Policy article

Drug Testing and Analysis

Published online in Wiley Online Library

(www.drugtestinganalysis.com) DOI 10.1002/dta.1352

Risk assessment and risk management at the Canadian Food Inspection Agency (CFIA): A perspective on the monitoring of foods for chemical residues

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The Canadian Food Inspection Agency (CFIA) uses 'Ranked Risk Assessment' (RRA) to prioritize chemical hazards for inclusion in monitoring programmes or method development projects based on their relative risk. The relative risk is calculated for a chemical by scoring toxicity and exposure in the 'risk model scoring system' of the Risk Priority Compound List (RPCL). The relative ranking and the risk management options are maintained and updated in the RPCL. The ranking may be refined by the data generated by the sampling and testing programs.

The two principal sampling and testing programmes are the National Chemical Residue Monitoring Program (NCRMP) and the Food Safety Action Plan (FSAP). The NCRMP sampling plans focus on the analysis of federally registered products (dairy, eggs, honey, meat and poultry, fresh and processed fruit and vegetable commodities, and maple syrup) for residues of veterinary drugs, pesticides, environmental contaminants, mycotoxins, and metals. The NCRMP is complemented by the Food Safety Action Plan (FSAP) targeted surveys. These surveys focus on emerging chemical hazards associated with specific foods or geographical regions for which applicable maximum residue limits (MRLs) are not set. The data from the NCRMP and FSAP also influence the risk management (follow-up) options. 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 a product representing a potential risk to human health.

Keywords: monitoring; ranked risk assessment; chemical hazards; NCRMP; FSAP

Introduction

In 2000, the World Health Organization (WHO) deemed food safety to be an essential public health function in response to the prevalence of foodborne illnesses and fatalities worldwide.[1] Food safety has been defined as the 'scientifically based prevention of foodborne illness by appropriate handling, preparation, and storage of food'.[2] An effective food safety system requires effective regulations, policies and procedures along the entire farm to fork continuum. It also requires co-operation by a multitude of partners, including governments, international standard-setting bodies such as the Codex Alimentarius Commission, industry (farmers, producers, processors, importers, exporters, and retailers) and individual consumers.

Governments and international standard-setting bodies provide a legislative framework to promote food safety and to ensure fair trade practices. Food safety authorities enforce laws which protect the consumer from unsafe, impure and fraudulently presented food. This is achieved by preventing the introduction of hazards into the food supply and by prohibiting the sale of food that does not meet these standards.[3]

Industry plays an important role in food safety by identifying and managing food safety risks, and by complying with all applicable food safety regulations. Industry works to: (1) identify potential sources of food contamination, (2) update production practices to eliminate risk, (3) comply with the inspection and testing protocols, and (4) recall unsafe products from the marketplace. Industry monitors their production processes to ensure food safety by conducting their own inspection and testing programmes (some over and above what has been mandated by regulations) which also serves to maintain consistency and quality of their products.[5]

Consumers play a role in food safety by storing, preparing, and serving food in a manner that minimizes foodborne illness. Additionally, many consumers are taking greater interest in how their food is produced, processed, and marketed, and they are increasingly calling for their governments to accept greater responsibility for food safety and consumer protection. Confidence in the safety and integrity of the food supply is important to consumers. The occurrence and reporting of foodborne disease outbreaks 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.[5]

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The Canadian context

In Canada, Health Canada and the Canadian Food Inspection Agency (CFIA) share the responsibility for food safety. Health Canada is committed to improving the lives of all of Canada's people and to making the country's population among the healthiest in the world as measured by longevity and lifestyle. The mandate of the CFIA is to safeguard food, animals, and plants, which enhances the health and well-being of Canada's people, environment, and economy.

Effective food safety systems are essential in protecting the health and safety of Canadians, in assuring the safety and quality of Canadian food presented for export, and in ensuring that imported foods conform to Canadian requirements. Global trade in food places considerable obligations on Canada and on the CFIA to ensure that both domestic and imported foods are safe. Effective food safety systems require policy and operational co-ordination at the national level. This includes establishing regulatory measures, monitoring system performance, facilitating continuous improvement, and providing overall policy guidance. Inherent in this framework is a need to sample food during harvest, processing, storage, transport and sale to establish compliance, to contribute data for risk assessments, and to take appropriate enforcement actions.

Relevant and enforceable food laws and regulations are essential to Canada's food safety system. These laws and regulations apply to all foods sold within Canada and are applied equally to domestically produced and to imported foods. The CFIA administers and enforces 13 Acts and Regulations which govern food safety and the sampling and testing activities carried out by the CFIA. The legislation includes enforcement tools which allow for the removal of unsafe food from commerce and the punishment of responsible parties after the fact.

Within the legislative framework, Health Canada is charged with setting regulatory standards and the CFIA enforces the standards. As the CFIA is a risk-based science organization, the level of verification is dependent on the relative risk posed by a specific chemical hazard to the health of Canadians. The main tools used by the CFIA for verification of compliance are robust inspection and sampling/testing programs.

Global perspective

With an expanding world economy, liberalization of the food trade, growing consumer demand for fresh, safe food from anywhere in the world, developments in food science and technology, and improvements in transportation, the international trade in fresh and processed food has and will continue to increase. In addition, innovations in food science have resulted in changes in the trading patterns observed, such that whole foods, food ingredients and components of food ingredients (i.e. animal fat) are crossing national boundaries.

The diversification of Canada's cultural population has resulted in the demand for foods that have not traditionally been part of the Canadian diet. Ethnic foods are traditionally processed or manufactured prior to entry into the country. Though Canada remains a net importer of fresh fruit and vegetables and a net exporter of foods of animal origin (e.g. meat, milk, and eggs), the nature and diversity of foods being imported and exported have increased dramatically.

Canada's access to the global food export markets depends on its capacity to meet the regulatory requirements of importing countries. Creating and sustaining demand for Canadian food products in world markets depends on building the trust and confidence of importers and consumers in Canada's food safety system.

Food safety system with respect to chemical hazards

With respect to chemical hazards, an effective food safety system should minimize the levels of agricultural chemical residues through good agricultural practice (GAP) while also pursuing the reduction of exposure to environmental contaminants in accordance to the principle of As Low as Reasonably Achievable (ALARA). For this reason, a robust food safety system must include a science-based sampling and testing programme to ensure the detection of potential hazards. These hazards may be present in foods at unacceptable levels because of:

- improper agricultural practices
- poor hygiene at all stages of the food chain
- lack of preventive controls in food processing or preparation operations
- misuse of chemicals
- contaminated raw materials, ingredients or water
- inadequate or improper storage
- addition of chemicals for fraudulent gains

The nature of the hazard, its level, and where it may be introduced into the food supply provide direct guidance as to the risk management strategies necessary to bring the product into compliance.

Monitoring programmes for chemical hazards are an essential component of the Canadian food safety system. The CFIA cannot 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, pharmacokinetic and physiological parameters of the hazard, it is possible to quantitatively assess its risk to public health. This approach is usually referred to as Ranked Risk Assessment.

This paper will describe Ranked Risk Assessment and how it is used at the CFIA for assessing the relative human health risks of chemical residues in food. It will also describe the sampling and testing programmes and the guiding principles used by the CFIA when instances of non-conformity are observed in the monitoring of the food supply.

Ranked Risk Assessment

The WHO defines risk assessment as a process for determining the nature and likelihood of human health risks associated with a chemical, microbiological or physical hazard in a food. The characterization of the risk depends on the qualitative and quantitative information available and is associated with a certain degree of scientific uncertainty.'[4]

The steps and processes involved in the risk assessment of chemical hazards have been defined and established internationally.[5] Within the Canadian government, the responsibility for carrying out the risk assessment of chemicals used in agriculture, in food production, or those present in foods as a result of incidental (e.g. environmental) contamination is the responsibility of Health Canada. Any risk assessment will be limited by the quality of the data available to the risk assessor. Compounds submitted for pre-market approval for use in agriculture (i.e. veterinary drugs or pesticides) or food production (i.e. food additives) will generally be supported by a substantial amount of scientific data that is evaluated prior to the chemical being allowed for use. In this case,

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the hazard is well characterized and any uncertainty with the toxicological database has been identified. For compounds that are not intended for use in foods, the availability and integrity of the data used to carry out the risk assessment can be problematic.

The CFIA uses the risk assessments of registered and non-registered chemicals performed by Health Canada and other governments/international organisations to rank the relative risks of specific chemicals. This allows the CFIA to allocate its limited testing and inspection resources toward the chemical hazards which pose the greatest assessed health risks. The Risk Priority Compound List (RPCL) risk model scoring system is a simple tool used to rank the relative risk to humans from chemical residues in foods.

The RPCL risk model scoring system

The RPCL can be used for compounds that have a strong database as well as compounds for which the toxicological data is incomplete. Compounds pre-approved for use in Canada or those for which Health Canada has established maximum residue limits (MRLs) have undergone an extensive quantitative risk assessment process which is carried out in accordance with established principles and guidelines and therefore the outputs from the RPCL using this data are considered to be more robust. When the toxicological information for a given compound is incomplete, care must be taken when using the RPCL. It is particularly important for these compounds that the uncertainties used in the input to the model be carefully documented for consideration by the risk managers.

The RPCL has been formulated with its own risk models (i.e. Foods of Animal Origin (FAO) and Foods of Plant Origin (FPO)) where total points are computed. This distinction is needed because the parameters that define use of chemicals on a crop and animals are vastly different. The point system is described in Table 1, and the total points are computed as follows:

$$\text{Final Score} = (\text{Score in Category A} + \text{Score in Category B}) \times (\text{Score in Category C} + \text{Score in Category D})$$

where,
Toxicity Category A is a toxicity category based on acute and chronic animal toxicity; Toxicity Category B is a toxicity category based on human health and condition; Exposure Category C is an exposure category based on food commodities that are treated, exposed or contaminated; Exposure Category D is an exposure category based on times of harvest application in FPO or withdrawal times in FAO.

Table 1 is a reproduction of the form used for ranking compounds in the RPCL.

The 'Risk Assessment' section provides the criteria for assigning a score for a particular compound. The 'Risk Management' section describes the risk management options for foods of plant or of animal origin, depending on the specific toxicity and/exposure scores or on the overall score. Please see Appendix A for the list of abbreviations.

The RPCL is a tool that allows the ranking of a large number of compounds. The RPCL is a dynamic list, i.e. new chemical substances are continuously being added and risk rankings are continuously being generated or modified based on the best available information. The following sources of information may alter the ranking of a chemical:

1) Results of new quantitative risk assessment.
2) Additional data that addresses some of the uncertainties in the toxicology profile.
3) Better exposure data.
4) Input from professionals in the field who can provide clarity on the use of a compound.
5) The results from different types of monitoring activities.
6) Data from total diet studies.
7) Public perception and expectations.

The RPCL risk rankings are used to determine which chemicals are added to sampling and testing programs and to prioritize method development projects. These projects must be carried out before sampling and testing programs are established. The prioritization of method development projects depends on the relative risk ranking and the risk management decisions.

Applicability of the RPCL

The validity of RPCL as a tool relies on the availability of data in which the user has confidence. Consistency in the interpretation and application of the model is required. The nature of the toxicological result or the nature of the exposure pattern must be of sufficient quality to ensure confidence in the resulting ranking. Within the CFIA, the quality of the data is evaluated in accordance with the confidence in the data source. The data sources include government reviews of pre-market assessment, documents posted by international review bodies such as JECFA, and peer reviewed scientific literature. When less than optimum data is used in the RPCL, the uncertainties must be documented and communicated to the risk managers.

When the data used in the ranking is sufficiently sound, the resulting list from the RPCL is in fact a prioritization for monitoring activities. The definitions and starting principles of monitoring activities are well established and are defined below in the section on Sampling and Testing. The results of the monitoring activity will be used to confirm the assumptions made in the initial ranking.

When there is insufficient toxicological or exposure data, any result from the RPCL must be used with care. In the absence of a comprehensive data set, the CFIA relies on expert opinion to determine if further work is needed. When deemed appropriate, an estimate of the risk to Canadians from a specific hazard can be gauged by assessing the exposure of the population. This assessment of exposure can be done by targeted surveys, rather than traditional monitoring programs.

Comparisons of the CFIA's RPCL with other prioritization systems

Different nations use prioritization systems that suit their particular needs. A detailed comparison of the RPCL with these systems is outside the intended scope of this paper. Of note however, is the ranking system used in the United Kingdom in their 'Matrix Ranking for Prioritising Substances for Non-Statutory Surveillance Scheme'.[6] Although this ranking system is limited to veterinary drug residues, it provides a valuable comparison with the RPCL. When comparing the relative ranking obtained in the UK with the ranking obtained in the RPCL, general concurrence is observed.

Table 1. Form used for ranking compounds in the Risk Priority Compound List (RPCL)

RISK ASSESSMENT	
Toxicity Category A	
Acute and chronic animal toxicity	Points
Compound is a carcinogen, teratogen, mutagen, has a q1* > 1.0/mg/(kg-bw)/day, is potentially life threatening or has high acute toxicity (LD50 < 25 mg/kg-bw).	30
Moderate acute animal toxicity (LD50 = 25–249 mg/kg-bw), High chronic toxicity (ADI/TDI/RfD < 0.005 mg/kg-bw/day or q1* = 0.06 to 1.0/mg/(kg-bw)/day).	24
Low acute animal toxicity (LD50 = 250–1000 mg/kg-bw), Moderate chronic toxicity (ADI/TDI/RfD = 0.005-0.05 mg/kg-bw/day or q1* = 0.006 to 0.06/mg/(kg-bw)/day).	15
Negligible acute animal toxicity (LD50 > 1000 mg/kg-bw), Low chronic toxicity (ADI/TDI/RfD = 0.051-0.5 mg/kg-bw/day or q1* = 0.0006 to 0.006/mg/(kg-bw)/day).	9
Negligible chronic toxicity (ADI/TDI/RfD > 0.51 mg/kg-bw/day or q1* < 0.0006/mg/(kg-bw)/day).	3
Comments:	
Toxicity Category B	
Impact on human health and condition	**Points**
Scientific information gathered from a variety of reliable sources indicates that possible widespread use of this compound might significantly modify drug resistance patterns of human pathogenic organisms.	30
May trigger possible anaphylactic response or other idiosyncratic lethal response.	30
Chemical is classified as a Proven Human Carcinogen -IARC Group 1.	28
Chemical is an endocrine disrupter, negatively impacts on fetal development or causes suppression of immune system.	22
Chemical is classified as a Probable Human Carcinogen - IARC Group2A.	22
Scientific information is available documenting acute or chronic health risk.	15
Chemical is classified as a Possible Human Carcinogen - IARC Group2B.	12
Scientific information suggests that the compound has potential to affect micro-flora.	10
Scientific information indicates that the compound bio-accumulates in certain tissues.	9
Scientific information is available suggesting acute health risk or exerts toxicity via common mechanism, For example OP or carbamate pesticides.	3
None of the above.	0
Category B represents the extent to which the use or misuse of this compound may contribute to new and existing human disease condition.	
Comments:	
Exposure Category C for foods of plant origin	
Food commodity types that are treated, exposed or contaminated	**Points**
Direct exposure to a chemical (pesticide, drug or contaminant) is anticipated for 6 or more food commodity groups.	20
Direct exposure to the chemical is anticipated on a few (1 to 5) major food commodities.	15
Direct exposure to the chemical is anticipated on only minor food commodities.	10
A pesticide is used 'off-label' on commodities for which there has been no approval.	10
A pesticide is used for some forestry applications.	4
A pesticide is used in cosmetic lawn and ornamental plants.	4
The chemical is not available for general use. Only licensed applicators have access.	4
The chemical is not available for use or is not used on foods of plant origin.	1
Major plant food types are Wheat, Corn, Apple, Orange, Potato, Tomatoes, Sugar(s), Banana and Grape. If the pesticide is used on food commodity type consumed by infants, such as Apple, Cereal, Root & Tuber vegetables, Legumes or Stone fruit, add 5 point to this category score.	
Comments:	
Exposure Category C for foods of animal origin	
Food animal groups that are treated, exposed or contaminated	**Points**
Direct exposure to a chemical (pesticide, drug or contaminant) is anticipated in numerous (5+) food animals groups. (Includes imported food products when not approved in Canada).	10
Direct exposure to the chemical occurs in some major food animal groups.	8
Direct or indirect exposure is anticipated in laying hens, dairy or honey production.	7

(Continues)

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Table 1. *(Continued)*

RISK ASSESSMENT	
Indirect exposure to the chemical occurs in some major food animal groups.	6
Direct exposure is anticipated in only minor food animal groups.	4
The chemical is likely to be available as a black-market formulation illegally imported	4
A chemical is approved for only companion animals and food animal usage is unlikely. Indirect exposure occurs in only minor food animal groups.	2
The chemical is not available for use or is used only on plant crops with no animal exposure anticipated.	1
Note 1: Major animal food groups are milk/dairy, cattle, chicken, swine/pork, egg, fish and turkey, all other food species are to be considered minor.	
(Add 5 points if the drug is available OTC thus permitting ELDU by non-professional)	
(Add 5 points to any score if the food item includes **a dairy product, thus consumed in greater portions by infants.)**	
Comments	
Exposure Category D for foods of plant origin	
Pre-harvest interval (PHI) and post harvest application	**Points**
Chemical application or contamination occurs post-harvest or requires no PHI.	25
The chemical is ubiquitous in environment. Potential for persistence/bio-accumulation.	20
Pesticide or chemical is a systemic.	15
Pre-harvest interval is lengthy but late usage is feasible.	15
Pre-harvest interval is less than 7 days.	12
Pre-harvest interval is between 7 and 21 days and near harvest use is ineffective and not feasible.	5
Pre-harvest interval is greater than 21 days and late season misuse is ineffective and not feasible.	3
Chemical not used on food crops but contamination from incidental sources is possible. (An example might be a seed treatment, an application to a food storage facility, etc.)	3
The pre-harvest interval is the number of hours/days that must pass between the last application of the chemical and the harvesting of the crop.	
Comments:	
Exposure Category D for foods of animal origin	
Withdrawal Time	**Points**
Chemical is ubiquitous in environment or has high potential for feed contamination or for unapproved use prior to close to slaughter.	20
The withdrawal time is greater than 21 days or half-life in the target tissue is anticipated to exceed 50 hrs. Compound is insoluble in water (Solubility < 1 ppm) Compound is likely to bioaccumulate (Log P > 5.0)	15
The withdrawal time is between 15 and 21 days or half-life is anticipated to be from 36 to 50 hours	10
The withdrawal time is between 8 and 14 days or half-life is anticipated to be from 20 to 35 hours. Compound is somewhat soluble in water. ($1 <$ solubility in ppm < 10)	7
The withdrawal time is between 1 and 7 days or half-life is anticipated to be from 4 to 19 hours	4
Compound is soluble in water (Solubility > 10 ppm)	2
Zero-day withdrawal time or half-life is anticipated to be less than 3 hours	1
The withdrawal time is the number of hours/days that must pass between completion of the dosing regimen and the time of slaughter. For approved drugs, the scores are based on withdrawal time and for unapproved drugs, scores were assigned based on estimates of the longest half-lives in an edible tissue.	
Comments:	
Risk Management	
Pilot survey, blitz or other intelligence gathering should be undertaken to gather information on potential exposure.	
1 - For **high toxicity (∃ 30)-high exposure (∃ 23)** the pilot survey to confirm prevalence could be a limited number (#300 initial samples) of random lots from the most likely food group. If prevalence is confirmed immediate regulatory corrective action is suggested for both the short and long terms. Long term risk management could focus on HACCP, other industry controls or control of importation; with end product monitoring by regulatory authority to confirm effectiveness.	
2 - For **high toxicity (∃ 30)-lower exposure (#22)** the pilot survey requires higher numbers or multiple years (∃ 300 initial samples) of random lots from the most likely food group. If exposure potential is confirmed long term risk management should focus on HACCP, other industry controls or control of importation; with end product monitoring by regulatory authority to confirm effectiveness of those controls. Such monitoring would	

(Continues)

Table 1. *(Continued)*

RISK ASSESSMENT

permit rapid reaction should exposure increase beyond acceptable triggers. Decisive regulatory action in the short and long term may be required.

3 - For **lower toxicity (#29)-high exposure (∃ 23)** the pilot survey requires only low numbers (#300 initial samples) of random lots from the most likely food group to confirm contamination. If prevalence is confirmed long term risk management could focus on HACCP, other industry controls or control of importation; with end product monitoring by regulatory authority to confirm effectiveness. A risk assessment and tolerance guideline should be developed to establish acceptable limits for the contamination and prevent the emergence of a chronic health treat. Decisive regulatory action in the short and long term may be required.

4 - For **lower toxicity (#29)-lower exposure (#22)** the pilot survey requires higher numbers or multiple years (∃ 300 initial samples) of random lots from the most likely food group. Since the risk estimate is low a pilot survey for this compound could be delayed if resources are limited. Regulatory action is not a priority.

RISK MANAGEMENT FOR FOODS OF PLANT ORIGIN

Information needs required prior to the evaluation.

Acute and Chronic Toxicity	Human Health and Condition
Food commodity types that	Pre-Harvest interval (PHI) and
are treated, exposed or contaminated	Post Harvest Application

Point ranking for pilot survey priority scoring.

Risk Priority Formula:

Points = {(A + B)*(C + D)}

Point range	Priority	Point range	Priority
1350 to 2700	P1	120 to 649	P3
650 to 1349	P2	Up to 119	P4

RISK MANAGEMENT FOR FOODS OF ANIMAL ORIGIN

Information needs required prior to the evaluation.

Acute and Chronic Toxicity	Human Health and Condition
Food Animal Groups Treated or Exposed	Withdrawal Times

Point ranking for pilot survey priority scoring.

Risk Priority Formula:

Points = {(A + B)*(C + D)}

Point range	Priority	Point range	Priority
1350 to 2700	P1	120 to 649	P3
650 to 1349	P2	Up to 119	P4

Sampling and testing activities at the CFIA

The aim of the CFIA's sampling and testing activities is to ensure the effectiveness of the control measures and to mitigate the presence of chemical hazards in foods. They allow the CFIA to assess dietary exposure, perform risk assessments, monitor trends, identify potential problems and at-risk population groups, and to support the setting of standards and guidelines.

The sampling and testing programme has four purposes:

- To determine the extent to which there is deviation from good agricultural practices or good practice in veterinary medicine. This is assessed from the violation rates found in the monitoring phase. When rates of violation for a specific hazard exceed acceptable levels (usually 1%), further surveillance and control activities may be triggered.
- To prevent the distribution of adulterated food products. Growers and distributors of foods that violate Canadian standards are placed on an enhanced inspection regime in order to identify causes and reduce or prevent recurrences.
- To provide data for calculation of comparative risk associated with domestic and imported sources of foods. This allows an estimation of equivalency of the various foreign control programs with Canadian control programmes.
- To provide information on the effectiveness of control measures and, more specifically, the effectiveness of programme modifications with respect to bringing about the desired changes. For example, to learn if a training initiative for producers has been effective in bringing about a reduction in the violation rates or if a restriction in the accessibility to a specified adulterant has brought about an increase in the compliance rate.

Sampling and testing activities form part of risk management activities undertaken by the CFIA. These can take multiple forms and have been called by different names. The activities carried out by the CFIA as part of a residue control programme include monitoring, directed sampling, compliance testing, pre-market surveys, post-market surveys and all other data gathering activities. Based on the design and purpose of the sampling and testing, different terminology is used to describe the different activities. A brief summary of the different types of activities are presented below.

Monitoring (also known as non-biased sampling) 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. The sampled lots are not held and are usually available

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to consumers before the results are known. 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 programme, trace-back activities to identify the source of the residue should be considered to be optional.

Directed sampling is biased, 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 techniques before any follow-up control action is taken. In these cases, trace-back activities should be implemented.

Targeted surveys are pilot surveys used to gather information regarding the potential occurrence of chemical residues in defined commodities. The surveys are designed to answer specific questions; therefore, unlike monitoring activities, testing of a particular chemical hazard is targeted to commodity types and/or geographical areas.

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 indicate the appropriate disposition. The establishment of a chain of custody of the sample is essential if legal proceedings are expected to ensue. Compliance testing is a regulatory control measure to prevent the marketing or remove from market a product that poses a health risk to the consumer.

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

'**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.

Legal sampling is undertaken for specific conditions 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.

Planning for sampling and testing activities

Two of the major sampling and testing activities will be discussed further. These are the National Chemical Residue Monitoring Program (NCRMP) and the Food Safety Action Plan targeted surveys. For both of these initiatives, there must be a potential for the chemical, be it a veterinary drug, agricultural chemical, or environmental pollutant, to leave a residue in food. Since all compounds cannot be assessed at the same time based on resources available, the RPCL described above is the basis of a prioritization process. The process is based on a risk estimate – compounds with the highest risk are preferentially included in monitoring or surveillance programmes. Lower priority compounds are sometimes included because they are amenable to analysis by the multi-residue methods (MRMs) in use.

Though the RPCL ranking is based solely on scientific data, public confidence in the safety of the food supply must play a role in setting the priorities of any regulatory agency. Recent events such as the addition of melamine to infant formulae and dairy products or the use of plasticizers as substitutes for natural compounds have attracted considerable media attention. The unease created by these events must be considered in setting priorities for sampling and testing activities by the Canadian government.

There are other factors that need to be considered in the planning of sampling and testing activities. These factors include, but are not limited to, the RPCL ranking, the requirements of trading partners for export, the intent of the sampling and testing activity, the availability of an analytical method, product availability, monetary resources, and laboratory capacity.

The intent of the sampling programme may be linked to the magnitude and soundness of the RPCL ranking. Chemical hazards for which the RPCL ranking is scientifically sound and for which the risk ranking is high may be subject to monitoring. For an emerging chemical hazard, the toxicity or exposure data may be incomplete. A targeted survey, which can be used to provide baseline levels, can establish the extent of exposure of the Canadian population to a particular hazard from consumption of certain foods.

The availability of an appropriate analytical method which has been validated for the food matrices of interest is another important factor. If an appropriate analytical method is available, sampling and testing may proceed. If not, a method development and validation project must be completed before implementation of a sampling and testing programme.

Another 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 National Chemical Residues Monitoring Program (NCRMP)

A monitoring programme is one of the tools used to assess the degree of compliance with national regulations and often serves as an early indicator of potential risk. If there is evidence of unacceptable levels of chemical contaminants in the food supply, a monitoring programme is not a suitable tool to assess and to effectuate mitigation of the identified risk. Some of the different types of sampling and testing activities, such as directed sampling, described above will need to be used.

The main monitoring programme for chemical hazards in meat, milk, eggs, honey, fresh fruit and vegetables as well as processed products is generally known as the National Chemical Residue Monitoring Program (NCRMP). The monitoring programme is designed to test foods for chemical hazards based on estimated risk to human health. As such, food items consumed in greater quantities by Canadians, those that are likely to be more contaminated or those that may be contaminated with more toxic components are sampled and tested in the greatest numbers. The results of these sampling and testing activities are available on the CFIA website.[7]

The CFIA has based its monitoring activities on the principles outlined by the Codex Alimentarius Commission. The Codex Alimentarius Commission has established guidance on the conduct of different types of residue monitoring activities. This guidance is detailed in the Codex Alimentarius Commission publications

Residues of Veterinary Drugs in Foods[8,9] and *Pesticide Residues in Food*.[10] These manuals provide a comprehensive description of the approaches utilized in the development of sampling plans.

When designing a monitoring plan, it is important to note that the primary aim of this type of sampling and testing is not to elucidate dietary exposure patterns or actual exposure in the food as consumed. Rather, the primary aim of the monitoring programme is to provide information about the compliance status of the food supply. The information gathered during monitoring activities can be used to refine dietary exposure assessments; however, the different processes and techniques used to produce this data must be considered.

Although the monitoring programme is not designed to provide highly accurate estimates of the violation rate of a population, such estimates are conveniently made available as auxiliary information. For example, if no violative samples are detected in a sample size of 300, it is convenient to infer with 95% confidence that the violation rate in the population is less than 1.00%. Although precision decreases rapidly as sample size decreases, useful information can still be obtained from smaller sample sizes. When the sample size is small, data must be collected over a longer period of time before significant inferences can be drawn. With a sample size of 300, seasonal trends may be evident, especially if there is a large seasonal variation. By comparison, seasonal variations would not be as evident with smaller sample sizes. It is understood that a pool of 300 distinct samples may not be available for all commodities. Care must be taken in the interpretation of the results when the sample size is small.

If initial monitoring indicates that a contaminant in a given food commodity presents a significant problem, sampling plans may be adjusted, but only to the point that such an effort will aid in the understanding of the problem or facilitate regulatory control. Such increased sampling may permit a study of trends, geographical variation and seasonal prevalence, and thereby aid in the design of more effective control strategies. Merely increasing the monitoring sample size without a strategy that first addresses potential benefits from such an increase is of little practical use. Once a problem has been identified by the monitoring programme, an effective risk management strategy would depend on the implementation of effective follow-up or directed sampling rather than on increased monitoring.

The Food Safety Action Plan targeted surveys

In 2007, the Canadian government launched a five-year initiative in response to a growing number of product recalls and concerns about food safety. This initiative, called the Food and Consumer Safety Action Plan (FCSAP), aims to modernize and strengthen the food safety regulatory system. The FCSAP initiative unites multiple partners in ensuring safe food for Canadians.

The Food Safety Action Plan (FSAP) at the CFIA is one element of the government's broader FCSAP initiative. The goal of FSAP is to identify risks in the food supply, limit the possibility that these risks occur, improve import and domestic food safety, and identify importers and manufacturers. FSAP also looks to verify that industry is actively applying preventative measures and that there is a rapid response in the case that these measures fail. One aspect of the plan involves the creation of a series of targeted surveys to test for the presence and level of a particular hazard in specific foods. Targeted surveys are largely directed towards the ever increasing amount of processed and manufactured foods of domestic and imported origin.

Targeted surveys are pilot surveys used to gather information regarding the potential occurrence of chemical residues in defined commodities. The surveys are designed to answer specific questions. Therefore, unlike monitoring activities, testing of a particular chemical hazard is targeted to specific commodity types and/or geographical areas.

Targeted surveys may be used to identify emerging food-hazard issues. In such cases, toxicological, human health impact and/or exposure data may be incomplete. Also, proposed or established maximum limits may be lacking. The results from targeted surveys can provide baseline data for future comparisons, identify potential emerging food safety issues, verify that historical issues have been addressed by industry, and provide data which may be used to perform or refine health risk assessments, and subsequently establish maximum limits as needed.

Targeted survey results may be used by Health Canada to assess the potential risk of a specific hazard and estimate the potential risk to the population. In the absence of a pre-market approval process such as that used for pesticides and veterinary drugs, the various limitations of the RPCL discussed above need to be considered. The CFIA relies on a committee of experts in these cases. These experts assist in the identification and prioritization of chemical hazard-commodity combinations. The group must rely on their knowledge of the scientific literature, agricultural practices, food manufacturing/processing practices, and developments in analytical methodology or instrumentation to determine the priority of a given survey or hazard/commodity combination.

Through an iterative consultation process, the hazard-commodity combinations are refined and prioritized to develop meaningful surveys. It is always accepted that a significant amount of 'educated guesswork' is inherent in the process. For this reason, the results from previous surveys are used to inform future surveys.

Evaluation and reporting of the results

The results from the sampling and testing activities are assessed for compliance with applicable Canadian standards. Monitoring results from the NCRMP, including summaries of the overall compliance rates and an interpretation of the results, are published in the form of an annual report for the NCRMP.[10]

Many of the FSAP surveys test for hazard or hazard-commodity combinations for which there are no applicable numerical Canadian standards. In this case, the evaluation of the results will occur in collaboration with the risk assessors at Health Canada. The results of the surveys and their interpretation are published on the CFIA website.[11]

Risk management considerations and enforcement actions

Risk management is the process of weighing policy alternatives to accept, minimize or reduce assessed risks and to select and implement appropriate options.[12]

All findings of measurable chemical residues or contaminants in food products must be evaluated to determine if there is a risk to human health or a violation of applicable standards. The result obtained must be placed in an appropriate context based on the potential human health risk. When a violation is identified, appropriate follow-up action is pursued. These actions can include follow-up

Drug Test. Analysis **2012**, *4* (Suppl. 1), 50–58
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inspections, further directed sampling according to a surveillance plan, or even 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 violative product representing a potential risk to human health.

Conclusions

The CFIA relies on the relative risk ranking in the form of the RPCL and on expert opinion to prioritize sampling, testing, and method development activities. The manner in which the CFIA tests for chemical residues depends on the intent of the testing activity. The two principal sampling and testing programs for chemical hazards are the NCRMP and the FSAP. The former programme focuses on agricultural; chemicals, veterinary drugs, mycotoxins, metals and environmental contaminants in agricultural commodities (meat, egg, dairy, fresh fruits and vegetables, honey, processed fruits and vegetables). The FSAP surveys are complementary; they are intended to collect information on baseline levels of a specific hazard in a specific food, usually a processed or manufactured food. These sampling and testing programmes are by no means exhaustive; resources are directed to the hazard-commodity combinations that are assessed to pose the highest risk and which are feasible to carry out.

The data obtained from these testing activities may be used to refine the risk assessments (e.g. exposure may be higher or lower than expected) and to inform the subsequent risk management options. If unacceptable levels of chemical contaminants are found in a food, no risk management is required. If chemical residues are detected in a food, risk management options must be considered. Risk management options or follow-up actions may include follow-up inspections, further directed sampling according to a surveillance plan, or even seizure and recall of products. The risk management option selected will depend on a number of factors, the most important being the potential human health impact.

Conflicts of interest

The authors have no conflicts of interest to declare.

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