World Health Organization

Food and Agriculture Organization of the United Nations

International Food Safety Authorities Network (INFOSAN)

13 March 2009

INFOSAN Information Note No. 1/2009 - Monitoring for Chemicals in Foods

Monitoring for Chemicals in Foods

SUMMARY NOTES

- The contamination of food by chemical hazards is a worldwide public health concern and is a leading cause of trade problems internationally.
- The Codex Alimentarius Commission establishes maximum residue limits for pesticides and veterinary drugs, and maximum limits for contaminants on the basis of Joint FAO/WHO risk assessments and provides guidance on residue monitoring activities.
- National authorities responsible for food safety have the role of working with food producers to ensure levels of chemical contamination are minimized, to monitor for the presence of chemicals in food and to undertake necessary follow up activities proportionate to the public health risk, as required.

Introduction

Chemicals that are present in foodstuffs can be intentionally added (i.e. food additives, or the illegal addition for adulterant purposes), are present as residues from defined uses (e.g. pesticides and veterinary drugs) or are contaminants (formed during production, processing, storage or stemming from the environment). Governments operating a food safety programme do so to ensure that food available to the population is safe and compliant with established standards. An effective food safety system should minimize the levels of these chemicals through the application of good practices and guidelines, such as Good Manufacturing Practice, Good Agricultural Practice, Guidelines on responsible and prudent use of antimicrobial agents in veterinary medicine[1], while also pursuing the reduction of exposure to environmental contaminants in accordance to the principle of As Low As Reasonably Achievable (ALARA). Individual jurisdictions will thus establish maximum residue limits (MRL) or Maximum limits (ML) to establish the level of chemical that is acceptable in the food.

Internationally, the Codex Alimentarius Commission (CAC) establishes maximum residue limits (MRLs)[2] for pesticides and veterinary drugs, on the basis of Joint FAO/WHO Meeting on Pesticide Residues (JMPR) and the Joint FAO/WHO Expert Committee on Food Additives (JECFA) risk assessments[3]. The CAC also establishes maximum limits (ML)[4] for contaminants in food taking JECFA risk assessments into account. Codex MRLs and MLs serve as an important basis for national MRLs and MLs in order to promote greater consistency, facilitate the international trade of foods that may contain such chemicals and to provide guidance to countries with limited resources available to undertake risk assessments. CAC, as well as the

[1] Guidelines on responsible and prudent use of antimicrobial agents in veterinary medicine (www.oie.int/eng/normes/mcode/en_chapitre_1.6.7.htm)

[2] Codex Maximum Residue Limits for Veterinary Drugs can be found on Codex website: (www.codexalimentarius.net/mrls/vetdrugs/jsp/vetd_q-e.jsp and MRLs for pesticides on www.codexalimentarius.net/mrls/pestdes/jsp/pest_q-e.jsp)

[3] See Risk Analysis Principles applied by the CCRVDF – Codex Procedural Manual available at www.codexalimentarius.net/web/procedural_manual.jsp

[4] See www.codexalimentarius.net/download/standards/17/CXS_193e.pdf and levels set in commodity standards www.codexalimentarius.net/web/index_en.jsp

World Organisation for Animal Health (OIE), establishes guidance on the conduct of different types of residue monitoring activities[5].

No government agency can routinely monitor for all residue/commodity combinations nor is it necessary to do so in order to protect consumers. With a clear understanding of toxicological parameters and potential exposure it is possible to quantitatively identify concerns that have the greatest impact on public health. The adoption of such a system will allow jurisdictions to focus monitoring activities to areas of priority.

Programme Definitions

Activities carried out as part of a residue and contaminant control programme include monitoring, directed sampling, compliance testing, pre-market surveys, post-market surveys and all other data gathering activities. A brief summary of the different types of activities are presented below:

Monitoring is a statistically-based, unbiased, random sampling, processing and analysis of samples to provide profile information on the occurrence and/or levels of chemical residues in pre-defined, normal sample populations. In general, no direct enforcement action is taken on the basis of monitoring alone. Monitoring activities are particularly useful for discerning residue trends and identifying potential areas where directed sampling might be indicated. In this type of program, trace-back activities to identify the source of the residue should be undertaken. Total Diet Studies are an example of a chemical monitoring programme[6]. The WHO Global Environment Monitoring System - Food Contamination Monitoring and Assessment Programme (GEMS/Food)[7], provides information on levels and trends of contaminants in food, their contribution to total human exposure, and significance with regard to public health and trade.

Directed sampling is focussed, directed at targeted sample populations (e.g. commodity types, or geographical areas) to investigate and verify any suspected problems of potential health risk suggested in the monitoring programme. Directed sampling is investigative in nature, and can trigger detention of product pending risk assessment and compliance action. All results which violate applicable standards must be confirmed by prescribed confirmatory analysis techniques before any follow-up control action is taken. In these cases, trace-back activities should be implemented.

Compliance testing is directed at specific samples suspected of not complying with specific regulations and guidelines governing the sale and distribution of food. The product is detained until the test results are available to determine the appropriate disposition. Compliance testing is a regulatory control measure to prevent the marketing, or to support the removal from the market of a product that poses a health risk to the consumer.

Special or pilot surveys are used to gather information about the occurrence of residues not meeting the requirement of other programme components (i.e. monitoring, compliance). For example, initial surveys or surveys for components outside of the health and safety criteria might be included here. These are usually limited in scope and duration.

Targeted sampling or “blitzes” are used to obtain a snapshot in time. The scheduling of blitzes is unannounced. For example, a blitz may allow for the sampling of every herd presented for slaughter for a specified, usually short, period of time not exceeding 2 to 6 weeks.

[5] Recommended International Code of Practice for Control of the Use of Veterinary Drugs (CAC/RCP 38-1993 (Available at: www.codexalimentarius.net/download/standards/46/CXP_038e.pdf) and Guidelines for the Establishment of a Regulatory Programme for Control of Veterinary Drug Residues on Foods (CAC/GL 16-1993)[5] (a revised edition is currently under elaboration).(Available at: www.codexalimentarius.net/download/standards/46/CXP_038e.pdf)

[6] Further information is available at: www.who.int/foodsafety/chem/gems/en/index3.html and the INFOSAN Information Note: Total Diet Studies: A Recipe for Safer Food. Available at: www.who.int/foodsafety/fs_management/infosan_archives/en

[7] Further information is available at: www.who.int/foodsafety/chem/gems/en

Legal sampling is undertaken for specific situations where legal action is the anticipated follow up action. Certain additional criteria are demanded during the sampling submission and laboratory testing of these samples. Adherence to all quality assurance measures is essential. Legal advice should be sought prior to the initiation of such activities.

Regulatory Authority

All of the monitoring activities described above must be carried out under the responsibility of the regulatory authorities in place. Countries should establish the competent regulatory authority under which it undertakes sample testing and the establishment of standards for the evaluation of any laboratory result. The establishment of MRLs and MLs should be carried out in a scientific manner that is open and transparent to both domestic and international stakeholders.

The World Trade Organization Agreement of Sanitary and Phytosanitary Measures (SPS Agreement) recognizes that international standards, such as the OIE standards for animal health and zoonoses and Codex standards, including MRLs for veterinary drug, pesticide residues and MLs for contaminants, are generally based on risk assessments using scientific principles and methods and Codex standards are the international (global) benchmark for food safety. National measures and regulations consistent with Codex standards are deemed to meet the requirements of the SPS Agreements. The SPS Agreement recognizes that individual nations can set more restrictive limits, however in doing so, countries should provide scientific justification that such more restrictive measures are required to achieve their appropriate level of protection, as well as demonstrate that the measure taken is based on an assessment of risk.

Sampling

Sampling should be designed to focus on and select foods for testing on the basis of estimated risk. As such, food items consumed in greater quantities, those that may be contaminated to a higher degree should be sampled and tested with higher frequency. All sampling plans must consider the statistical relevance of the number of samples analysed. The sampling plan should lead to a well defined sampling schedule which would also identify the follow up activities that will occur in relation to the sample including the testing that is planned. Internationally agreed sampling plans, e.g. within Codex, should preferably be used, if existing for the substance and commodity in question.

Determining inclusion of compounds in monitoring activities

For inclusion, there must be a potential for the chemical, be it a veterinary drug, agricultural chemical or environmental pollutant to leave a residue in food. Therefore a good knowledge of the use of veterinary biologicals, agricultural practices and environmental pollution is critical in the determination of the compounds to include in the monitoring programme. Since all compounds cannot be assessed at the same time based on resources available, a prioritization process based on a risk estimate is conducted to determine the compounds for inclusion in the monitoring programme.

The risk prioritization of residues in foods is an ongoing process. As new compounds are used and as monitoring information becomes available, the inclusion of specific residues should be reviewed periodically. Within these revisions, national authorities should consider factors such as the potential occurrence of all sorts of residues in foods including those that result from the deliberate addition to the food and those that are present from incidental exposure. The primary focus of a monitoring plan is to ensure the safety of the food supply and to demonstrate to the population that the food supply is safe, whether or not the compounds monitored are intended for direct use in foods or residues result from indirect use.

Planning cycle

Once the residue programme content is identified and ranked from the highest to the lowest, three important factors have a direct impact on the planning cycle of the chemical residue monitoring programme.

The first factor is related to the availability of an appropriate analytical method. If there are residues anticipated but their detection is not possible then clearly a monitoring programme could not be implemented. Under these circumstances the need for an appropriate analytical method would be identified as a research need leading to method development activities.

The second factor is the availability of the products to be assessed in the programme. Some products may be available on a seasonal basis requiring that the monitoring programme be adjusted accordingly.

The third factor is the evaluation of information and data generated from the previous monitoring activities. After testing programmes have been in place for some time, e.g. a minimum of three years, the accumulated data is evaluated to determine if the continuation of the sampling and testing programme is still warranted. The time period will be considerably longer for those programmes in which the sampling frequency is low, e.g. less than 300 samples per year. Thus after an initial monitoring phase of three consecutive years, if a statistically valid sample size indicates no residue findings, then the annual programme may be discontinued until there is a change in usage, tolerance or analytical sensitivity which would warrant re-institution of the analysis.

Implementation of a Sampling Plan

At the beginning of this document, definitions are established for the different types of activities that can be carried out by a Regulatory Authority. A monitoring plan is based on a random sampling of the food supply. Care must be taken at every step of the process to ensure that different biases are not introduced in to the execution of the plan. Care must be taken in the following general areas:

1) **In ensuring that representative sampling of a commodity occurs.** As such a green house tomato belongs to a different population than field tomatoes. Each should be considered differently in the design of the sampling plan.
2) **In eliminating the potential of bias when the samples are collected.** If field inspection staff has suspicions related to specific samples they should not be collected in the framework of a monitoring plan. These types of samples are best collected under a targeted plan.
3) **In the laboratory to eliminate bias based on previous history.** If using third party contract laboratories, care must be exercised to eliminate the potential for conflict of interest.
4) **In order to facilitate the evaluation of the results and ensure appropriate follow-up.** For example, care must be taken in recording all of the needed information regarding the origins of the sample.

Risk Management Considerations and Enforcement Actions

All findings of measurable chemical residues or contaminants in food products must be evaluated to determine if there has been a violation of applicable standards and the need for corrective actions. Follow-up activity should be proportional to the potential risk to human health resulting from the potential dietary exposure. Actions can include follow-up inspections, further directed sampling according to a surveillance plan, seizure and recall of products when the health risk is considered unacceptable. Follow-up actions vary according to the magnitude of the health risk, all with the objective of preventing any repeat occurrence to minimize consumer exposure to products contaminated above legal limits, thereby representing a potential risk to human health.

Evaluation and Reporting of the Results

National Authorities should report the results of monitoring activities. In the framework of this reporting, a clear description of the intent of these activities should be stated as well as a clear description of the process/methodology used. These reports should be produced in a timely manner in order to aid in the decision making process on whether to initiate targeted monitoring

activities in accordance with the legislative requirements. The report should also include a discussion of the follow-up action if applicable. The aim of this report should be to increase transparency for regulators and regulated parties. The reports may also be useful for refined exposure and risk assessments of the chemicals monitored, at the national and the international level.

References and further information

Joint FAO/WHO Expert Committee on Food Additives (JECFA) - www.who.int/ipcs/food/jecfa/en/ and www.fao.org/ag/agn/agns/jecfa_index_en.asp

Joint FAO/WHO Meeting on Pesticide Residues (JMPR) - www.who.int/ipcs/food/jmpr/en/

FAO web site on chemicals in food - www.fao.org/ag/agn/agns/chemicals_en.asp

WHO web site on chemical risks in food - www.who.int/foodsafety/chem/en/

OIE web side on the role of the veterinary services in food safety and responsible and prudent use of antimicrobial agents in veterinary medicine - www.oie.int/eng/normes/mcode