TRAINING MANUAL

RESIDUE MONITORING PLAN TRANING IN EAST AFRICAN COMMUNITY MEMBER STATES

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1 introduction

Agricultural products, especially including fresh products, constitute the main export products in many AEC countries contributing to GDP and employment. With the globalization of trade food safety has become an issue of great concern putting pressure on Food Control System to find ways to address the risks posed. Regulatory authorities have to deal with a wide range of risks that may occur at different points of the food chain from the production to the consumption of food. Pesticide residues, direct or indirect, have emerged as a major food safety issue and are posing threats to both human health and ecosystems.

EAC Countries have identified and prioritised their specific, urgent, and important capacity building needs in the area of NTBS related to SPS so that systematic and effective trade can be streamlined accordingly not only with countries outside EAC but also within the economic sub-region.

SPS are widely shared responsibility therefore, awareness, training and implementation of proper practices along the value chain can contribute to counter food-related risks.

Food safety and diseases notifications can raise consumer and Competent Authorities concerns that highlight the need for proper controls to protect consumer's health.

Countries have long recognized the deep interconnectivity that exists among them throughout the production, processing, and distribution of food while acknowledging the importance of ensuring access to safe food, as a result, food safety has required actions within national borders, as well as surveillance and monitoring of risks including diseases based on risk analysis.

The official food control services play a key role in ensuring that food is safe and suitable for human consumption. While the responsibility for the supply of safe food is shared by all involved in the production, processing and trade along the entire food chain, the official control services are responsible for the enforcement of food safety legislation. Competent /Regulatory Authority inspecting food establishments and processes prevent the trade of unsafe food and protect consumer's health at national, regional and international level.

EAC Countries are willing to increase intra-regional trade and for this should implement procedures risk based transparent procedures in order to avoid unnecessary and unjustifiable Non-Tariff Barriers (NTBs)s.

Food trade is important as it contributes to economic development and food security in line with CAADP goals set by the African Union.

In this context, the rationale for the development of Residues Control Plan includes a large market-science component. To access and maintain, increase or capture new export markets EAC Countries must demonstrate their ability to produce safe food products provide assurance that that requirements are met and demonstrate that the can they can effectively manage any incidents that may occur along value chains.

In addition for main export market, robust control systems should be in place so that specific requirements are constantly met in order to maintain export flows i.e residues and MRL).

In addition to other measures that may be required (e.g HACCP), National Residues Control Plans constitute a safeguard by effectively, preventing, minimizing the introduction or contamination with hazards/substances/pests that can cause health adverse effects or economic losses.

National Residues Control Plan for animal and plant products therefore aim try among others at:

1. Detecting any illegal treatment(s) / abuse of substances in the production of food of plant or animal origin animal with the purpose of verifying compliance with the Maximum Residue Limits (MRLs) for Pesticides and or for Veterinary Medicinal Products and other contaminants including pathogens and the maximum limits for heavy metals and environmental contaminants as per SPS requirements guided by risk assessment.
2. Communicate and carry out follow-up actions in the event of detection of illegal treatment(s) with substances of concern or detection of residues above acceptable limits in food products.
3. Assist government identify potential residue problems including failure to comply with good agricultural practices, and can indicate where follow-up action is needed to prevent or solve the problems (maintain reputation as a supplier of clean produce).
4. To manage the risk of chemical residues and environment contaminants
5. support country's agriculture production and food industry.

Official Controls, Monitoring Plans and Control Plans fall under two different strategies and are complementary. On the basis of representative samples of production or consumption, the monitoring plans make it possible to assess the overall exposure of the consumer to a particular risk and thus to identify the management measures to control it. Control Plans will focus on targeted commodities that represent an increased risk of contamination and will thus be able to evaluate the effectiveness of the management measures that have been implemented.

Monitoring and control plans are an essential tool for preserving the public health of consumers and at the same time contributing to the development of EAC agricultural and agri-food products for export. Therefore, National Control Plans constitute also a tool to measure the performance of the Food Safety Management System implemented by the Food Business Operator and for the Competent/Regulatory Authorities to readjust when necessary the control measures. In this way, Competent/Regulatory Authorities can "maintain "the control pressure on so-called "sensitive/risky" products, consumer risk exposure in order to be able to promote the most appropriate risk management measures, quality assessment of national production, in particular as a means of preventing crises.

2. The Legal basis

EAC Countries must demonstrate their ability to produce safe food products, prove that requirements (and to effectively manage any incidents that may occur along the identified value chains.

Therefore in order to clearly ensure a high level of protection of the health of persons and the interests of consumers, EAC Member States to draw up an integrated multiannual national control plan which defines a comprehensive, uniform and harmonized approach based on risk and the most effective control procedures.

3. Risk Analysis

Regular official controls must be conducted at an adequate frequency according to the risks. Risk analysis remains an essential tool in order to achieve the general objective of a high level of protection of human life and health.

The methodology of risk assessment according to the paradigm proposed by the *Codex Alimentarius* is now the corner stone for implementing food safety along the food value chain as well as for undertaking control activities by the Competetnt/Regulatory Authorities. The Risk assessment I componenet of the paradigm, is a prerequisite for the risk prioritization activities, for laboratory controls and all other risk management activities.

The authorities have an important role to play to ensure food safety but the private sector is the first concerned as producer of primary agricultural products and processed foodstuffs. Food safety management systems have to be developed and implemented at all links of the chain. This involvement of the private sector will be the second shade of food safety.

The sampling to be undertaken in residue monitoring must be targeted 'targeted', meaning that the animals, plant and sample matrices selected for sampling for particular substances should be those where noncompliant results are most likely to be found. A further refinement of this targeted approach to sampling is the development of a semi quantitative ranking system for substances to underpin the application of a risk-based approach to the development of residue testing programme and sample size calculation.

Figure 1. FAO 1995

3.1 Hazards identification

Hazard identification is the first step in the effective risk analysis . This first stage involves the screening of publications and literature on the relevant hazard (i.e. pesticides, mycotoxins, pathogens, etc…) (results of previous official controls, results of controls in other countries and inspections results), in order to obtain an initial list of hazards most analyzed and most often found in foodstuffs during checks.

This step makes it possible to link a danger with a foodstuff and thus to create matrix pairs (the food) - hazards. At this stage reference can also be made to other relevant legislation (e;G; EU; USA, etc….)

This first list is then confronted with the database like RASFF/INFOSAN others notifications concerning the contamination of foodstuffs by the relevant hazards and help to refine ne the matrix-hazards couples already defined and to add couples that would not have been foreseen. Hazards may include : pathogens like *clostridium perfringens, listeria monocytogenes*, mycotoxins (aflatoxins B1, B2, Fumonsins F1, F2, F3) dioxins, PAHs, PCBs, acrylamide; POPs, pesticide residues, veterinary medicinal product residues, heavy metals (Pb, Hg, Cd), etc…

3.2 Hazard Characterisation

This second step is based on the list of hazards defined in the hazard identification. It is necessary to characterize the hazard by defining the degree of toxicity of the hazards) selected using scientific advice from the official agencies where they exists ((JEMRA, JEFCA, JMPR, EFSA) scientific publications on toxicological data, IARC (IARC, 2009).

Following this step, the hazards are classified according to the health adverse effect (magnitude of adverse effect).

The inherent toxicity of contaminants is a factor that also makes it possible to prioritise hazards. ADI, TDI, ARfD, TRV (Toxicity Reference Value) or BMDL (Benchmark Dose Limit)

Table 1: Rating of hazards

Parameters		Severity level	Scientific justification
Hazard groups	Hazards		
Bacteria	*Clostridium perfringens*	2	Moderate risk with limited diffusion (Sutra et al., 1998 ; Gélinas, 1995)
	Salmonella spp.	3	Moderate risk with possibility of broad diffusion and serious risk for at-risk population
	Vibrio cholerae types O1 and O139	4	High risk. Agents provoking diseases with a high mortality rate
Furans	All furans	3	IARC group 2B
dye	Sudan red	2	IARC group 3
	Malachite green	3	Potentially mutagenic and carcinogenic for humans
Heavy metals	Lead	3	IARC group 2A but ingestion leads to chronic effects, colic, constipation and anaemia
	cadmium	4	IARC group 1 carcinogenic
Auxiliary products	Additive residues (Groups A/D/J)	3	Group of drug substances that can be prohibited for certain animal categories
Pesticides	Carbendazim	3	On the basis of the ARfD (available) and the ADI
	Dichlorvos	3	IARC group 2B neurotoxic effects including perspiration, vomiting, diarrhea, drowsiness, fatigue, headache, and at high concentrations, convulsions, and coma.

(adapted from AFSCA, 2009 Belgium)

3.3 Exposure assessment

When assessing the exposure included in the risk assessment, it is necessary to know the relationship between the population and a specific foodstuff, and the contamination susceptibility of identified hazards. For example, there are a number of consumption surveys that categorize the foods consumed by the population of a given country and quantify they consumption on a daily, weekly or annual basis.

These data are the basis of the exposure assessment because they make it possible to precisely define the exposure of a given population to a hazard.

The prevalence that is used indicates to which extent the hazard is present and its importance in the population. In order the define the prevalence it is necessary to review scientific studies, databases of results to assess the frequency of standards exceedances and analytical detections limits.

The contribution to the contamination will include the analysis of the consumption studies in order to evaluate the frequency and the level at which the food is consumed by possibly affected population. Therefore, it is necessary to have consumption data or generate them.

3.4 Risk characterization

The risk characterization makes it possible to assess the presence of potentially contaminated products on the market. This stage makes it possible to define the populations to be tested, that is to say all of the products likely to have been contaminated by the hazards that we want to characterize. For example, in the case of a given mycotoxin (e.g Fumonisins F1, F2, F3), it is necessary to list the number of brands and varieties of relevant products that can be found in supermarkets and other main outlets. To ensure that the market is properly assessed, country-specific producers (millers,bakeries, etc.) have also to be integrated into the population.

The number of samples to be tested cannot be calculated without this step, once the number of lots per matrix has been defined, because a population may be composed of several matrices.

4. Food Safety Hazards and Consumers' Health

The foremost responsibility of food control is to enforce the food law(s) protecting the consumer against unsafe, impure and fraudulently presented food by prohibiting the sale of food not of the nature, substance or quality demanded by the purchaser. Confidence in the safety and integrity of the food supply is an important requirement for consumers.

Globalization of the food supply has created conditions favourable for emergence, re-emergence, and spread of food-borne pathogens and has compounded the challenge of anticipating, detecting, and effectively responding to food-borne threats to health.

The interconnectedness of individual, regional, and global public health; the health of the planetary environment(s); and billions of food animals and wildlife would suggest the need for a new paradigm—one that shifts away from a reactive to a more anticipatory, proactive approach to food safety.

Foodborne disease microbiological hazards and chemical contaminants highlight problems with food safety and increase public anxiety that modern farming systems, food processing and marketing do not provide adequate safeguards for public health.

Main hazards include on:

- Microbiological hazards;
- Chemical hazards;
- Pesticide residues;
- Veterinary medical products;
- Heavy metals;
- Environmental contaminants
- PCB's, POP's, etc…
- Endocrine disruptors
- Allergens
- Growth promoting hormones
- Misuse of food additives;

Consumers expect protection from hazards occurring along the entire food chain, from primary producer through consumer "***farm-to-fork"***. Protection will only occur if all sectors in the chain operate in an integrated way, and food control systems address all stages of this chain. The "farm to fork" has also gone global requiring that new procedures be put in place to ensure that unsafe food or product do not enter the territory.

Therefore, there is an important need to strengthen surveillance systems for food-borne diseases as surveillance data are useful for the planning, implementation and evaluation of public health policies that will be targeted in the controls and control plans.

5. Risk Ranking

The food chain is complex, and countless risks can pose a threat to the health of humans, animals and plants. It is practically impossible for the authorities and food producers to devote (simultaneously) to each individual risk so much, given the limitation of financial resources. Choices are necessary as we have restricted resources for managing them. Through the assessment and classification of risks, it is Risk Ranking that has been recognised as the starting point for risk-based priority setting and resource allocation helps policymakers to focus attention on the most significant public health problems and develop strategies for addressing them. Indeed, in a In a science and risk-based system, resources for food safety should be deployed in a manner that maximizes the public health benefit achieved through risk reduction.

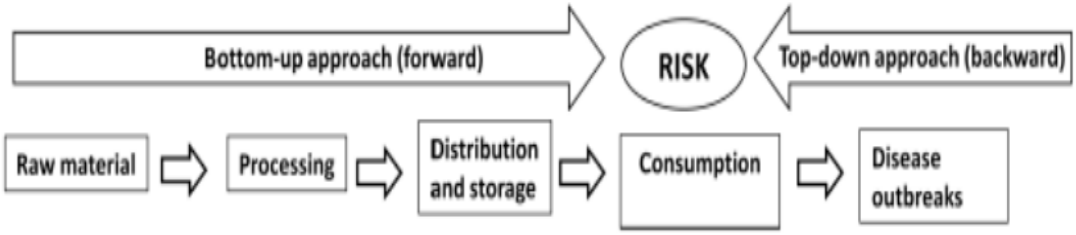


Figure 2.

There are three main type of Risk Ranking that can be used depending on resource and data availability

- Qualitative
- Semi quantitative and
- Quanttiative

In qualitative risk ranking, information is combined using a set of logical rules to arrive to a final result. This can be in the form of reasoned opinion e.g. the collected information is compared with a set of predefined criteria, without any hierarchy of these criteria) or in the form of a decision tree.

In semi-quantitative risk ranking, scores for each criterion are combined with the appropriate weights produce a final risk estimate using simple additive or multiplicative models

In quantitative risk ranking, model equations guide the integration of input parameters and other model factors to produce risk estimates

All risk rankings include the three fundamental requirements: the list of the objects to be ranked, criteria for assessment and a ranking step. The three main components are generally implemented within a risk ranking process that may be divided into different steps. There are six steps in the process:

1. Define the risks to be ranked
2. Identify the risk attributes and determinants that need to be evaluated
3. Collect data and describe the risks in terms of their risk attributes and determinants
4. Choose the evaluation method: qualitative, semi-quantitative or quantitative
5. Perform the risk rankings

5.1 Define the risks to be ranked

The results of risk ranking exercises can be sensitive to the way in which risks are defined and grouped. Risk can be defined in many ways, including by hazards or agent responsible for harm (e.g. Campylobacter, Salmonella, Listeria monocytogenes…), by source (e.g. farm derived, processing derived), by pathway (food versus environmental, cheese, meat, salads…), the end point (e.g. infection, disease, death...), the group at risk (e.g. general population, elderly, …).

5.2 Risk attributes and determinants

Different methods have been developed that provide a common metric for comparing health risks. The two most important metrics are quality-adjusted life years (QALYs) and disability adjusted life years (DALYs).

In "top-down" approach (or backward) first epidemiological surveillance data are used to provide the most accurate counts of illnesses: the total disease burden

The "bottom-up" (or forward) approach adheres in principle to the microbial risk assessment pattern and follows the biological hazard fates through the food chain to permit the prediction of health risk relative to other agents and/or foods.

5.3 Data collection and organization

Data are usually gathered from a variety of sources. Data and information are then synthesized and generally presented in risk summary sheets or reports. The summary sheets or reports are designed to inform equally the participants about each risk to make knowledgeable personal ranking judgments and contribute to group discussions.

5.4 Qualitative, semi-quantitative or quantitative risk assessment

The risk rankers should determine the type of risk assessment to be used - qualitative, semi quantitative or quantitative. Each of these approaches can be valid with the criteria for selection including: time availability, data availability and quality, resources availability to collect and analyse the data to build the model.

5.5 Perform the risk ranking

Once the attributes and determinants of overall risk have been defined through head topics and subtopics, the evaluation should be established by the participants. The participants can be asked to review the collected data and information, to assign scores or provide a qualitative judgment

6. The plans

Currently, the trend is to implement risk-based controls instead of verify prescription through inspections. In a risk-based sampling plan, monitoring should be proportionate to the attributed level of risk of particular commodities and processing methods and should be well balanced. In addition, precedence should be given to consumer health protection and assurance of fair practices in food trade.

Controls are conducted by the Competent/Regulatory Authorities to verify the effectiveness of the management measures put in place by the food business operators but also implement surveillance/monitoring plans at the country level to verify if there was no breach with set regulations i.e. pesticides or veterinary medicinal products or any other relevant hazards to ensure protection and well-being.

7. Multi-annual National Control Plan (MANCP)

This is a document that outlines the **country's strategy** (for a given period of time at usually 3 years) to ensure an effective outcome of the controls and on-going compliance with food legislation by operators. In the context of the European Union (EU) **the MANCP is an** official document that is drawn up by each country, primarily for communication purposes (especially with European bodies such as the Food and

Veterinary Office (FVO) that performs audits in the EU and in third countries that trade with the EU.

In terms of food safety, it is necessary to be able to justify the different choices that have been made to organise the official controls. To the extent that the MNACP is drawn up for comprehensive planning of official controls and use by the Competent/Regulatory Authority, it must follow a pattern and a reproducible logic.

The tools used to create the multi-year plan are as follows:

- the legal basis for legislation relating to hazards of concern in the foodstuffs,
- risk analysis according to the Codex Alimentarius (WHO, 2007),
- date on rapid alerts: IFOSAN, RASF, etc…
- inspection plans and other documents concerning hazards in the food.

The MANCP include the description of the overall organisation of the country control framework, management of official controls, the identification of Competent

/Regulatory Authorities at national level and their tasks, the laboratories designated to conduct analysis, and the various control systems they have established.

There are therefore different levels and types of **controls activities (Figure 1)**.

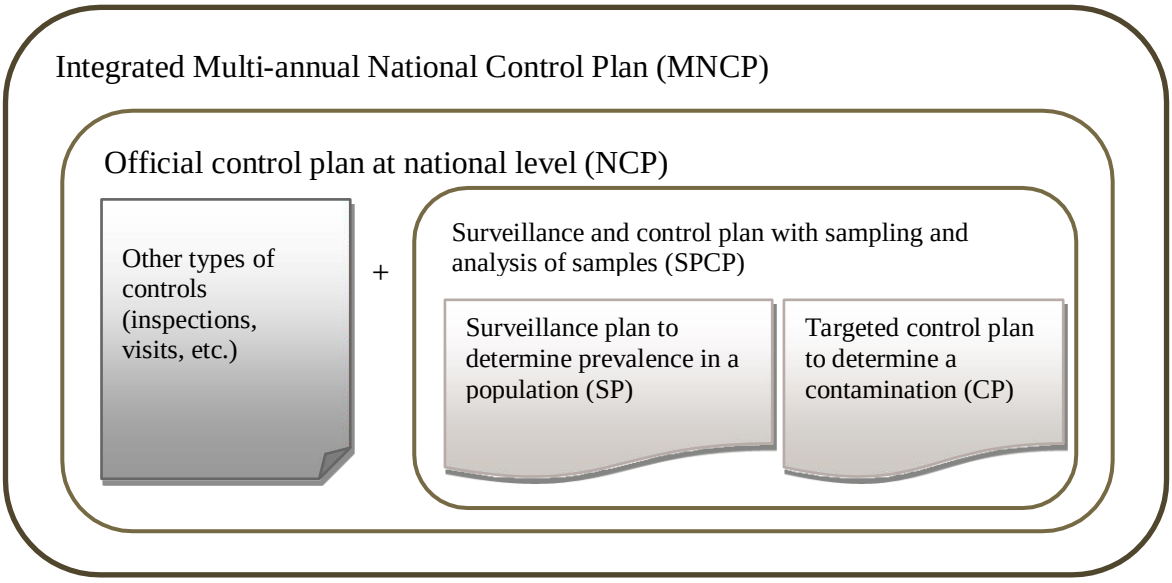


Figure 3 Diagram representing different levels of Controls (ANSES), France

8. The National Control Plan (NCP)

Official controls can be split in two main components the ones done at plan level and the surveillance and targeted controls.

This system monitors the contamination of primary animal and plant production, foodstuffs of animal origin and feed, domestic or imported.

Contaminants monitored are known to have a suspected or proven adverse effect on short or long-term on public health or animal health. These may include chemicals (residues growth promoters, veterinary medicinal products, plant protection products or environmental and industrial pollutants), physical (radionuclides) or biological agents (bacteria, viruses, parasites).

9. Controls

Controls: depending on the context, the term can be understood in a broad sense as physical control, identity control, document control, etc. but also as an inspection, verification, audit, sampling, testing, etc…

10. The other types on controls

These are mainly inspections of premises along the value chain that are carried out regularly on a risk basis according. For this purpose, a risk grading should be used to determine the frequency of inspection taking into account account the theoretical risks (linked to the process or the type of product), production volume and size of the company, the food safety management system, consumer sensitivity e.g. children) and the score awarded following the previous inspection.

1. Inspections, audits, follow-up, verifications, investigations following complaints, sampling and testing.

2. Sampling (followed by analyses of the samples): on-site sampling may or may not be carried out in line with a sampling plan.

11. Monitoring and control plans

They provide a key indicator for the safety of foodstuffs and at the same time add value to the agricultural and agri-food products that can be exported.

The objectives of the monitoring and and control plan include the following:

1. Monitoring of contamination levels in domestic and imported production and identification of trends or even emergencies, thanks to the annual or multi-annual renewal of certain plans.
2. Verification of the sanitary quality of foodstuffs produced and placed on the market, of national origin or imported, for contaminants benefiting from maximum thresholds regulations (MRLs)
3. Maintenance of control pressure by operators, by increasing the presence of services on the ground.
4. Audit of good agricultural practices (respect of pre-harvest interval, withholding time and authorisations) and detection of fraudulent practices (use of prohibited substances such as prohibited growth promoters, veterinary antibiotics or pesticides), concerning the use of inputs, such as veterinary medicinal products and plant protection products.
5. Valorisation of national agricultural and agri-food products vis-à-vis trading partners by providing evidence of the high level of sanitary quality of the products, guaranteeing the effectiveness of the sanitary and safety system set up in a country.
6. Maintenance of a network of competent and functional laboratories, essential in the event of a crisis (example of the search for salmonella, pesticides etc…).

The monitoring system put in place may consists of several plans that target a contaminant or family of contaminants in a given production, at a specific stage of the food chain. We distinguish two types of plans according to the expected objective:

1. monitoring plans (SPs), the objective of which is to estimate the overall level of contamination monitored production and for which samples are taken at random;
2. control plans (CPs), which aim to increase the probability of detection of products non-compliant and for which samples are made on products

presenting a risk increased contamination. They include also fraudulent practices. Sampling is done at predetermined criteria in order in increase the probability of detection.

The system of monitoring plans and control plans (SPCP) also allows for surveys which are conducted in case of need for data on a contaminant / product pair or validation of analytical method. They are called exploratory plans.

12. Constraints and challenges

Implementing such a system does not only have benefits but also constraints and challenges beyond meeting the legal obligation. Risk based controls are important in ensuring effective controls and efficient use of resources -in designing, developing and implementing risk-based planning processes

1. Balance between consumer, political and economic risks
2. Cost-effective way of providing reasonable assurances and increasing compliance by means of effective prioritisation
3. Need to have sufficient knowledge of activities to be controlled
4. To ensure adequate level of controls in low risk FBO/activities
5. Need to keep low risk operations under review to ensure no significant changes missed
6. New riskier product lines introduced without notification of authorities
7. Relationship between central and local authorities
8. Co-operation and integration
9. Intelligence sharing with partners
10. Flexibility
11. Determining the frequency of controls (other parameters as well)
12. Adjustment (long term, short term)
13. Suitability for all types of planning at all levels
14. Distortion of risk categorisation by media/political/interest group intervention
15. Pressure to relax or to increase control activity on certain sectors or commodities in response to media coverage of issues or lobbying
16. Certification requirements are sometimes not compatible with risk-based approach

17. International acceptance of risk-based controls

*In the context of the EU, **Official Controls** are defined as any form of control performed by the Competent/Regulatory Authority (ies) in a country to verify compliance with the legislation on food and feed, as well as the provisions relating to animal health and animal welfare rules on a risk basis and with appropriate frequency. taking account of identified risks associated with animals, feed or food, feed or food businesses, the use of feed or food or any process, material, substance, activity or operation that may influence feed or food By extension, any form of control **performed by the competent authority of a third country** to verify compliance with the legislation on food and feed, and any other sanitary or phytosanitary legislation, in particular in the context of international trade and the protection of local consumers (e.g. official controls performed in Europe on imports from third countries, such as the analysis of pesticide or antibiotic residues, verification of phytosanitary certificates at the borders or the search for regulated pests in plants) that is required to export commodities to the EU and that is validated by the European Commission.* (Regulation (EC) 882/2004).

13. Microbiological Criteria

Microbiological Criteria (MC) have been used in food production and the food regulatory context for many years; According the Codex (CAC, 2013) "A microbiological criterion is a risk management metric which indicates the acceptability of a food, or the performance of either a process or a food safety control system following the outcome of sampling and testing for microorganisms, their toxins/metabolites or markers associated with pathogenicity or other traits at a specified point of the food chain"

In addition, the components of MC for foods include

- The purpose of the microbiological criterion;
- The food, process or food safety control system to which the microbiological criterion applies;

- The specified point in the food chain where the microbiological criterion applies;
- The microorganism(s) and the reason for its selection;
- The microbiological limits (m, M) or other limits (e.g. a level of risk);
- A sampling plan defining the number of sample units to be taken (n), the size of the analytical unit and where appropriate, the acceptance number (c);
- Depending on its purpose, an indication of the statistical performance of the sampling plan; and
- Analytical methods and their performance parameters.

As a management metric MC can be used to decide the acceptance or rejection of a consignment or a lot making it is a useful instrument to use in official controls.

14. Tools to develop a MANCP

14.1 Calculation of Sample size

The calculation of sample size (population) comprise the step outline below.

14.1.1 Severity Effect

Level 1: low toxicity - low or negligible: in general, for parameters not directly related to food safety or molecules classified in group 4 of the International Agency for Research on Cancer (IARC) classification

Level 2: probably toxic - probably dangerous: this is the default value for lack of information or for molecules in group 3 of the IARC classification

Level 3: toxic - Hazardous: concerns toxic agents or infectious agents, concerns molecules of group 2 of the IARC classification (2a and 2b).

Level 4: very toxic - very hazardous: for toxic food agents and agents causing low-dose infections and / or a high risk of mortality or group 1 of the IARC classification

14.1.2 Prevalence

The occurrence/prevalence in the population (O) specifies o scale from 1 to 4 the extent to which the hazard under consideration (exceeding the limits of the defined molecules e.g; MRL) is likely to pose a problem for the foodstuffs concerned different in different matrices).

The occurrence is the number of times an event occurs:

Level 1: very low probability of occurrence: low detection and no exceedance of the the standard.

Level 2: low probability of occurrence: low detection and limited exceedance of the standard or regular detection but not of exceeding of the standard (default value in case of insufficient data).

Level 3: average probability of occurrence: exceedances of the standard occurs regularly or frequent detection but few exceedances of the standard

Level 4: high probability of occurrence: frequent detections of exceedances of the standard.

14.1.3. Contribution

Contribution to total contamination (C) determines whether a given matrix is an important source of total consumer exposure to the hazard (scale of 1 to 4):

Level 1: limited: because the population (sampled matrix) is consumed insignificantly and / or other matrices account for a significant part of the overall exposure to the hazard under consideration

Level 2: Average , (default value if no precise information).

Level 3: Significant contribution because the population (sampled matrix) is consumed significantly and / or contributes substantially to the overall exposure

Level 4: Very important contribution because the population (sampled matrix) is consumed very significantly and / or is potentially the sole source of exposure.

14.1.4 Confidence level

Confidence level (NC) = confidence interval. It takes into account:

- the scale of risks according to the hazard and the exposure, hence the harmful effect,
- occurrence in the population (O),
- the contribution to total contamination (C)

According to the formula:

NC = (Harmful effect) + (O) x (C)

Depending on the result, it is possible to define the confidence level, which is a parameter to be taken into account during the statistical calculations with Win Epidemiology to calculate the number of samples to be taken. (Level of confidence on the software)

- When the score is between **2 and 6**, it is considered that there is limited contamination for the foodstuffs considered: the confidence interval is therefore 90%
- When the score is between **7 and 12**, it is considered that there is an acceptable contamination for the foodstuffs considered: the confidence interval is therefore 95%
- When the score is between **13 and 20,** the considered food is considered to be a substantial source of contamination of the food chain with a hazardous contaminant: the confidence interval is therefore 99%

The percentage of the NC, Level of Confidence, is to be taken into account in the statistical calculations with Win Epidemiology to calculate the number of samples to be analysed.

The level of prevalence to be controlled (NPC) is the level of contamination that is detected with a certain level of confidence. This is the value to be entered at the "Expected prevalence" level of the Win Epidemiology software.

This value is defined according to the harmful effect, proportional to the prevalence. Logically, the higher the danger, the less one accepts the occurrence.

The NPC is divided into 4 levels of risk:

- Level 1: adverse effect: not severe: NPC = 10%
- Level 2: adverse effect: probably severe: NPC = 5%

- Level 3: adverse effect: severe: NPC = 2.5%
- Level 4: adverse effect: very severe: NPC = 1%

After defining the number of batches in the population, the level of prevalence to be monitored, the accepted error and the confidence level, it is therefore possible to determine the number of samples to be tested per population using statistical calculations.

15. Calculations using a mathematical formula

$n = [1 - (1 - alpha)^{1/NPC}] * [N - (NPC - 1)/2]$

where n is the sample size required to have the probability *alpha* that at least one non-conform result is detected in the sample

alpha is the confidence level

N is the size of the sampling population

NPC prevalence level of controlled hazards

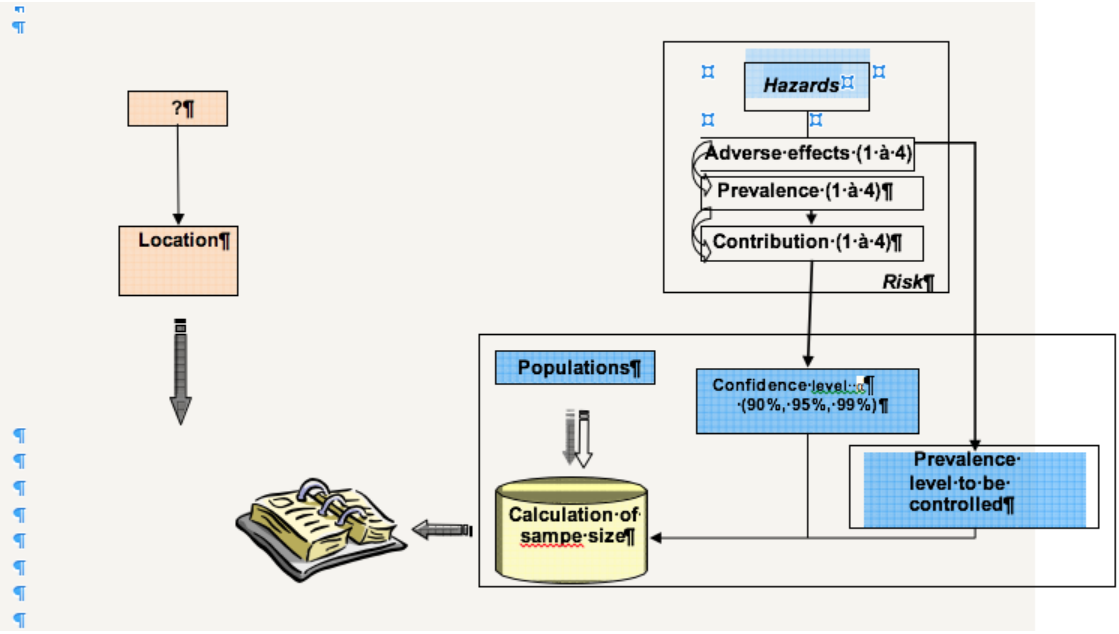


Figure 2 calculation procedure for sample size base of risk (according to AFSCA)

16. Use of software

The calculation of the number of samples to be taken per matrix is based on a statistical approach of various parameters which are defined during the risk assessment. These parameters allow to define the risk. **A fre**e software can be used to calculate the number of samples, it is **Win Epi** which has been developed to solve simple epidemiological problems http://www.winepi.net/uk/index.htm.

17. Food Business Operators Inspections

Achievement of Food safety requires a comprehensive and integrated planning of controls of all Food Business Operators (FBOs) from the farm to fork (producer, processor, transporter, distributor). FBOs are primarily responsible for food safety of the product they release on the market. Depending on whether their practices are the level of risk can increase or decrease hence the programming of controls should therefore include information of FBOs, from primary production to distribution. Where samples will be drawn. The concept of a company's overall risk assessment is the basis for the determination of inspection the frequency.

Therefore, there is need to implement control of operators based on the risk of individual businesses, parameters to take into account may include; self-check system, the types of foodstuffs, activities and processes, layout and facilities, history management and fraud, size and type of consumer (ACCS, 2014). This procedure does not rely on complicated theories of risk, but on pragmatic assessment of the hazards, it is an objective and reproducible tool.

18. Control laboratories

On the basis of the list of hazards previously established, it will be necessary to identify laboratories capable of undertake the required analyses for the chemical, microbiological or environmental hazards. Usually laboratories are part of the Competent/Regulatory set up or are designated to conduct controls analyses.

In designating the laboratories care should be taken to select those with quality management system based on ISO 17025 and or participating in in proficiency testing schemes for the relevant parameters. These may be be public or private in order to use efficiently the potential available in a country. -

Other consideration will include method validation and measurement uncertainty.

19. Residues Monitoring –EU Export for product of animal origin

Directive 96/23/EC requires national authorities to draw up and implement residue control plans, sets out key obligations for primary producers and processors of primary produce and deals with infringements and penalties. Also, it requires countries exporting to the EU to have equivalent controls including residue control plans that are approved by the EU. In the EU specific legislation protects consumers from exposure to potentially harmful residues of veterinary medicines, pesticides and environmental contaminants in food of animal origin. EU countries implement residue monitoring plans for the detection of illegal use of substances in animal production and the misuse of authorised veterinary medicines. They must also take appropriate action to minimise the recurrence of such residues in food. The European Commission approves the submitted residue monitoring plans every year.

The monitoring plan for residues of veterinary medicinal products, pesticides and other environmental contamination are designed to meet the EU import requirements.

A Residue Monitoring Plan gives guarantee that the system put in place by the exporting country is equivalent to the importing country.

The monitoring plan must include all production (primary/farm/suppliers of primary producers) and procurement for processing aids and the approved establishments processing the products meant for export to the EU.

The objective of the plan is:

- To detect any illegal treatment (s) / abuse of substances in the production of food of animal origin
- To comply with the Maximum Residue Limits (MRL) for Veterinary drugs, pesticides and other pharmacologically active substances and the Maximum Limits (ML) for heavy metals and other environmental contaminants in the food of animal origin as per international requirements.

- To communicate and carry out follow-up actions in the event of detection of illegal treatment (s) of pharmacologically active substances or the detection of residues higher than the acceptable limits, in food of animal origin.

EU countries must also sample imported food-stuffs (Regulation 136/2004). Food consignments containing residues above EU maximum limits or levels for veterinary medicines, pesticides and contaminants or that contain residues of substances without EU limits will be rejected.
In the case of a residue problem, the EU or individual EU countries may reinforce point of import checks (Article 24, Directive 97/78/EC).

19.1 Legal basis.

As for the case of risk-based monitoring plan, the legal basis in this case is laid down in Directive 96/23). and Regulation 136/2004). These documents provide guidance on the residues, the matrices, the sampling plans and the methods of analysis requirements.

19.2 Sampling Plan

The establishments must be approved to process the food of animal origin for export from the identified population of animals or primary production sites, and they have to be assessed and approved by the Competent /Regulatory Authority. The sampling plan is based on the animal and or their products from eligible premises (FBOs.
The sampling plan is this case are defined by the EU and need to be applied as such. The parameters to be tested in the samples are also specified in the sampling plans. The number of samples will be proportionate to the size/production of the FBOs involved in the export to the EU.

20. Worked examples

Risk based sampling

Contamination by a microbiological pathogen

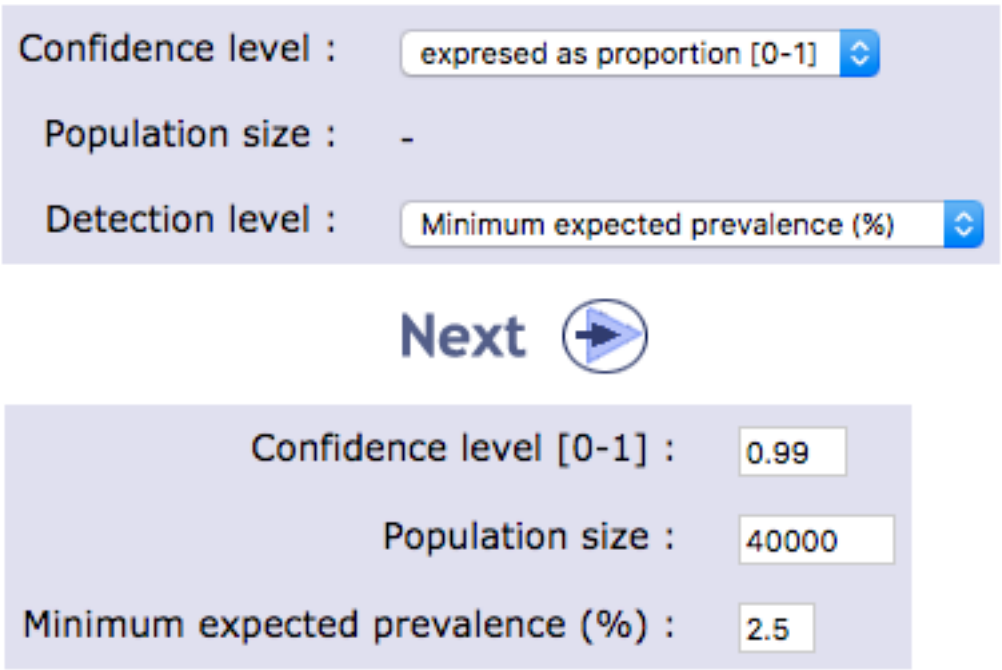
Case statement

A significant proportion of the national beef production is intended for the production of minced meat and meat preparations; the latter being intended to be eaten raw. These may be contaminated with certain bacteria such as *E.Coli 0157:H7* (s a higa toxin producing E.coli)-STEC. The symptoms of the disease, include acute gastroenteritis (Shiga toxin-producing *E. coli* (STEC) may also be referred to as verocytotoxin-producing *E. coli* (VTEC) or enterohemorrhagic *E. coli* (EHEC). STEC strains can cause serious illness in humans by producing toxins that can severely damage the lining of your intestines and kidneys. Infection with STEC strains can lead to serious complications like hemolytic uremic syndrome (HUS), which sometimes is fatal.5% of cases (mostly in infants, the elderly, or immunocompromised people). That is why the Competent Regulatory Authority has decided to control the prevalence of *E.Coli 0157:H7* in minced meat and bovine meat preparations in the retail sector (supermarkets and hypermarkets) and restaurants (fast-food restaurants and sandwich outlets).

Annual volume of minced beef meat in the retail/fast food sector	10,000
Average batch size of mince meat	0,25 tonnes (=quantity bought by the supermarket/ fast food outlets
Prevalence of *E. Coli 0157:H7*	Average to high
Adverse health effects	Symptoms of *E.coli* O157:H7 infection include severe diarrhoea (often bloody) and abdominal cramps. a fever or vomiting. Symptoms usually begin 2 to 5 days after exposure to the bacteria. Sometimes people infected with *E. coli* O157 have no symptoms at all, but can still pass the bacteria to others. In some people, especially in children under 5 years old, the elderly, and immunocompromised. *E.coli* O157:H7 infections can cause a complication called Hemolytic Uremic Syndrome (HUS). About 2 – 7% of *E. coli* O157:H7 infections lead to HUS. HUS occurs when the *E. coli* O157:H7 toxin destroys red blood cells. HUS can lead to kidney failure, neurologic damage, and in some cases, death. Approximately 5 – 10% of HUS cases are fatal.
Consumption of beef and derived products in the country	Consumption of minced meat is significant especially in big cities

Determination of parameters

Population size (number of batches)	N= 10, 000/0.25 = 40,000 batches
Level of prevalence to be controlled (NPC)	NPC=2.5% (very severe)
Confidence level	NC= Harmful effect + (OxC)= 3+(3x4)=15
Alpha confidence level	99% as >15



Confidence level [0-1] :	0.99
Population size :	40000
Expected minimum prevalence (%) :	2.50%

N. of infected animals to detect :	1000
Needed sample size :	**182**
Sampling fraction :	0.46%

The number of samples to collect is in thjs case182. When checking at the table below

Table 2: Minimum sample size for confidence levels of 95% and 99% according to the batch size.(FAO, 2008)

Number of units in lot	P = 95% (confidence level) % level of detection □ efficacy of detection					P = 99% (confidence level) % level of detection □ efficacy of detection				
	5	2	1	0.5	0.1	5	2	1	0.5	0.1
25	24*	-	-	-	-	25*	-	-	-	-
50	39*	48	-	-	-	45*	50	-	-	-
100	45	78	95	-	-	59	90	99	-	-
200	51	105	155	190	-	73	136	180	198	-
300	54	117	189	285*	-	78	160	235	297*	-
400	55	124	211	311	-	81	174	273	360	-
500	56	129	225	388*	-	83	183	300	450*	-
600	56	132	235	379	-	84	190	321	470	-
700	57	134	243	442*	-	85	195	336	549*	-
800	57	136	249	421	-	85	199	349	546	-
900	57	137	254	474*	-	86	202	359	615*	-
1 000	57	138	258	450	950	86	204	368	601	990
2 000	58	143	277	517	1553	88	216	410	737	1800
3 000	58	145	284	542	1895	89	220	425	792	2353
4 000	58	146	288	556	2108	89	222	433	821	2735
5 000	59	147	290	564	2253	89	223	438	840	3009
6 000	59	147	291	569	2358	90	224	442	852	3214
7 000	59	147	292	573	2437	90	225	444	861	3373
8 000	59	147	293	576	2498	90	225	446	868	3500
9 000	59	148	294	579	2548	90	226	447	874	3604
10 000	59	148	294	581	2588	90	226	448	878	3689
20 000	59	148	296	589	2781	90	227	453	898	4112
30 000	59	148	297	592	2850	90	228	455	905	4268
40 000	59	149	297	594	2885	90	228	456	909	4348
50 000	59	149	298	595	2907	90	228	457	911	4398
60 000	59	149	298	595	2921	90	228	457	912	4431
70 000	59	149	298	596	2932	90	228	457	913	4455
80 000	59	149	298	596	2939	90	228	457	914	4473
90 000	59	149	298	596	2945	90	228	458	915	4488
100 000	59	149	298	596	2950	90	228	458	915	4499
200 000+	59	149	298	597	2972	90	228	458	917	4551

Determination of sample to be taken in case of a phytosanitary risk

Country A exports mangoes to country B. The fruit fly is a pest that is well established in country A but absent in country B. Country B requires country A to provide a guarantee that the controls performed when exporting mangoes are severe enough to limit the risk of the fruit fly contaminating the batches intended for export. Visual controls are performed by country A following a sampling plan based on the risk, given that on average 2% of fruits are infested. We want to ensure that on average only 5% of infested fruit may eventually escape control.

Determining the value of the parameters

Size of the batch of fruit for export: 5000
Prevalence level to be controlled: 2%%
Prevalence level to be controlled: 3%%

Confidence level: 95% (in this case, the confidence level is imposed and is not linked to a confidence index that depends on the severity of the hazard, its prevalence and the contribution of the commodity to exposure. The confidence level of 95% means that on average only 5% of infested fruit will not be detected).

Determination of sample size

For 2% of controlled prevalence you can use table 2 above it give **147 fruits** from a batch of 5000 fruits. In case on 3% prevalence level to be controlled (not in the table) WinEpi gives **98 fruits.**

Detection of contamination with a chemical agent

Country B exports maize to country A that may be contaminated with fumonisin (a group of mycotoxins particularly present in maize). This maize is used for human consumption. The maximum limit (ML) of fumonisin that is permissible is 2 mg/kg for flour and 4 mg/kg for grains. You are asked to help the CA in country A to prepare a targeted control plan to verify the compliance of maize imports from country B.

What data are available? Annual volume of maize imported by country A:	21,000 tonnes
Average size of a batch of maize:	30 tonnes (transport by road, in lorries)
Prevalence of fumonisin (FB1, FB2 et FB3) in the maize:	High (many cases of non-compliance reported over previous years)
Toxicity of the fumonisin:	FB1 and FB2 are mycotoxins that are regulated due to their risk for human health. FB1 is classified in the group 2B by IARC (possibly carcinogenic for humans) The TDI for FB1 = 2 µg/kg p.c. The Maximum Limit for FB1 + FB2 in maize used for human consumption = 2 µg /kg (Regulation (EC) 1881/2006)
Consumption of maize and derived products in country A:	Average consumption of maize flour = 300/day Consumption is high.

Determination of the value of the parameters:
Size of the population (or number of batches, N): N = 21,000/30 = 700 batches
Level of prevalence to be controlled (NPC) NPC = 5% (as probably serious hazard)
Confidence Index (IC): IC = G + (P x C) = 2 + (3 x 2) = 8
Where:

- G = 2 (probably serious hazard)
- P = 3 (frequent detection with possible exceedances of the norm)
- C = 4 (high exposure to the hazard via maize flour)

Alpha confidence level: 95% (as IC between 13 and 20)

Sampling: Detection of Disease (3)

Data

Target is to determine minimum sample size needed to dected a disease (or infection) in a population:

Confidence level % :	95%
Population size :	700
Expected minimum prevalence (%) :	2.00%

Results

N. of infected animals to detect :	14
Needed sample size :	**134**
Sampling fraction :	19.14%

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Sampling: Detection of Disease (2)

Confidence level % :	95
Population size :	700
Minimum expected prevalence (%) :	2.0

Note: Use dot (.) as decimal separator

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If the prevalence level is set at 1%

Sampling: Detection of Disease (3)

Data

Target is to determine minimum sample size needed to dected a disease (or infection) in a population:

Confidence level % :	95%
Population size :	700
Expected minimum prevalence (%) :	1.00%

Results

N. of infected animals to detect :	7
Needed sample size :	**243**
Sampling fraction :	34.71%

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Residue monitoring plan for EU export

Monitoring of Chemical Residues in Poultry Meat

Your country is a chicken producer and you want to export part of your production to the countries of the European Union. To do this, you must comply with the requirements of Directive 96/23:
Families and groups of contaminants to be monitored (p 23 and 24)
Sampling strategy (p 25)
Sampling levels and frequency (p 27)
Your annual production is 1,000,000 tons per year, and all production is likely to export.
Your country is made up of 5 provinces, with the following production volumes

Province 1	500000
Province 2	100000
Province 3	100000
Province 4	100000
Province 5	100000

(all poultry produced in a province are considered to be slaughtered in the same province)

QUESTIONS

What is the protocol to be implemented?

- Target population and sampling unit
- List of contaminant families and groups to be controlled
- Sampling plan: sampling strategy, sample size, sample distribution by family / group of contaminants, method of distribution of sampling in the territory, targeting criteria)

What extrapolation can be made of the non-compliance rate calculated from the sample, to the general population of chickens?
Target population: all broilers
Sampling unit: chicken

Type of animal, feeding-stuffs 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							

GROUP A — **Substances having anabolic effect and unauthorized 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 Annex IV to Council Regulation (EEC) No 2377/90 of 26 June 1990

GROUP B — **Veterinary drugs (1) and contaminants**

(1) Antibacterial substances, including sulphonomides, 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

(a) Organochlorine compounds including PcBs

(b) Organophosphorus compounds

(d) Chemical elements

(d) Mycotoxins

(e) Dyes

(f) Others

Group A

The samples must be targeted taking into account the following minimum criteria for the fattening system, any information available to the Member State and any evidence of misuse or abuse of such substances

Group B

Unless random sampling may be justified by the Member States when submitting their national residue monitoring plan to the Commission, all samples shall be targeted according to the criteria laid down in the Commission Decision in Article 15 paragraph 1

Group A

Group A: 50 % of the total samples
The equivalent of one fifth of these samples must be taken at farm level.
Each sub-group of Group A must be checked each year using a minimum of 5 % of the total number of samples to be collected for Group A.
The balance will be allocated according to the experience and background information of the Member

- number of samples: 0.5x5000 = 2500
- minimum required in each subgroup: 0.05x2500 = 125
- or a balance of: 2500- (6x125) = 1750

Group A	**Minimum required**	**With balance distribution**	**Poultry farms (1/5)**	**Abattoir (4/5)**
A1	125	275	55	220
A2	125	275	55	220
A3	125	275	55	220
A4	125	275	55	220
A5	125	275	55	220
A6	125	1125	225	900
Balance	1750	0	0	0

Group B

Group B 50% of the total samples

30 % must be checked for Group B 1 substances,
30 % must be checked for Group B 2 substances
10 % must be checked for Group B 3 substances.

The balance will be allocated according to the situation of the Member State

Total number of samples: 0.5x5000 = 2500
number of samples in group B1: 0.3x2500 = 750
number of samples in group B2: 0.3x2500 = 750
number of samples in group B3: 0.1x2500 = 250
balance of: 2500- (750 + 750 +250) = 750

Group B	Minimum required	With balance distribution
B1	750	1000
B2	750	
B2a	150	150
B2b	300	350
B2c	150	200
B2d	150	250
B3	250	
B3a	150	300
B3b	50	150
B3c	50	100
Balance	750	0

Distribution of samples on the territory

- on a pro rata basis
- Thus
  - 50% of samples in province 1
  - 20% in the province 2
  - 10% in provinces 3, 4 and 5

					Province 1		**Province 2**		**Province 3**		**Province 4**		**Province 5**	
					0.5		0.2		0.1		0.1		0.1	
Group A	Minimum required	With bal. distribution	Farm(1/5)	Abattoir (4/5)	Farm(1/5	Abattoir (4/5)	Farm(1/5	Abattoir (4/						
A1	125	275	55	220	28	110	11	44	6	22	6	22	6	22
A2	125	275	55	220	28	110	11	44	6	22	6	22	6	22
A3	125	275	55	220	28	110	11	44	6	22	6	22	6	22
A4	125	275	55	220	28	110	11	44	6	22	6	22	6	22
A	125	275	55	220	28	110	11	44	6	22	6	22	6	22
A6	125	275	55	220	28	110	11	44	6	22	6	22		22

Targeting criteria:

- Emergency slaughter,
- High mortality in livestock,
- Recent Use of Pharmacological Products
- Farming in an area of environmental contamination

Inference to the population

- If breakdown by provinces and risk levels, extrapolation to the total population, by weighting the prevalence calculated in each sub-population according to the risk of contamination

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