardsandcontrolsguide/default.htm

6.2. Web pages

Codex Alimentarius International Food Standards (WHO/FAO) http://www.codexalimentarius.org/standards/list-of-standards/en/

European Commission > Food and Feed Safety > Food Contaminants > Heavy Metals http://ec.europa.eu/food/food/chemicalsafety/contaminants/cadmium_en.htm

European Commission > EU Reference Laboratories > EU-RL heavy metals > Legislation http://irmm.jrc.ec.europa.eu/EURLs/EURL_heavy_metals/legislation/Pages/index.aspx

European Food Safety Authority (EFSA) > Publications > EFSA Journal http://www.efsa.europa.eu/en/publications/efsajournal.htm

GEMS (Global Environment Monitoring System - Food Contamination Monitoring and Assessment Programme GEMS/Food) http://www.who.int/foodsafety/chem/gems/en/

RASFF
http://ec.europa.eu/rasff

6.3. EU legislation

Commission Decision 97/747/EC fixing the levels and frequencies of sampling provided for by Council Directive 96/23/EC for the monitoring of certain substances and residues thereof in certain animal products (OJ L 303, 06.11.1997, p. 12)

Commission Decision 98/179/EC laying down detailed rules on official sampling for the monitoring certain substances and residues thereof in live animals and animal products (OJ L 65, 5.3.1998, p. 31)

Commission Decision 2002/657/EC implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results (OJ L 221, 17.8.2002, p. 8)

Commission Decision 2005/34/EC laying down harmonised standards for the testing for certain residues in products of animal origin imported from third countries (notified under document number C(2004) 4992) (Text with EEA relevance) (OJ L 16, 20.1.2005, p. 61).

Commission 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 and repealing Directive 79/700/EEC (OJ L 187, 16.7.2002, p. 30)

Commission Implementing Regulation (EU) No 788/2012 concerning a coordinated multiannual control programme of the Union for 2013, 2014 and 2015 to ensure compliance with maximum residue levels of pesticides and to assess the consumer exposure to pesticide residues in and on food of plant and animal origin (OJ L 235, 1.9.2012, p. 8)

Commission Recommendation 2011/516/EU on the reduction of the presence of dioxins, furans and PCBs in feed and food (OJ L 218, 24.8.2011, p.23)

Commission Regulation (EEC) No 2676/90 determining Community methods for the analysis of wines (OJ L 272, 3.10.1990, p. 1) http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31990R2676:EN:NOT

Commission Regulation (EC) No 178/2006 amending Regulation (EC) No 396/2005 of the European Parliament and of the Council to establish Annex I listing the food and feed products to which maximum levels for pesticide residues apply (OJ L 29, 2.2.2006, p. 3)

Commission Regulation (EC) No 401/2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs (OJ L 70, 9.3.2006, p. 12)

Commission Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs (OJ L 364, 20.12.2006, p. 5). Consolidated version: 2012-09-01 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2006R1881:20120901:EN:PDF

Commission Regulation (EC) No 1883/2006 laying down methods of sampling and analysis for the official control of levels of dioxins and dioxin-like PCBs in certain foodstuffs (OJ L 364, 20.12.2006, p. 32)

Commission Regulation (EC) No 333/2007 laying down the methods of sampling and analysis for the official control of levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs (OJ L 88, 29.3.2007, p. 29)

Commission Regulation (EC) No 124/2009 setting maximum levels for the presence of coccidiostats or histomonostats in food resulting from the unavoidable carry-over of these substances in non-target feed (OJ L 40, 11.2.2009, p. 7)

Commission Regulation (EU) No 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin (OJ L 15, 20.1.2010, p. 1)

Commission Regulation No 258/2010 imposing special conditions on the imports of guar gum originating in or consigned from India due to contamination risks by pentachlorophenol and dioxins, and repealing Decision 2008/352/EC (OJ L 80, 26.3.2010, p. 28)

Commission Regulation (EU) No 600/2010 amending Annex I to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards additions and modification of the examples of related varieties or other products to which the same MRL applies (OJ L 174, 9.7.2010, p. 18)

Commission Regulation (EU) No 1259/2011 amending Regulation (EC) No 1881/2006 as regards maximum levels for dioxins, dioxin-like PCBs and non-dioxin-like PCBs in foodstuffs (OJ L 320, 3.12.2011, p. 18)

Commission Regulation (EU) No 252/2012 laying down methods of sampling and analysis for the official control of levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in certain foodstuffs and repealing Regulation (EC) No 1883/2006 (OJ L 84, 23.3.2012, p. 1)

Commission Regulation (EU) No 277/2012 amending Annexes I and II to Directive 2002/32/EC of the European Parliament and of the Council as regards maximum levels and action thresholds for dioxins and polychlorinated biphenyls (OJ L 91, 29.3.2012, p. 1)

Council Directive 96/23/EC on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and decision 89/187/EEC and 91/664/EEC (OJ L 125, 23.5.96, p. 10)

Council Directive 2002/32/EC on undesirable substances in animal feed (OJ L 140, 30.5.2002, p. 10). Consolidated version: 2012-09-06 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2002L0032:20120906:EN:PDF

Regulation (EC) No 178/2002 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)

Regulation (EC) No 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (OJ L 165, 30.4.2004, p. 1)

Regulation (EC) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1) (as amended)

Regulation (EC) No 470/2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L1 52, 16.6.2009, p. 11)

7. Appendices

Annex 1: Substances or Group of substances to be monitored (veterinary drugs)

Source: http://ec.europa.eu/food/food/chemicalsafety/residues/docs/table_2_101106_en.pdf

Table 2 Substances or Group of substances [1] to be monitored for in the relevant commodity. E = 'essential' HD = 'highly desirable'

Animal species or food covered by the plan →			bovine	ovine/ caprine	swine	Equine [7]		poultry	aquaculture		milk	eggs	rabbit	wild game	farmed game	honey
						slaughtered	live equidae for direct slaughter		finfish	crustaceans						
Substances / groups of substances to be monitored																
A1	**Stilbenes** (e.g. diethylstilbestrol, hexestrol, dienestrol)		E	E	E	E		E	E				E		E	
A2	**Thyrostats** (e.g. thiouracil, tapazol etc)		E	E	E	E										
A3	**Steroids** [androgens, estrogens and (pro)gestagens] [3]		E	E	E	E	E	E	E				E		E	
A4	**Resorcylic acid lactones** (e.g. zeranol)		E	E	E	E		E					E		E	
A5	**Beta agonists** (e.g. clenbuterol, ractopamine, zilpaterol, mabuterol etc)		E	E	E	E	E	E					E		E	
A6	**Compounds included in Annex IV to Council Regulation (EEC) No 2377/90**	Chloramphenicol	E	E	E	E	E	E	E	E	E	E	E		E	E
		Nitrofurans [4]			E			E	E	E		E	E		HD	E
		Nitroimidazoles [5]			E	E	E	E	HD	HD		HD	E		HD	
B1	**Antibacterial substances** [6]		E	E	E	E		E	E	E	E	E	E		E	E [8]
B2a	**Anthelmintics**		HD	HD	HD	HD		HD	HD	HD	HD		HD		HD	
B2b	**Anticoccidials**		HD	HD	HD	HD		E				HD	E		HD	
B2c	**Carbamates and pyrethroids**		HD	HD	HD	HD		HD					HD		HD	HD
B2d	**Sedatives**		HD	HD	HD	HD										
B2e	**Non steroidal anti-inflammatory drugs (NSAIDs)** (e.g. phenylbutazone)		HD	HD	HD	E	E	HD			HD		HD		HD	
B2f	**Other pharmacologically active substances**	Carbadox, olaquindox			E [9]											
B3a	**Organochlorine compounds including PCBs**		HD	HD	HD	HD		HD	HD	HD	HD	HD	HD		HD	HD
B3b	**Organophosphorus compounds**		HD	HD	HD	HD					HD					HD
B3c	**Chemical elements**		HD	HD	HD	HD		HD	HD	HD	HD		HD	E	HD	HD
B3d	**Mycotoxins**		HD	HD	HD	HD		HD	HD	HD	HD					
B3e	**Dyes** (in particular malachite green and its major metabolite leucomalachite green)								E	E						

(1) Groups defined in Annex I of Directive 96/23/EC. Monitoring of E (essential) substances or group of substances is mandatory. Monitoring of HD (highly desirable) groups is mandatory in the Member States. Ideally a third country should also monitor these groups, however, if they are not monitored, evidence must be provided justifying this decision. A full list of substances is included on the DG SANCO third country residues web page.

(3) Typical steroids to be monitored for include testosterone, methyl testosterone, trenbolone, nortestosterone, boldenone, stanozolol, estradiol, ethinyl estradiol, progesterone, medroxyprogesterone acetate, megoestrol acetate, flugestone etc

(4) The stable metabolites/marker residues of the four main nitrofuran drugs (furazolidone, furaltadone, nitrofurazone and nitrofurantoin) should be analysed. The metabolites are: Furazolidone: amino-oxazolidinone (AOZ); Furaltadone: 3-amino-5-morpholinomethyl-2-oxazolidinone (AMOZ); Nitrofurazone: semicarbazide (SEM) and nitrofurantoin: aminohydantoin (AHD).

(5) The nitroimidazoles include dimetridazole, ronidazole, metronidazole, ipronidazole etc

(6) Antibacterial substances should be chosen on the basis of what is authorised and used in the relevant livestock production sector. Examples include beta-lactams, tetracyclines, sulphonamides, fluoroquinolones, aminoglycosides, macrolides etc.

(7) The reduced number of substances to be looked for in live equidae exported for direct slaughter to the EU presupposes that there is no slaughter of horses in that third country, hence the substances chosen may be looked for in body fluids (i.e blood and urine) which can be sampled from live horses. It is stressed that if there is slaughter of horses in the third country and only live horses are exported for direct slaughter, sampling should be based on the slaughtered animals and take account of the wider range of substances that can be checked.

(8) Honey should be tested for antibacterial substances including sulphonamides, tetracyclines, tylosin and streptomycin.

(9) If carbadox or olaquindox are authorised in swine production, residue testing of tissues and/or feedingstuffs should be carried out.

Annex 2: Information required for third country residue control programmes (veterinary drugs)

Source: http://ec.europa.eu/food/food/chemicalsafety/residues/docs/table_1_information_required_for_tc_residue_control_programmes_20032012_en.pdf

Table 1: Information required for third country residue control programmes

General area / Specific question/information required	Competent Authority response. Should be provided by e-mail to: SANCO-TCRESIDUEPLANS@ec.europa.eu preferably in ENGLISH or in one of the other working languages of the EC – French or German

Country: | **Date of completion of form by Competent Authority** |

1. General information on the Competent Authority / authorities responsible for residues controls in all commodities included in the residue monitoring plan (e.g. beef, pork, fish, milk, eggs, honey etc).	
1.1. **Contact Details:** Provide name and address of the central competent authority or authorities and contact point details for correspondence on the residue monitoring plan (e-mail addresses, fax, phone details etc). [Article 4 of Council Directive 96/23/EC]	
1.2. Describe the **structure of the competent authority** e.g. the levels involved (central, regional, local etc) and the personnel resources allocated for residues controls. If different competent authorities are involved for different commodities, data on their structure should be provided separately. [Article 7§2 of Council Directive 96/23/EC]. If possible include an organisational chart for each competent authority as a separate annex.	
1.3. Describe the **role of the Central Competent Authority** e.g. drawing up the residue monitoring plan, co-ordinating and supervising residue control activities at different levels (central, local, regional etc), collection of data (e.g. results of monitoring), evaluation of data (e.g. has sampling been carried out in accordance with the plan), application of corrective measures if required, submission of annual data to the Commission etc. [Article 4 of Council Directive 96/23/EC]	

Table 1: Information required for third country residue control programmes

General area / Specific question/information required	Competent Authority response. Should be provided by e-mail to: SANCO-TCRESIDUEPLANS@ec.europa.eu preferably in ENGLISH or in one of the other working languages of the EC – French or German

2. The residue monitoring plan (and results from the previous year) ‡

In the cells below please tick those commodities which are currently listed in Commission Decision 2011/163/EU (as per last amendment of this Decision)

Bovine ☐ Ovine/Caprine ☐ Swine ☐ Equine ☐ Poultry ☐ Aquaculture ☐ Milk ☐ Eggs ☐ Rabbit ☐ Wild Game ☐ Farmed game ☐ Honey ☐

Please indicate in the box below those commodities which are not currently listed in Commission Decision 2011/163/EU but which you wish to have included in the list in when the Decision is updated. i.e. which commodities do you wish to export to the EU. (A residue plan and if available results from the previous year's residue monitoring must be presented for these commodities).

Please indicate in the box below if there are any commodities which you no longer wish to export to the EU i.e. to be DELISTED from Commission Decision 2011/163/EU.

In the cells below please tick those commodities which are covered by the current residue monitoring plan.

Bovine ☐ Ovine/Caprine ☐ Swine ☐ Equine ☐ Poultry ☐ Aquaculture ☐ Milk ☐ Eggs ☐ Rabbit ☐ Wild Game ☐ Farmed game ☐ Honey ☐

In the cells below please tick those commodities for which you have provided results from the previous year's residue monitoring.

Bovine ☐ Ovine/Caprine ☐ Swine ☐ Equine ☐ Poultry ☐ Aquaculture ☐ Milk ☐ Eggs ☐ Rabbit ☐ Wild Game ☐ Farmed game ☐ Honey ☐

‡ Please ensure that the list of substances to be detected, the matrices to be tested, the screening and confirmatory methods used, the analytical limits of detection and the action levels / national tolerances (to determine non-compliant results) are clearly laid out in the plan. [Article 7§5 of Council Directive 96/23/EC]. *(It is strongly recommended to use the Microsoft Excel templates on the DG SANCO third country residue website for constructing the plan and reporting the results).* The Excel templates may be downloaded from: http://ec.europa.eu/food/food/chemicalsafety/residues/third_countries_en.htm

Table 1: Information required for third country residue control programmes **Page 3 of 7**

General area / Specific question/information required	Competent Authority response. Should be provided by e-mail to: SANCO-TCRESIDUEPLANS@ec.europa.eu preferably in ENGLISH or in one of the other working languages of the EC – French or German
2.1. Provide information on the **legal basis** of the **residue monitoring plan** (e.g. the legislation giving the competent authority the right to enter farms, take corrective action in the event of a non-compliant result, such as destruction of animals, imposition of fines etc). Please quote the articles in this legislation which confers these powers. [Article 7§8, Article 15, 16, 17, 18, 22, 23, 24, 25, 27 of Council Directive 96/23/EC	
2.2. Please state whether the plan is **based on Council Directive 96/23/EC** or on an **equivalent standard** (e.g. Codex Alimentarius)? If an equivalent standard has been used, please describe.	
2.3. Please provide **national production data** on **those animal species and products covered by the plan and which are eligible (or are planned) to be exported to the EU.** [Article 6 of Council Directive 96/23/EC, Annex IV to the Directive and Commission Decision 97/747/EC?]	
2.4. Please indicate for each commodity whether the plan covers (and the number of samples taken represents a proportion of) the **total** national animal population or production. **This is required if *all* animals or commodities are eligible for export to the EU.** If a **split system** is in place i.e. the animals or commodities are produced within a segregated system and these are the only animals/commodities which are eligible for export to the EU, the plan may be based on the **export data** (e.g. production tonnages or numbers of animals exported to the EU). **Please indicate whether the plan is based on national production data or export data.** *(It is strongly recommended to use the Microsoft Excel templates on the DG SANCO third country residue website for constructing the plan – the numbers of samples to be taken for each of the relevant subgroups of substances is automatically calculated).*	
2.5. **Please indicate whether all groups of residues are included in the plan** for each of the relevant commodities (as listed in Annex I to Council Directive 96/23/EC)? If not please explain on what basis substance groups have been excluded from the plan.	

Table 1: Information required for third country residue control programmes **Page 4 of 7**

General area / Specific question/information required	Competent Authority response. Should be provided by e-mail to: SANCO-TCRESIDUEPLANS@ec.europa.eu preferably in ENGLISH or in one of the other working languages of the EC – French or German
2.6. Please indicate whether the **breakdown of substances monitored for in each substance group (Annex I to Council Directive 96/23/EC) for each animal species/commodity is in accordance with the sampling levels and frequencies laid out in Annex IV to the Directive and in Commission Decision 97/747/EC.** Please explain how this breakdown has been worked out. *(NB. If the Microsoft Excel template on the DG SANCO third country residue website has been used for constructing the plan – the numbers of samples to be taken for each of the relevant subgroups of substances is automatically calculated).*	
2.7. The list of **substances to be detected**, the **matrices to be tested**, the **screening** and **confirmatory methods** used, the **analytical limits of detection** and **action levels / national tolerances** (to determine non-compliant results) should be clearly laid out in the plan. [Article 7§5 of Council Directive 96/23/EC]. *(It is STRONGLY SUGGESTED that the Microsoft Excel template on the DG SANCO third country residue website should be used for constructing the plan as this will facilitate the recording of the data referred to above.)*	
2.8. Please indicate whether there are any national tolerances or Maximum Residue Limits/Levels (MRLs) which **do not correspond with EU MRLs**. NB: EU MRLs may be downloaded from the following links: **pharmacologically active substances (veterinary medicines):** http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:015:0001:0072:EN:PDF **coccidiostat residues in non-target species** due to carry over in feed: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:040:0007:0011:EN:PDF **pesticides**: http://ec.europa.eu/sanco_pesticides/public/index.cfm **contaminants**: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32006R1881:EN:NOT For residues of substances which are *unauthorised* or *illegal* in your country, please indicate what action limits are applied and the rationale for setting these? When those limits exist, specify if they are consistent with EU	

General area / Specific question/information required	Competent Authority response. Should be provided by e-mail to: SANCO-TCRESIDUEPLANS@ec.europa.eu preferably in ENGLISH or in one of the other working languages of the EC – French or German
minimum required performance limits (MRPLs) where applicable.	
2.9. Please indicate which services/personnel are involved in **official sampling.** Is sampling only carried out by officials or are third parties involved? [Article 7§7, Article 15 of Council Directive 96/23/EC and Commission Decision 98/179/EC].	
2.10. Describe whether sampling is **targeted** (to maximise the chances of detecting illegal use) or is it **random**? Is all sampling unforeseen (by the stock owner) and unexpected (i.e. effected at no fixed time and on no particular day of the week and at no fixed time of the year)? Is sampling equally spread throughout the year? [Article 12 of Council Directive 96/23/EC and section 2.1. of the Annex to Commission Decision 98/179/EC]	
2.11. With regard to the **results of the previous year's residue monitoring**, please explain any discrepancies in the number of samples planned versus the number of samples analysed. If sampling was not carried out as planned (or results are not available), please explain. [Articles 8.3. and 29.1 of Council Directive 96/23/EC].	
2.12. In respect of the previous year's results, **briefly describe the measures taken** - administrative, penal, professional and procedural (reinforcement of monitoring on the farms concerned) - **for the non-compliant results** detected. (These data may be supplied in a separate Annex).	
3. The Laboratory Network	
3.1. Provide the **name(s) and address(es)** of **all laboratories** involved in official residue testing (including laboratories in foreign countries if certain analyses have been outsourced). [Article 2(f), Article 7§3 and Article 15.1. of Council Directive 96/23/EC]. (The name of each laboratory should be listed in the residue monitoring plan along side each residue they are responsible for analysing – *see the Microsoft Excel template on the DG SANCO third country residue website for formulating the plan.*	
3.2. Please provide information on the **level of competence** of the National Reference Laboratory (if one has been established in your country), as well as the routine laboratories, particularly as regards the implementation of Quality Assurance in accordance with **ISO 17025:2005**, including the **identity of the accrediting body** (if applicable)?	

General area / Specific question/information required	Competent Authority response. Should be provided by e-mail to: SANCO-TCRESIDUEPLANS@ec.europa.eu preferably in ENGLISH or in one of the other working languages of the EC – French or German
[Section 1.2.of the Annex to Commission Decision 98/179/EC]	
3.3. Please provide information on the performance of the laboratories regarding their participation in **proficiency testing schemes** for residues of veterinary medicines, pesticides and contaminants (preferably internationally recognised proficiency testing schemes). [Section 1.2. of the Annex to Commission Decision 98/179/EC]	
4. The authorisation and use of pharmacologically active and other substances in food producing animals (See Article 7§1 of Council Directive 96/23).	
4.1. Indicate whether **stilbenes** or **thyrostats** are authorised for use in food producing animals. [Article 11.1 of Council Directive 96/22/EC]. If such use is prohibited, please provide the national legal basis for the prohibition.	
4.2. Indicate whether the use of **hormones and beta-agonists for growth promotion** in food producing animals is permitted. [Article 11.2 of Council Directive 96/22/EC]. If so, describe the measures in place to guarantee that animals treated are not exported to the EU (e.g. is there a **split system** in place). If such use is prohibited, please provide the national legal basis for the prohibition.	
4.3. Indicate whether substances which are included in Table 2 of the Annex to Commission Regulation (EU) No 37/2010 are used in food producing animals (e.g. **chloramphenicol, nitrofurans** and **nitroimidazoles**). If such use is prohibited, please provide the national legal basis for the prohibition. If these substances are authorised, describe the measures in place to guarantee that residues of these substances are not present in product exported to the EU.	
4.4. Indicate whether substances which are expressly prohibited from in-feed administration to food producing animals in the EU because of chemical	

General area / Specific question/information required	Competent Authority response. Should be provided by e-mail to: SANCO-TCRESIDUEPLANS@ec.europa.eu preferably in ENGLISH or in one of the other working languages of the EC – French or German
safety concerns (e.g. **carbadox, olaquindox, nifursol etc**) are used in food producing animals in your country. If so describe the measures in place to guarantee that residues of these substances are not present in product exported to the EU.	
4.5. In respect of **honey**, if this is a commodity which is (potentially) being exported to the EU, please indicate whether **antibiotics** are authorised for the treatment of certain diseases in honey bees (e.g. American and European foulbrood).	
4.6. In respect of **aquaculture** (fin fish), if this is a commodity which is (potentially) being exported to the EU, please indicate whether dyes such as **malachite green** and **crystal violet** are authorised for the treatment or prevention of disease in such fish at any stage of their production. If so describe the measures in place to guarantee that residues of these substances are not present in product exported to the EU.	

Annex 3: An example of a completed specimen plan for aquaculture products (veterinary drugs)

Source: http://ec.europa.eu/food/food/chemicalsafety/residues/plan_template_specimen_en.pdf

Instructions for using the Residues Planning Template

Note	INSTRUCTIONS
1	The competent authority is requested to fill in each sheet (for the relevant commodity). Numerical data should only be included for those commodities currently being exported to the European Union (EU) or which the third country intends to export to the EU. Numerical data should be entered in those cells shaded light yellow thus: →
2	Basis of the calculation: The tables are set up to calculate the required sample numbers on the basis of Directive 96/23/EC and Commission Decision 97/747/EC. Data in cells shaded light blue are automatically calculated when the **production data cell (Cell C8)** is completed (**see note 4 below**). In the case of **milk, eggs, farmed game** and **wild game**, the minimum numbers of samples to be taken have already been entered in the blue cells and are independent of the production volumes.
3	In order to ensure that all samples are tested and to facilitate the allocation of the balance of samples between groups (as is required for several commodities), explanations are given at the foot of each individual Excel worksheet.
4	It is important that for those countries where animals and products from **any farm** are eligible to be exported to the EU, the proportion of animals sampled should be taken relative to the **annual national production figures**. [IN THIS CASE THE ANNUAL PRODUCTION DATA SHOULD BE ENTERED IN CELL C8]. For those countries where only a **defined population of animals are eligible for export** to the EU, and where there is a system in place guaranteeing that only those animals from those farms are eligible for export **(i.e. a split system**), it is permissible that the proportion of animals sampled is relative to that defined population. [IN THIS CASE THE EU EXPORT DATA ONLY SHOULD BE ENTERED IN CELL C8].
5	With regard to the **selection of residues to be analysed**, guidance is given on this web page and is summarised in Table 2 below. The European Community considers that certain substances are 'essential' for monitoring. **These are indicated in the table as 'E' and must be monitored for.** Other substances are designated as 'highly desirable – HD' and the Community expects that these substances will be included in all residue monitoring plans of third countries. However, deviations concerning HD substances may be acceptable. In this case arguments based on an analysis of the risk of residues remaining in food are to be submitted by the third country. These arguments should demonstrate that, for example, because of the production conditions in that third country it is not necessary to test for the substance. When selecting individual substances in the HD groups, third countries should consider what veterinary medicines or feed additives are authorised and used legally in the country in each of the production sectors and what contamination might occur e.g. via feed and water or directly through the environment. Consideration should also be given to the possibility of illegal or unauthorised use.
6	The reduced number of substances to be looked for in **live equidae exported for direct slaughter** to the EU presupposes that there is no slaughter of horses in that third country, hence the substances chosen may be looked for in body fluids (i.e blood and urine) which can be sampled from live horses. It is stressed that if there*is* slaughter of horses in the third country and only live horses are exported for direct slaughter,*sampling should be based on the slaughtered animals* and take account of the wider range of substances that can be checked.

REGULATORY PROGRAMME FOR CONTROL OF RESIDUES IN FOOD

For official use
50

COUNTRY	Wonderland		DATE	17-juin-08
YEAR OF PLAN IMPLEMENTATION	2008			
ANIMAL SPECIES / PRODUCT	AQUACULTURE FIN FISH			
National PRODUCTION DATA - in TONNES (referring to the previous year)	10000		EU EXPORT DATA in TONNES (referring to the previous year)	5000
PRODUCTION DATA in TONNES for calculation of SAMPLE NUMBERS. (referring to previous year's production)	5000	←	See Instruction sheet, note 4. If a **split system** is in place for exports to the EU, **actual export data** may be entered in this cell. If there is no split system, and **farmed FINFISH from ALL FARMS** are eligible for export to the EU, **national production data** must be entered in this cell.	
NUMBER OF SAMPLES †	ACCORDING TO EU REQUIREMENTS	ACCORDING TO CODEX ALIMENTARIUS	OTHER	
MINIMUM #	50			
PLAN	52			

GROUP OF SUBSTANCES TO BE MONITORED		NUMBER OF SAMPLES MIN	NUMBER OF SAMPLES PLAN	COMPOUND or MARKER RESIDUE	MATRIX ANALYSED	SCREENING METHOD	CONFIRMATORY METHOD	SCREEN.METH. DETECTION LIMIT [µg/Kg]	CONFIR.METH. DETECTION LIMIT [µg/Kg]	LEVEL OF ACTION (i.e. conceentration above which a result is deemed non-compliant) [µg/Kg]	LABORATORY
A1	STILBENES	6	6	Diethylstilbestrol	Muscle	GC-MS	GC-MS	0,5	Same as for screening	Any confirmed	Laboratory B
				Dienestrol	Muscle	GC-MS	GC-MS	0,5	Same as for screening	Any confirmed	Laboratory B
				Hexestrol	Muscle	GC-MS	GC-MS	0,5	Same as for screening	Any confirmed	Laboratory B
A3	STEROIDS (WITH ANDROGENIC, ESTROGENIC OR PROGESTAGENIC ACTIVITY)	6	6	17-beta-estradiol	Muscle	GC-MS	GC-MS	0,5	Same as for screening	Any confirmed	Laboratory B
				17-beta-19-nortestosterone	Muscle	GC-MS	GC-MS	1,3	Same as for screening	Any confirmed	Laboratory B
				17-beta-testosterone	Muscle	GC-MS	GC-MS	1,2	Same as for screening	Any confirmed	Laboratory B
				trenbolone	Muscle	GC-MS	GC-MS	1,1	Same as for screening	Any confirmed	Laboratory B
				bolasterone	Muscle	GC-MS	GC-MS	1	Same as for screening	Any confirmed	Laboratory B
				norethandrolone	Muscle	GC-MS	GC-MS	0,5	Same as for screening	Any confirmed	Laboratory B
				methyltestosterone	Muscle	GC-MS	GC-MS	1,3	Same as for screening	Any confirmed	Laboratory B
				chlormadinone	Muscle	GC-MS	GC-MS	1	Same as for screening	Any confirmed	Laboratory B
				medroxyprogesterone	Muscle	GC-MS	GC-MS	0,8	Same as for screening	Any confirmed	Laboratory B
				megestrol	Muscle	GC-MS	GC-MS	0,8	Same as for screening	Any confirmed	Laboratory B
A6	Chloramphenicol + Nitrofurans+ Nitroimidazoles	6	6								
	CHLORAMPHENICOL		3	Chloramphenicol	Muscle	EIA	GC-MS-NCI	0,2	0,25	0,3 *	Laboratory A
	NITROFURANS		3								
	Nitrofurantoin metabolite			AOZ	Muscle	LC-MS-MS	LC-MS-MS	0,5	Same as for screening	1 *	Laboratory B
	Furaltadone metabolite			AMOZ	Muscle	LC-MS-MS	LC-MS-MS	0,4	Same as for screening	1 *	Laboratory B
	Furazolidone metabolite			AHD	Muscle	LC-MS-MS	LC-MS-MS	0,3	Same as for screening	1 *	Laboratory B
	Nitrofurazone metabolite			SEM	Muscle	LC-MS-MS	LC-MS-MS	0,5	Same as for screening	1 *	Laboratory B
	NITROIMIDAZOLES										

GROUP OF SUBSTANCES TO BE MONITORED		NUMBER OF SAMPLES		COMPOUND or MARKER RESIDUE	MATRIX ANALYSED	SCREENING METHOD	CONFIRMATORY METHOD	SCREEN.METH. DETECTION LIMIT [µg/Kg]	CONFIR.METH. DETECTION LIMIT [µg/Kg]	LEVEL OF ACTION (i.e. conceentration above which a result is deemed non-compliant) [µg/Kg]	LABORATORY
		MIN	PLAN								
B1	ANTIBACTERIAL SUBSTANCES	17	17	Tetracycline	Muscle	Four Plate Test	HPLC-Fluor	30	50	100	Laboratory A
				Chlortetracycline	Muscle	Four Plate Test	HPLC-Fluor	20	30	100	Laboratory A
				Oxytetracycline	Muscle	Four Plate Test	HPLC-Fluor	50	40	100	Laboratory A
				Sulphamethazine	Muscle	Charm II	LC-MS-MS	50	25	100	Laboratory A
				Sulphadimethoxine	Muscle	Charm II	LC-MS-MS	20	25	100	Laboratory A
				SulphamerBzine	Muscle	Charm II	LC-MS-MS	20	25	100	Laboratory A
				Sulphathiazole	Muscle	Charm II	LC-MS-MS	40	25	100	Laboratory A
				Sulphadiazine	Muscle	Charm II	LC-MS-MS	20	25	100	Laboratory A
				Amoxycillin	Muscle	Four Plate Test	LC-MS-MS	20	25	50	Laboratory A
				Trimethoprim	Muscle	HPLC	LC-MS-MS	20	25	50	Laboratory A
				Tylosin	Muscle	HPLC	LC-MS-MS	50	50	100	Laboratory A
				Danofloxacin	Muscle	HPLC	LC-MS-MS	20	20	Any confirmed	Laboratory A
				Marbofloxacin	Muscle	HPLC	LC-MS-MS	15	15	30	Laboratory A
				Ofloxacin	Muscle	HPLC	LC-MS-MS	20	25	Any confirmed	Laboratory A
				Sarafloxacin	Muscle	HPLC	LC-MS-MS	20	20	Any confirmed	Laboratory A
				Difloxacin	Muscle	HPLC	LC-MS-MS	20	30	Any confirmed	Laboratory A
				Norfloxacin	Muscle	HPLC	LC-MS-MS	10	10	Any confirmed	Laboratory A
				Cirpfloxacin	Muscle	HPLC	LC-MS-MS	10	10	Any confirmed	Laboratory A
				Enrofloxacin	Muscle	HPLC	LC-MS-MS	10	10	Any confirmed	Laboratory A
				Flumequin	Muscle	HPLC	LC-MS-MS	5	20	600	Laboratory A
				Oxolinic acid	Muscle	HPLC	LC-MS-MS	3	5	100	Laboratory A
				Florfenicol	Muscle	HPLC	LC-MS-MS	17	30	1000	Laboratory A
				Thiamphenicol	Muscle	HPLC	LC-MS-MS	10	25	50	Laboratory A
B2a	ANTHELMINTICS	7	7	Albendazole (+sulfone & sulfoxide)	Muscle	LC-MS-MS	LC-MS-MS	25	Same as for screening	Any confirmed	Laboratory A
				Fenbendazole	Muscle	LC-MS-MS	LC-MS-MS	25	Same as for screening	Any confirmed	Laboratory A
				Flubendazole	Muscle	LC-MS-MS	LC-MS-MS	25	Same as for screening	Any confirmed	Laboratory A
				Mebendazole	Muscle	LC-MS-MS	LC-MS-MS	25	Same as for screening	Any confirmed	Laboratory A
				Oxfendazole	Muscle	LC-MS-MS	LC-MS-MS	25	Same as for screening	Any confirmed	Laboratory A
				Emamectin (B1a)	Muscle	LC-MS-MS	LC-MS-MS	50	Same as for screening	100	Laboratory A
				Ivermectin	Muscle	LC-MS-MS	LC-MS-MS	1	Same as for screening	Any confirmed	Laboratory A
B2f	Other pharmacologically active subs										

GROUP OF SUBSTANCES TO BE MONITORED		NUMBER OF SAMPLES MIN	NUMBER OF SAMPLES PLAN	COMPOUND or MARKER RESIDUE	MATRIX ANALYSED	SCREENING METHOD	CONFIRMATORY METHOD	SCREEN.METH. DETECTION LIMIT [µg/Kg]	CONFIR.METH. DETECTION LIMIT [µg/Kg]	LEVEL OF ACTION (i.e. concentration above which a result is deemed non-compliant) [µg/Kg]	LABORATORY
Sum of B3a + B3c + B3d + B3e		10	10								
B3a	ORGANOCHLORINE COMPOUNDS INCLUDING PCBS		3	Aldrin	Muscle	GC-MS	GC-MS	2	Same as for screening	Various 2-100	Laboratory A
				Chlordan-Alpha-Cis	Muscle	GC-MS	GC-MS	2	Same as for screening	Various 2-100	Laboratory A
				Chlordan-Gamma- Trans	Muscle	GC-MS	GC-MS	2	Same as for screening	Various 2-100	Laboratory A
				DDE, pp'-	Muscle	GC-MS	GC-MS	2	Same as for screening	Various 2-100	Laboratory A
				DDT, op-	Muscle	GC-MS	GC-MS	2	Same as for screening	Various 2-100	Laboratory A
				DDT, pp'-	Muscle	GC-MS	GC-MS	2	Same as for screening	Various 2-100	Laboratory A
				Dieldrin	Muscle	GC-MS	GC-MS	2	Same as for screening	Various 2-100	Laboratory A
				Endosulfan-Alpha	Muscle	GC-MS	GC-MS	2	Same as for screening	Various 2-100	Laboratory A
				Endosulfan-Beta	Muscle	GC-MS	GC-MS	2	Same as for screening	Various 2-100	Laboratory A
				Endosulfansulfat	Muscle	GC-MS	GC-MS	2	Same as for screening	Various 2-100	Laboratory A
				HCH-Alpha	Muscle	GC-MS	GC-MS	2	Same as for screening	Various 2-100	Laboratory A
				HCH-Beta	Muscle	GC-MS	GC-MS	2	Same as for screening	Various 2-100	Laboratory A
				HCH-Gamma (lindane)	Muscle	GC-MS	GC-MS	2	Same as for screening	Various 2-100	Laboratory A
				Heptachlor	Muscle	GC-MS	GC-MS	2	Same as for screening	Various 2-100	Laboratory A
				Heptachlorepoxid-Cis-Trans	Muscle	GC-MS	GC-MS	2	Same as for screening	Various 2-100	Laboratory A
				Oxychlordane	Muscle	GC-MS	GC-MS	2	Same as for screening	Various 2-100	Laboratory A
				PCB 101	Muscle	GC-MS	GC-MS	2	Same as for screening	Various 2-100	Laboratory A
				PCB 118	Muscle	GC-MS	GC-MS	2	Same as for screening	Various 2-100	Laboratory A
				PCB 138	Muscle	GC-MS	GC-MS	2	Same as for screening	Various 2-100	Laboratory A
				PCB 153	Muscle	GC-MS	GC-MS	2	Same as for screening	Various 2-100	Laboratory A
				PCB 180	Muscle	GC-MS	GC-MS	2	Same as for screening	Various 2-100	Laboratory A
				PCB 28	Muscle	GC-MS	GC-MS	2	Same as for screening	Various 2-100	Laboratory A
				PCB 52	Muscle	GC-MS	GC-MS	2	Same as for screening	Various 2-100	Laboratory A
B3c	CHEMICAL ELEMENTS		2	Cadmium	Muscle	ICP-MS	ICP-MS	0,92	Same as for screening	50	Laboratory A
				Lead	Muscle	ICP-MS	ICP-MS	3,1	Same as for screening	200	Laboratory A
				Mercury	Muscle	ICP-MS	ICP-MS	0,03	Same as for screening	500	Laboratory A
B3d	MYCOTOXINS		1	Aflatoxin B1	Muscle	HPLC-Fluor	LC-MS-MS	0,3	Same as for screening	Any confirmed	Laboratory A
				Aflatoxin B2	Muscle	HPLC-Fluor	LC-MS-MS	0,25	Same as for screening	Any confirmed	Laboratory A
				Aflatoxin G1	Muscle	HPLC-Fluor	LC-MS-MS	0,4	Same as for screening	Any confirmed	Laboratory A
				Aflatoxin G2	Muscle	HPLC-Fluor	LC-MS-MS	0,5	Same as for screening	Any confirmed	Laboratory A
B3e	DYES e.g. Malachite Green (+ leucomalachite green), crystal violet etc		4	Malachite green + leuco MG	Muscle	LC-MS-MS	LC-MS-MS	1	Same as for screening	2 *	Laboratory B
				Crystal violet + leuco crystal violet	Muscle	LC-MS-MS	LC-MS-MS	1	Same as for screening	Any confirmed	Laboratory B

NB: * Indicates Community Minimum Required Performance Limit (MRPL). Third countries may either use this as a 'level of action' or alternatively any confirmed concentration.

† A sample is one or more fish. The **minimum number of samples to be collected each year must be at least 1 per 100 tonnes of annual production**.
The following breakdown must be respected: ***Group A: one third of the total samples.***
All of these samples must be taken at farm level, on fish at all stages of farming , including fish which is ready to be placed on the market for consumption.
Group B: two thirds of the total samples.
This sampling should be carried out: (a) preferably at the farm, on fish ready to be placed on the market for consumption;
(b) either at the processing plant, or at wholesale level, on fresh fish, on condition that tracing-back to the farm of origin, in the event of positive results, can be done.
In order to facilitate this breakdown and ensure that the correct number of samples are tested, the spreadsheet has made the following calculations distributing samples between each of the (sub) groups in the following way:
- Of the samples to be tested for in Groups A1, A3 and A6, one third of the total Group A samples are allocated to each of the three subgroups.
- Of the samples to be tested for Group B, 50% of these have been allocated to Group B1, 20% to Group B2 and 30% to Group B3. It is essential that dyes are tested for.
 # For very small production volumes (e.g. < 500 tonnes) where the spreadsheet would calculate < 1 sample per substance group, a minimum of one sample per compound group has been assigned.

REGULATORY PROGRAMME FOR CONTROL OF RESIDUES IN FOOD

COUNTRY	Wonderland			DATE	24-juin-10
YEAR OF PLAN IMPLEMENTATION	2008				
ANIMAL SPECIES / PRODUCT	AQUACULTURE CRUSTACEANS				
National PRODUCTION DATA - in TONNES (referring to the previous year)	3000		EU EXPORT DATA in TONNES (referring to the previous year)	3000	
PRODUCTION DATA in TONNES for calculation of SAMPLE NUMBERS. (referring to previous year's production)	3000		See Instruction sheet, note 4. If a split system is in place for exports to the EU, actual export data may be entered in this cell. If there is no split system, and FARMED SHRIMP from ALL FARMS are eligible for export to the EU, national production data must be entered in this cell.		
NUMBER OF SAMPLES †	ACCORDING TO EU REQUIREMENTS	ACCORDING TO CODEX ALIMENTARIUS	OTHER		
MINIMUM	30				
PLAN	36				

	GROUP OF SUBSTANCES TO BE MONITORED	NUMBER OF SAMPLES MIN	NUMBER OF SAMPLES PLAN	COMPOUND or MARKER RESIDUE	MATRIX ANALYSED	SCREENING METHOD	CONFIRMATORY METHOD	SCREEN.METH. DETECTION LIMIT [µg/Kg]	CONFIR.METH. DETECTION LIMIT [µg/Kg]	LEVEL OF ACTION (i.e. concentration above which a result is deemed non-compliant) [µg/Kg]	LABORATORY
A6	**Chloramphenicol + Nitrofurans+ Nitroimidazoles**	10	10								
	CHLORAMPHENICOL		4	Chloramphenicol	Muscle	EIA	GC-MS-NCI	0,1	0,2	0,3 *	Laboratory A
	NITROFURANS										
	Nitrofurantoin metabolite		4	AOZ	Muscle	LC-MS-MS	LC-MS-MS	0,4	Same as for screening	1 *	Laboratory B
	Furaltadone metabolite			AMOZ	Muscle	LC-MS-MS	LC-MS-MS	0,3	Same as for screening	1 *	Laboratory B
	Furazolidone metabolite			AHD	Muscle	LC-MS-MS	LC-MS-MS	0,3	Same as for screening	1 *	Laboratory B
	Nitrofurazone metabolite			SEM	Muscle	LC-MS-MS	LC-MS-MS	0,4	Same as for screening	1 *	Laboratory B
	NITROIMIDAZOLES		2	Dimetridazole (HMMNI)	Muscle	LC-MS-MS	LC-MS-MS	5	Same as for screening	Presence	Laboratory B
				Ipronidazole	Muscle	LC-MS-MS	LC-MS-MS	5	Same as for screening	Presence	Laboratory B
				Metronidazole	Muscle	LC-MS-MS	LC-MS-MS	5	Same as for screening	Presence	Laboratory B
				Ronidazol	Muscle	LC-MS-MS	LC-MS-MS	5	Same as for screening	Presence	Laboratory B

GROUP OF SUBSTANCES TO BE MONITORED		NUMBER OF SAMPLES		COMPOUND or MARKER RESIDUE	MATRIX ANALYSED	SCREENING METHOD	CONFIRMATORY METHOD	SCREEN.METH. DETECTION LIMIT [µg/Kg]	CONFIR.METH. DETECTION LIMIT [µg/Kg]	LEVEL OF ACTION (i.e. concentration above which a result is deemed non-compliant) [µg/Kg]	LABORATORY
		MIN	PLAN								
B1	ANTIBACTERIAL SUBSTANCES	10	10	Tetracycline	Muscle	Four Plate Test	HPLC-Fluor	30	50	100	Laboratory A
				Chlortetracycline	Muscle	Four Plate Test	HPLC-Fluor	20	30	100	Laboratory A
				Oxytetracycline	Muscle	Four Plate Test	HPLC-Fluor	50	40	100	Laboratory A
				Sulphamethazine	Muscle	Charm II	LC-MS-MS	50	25	100	Laboratory A
				Sulphadimethoxine	Muscle	Charm II	LC-MS-MS	20	25	100	Laboratory A
				SulphamerBzine	Muscle	Charm II	LC-MS-MS	20	25	100	Laboratory A
				Sulphathiazole	Muscle	Charm II	LC-MS-MS	40	25	100	Laboratory A
				Sulphadiazine	Muscle	Charm II	LC-MS-MS	20	25	100	Laboratory A
				Amoxycillin	Muscle	Four Plate Test	LC-MS-MS	20	25	50	Laboratory A
				Trimethoprim	Muscle	HPLC	LC-MS-MS	20	25	50	Laboratory A
				Tylosin	Muscle	HPLC	LC-MS-MS	50	50	100	Laboratory A
				Danofloxacin	Muscle	HPLC	LC-MS-MS	20	20	Any confirmed	Laboratory A
				Marbofloxacin	Muscle	HPLC	LC-MS-MS	15	15	30	Laboratory A
				Ofloxacin	Muscle	HPLC	LC-MS-MS	20	25	Any confirmed	Laboratory A
				Sarafloxacin	Muscle	HPLC	LC-MS-MS	20	20	Any confirmed	Laboratory A
				Difloxacin	Muscle	HPLC	LC-MS-MS	20	30	Any confirmed	Laboratory A
				Norfloxacin	Muscle	HPLC	LC-MS-MS	10	10	Any confirmed	Laboratory A
				Cirpfloxacin	Muscle	HPLC	LC-MS-MS	10	10	Any confirmed	Laboratory A
				Enrofloxacin	Muscle	HPLC	LC-MS-MS	10	10	Any confirmed	Laboratory A
				Flumequin	Muscle	HPLC	LC-MS-MS	5	20	600	Laboratory A
				Oxolinic acid	Muscle	HPLC	LC-MS-MS	3	5	100	Laboratory A
				Florfenicol	Muscle	HPLC	LC-MS-MS	17	30	1000	Laboratory A
				Thiamphenicol	Muscle	HPLC	LC-MS-MS	10	25	50	Laboratory A
B2a	ANTHELMINTICS	4	4	Albendazole (+sulfone & sulfoxide)	Muscle	LC-MS-MS	LC-MS-MS	25	Same as for screening	Any confirmed	Laboratory A
				Fenbendazole	Muscle	LC-MS-MS	LC-MS-MS	25	Same as for screening	Any confirmed	Laboratory A
				Flubendazole	Muscle	LC-MS-MS	LC-MS-MS	25	Same as for screening	Any confirmed	Laboratory A
				Mebendazole	Muscle	LC-MS-MS	LC-MS-MS	25	Same as for screening	Any confirmed	Laboratory A
				Oxfendazole	Muscle	LC-MS-MS	LC-MS-MS	25	Same as for screening	Any confirmed	Laboratory A
B2f	Other pharmacologically active subs										

GROUP OF SUBSTANCES TO BE MONITORED		NUMBER OF SAMPLES		COMPOUND or MARKER RESIDUE	MATRIX ANALYSED	SCREENING METHOD	CONFIRMATORY METHOD	SCREEN.METH. DETECTION LIMIT [µg/Kg]	CONFIR.METH. DETECTION LIMIT [µg/Kg]	LEVEL OF ACTION (i.e. conceentration above which a result is deemed non-compliant) [µg/Kg]	LABORATORY
		MIN	PLAN								
Sum of B3a + B3c + B3d + B3e		**6**	**12**								
B3a	**ORGANOCHLORINE COMPOUNDS INCLUDING PCBS**		**4**	Aldrin	Muscle	GC-MS	GC-MS	2	Same as for screening	Various 2-100	Laboratory A
				Chlordan-Alpha-Cis	Muscle	GC-MS	GC-MS	2	Same as for screening	Various 2-100	Laboratory A
				Chlordan-Gamma- Trans	Muscle	GC-MS	GC-MS	2	Same as for screening	Various 2-100	Laboratory A
				DDE, pp'-	Muscle	GC-MS	GC-MS	2	Same as for screening	Various 2-100	Laboratory A
				DDT, op-	Muscle	GC-MS	GC-MS	2	Same as for screening	Various 2-100	Laboratory A
				DDT, pp'-	Muscle	GC-MS	GC-MS	2	Same as for screening	Various 2-100	Laboratory A
				Dieldrin	Muscle	GC-MS	GC-MS	2	Same as for screening	Various 2-100	Laboratory A
				Endosulfan-Alpha	Muscle	GC-MS	GC-MS	2	Same as for screening	Various 2-100	Laboratory A
				Endosulfan-Beta	Muscle	GC-MS	GC-MS	2	Same as for screening	Various 2-100	Laboratory A
				Endosulfansulfat	Muscle	GC-MS	GC-MS	2	Same as for screening	Various 2-100	Laboratory A
				HCH-Alpha	Muscle	GC-MS	GC-MS	2	Same as for screening	Various 2-100	Laboratory A
				HCH-Beta	Muscle	GC-MS	GC-MS	2	Same as for screening	Various 2-100	Laboratory A
				HCH-Gamma (lindane)	Muscle	GC-MS	GC-MS	2	Same as for screening	Various 2-100	Laboratory A
				Heptachlor	Muscle	GC-MS	GC-MS	2	Same as for screening	Various 2-100	Laboratory A
				Heptachlorepoxid-Cis-Trans	Muscle	GC-MS	GC-MS	2	Same as for screening	Various 2-100	Laboratory A
				Oxychlordane	Muscle	GC-MS	GC-MS	2	Same as for screening	Various 2-100	Laboratory A
				PCB 101	Muscle	GC-MS	GC-MS	2	Same as for screening	Various 2-100	Laboratory A
				PCB 118	Muscle	GC-MS	GC-MS	2	Same as for screening	Various 2-100	Laboratory A
				PCB 138	Muscle	GC-MS	GC-MS	2	Same as for screening	Various 2-100	Laboratory A
				PCB 153	Muscle	GC-MS	GC-MS	2	Same as for screening	Various 2-100	Laboratory A
				PCB 180	Muscle	GC-MS	GC-MS	2	Same as for screening	Various 2-100	Laboratory A
				PCB 28	Muscle	GC-MS	GC-MS	2	Same as for screening	Various 2-100	Laboratory A
				PCB 52	Muscle	GC-MS	GC-MS	2	Same as for screening	Various 2-100	Laboratory A
B3c	**CHEMICAL ELEMENTS**		**4**	Cadmium	Muscle	ICP-MS	ICP-MS	0,92	Same as for screening	500	Laboratory A
				Lead	Muscle	ICP-MS	ICP-MS	3,1	Same as for screening	500	Laboratory A
				Mercury	Muscle	ICP-MS	ICP-MS	0,03	Same as for screening	500	Laboratory A
B3d	**MYCOTOXINS**		**0**	Aflatoxin B1	Muscle	HPLC-Fluor	LC-MS-MS	0,3	Same as for screening	Any confirmed	Laboratory A
				Aflatoxin B2	Muscle	HPLC-Fluor	LC-MS-MS	0,25	Same as for screening	Any confirmed	Laboratory A
				Aflatoxin G1	Muscle	HPLC-Fluor	LC-MS-MS	0,4	Same as for screening	Any confirmed	Laboratory A
				Aflatoxin G2	Muscle	HPLC-Fluor	LC-MS-MS	0,5	Same as for screening	Any confirmed	Laboratory A
B3e	**DYES e.g. Malachite Green (+ leucomalachite green), crystal violet etc**		**4**	Malachite green + leuco MG	Muscle	LC-MS-MS	LC-MS-MS	1	Same as for screening	2 *	Laboratory B
				Crystal violet + leuco crystal violet	Muscle	LC-MS-MS	LC-MS-MS	1	Same as for screening	Any confirmed	Laboratory B

NB: * Indicates Community Minimum Required Performance Limit (MRPL). Third countries may either use this as a 'level of action' or alternatively **any confirmed** concentration.

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The following breakdown must be respected: ***Group A: one third of the total samples.***
All of these samples must be taken at farm level, on fish at all stages of farming , including fish which is ready to be placed on the market for consumption.
Group B: two thirds of the total samples.
This sampling should be carried out: (a) preferably at the farm, on fish ready to be placed on the market for consumption;
(b) either at the processing plant, or at wholesale level, on fresh fish, on condition that tracing-back to the farm of origin, in the event of positive results, can be done.
In order to facilitate this breakdown and ensure that the correct number of samples are tested, the spreadsheet has made the following calculations distributing samples between each of the (sub) groups in the following way:
- Only Group A6 needs to be tested for for shrimps.
- Of the samples to be tested for Group B, 50% of these have been allocated to Group B1, 20% to Group B2 and 30% to Group B3. It is essential that dyes are tested for.
 # For very small production volumes (e.g. < 500 tonnes) where the spreadsheet would calculate < 1 sample per substance group, a minimum of one sample per compound group has been assigned.