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Te Manatu Ahuwhenua, Ngaherehere

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National Chemical Contaminants Programme for Dairy

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Contents

Contents	ii
1. Executive Summary	1
2. Background	2
2.1 Current programme.....	2
2.1.1 Product Safety Programmes	2
2.1.2 National programmes	3
2.2 Dairy industry changes	4
2.2.1 Restructuring of the dairy industry.....	4
2.2.2 Animal Products Act for dairy.....	4
3. Management of Food Safety	5
3.1 WTO Sanitary and Phytosanitary Agreement	5
3.2 The risk management framework.....	5
4. Assessment of Existing Chemical Hazards Management System for Dairy	9
4.1. Risk evaluation	9
4.2 Risk management options assessment.....	10
4.3 Implementation of risk management decisions	10
4.4 Monitoring and review	11
4.5 Consultation and risk communication	12
4.6 Conclusion.....	12
5. Requirements of the New Programme for Dairy	13
5.1 Purpose	13
5.2 Outcomes	14
5.3 Principles	14
5.3.1 Scope	14
5.3.2 Precepts.....	15
5.3.3 Synergy and linkages.....	15
5.3.4 Operation	16
6. Preliminary Design of the NCCP for Dairy	17
6.1 Overview	17
6.1.1 Contaminants managed by the NCCP	17
6.1.2 Relationship with other regulatory organisations.....	18
6.1.3 Design of the NCCP	19
6.2 Elements	19
6.2.1 Risk assessment, conditions of use, and limits.....	19
6.2.2 Chemical contaminants profile database	20
6.2.3 Farm and operator databases	21
6.2.4 Regulated control scheme.....	21
6.2.5 Programmes (PSPs & RMPs).....	23
6.2.6 Results database.....	23
6.2.7 Regulatory non-compliance and management of non-conforming produce	24
6.2.8 Verification.....	24
6.2.9 Official assurances.....	24
6.2.10 Communication	25
6.2.11 Review	25
7. Plan for the development of the NCCP for Dairy	26

8. Your feedback	27
8.1 Making submissions	27
8.2 The next steps	28
9. References	29
Appendix: Background for the development of the NCCP for Dairy	31
History	31
Residues in raw milk	31
Contaminants in finished products	32
Current status	32
Current programmes for managing contaminants	32
New Zealand’s legal requirements	34
International standards and guidelines.....	35
Codex Alimentarius Commission.....	35
International Dairy Federation (IDF)	36
Importing country requirements	36
European Union.....	36
USA	37
Brazil	37
Other countries	38

1. Executive Summary

All food, including dairy produce, may carry microbiological, physical, and chemical hazards that constitute risks to human health. Chemical hazards, such as the residues of agricultural compounds, veterinary medicines, and environmental contaminants, may pose immediate or long-term risks to consumers' well being.

The New Zealand dairy industry is currently undergoing a number of structural and legislative changes. In addition, the existing programme for monitoring residues in raw milk ends in May 2002.

In light of these changes MAF Food: Dairy and Plant Products Group (MAF Dairy) is considering:

- the most appropriate way to ensure the effective management of chemical hazards in dairy produce and products from the “farm to the fork”; and
- the use of these management systems to provide information for:
 - communication with stakeholders;
 - provision of assurances; and
 - their ongoing monitoring and effectiveness review.

This Discussion Paper describes the risk management framework, the means by which New Zealand is moving towards the effective management of milk and dairy produce safety. It also assesses, in the context of the risk management framework, the strengths and weaknesses of current activities in managing chemical contaminants in dairy produce and products.

This paper considers requirements for the effective management of chemical hazards in dairy produce and products in New Zealand. It outlines the programme proposed to ensure management of chemical hazards in dairy produce and products, the National Chemical Contaminants Programme (NCCP), and presents the plan for its development.

This paper is provided for you and other interested stakeholders to consider and comment on. MAF encourages interested parties to make submissions by **7 December 2001**. Guidance on making submissions is provided.

2. Background

2.1 CURRENT PROGRAMME

A brief description of the existing programme for the management of chemical contaminants in dairy produce and products follows. Further details are provided in the Appendix.

2.1.1 Product Safety Programmes

Operators in the dairy industry are required to operate in accordance with a MAF-approved Products Safety Programme (PSP).

Operators of farm dairies generally operate in accordance with a MAF-approved farm dairy PSP owned by the dairy manufacturer to whom they are contracted to supply milk. Farm dairy PSPs must include:

- procedures ensuring the supply of milk from healthy animals and the segregation and safe disposal of milk from animals with infectious diseases communicable through milk, or treated with animal remedies (veterinary medicines) as specified by MAF Standard D105 Milking Animal Health; and
- procedures for ensuring that the milk complies with the requirements of MAF Standard D115, “Raw Milk Acceptance”.

Dairy manufacturers’ PSPs must include:

- procedures ensuring that all incoming raw materials, ingredients, additives, processing aids, packaging, and cleaning chemicals are suitable for their intended use and will not compromise dairy produce safety;
- procedures verifying that all milk, cream, and other dairy raw materials are safe and wholesome, including procedures for receiving and testing raw milk in accordance with MAF Standard D115, “Raw Milk Acceptance”;
- the HACCP plan for manufacturing safe dairy produce that meets the requirements of MAF Standard D107, “Dairy Product Safety”, including:
 - procedures for operating, monitoring, and recording all critical control points in the manufacturing process; and
 - sampling and testing to verify that dairy produce is safe and truthfully labelled as specified by MAF Standard D109, “Dairy Product Conformance”.

MAF Standard D115, “Raw Milk Acceptance” requires that raw milk used for the manufacture of dairy products for human consumption for sale in New Zealand and Australia complies with:

- New Zealand maximum residue limits (MRLs) for agricultural compounds and veterinary medicines; and
- limits for incidental constituents/contaminants (other than agricultural compounds and veterinary medicines) specified by the *Food Regulations 1984*, the *Australian Food Standards Code*, or the *Australia New Zealand Food Standards Code*.

Milk used for the manufacture for export (other than Australia) complies with Codex MRLs, unless there is an overriding requirement of the importing country. Minimum acceptable levels of supplied milk sampling and testing for inhibitory substances, which includes antibiotics, are specified.

MAF Standard D107, “Dairy Product Safety” sets limits for the residues of pesticides and veterinary medicines, nutrients used to fortify infant and follow-on formulae, toxic trace metal contaminants, and radionuclides. The limits used are based on New Zealand MRLs, maximum permitted limits established by the Ministry of Health (MoH), and Codex MRLs and standards.

MAF Standard D109, “Dairy Product Conformance” sets the minimum acceptable level of sampling and testing of finished product by dairy product manufacturers for residues of pesticides and veterinary medicines, nutrients used to fortify infant and follow-on formulae, and toxic trace metal contaminants. A national programme monitors radionuclides (see below), and manufacturers are not required to test for these contaminants.

2.1.2 National programmes

2.1.2.1 Residues

A national programme for monitoring residues of veterinary medicines and pesticides in raw milk, the National Residue Monitoring Programme for Raw Milk (NRMP), was established in 1996/97 to provide assurances for dairy products exported to the European Union (EU). The programme is funded by the New Zealand Dairy Board and operated by AgriQuality. The contract for this programme ends in May 2002.

2.1.2.2 Radionuclides

The radionuclides programme, operated in association with the MoH’s National Radiation Laboratory, analyses milk samples from areas susceptible to radionuclide deposition from the atmosphere, and monthly milk powder samples from Auckland, Taranaki, and Westland regions for ¹³⁷Cs and ⁹⁰Sr.

2.2 DAIRY INDUSTRY CHANGES

2.2.1 Restructuring of the dairy industry

The current restructuring of the dairy industry creates a new set of dynamics both for the dairy industry and MAF in managing chemical hazards.

The formation of Fonterra Co-operative Group creates a number of changes to the environment. First, the *Dairy Industry Restructuring Act 2001* has amended the *Dairy Industry Act 1952*, providing for regulations in monitoring residues in dairy produce. Previously, there had been no relevant legislative provision.

Second and looking to the future, the restructuring of the dairy industry creates the opportunity for other significant dairy organisations to process New Zealand milk to manufacture export dairy produce. The same level of management and monitoring of chemical hazards will be required for all milk producing and processing organisations, whether for export or for domestic consumption. In this context, it would no longer be appropriate for Fonterra Co-operative Group to operate the NRMP as the New Zealand Dairy Board did previously.

2.2.2 Animal Products Act for dairy

Drafting is currently in progress to amend the *Animal Products Act 1999* (APA) to include dairy produce and products. It is anticipated that these amendments will be passed by mid-2002, with several years' transitional period. An industry working group is assisting in preparation for the move to the APA.

This transition impacts the management of chemical contaminants in dairy produce in two ways:

- First, the APA aims to minimise and manage risks from animal products to human or animal health through measures that ensure all traded animal products are fit for their intended purpose. This, combined with the ability to set standards and specifications, means that specific criteria, including those relating to chemical contaminants, can be set for one or more groups of dairy produce, e.g. dairy products for human consumption.
- Second, the APA provides a number of ways to meet this objective, including individual risk management programmes (RMPs) and regulated control schemes. Processors of animal products for human or animal consumption are required to operate under registered and independently verified RMPs, which are individually tailored to their own particular animal material, products, and operations. An RMP has some similarities to a PSP. Regulated control schemes are used where individually tailored RMPs are impracticable or inappropriate. These schemes may be an alternative or a supplement to individual RMPs and provide the means to manage hazards such as contaminants.

Both these features provide more flexibility for the management of chemical contaminants compared to the existing dairy industry legislation.

3. Management of Food Safety

3.1 WTO SANITARY AND PHYTOSANITARY AGREEMENT

New Zealand is a member of the World Trade Organisation (WTO), and is a signatory to the Sanitary and Phytosanitary (SPS) Agreement and the Technical Barriers to Trade Agreement (TBT). The SPS Agreement defines principles governing sanitary measures for food in international trade, many of which require elements of risk assessment and risk management. Governments are obliged to:

- determine an appropriate level of protection;
- take into account the minimisation of trade effects when determining an appropriate level of protection;
- ensure that sanitary measures are not more restrictive than necessary to meet the appropriate level of protection; and
- assess the sanitary measures of exporting countries as equivalent if they achieve this level of protection.

Government sanitary measures should be based on scientific principles and an objective assessment of risk, be applied only to the extent necessary to protect human health, and be adapted to the health status of the areas of origin and destination of the food.

As a consequence, the development of any programme to manage chemical contaminants needs to take into account risk assessment and risk management.

3.2 THE RISK MANAGEMENT FRAMEWORK

New Zealand's food administration (MAF and MoH) is moving towards risk management to ensure the safety of food for domestic consumption and export. The risk management framework provides the template for developing a programme for the management of chemical hazards in dairy produce and products.

Food safety risk management is extensively described in the joint MoH and MAF publication entitled *Food Administration in New Zealand. A risk management framework for food safety*. Much of the following material is excerpted from this document. The risk management approach described in this publication relates to the management of food safety by the competent authority (MAF) at a national level, rather than in a factory, which is effectively managed through HACCP.

Applying a generic risk management framework involves four steps:

Step 1: Risk evaluation

Step 2: Risk management options assessment

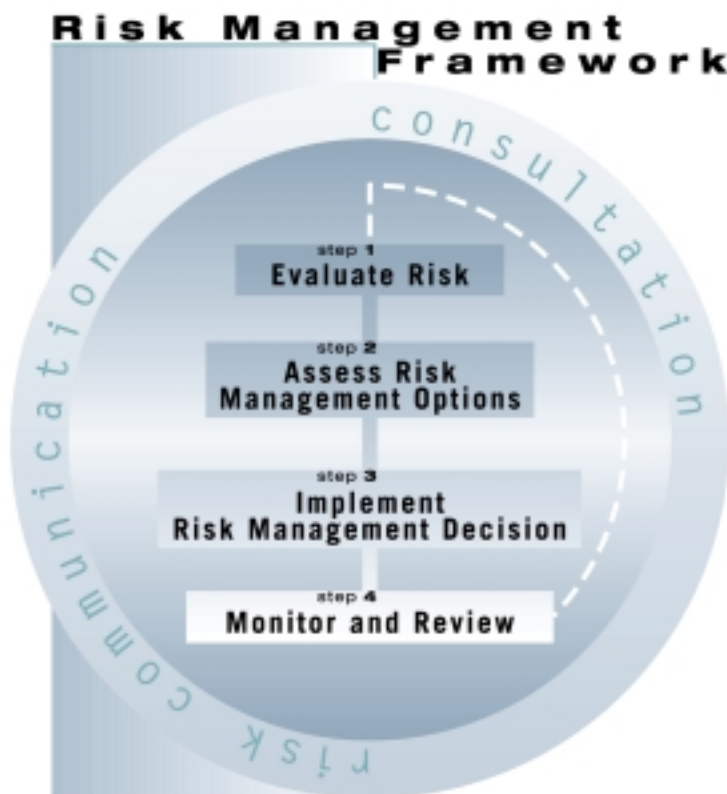
Step 3: Implementation of the risk management decision

Step 4: Monitoring and review

In addition, strategies for ensuring adequate communication and consultation among stakeholders are essential to all aspects of risk management.

Figure 1 illustrates the risk management framework. Further information on each step is provided below.

Figure 1: Risk management framework



Step 1: Risk evaluation

The first step in the risk management process is usually a result of:

- identification of a food safety problem;
- need to develop a food safety standard;
- development of a broad food safety policy; or
- development of sanitary measures necessary to achieve specific food safety goals.

Risk evaluation requires establishing a risk profile that places the issue in a particular food safety context. A formal risk assessment is commissioned in situations where it is possible and practicable to generate quantitative estimates of risks to human health, although food-borne risks to human health can often be managed systematically, without completing a formal risk assessment.

Step 2: Risk management options assessment

This step identifies available risk management options in light of quantitative information on risks, with several approaches to setting levels of consumer protection. The choice of a preferred management option primarily involves systematic assessment of the likely impact of different sanitary measures on preventing, eliminating, or reducing risks to human health. Other factors, e.g. risks from wrong or misleading labelling, can also be taken into account.

Sanitary measures that are HACCP- and/or outcome-based are the preferred risk management options, and development of food safety objectives and appropriate design of food controls are most likely to achieve optimal food control.

Step 3: Implementation of a risk management decision

In most cases, the risk management decision is introduced by designing and implementing specified sanitary measures. This involves a wide range of food safety activities, from setting regulatory standards to ensuring compliance. Initial implementation of sanitary measures may include establishment of performance and/or process parameters that reflect a specified food safety objective. System verification (including validation) is also an important element.

Step 4: Monitoring and review

An essential part of the risk management framework is the collection and analysis of data from appropriate points in the “farm to fork” continuum, for ongoing risk assessment and risk management activities. This involves monitoring of hazards in food (including water), and monitoring risks in the consumer population. Monitoring and surveillance data allow an evaluation of the effectiveness of the sanitary measures in all food safety contexts, and should identify new food safety problems as they emerge. Redesign of the food control system or its management should be initiated whenever indicated by monitoring and review.

Consultation and risk communication

Strategies for ensuring adequate communication and consultation among stakeholders are universal to all aspects of risk management (Steps 1—4).

Consultation and risk communication ensures interactive exchange of information and opinions on risk and risk-related factors among risk assessors, risk managers, consumers, and other interested parties. It ensures transparency and consistency in risk management decisions, and accurate and full information for the interested parties. Risk communication bridges gaps in understanding, and facilitates exchange of information allowing all parties to make informed decisions. All stakeholders should be involved to the extent that it is practicable and reasonable to facilitate an effective process.

4. Assessment of Existing Chemical Hazards Management System for Dairy

In considering the most effective means to manage chemical hazards in dairy produce and products, the existing management systems should be assessed in the context of the risk management framework, to identify system strengths and areas for improvement.

4.1. RISK EVALUATION

Chemical hazards, along with microbiological and physical hazards, constitute risks to human health. Dairy produce and products may carry hazards specific to the methods of production, handling, and processing. The range of potential chemical hazards in dairy products and dairy produce includes:

- residues of agricultural compounds, e.g. pesticides;
- residues of veterinary medicines, e.g. antibiotics;
- environmental contaminants, e.g. organochlorines, radionuclides;
- incidental contaminants, such as inadvertently added compounds, e.g. heavy metals; and
- other contaminants from different sources.

In New Zealand, registration of veterinary medicines and agricultural compounds by MAF Food: Agricultural Compounds and Veterinary Medicines (MAF ACVM) Group, in association with Environmental Risk Management Authority (ERMA), includes assessment of efficacy and toxicology of the active ingredients. Where there is an unacceptable level of risk, products are not registered. Where there are negligible levels of risk, products are exempt from registration. Where there is an acceptable level of risk, products are registered with restrictions on sale and use, including a withholding period. Assessments data are held by MAF ACVM, which provides profiles on specific active ingredients. This information is currently not electronically accessible.

MAF ACVM Group works with the MoH to set required MRLs for agricultural compounds and veterinary medicines. In addition, MRLs have been set for pesticides such as DDT, which are now no longer registered and are environmental contaminants. The MRLs are contained in the *New Zealand (Maximum Residue Limits of Agricultural Compounds) Mandatory Food Standard 1999*. MAF has developed a database of the MRLs set by New Zealand, Codex, and other importing countries such as the EU countries.

The risk management framework and its terminology such as appropriate levels of protection and food safety objectives, have not yet been introduced to the registration of veterinary medicines and agricultural compounds anywhere in the world. Appropriate levels of protection (apart from 100% safety), and understanding of what the MRLs provide have not been determined in respect of chemical hazards.

In preparing the Australia New Zealand Joint Food Standards Code, ANZFA has undertaken and published the results of assessing risks associated with chemical elements such as heavy elements. Where elements present a risk, the Code sets appropriate limits. Similarly, the Code restricts the use of food additives by setting highest limits for their use.

In spite of the considerable information on risks associated with chemical hazards, stakeholders have difficulty accessing this information. There is a requirement for the electronic availability of the summary-level information on chemical hazards so that stakeholders, such as dairy manufacturers, can readily access it for food safety management, e.g. in the development of HACCP plans.

4.2 RISK MANAGEMENT OPTIONS ASSESSMENT

In New Zealand, a range of organisations (ERMA, MAF ACVM, MAF Dairy, MAF Food: Animal Products Group, MoH, ANZFA) are involved in assessing risk management options for chemical hazards. As outlined above, these organisations consider the risk management options and make the risk management decision within the context of the risk assessment, e.g. the decision to register a veterinary medicine by MAF ACVM, refer to section 4.1 above.

While ultimately risk assessment and the lack of suitable options for risk management could drive the development of new or amended legislation, risk management options are generally defined by existing separate legislation. For many hazards, legislation provides a toolkit of risk management options. For example, for dairy products sold in New Zealand, at least four Acts stipulate regulation of pesticides: *Hazardous Substances and New Organisms (HSNO) Act 1996*, *Agricultural Chemicals and Veterinary Medicines Act 1997*, *Dairy Industry Act 1952*, and *Food Act 1981*. Insufficient understanding of their interface and lack of consultation among relevant organisations could cause potential difficulties.

Dairy Industry Act 1952 and its associated legislation relies primarily on one risk management option for managing produce and product safety, the Product Safety Programme (PSP). This has some limitations where a particular risk cannot be effectively managed by a single operator, e.g. radionuclide contamination following a nuclear accident. As mentioned above, the APA provides a number of options, such as the risk management programme (RMP) and the regulated control schemes, for risk management. In moving to the APA environment, MAF Dairy and dairy industry stakeholders will need to become more adept at assessing risk management options for a given situation and choosing the appropriate risk management option.

4.3 IMPLEMENTATION OF RISK MANAGEMENT DECISIONS

As expected, the organisations (ERMA, MAF ACVM, MAF Dairy, MAF Food: Compliance and Investigation Group (MAF Compliance), MoH, ANZFA) involved in managing risk from chemical hazards are reasonably adept at implementing appropriate risk management decisions within their sphere of jurisdiction. Implementing decisions includes consultation, issuing instruments, assessing compliance, and appropriate actions to manage non-compliance. Due to improving consultation and harmonisation among the relevant organisations, systems are being developed or overhauled to ensure the risk management decisions based on various legislation work effectively together.

Chemical contaminants are managed in raw milk and finished product by different means (Section 2.1) primarily dependent on the type of contaminant, and whether the substrate is raw milk or finished product. These various programmes are not effectively co-ordinated. In some instances requirements and responsibilities are poorly defined, and—as a result—efforts may be duplicated with certain contaminants managed by a number of programmes.

In particular, it is worth noting that the current sampling and testing requirements (MAF Standard D109) for assessing the levels of chemical hazards in finished product and determining conformance are difficult to interpret and implement. The Dairy Product Safety Advisory Council's (DPSAC) Technical Consultative Committee is currently reviewing this Standard, and it is anticipated that the revisions will be available for industry consideration in 2002.

4.4 MONITORING AND REVIEW

Currently, the collection and analysis of data on chemical hazards from appropriate points in the “farm to fork” continuum, and the risk to the consumer population are fragmented.

For dairy, limited data are available for ongoing risk assessment and risk management, e.g.:

- Lack of information on qualitative and quantitative risks in the human population, i.e. public health statistics.
- Access to data on levels of chemical hazards in finished products by MAF Dairy and regulatory organisations such as MAF ACVM, MoH, and ANZFA. This information is currently gathered by manufacturers, and although MAF Dairy does have the power to access this information, currently there is no mechanism to easily collect this information and present its summary to regulatory bodies.
- Although there is a system for reporting and managing regulatory non-compliance via TPA to MAF Compliance and MAF Dairy, there is no system of reporting non-compliance to the regulatory organisation that set conditions of use, e.g. registration of agricultural compounds, and limits, e.g. MRLs. This information would enable those organisations to monitor trends in non-compliance, and—if necessary—review the conditions and statutory limits

While the NRMP provides valuable data on chemical hazards in raw milk, its storage and presentation prevents it from being optimally used. In addition, dairy manufacturers have, through acceptance testing of raw milk, produced large quantities of data of varying quality on selected raw milk contaminants, which presents a considerable opportunity for monitoring and review.

4.5 CONSULTATION AND RISK COMMUNICATION

Consultation and risk communication relating to chemical contaminants in dairy is an area requiring improvement.

Some problems relating to the management of chemical hazards in the dairy industry are directly attributed to the lack of adequate consultation and risk communication. Many operators are unaware of some of the programmes managing chemical hazards, e.g. the MAF ACVM process of veterinary medicines registration, the New Zealand MRL system, and the NRMP. Furthermore, lack of communication on risk assessment and the status of some contaminants in New Zealand means that operators may be mis-directing the investment of their resources.

Communication and consultation with other stakeholders in the area of managing chemical hazards in dairy produce and products are not managed systematically. Stakeholders, including consumers, have little or no access to information (and its interpretation) on the level of chemical contaminants in New Zealand dairy products. An exception to this is the annual report to the EU, outlining the plan and findings of the NRMP.

Limited information on the levels and prevalence, or frequency of chemical hazards in dairy produce and products is provided to other regulatory organisations involved in risk assessments, evaluating risk management options, and implementing risk management decisions.

Consultation and communication should be specifically emphasised in designing and developing new programmes so that dairy industry operators, regulatory organisations, and other stakeholders can effectively participate in the risk management process, make informed decisions, and use their resources most efficiently.

4.6 CONCLUSION

This assessment indicates the work required to incorporate risk management principles in the design and implementation of contaminant programmes for dairy.

This assessment is also valuable in designing a new programme for dairy contaminants, though it cannot address all areas identified in this assessment due to timing or resource limitations. Also, the new programme will have a limited scope and will not incorporate all steps in the risk management framework, primarily the risk evaluation step. It is envisaged that these areas will be addressed in the next 5-10 years as the risk management framework becomes more widely accepted and used as the basis for food safety administration.

5. Requirements of the New Programme for Dairy

Before commencing the design of the new programme for managing chemical contaminants, it is important to clarify its purpose and outcomes.

5.1 PURPOSE

Consultation with the interested parties has identified two main purposes of the new programme.

The first purpose of the programme is **to ensure the effective and ongoing prevention and control of contaminant hazards and risk, from milk production to end product**, to the agreed appropriate level of protection.

In the context of risk management framework, “risk” is a function of probability and severity of adverse health effects of food in the consumer population. In addition to these food safety risks, broader categories of risk need to be included in designing the new programme. Generally, the term “risk” is used to describe exposure to potential danger for human health. “Risk” may occur from perceived contaminants, which in reality may not be present in the food or—if they are—not pose a risk to health. It is important to consider consumers’ perception of risk, as it can result in reduced purchasing and consumption.

Another type of “risk” is the risk to trade, resulting from the export of a product that fails to comply with an importing country’s requirements. Such risk also places demands on a contaminant programme. For example, the EU requirement to monitor some classes of compounds, none of which are registered for use in New Zealand and for which use there is no indication given our pastoral farming systems, needs to be addressed. The APA, through its programme of market access requirements, would enable managing such risks.

The second purpose of the programme is **to generate information on chemical contaminants in dairy production and processing to enable industry and MAF to provide credible assurances, communicate effectively with stakeholders, negotiate equivalence of access, and mitigate risk to trade.**

5.2 OUTCOMES

The outcomes of the planned programme are based on the input from the interested parties. In a constantly changing environment, the proposed programme will need to deliver:

1. A level of food safety such that:
 - dairy produce and dairy products are suitable for sale in New Zealand; and
 - the programme is equivalent to the corresponding programmes in importing countries;
2. Effective management of non-food safety risks;
3. Information to:
 - communicate effectively with stakeholders so they make informed decisions;
 - demonstrate credibility of assurances provided by MAF and/or dairy operators; and
 - demonstrate effectiveness of procedures for preventing and controlling hazards.

5.3 PRINCIPLES

A group of industry operators and MAF personnel involved in assessing the raw milk quality and operating the NRMP considered the founding principles for the design of the new programme. These principles fall into four broad categories: scope, precepts, synergy and linkages, and operation.

5.3.1 Scope

According to the scope of dairy legislation, the new programme must cover all domestic and export dairy operations in New Zealand. Consequently, the programme needs to include dairy cow, goat, and sheep operations, and to cover both raw milk and finished produce, as specific responsibilities and assurances are associated with production and processing of raw milk.

According to the scope of the dairy industry and animal products legislation and due to the industry concern that animal feeds may carry contaminants into the food chain, the programme should include dairy produce and products not only for human consumption, but also for animal feeds.

To avoid the fragmented character and lack of coordination in the existing systems, it is important to ensure that all chemical contaminants are managed within the same framework, although the procedures for preventing and controlling hazards may vary within the framework.

Finally, to effectively use resources, the programme needs to be suitable for monitoring organic produce, as well as produce from conventional agriculture. Thus, monitoring organic dairy produce will be consistent with the MAF assurances to importing countries.

5.3.2 Precepts

The group advised that the programme needs to operate under both legislations (dairy industry and animal products) so that the changes in the legislation would not cause changes in the designed and implemented programme. This may be less of a concern as the date for the amendments to the APA, and the proposed start date for the new programme appear aligned.

The new programme needs to deliver New Zealand's specific requirements based on its sanitary measures and the assurances provided by MAF and industry operators. Given New Zealand's commitment to the SPS Agreement, the programme needs to incorporate Codex guidelines in meeting specific importing country's requirements, e.g. information on hazards specified by the competent authority of the importing country.

Given the New Zealand food administration's move towards an environment based on the principles of food safety risk management, the relevant control measures and the level of activity must be in proportion to the risk associated with chemical hazards and based on sound scientific and statistical data.

5.3.3 Synergy and linkages

To make the best use of existing information, the group advised that the programme build strong linkages to the dairy industry, MAF ACVM, MAF Animal Products, and other organisations.

Given that industry support, both financially and in the supply of data, is required for the programme to operate, it is essential that industry participate in the design, development and ongoing reviews of the programme. In addition, normal industry consultation is required to ensure that appropriate decisions are taken, and that there is understanding of and commitment to the programme

Some chemical contaminants can be effectively managed by operators through PSPs or RMPs, while others are better managed through national (regulated) control schemes. The new programme needs to be flexible enough to enable, as a minimum, both these management systems to operate effectively. To maximise the use of information generated from both sources, it needs to be available to operators, MAF, other regulators, and stakeholders, with due respect for its confidentiality and commercial sensitivity. To enable the sharing of data, its quality needs to be satisfactory. This may place restrictions on the way samples are taken and tested, and the data reported and analysed.

Overall, there is a demand for the maximum use of the data already generated by the operators' PSPs as part of raw milk acceptance, verification of finished product conformance, and independent verification programmes. It has been speculated that with the NRMP replacement, PSPs may have already generated sufficient data for the programme to operate.

Finally, the group advised that the new programme make the best use of existing resources, such as databases and information.

5.3.4 Operation

Based on the experience in operating the NRMP, the group advised that there be a regular (annual) contaminant review cycle. The programme also requires flexibility to respond at short notice to contaminant-related issues and concerns. A longer cycle for review of legislation and specifications is also necessary. The group presumed that much of the work would be contracted on a regular tender basis.

The group acknowledged considerable work was required to undertake the risk assessments within the risk management framework, and may take years to complete. In the absence of an appropriate level of protection and a food safety objective, the group recognised that existing MRLs and maximum permitted limits would define food safety limits, above which corrective actions may be required.

The programme requires strong linkages to systems for managing regulatory non-compliance, non-conforming produce, and—where appropriate—handover to MAF Enforcement for investigation with a view to prosecution.

To be effective, the programme requires documented specification and quality systems. Screening and confirmatory test methods should be adequate to the purpose, and laboratories undertaking analysis should be competent. These requirements are similar for all contaminants programmes, and provide an opportunity for synergy with the already operating residues programmes for meat, honey, and poultry.

6. Preliminary Design of the NCCP for Dairy

The following preliminary design of the new programme for dairy, the National Chemical Contaminants Programme (NCCP), is based on the above purposes, outcomes, and principles, and has been ‘field-tested’ in a series of presentations to stakeholders.

This preliminary design is intended to provide the dairy industry and other stakeholders with some insights into the programme, its operation, and the information it will provide. It is important to note that the NCCP design is still evolving, and the feedback from industry and stakeholders will assist in finalising the NCCP design details.

6.1 OVERVIEW

The NCCP as a programme would be controlled by MAF Dairy to:

- ensure the effective and ongoing prevention and control of contaminant hazards and risks, from milk production to end product; and
- generate information on chemical contaminants in dairy production and processing to enable industry and MAF to provide credible assurances, communicate effectively with stakeholders, negotiate equivalence of access; and mitigate risk to trade.

Elements of the programme would be operated by:

- MAF Dairy;
- operators as part of PSP/RMPs;
- contracted parties and operators as part of regulated control schemes; and
- parties under contract to MAF Dairy.

6.1.1 Contaminants managed by the NCCP

The NCCP will manage the following chemical contaminants associated with raw milk and finished product:

- agricultural compounds (pesticides) and veterinary medicines;
- environmental contaminants;
- food additives with ADIs;
- incidental contaminants; and
- other contaminants with a defined risk.

6.1.2 Relationship with other regulatory organisations

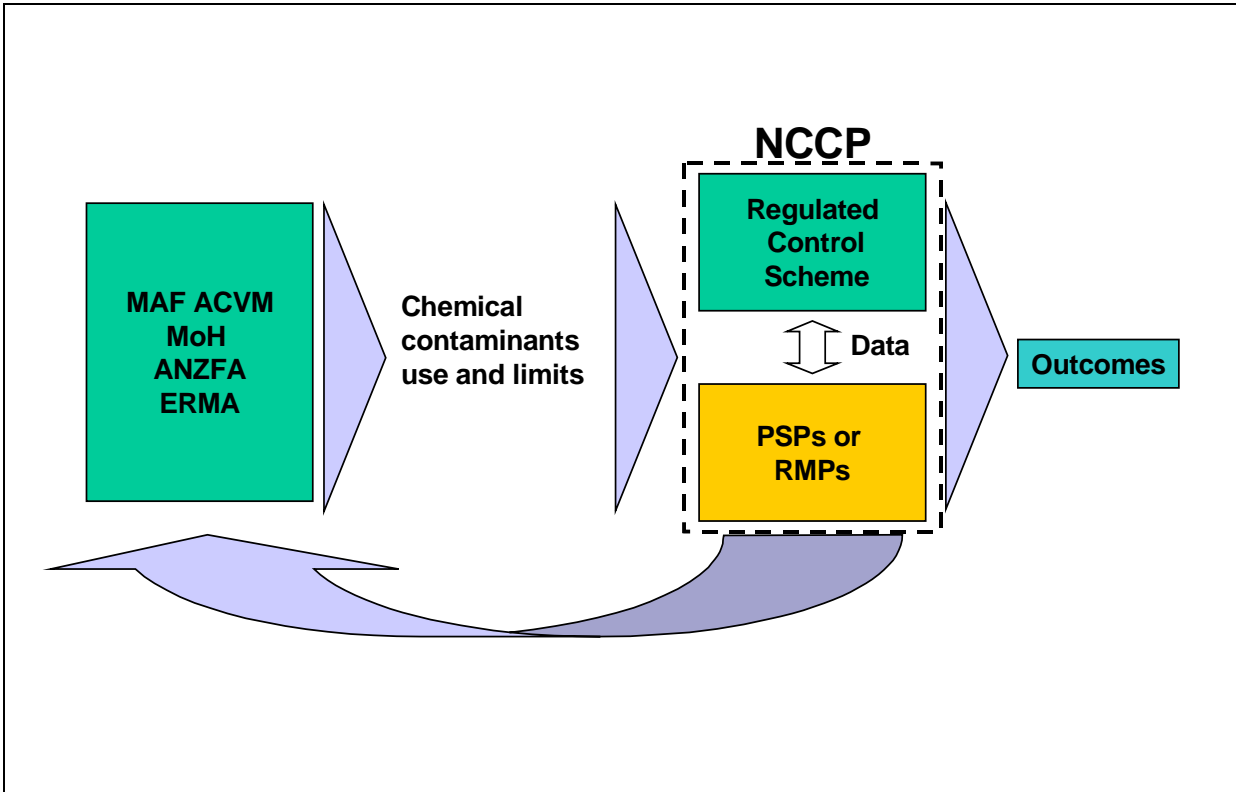
The NCCP would rely on risk assessments and risk management options assessments and decisions already made by regulatory organisations such as ERMA, MAF ACVM, ANZFA, and the MoH.

The NCCP would use the information, conditions, and limits generated by these processes, to determine whether the contaminant requires management in the NCCP context, and if so, whether it is best managed by the operators’ PSPs or nationally by a regulated control scheme.

The NCCP would provide information on the levels of hazards in dairy produce and dairy products to ERMA, MAF ACVM, ANZFA, and the MoH, and reports on violations for reviewing risk management decisions. The NCCP would also provide the outcomes outlined in Section 5.2.

This relationship with the regulatory organisations is illustrated in Figure 2.

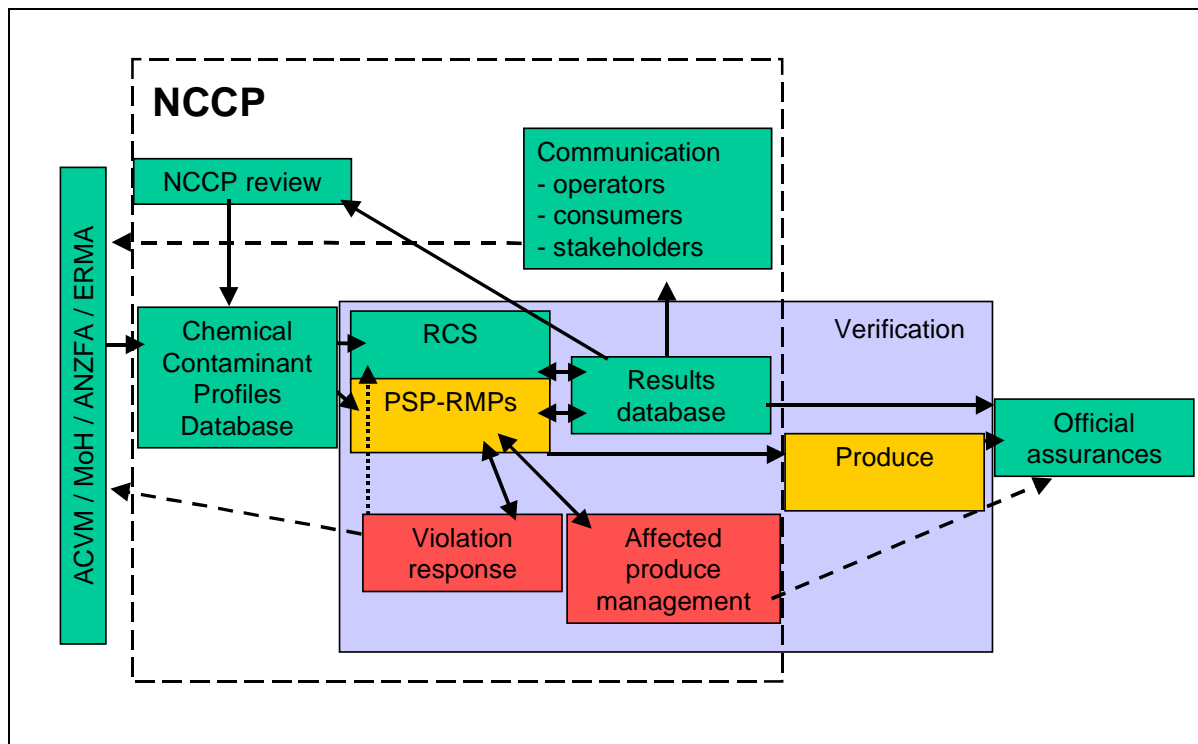
Figure 2: Relationship between regulatory organisations and the NCCP



6.1.3 Design of the NCCP

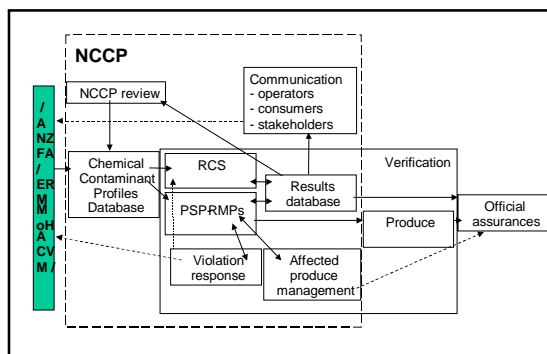
Figure 3 provides an overview of the NCCP. A detailed description of each NCCP element is presented in the following section.

Figure 3: Design of the NCCP



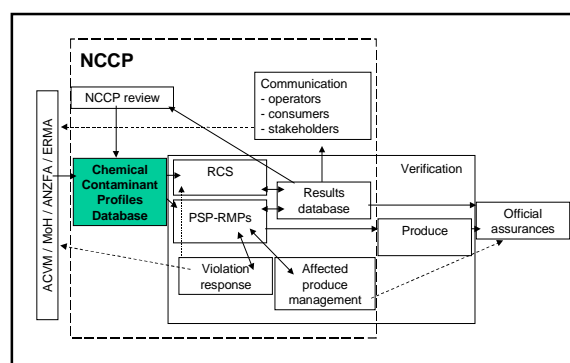
6.2 ELEMENTS

6.2.1 Risk assessment, conditions of use, and limits



As described in Section 6.1.2, the NCCP would rely on regulatory organisations to undertake risk assessments, assess risk management options, and implement risk management decisions such as setting conditions of use and limits.

6.2.2 Chemical contaminants profile database



The chemical contaminants profile database would contain a summary of information on each contaminant.

This database would be available on-line to provide operators and other stakeholders with quick reference to contaminant information and the risk management decision. Information on each contaminant would include its category, source, and use, including the information on how the contaminant enters the food chain and

is transferred, the affected materials, risk rating and description, control system, and any conditions and limits of use, e.g. MRLs. In addition, the database would contain references to key literature, sampling requirements, and test methodology.

The profile for each contaminant would specify its NCCP class (A to E), defining the contaminant's NCCP management. An outline of the NCCP classes is presented in Table 1.

Table 1: Outline of the NCCP classes (with examples)

NCCP Class	Risk	NCCP Management System	Examples
A	High	Mandatory PSP/RMP management using HACCP	Antibiotics, additives with ADIs
B	High	Management by PSP/RMP using HACCP or the regulated control scheme. Decision made by the operator based on capabilities	DDT/DDE, aldrin, and dieldrin
C	Medium	Management using the regulated control scheme	Organophosphates, radionuclides
D	Low	No management required	
E	Unknown	Investigation using regulated control scheme	1080 poison

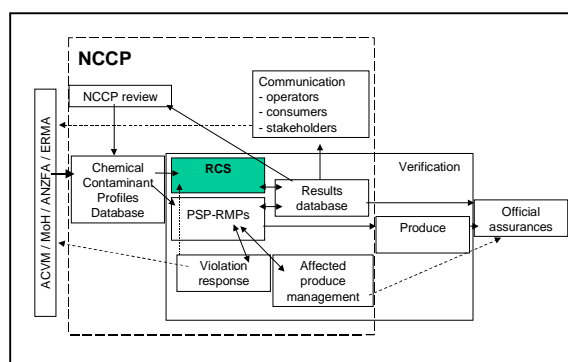
The majority of information in the profiles database would be obtained from the relevant regulatory organisation. The database would have the additional advantage of summarising information that may exist in paper files, and would communicate the outcomes of any assessments and risk management decisions.

6.2.3 Farm and operator databases

A database should hold records of all New Zealand dairy farms, including details on owner, farm operator, herd, location, and contact details. This database would be linked to the results database for geographical plotting of results. An existing database may have the relevant capabilities and be upgraded accordingly.

A dairy manufacturer's database should hold records of manufacturers such as PSP number, location, contact details etc. The existing dairy E-cert verification database operated by MAF has the required capabilities.

6.2.4 Regulated control scheme



Regulated control schemes are special regulatory regimes to provide for cases where:

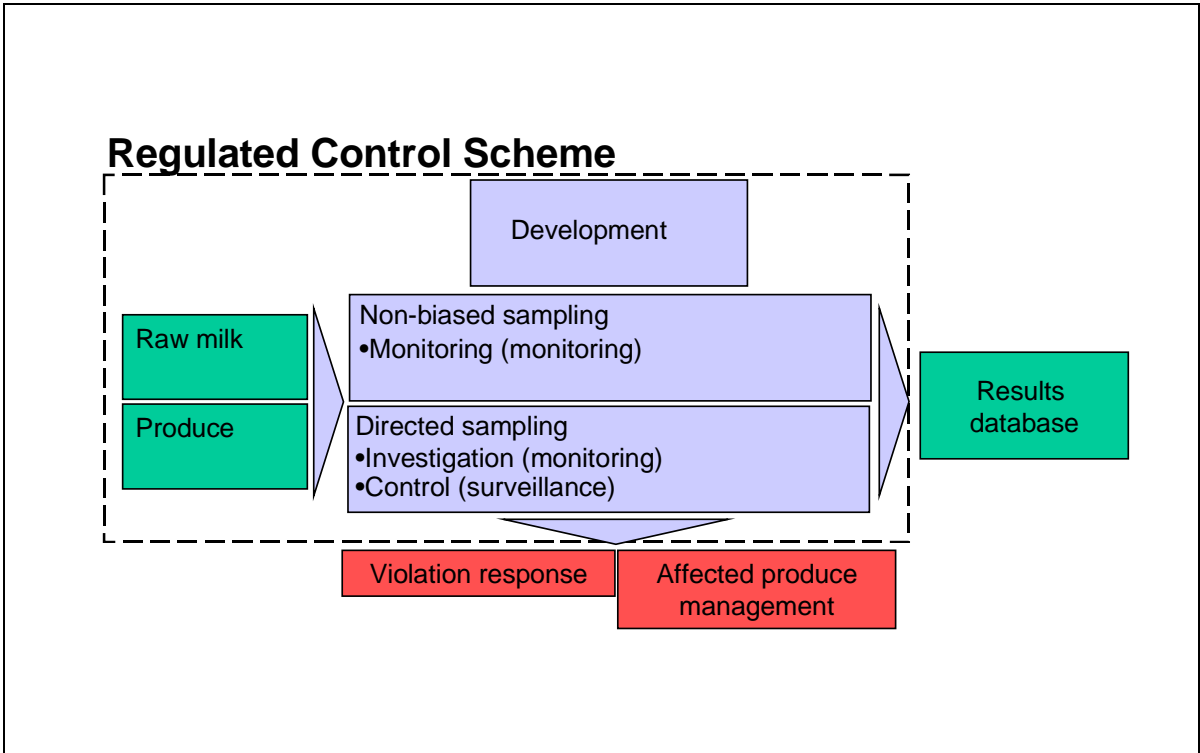
- It is inappropriate or impractical to manage risks under RMPs; or
- Risks may need to be addressed for producing animal material or processing animal product that is not required by the APA to be covered by a registered risk management programme; or

- Special provision is required for the purposes of overseas market access requirements.

The activities currently undertaken by the existing NRMP will use a regulated control scheme. Figure 4 provides an overview of the NCCP regulated control scheme, which would be used for monitoring, investigation, and surveillance of contaminants in raw milk and finished products. Raw milk and produce would be sampled and tested in accordance with the scheme specifications, and the results would be recorded in the results database.

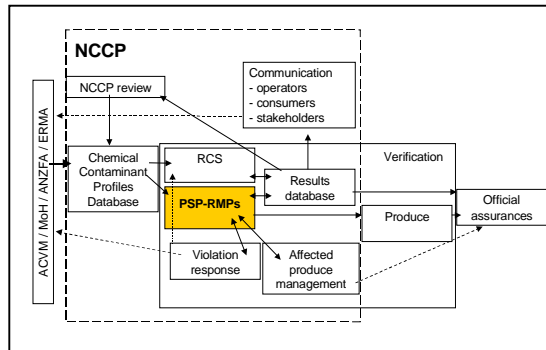
In addition to non-biased (random) sampling for providing contaminant population data for New Zealand, the scheme would also undertake biased (targeted) sampling for investigating the risk of the NCCP “Class E” contaminants. The scheme would also include a surveillance element (currently not part of the NRMP). Surveillance is a control tool for confirming the safe level of contaminants in milk or milk products on the “suspect list” before processing or selling it. Surveillance would be used where land has high levels of environmental contaminants not managed by the operators’ PSPs. Where the scheme found excess levels of contaminants, the violation would be investigated with the subsequent segregation and management of the affected produce.

Figure 4: Overview of the NCCP regulated control scheme



The regulated control scheme would also have a development component, consisting of the development of test methodologies and gaining knowledge, via survey, of the use of specific categories of contaminants, e.g. antibiotic use on farms.

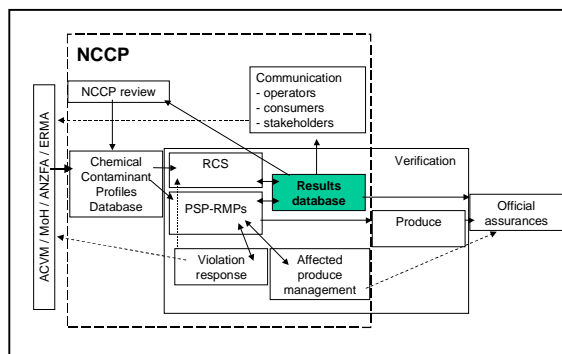
6.2.5 Programmes (PSPs & RMPs)



Operators using their programmes effectively manage a number of contaminants. Contaminants in raw milk and finished product would be managed, as they are now, via programmes. The key difference between current activities and the NCCP, would be entering a portion of the collected data in the results database. To ensure the data quality, sampling and testing requirements may be specified.

The MAF National Microbiological Database (NMD) for meat could serve as a useful model for the NCCP, as it requires programme operators to use trained samplers for sampling carcasses on specific days and at a specific time, and then testing the samples using prescribed test methods. The laboratory in the NMD enters the results. This data provides a sample of the microbiological condition of carcasses produced by each programme.

6.2.6 Results database

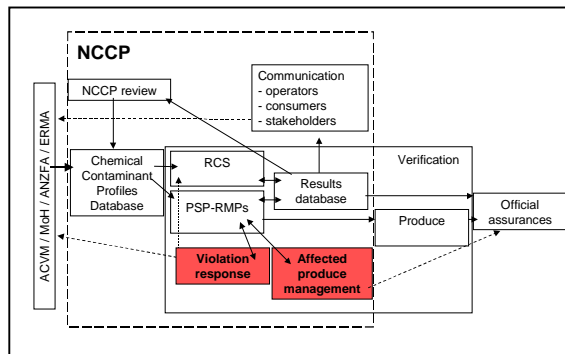


The results database would contain the regulated control scheme data submitted from programmes. The database would make it possible to summarise the information for assurances, communication, and feedback to regulatory organisations for monitoring and review.

Access to data would be restricted; operators will only be able to view their own data and data from the regulated control scheme related to their activities. This data would be viewed against summary information to enable the operator to assess how their contaminant types and levels differ from the general population level.

It has been proposed that the past five seasons' data from the existing NRMP be added to the results database. The feasibility of this proposal has not yet been investigated.

6.2.7 Regulatory non-compliance and management of non-conforming produce

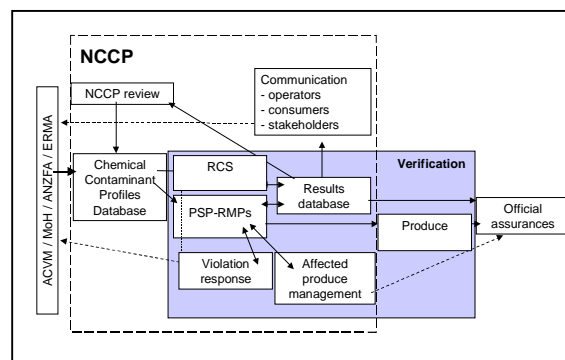


Whether identified by the regulated control scheme or the operator's programme, the NCCP would rely on the existing mechanism contained in MAF Standard D108 for the management of non-conforming produce.

Critical situations and non-compliances would be managed in accordance with the MAF Dairy Policy for the Resolution of Regulatory Non-compliances and the Application of Sanctions.

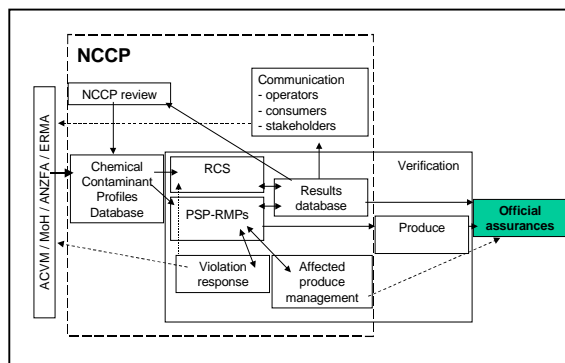
A database for tracking non-conforming produce is currently being developed as part of E-cert, and the NCCP would also rely on this database.

6.2.8 Verification



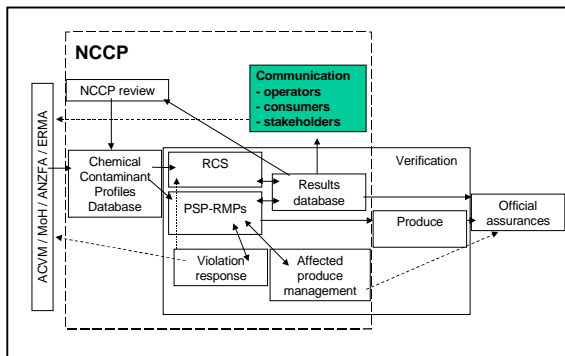
Similar to the operators' programmes and the existing NRMP, the NCCP regulated control scheme, results database, and systems for violation response and affected produce management will be subject to verification.

6.2.9 Official assurances



Official assurances will continue to be issued in accordance with MAF Standard D206, "Dairy Sanitary and Related Export Certification". The verification and provision of assurances will become increasingly automated as the dairy E-cert system is implemented. The NCCP design and development should be compatible with the E-cert system to utilise the information generated by the NCCP in verifying and providing export certificates.

6.2.10 Communication

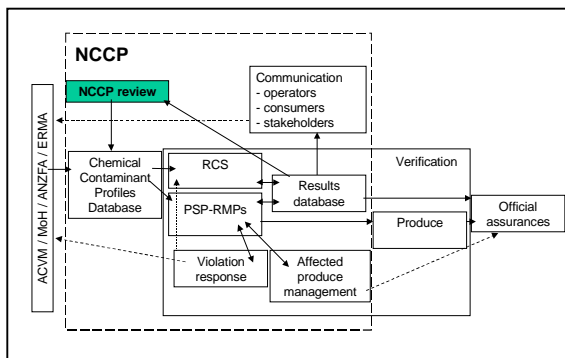


As mentioned in Section 6.2.6, the results database information will be summarised to provide information for communicating to farm operators, manufacturers, consumers, and stakeholders, and to ensure feedback to regulatory organisations for monitoring and review.

The NCCP would provide information for E-cert to generate a series of statements on the

MAF website on the New Zealand status with respect to certain contaminants.

6.2.11 Review



The NCCP will be subject to two review cycles.

The contaminants managed by the NCCP will be reviewed annually. This will result in changes to the NCCP classes of some contaminants and, consequently, to managing, sampling and testing. The review will also identify contaminants of specific concern that require follow-up with farm operators, manufacturers, or relevant regulatory

organisations.

Every five years the design, operation, legislation, and specifications of the NCCP programme would be reviewed. Contracts would be tendered and included in this five-years' cycle.

7. Plan for the development of the NCCP for Dairy

At its December 2001 meeting, the Dairy Product Safety Advisory Council (DPSAC) will be presented a paper, recommending whether to proceed with the NCCP development.

This paper will include a summary of the feedback on this Discussion Paper from the dairy industry and other stakeholders, outline the Terms of Reference, plan, and budget for the development and operation of the NCCP, and recommend the formation of a Steering Committee and project team (including the industry participants) for developing the programme.

If the DPSAC endorses the paper, the Steering Committee and project team would assume responsibility for the development and implementation of the NCCP.

The NCCP will be developed in three stages, with the priority given to the development and implementation of the regulated control scheme. As the existing NRMP comes to the end of its tenure in May 2002, the regulated control scheme starting in June 2002 should ensure there are no gaps in data collection. Development of the remainder of the NCCP will follow once the regulated control scheme is operational.

EU legislation requires that exporting countries operate a residue-monitoring programme complying with or equivalent to the legislative requirements (refer Appendix for further details). By March 2002, the NCCP would have documented and provided to the European Commission the supporting information necessary for acceptance of its equivalence to the EU legislation.

8. Your feedback

This Discussion Paper is provided for your and other interested stakeholders' information and comment. MAF encourages interested parties to consider the proposed programme for chemical contaminants and make submissions as outlined in the following section.

8.1 MAKING SUBMISSIONS

MAF Food: Dairy and Plant Products will consider all submissions received by the deadline of **7 December 2001**. Your submission should include the following information and comply with the following requirements:

- title of the discussion document;
- your name and title (if applicable);
- your organisation's name (if applicable);
- your address;
- section and page numbers to which your comments refer. All major sections are numbered, and these numbers should be used to link comments to the document;
- wherever possible, comments should be specific to a particular section of the Discussion Paper.
- comments should be to the point, and, where possible, we request you provide reasons and relevant data in support of your comments. Clearly specify the requested change;
- we encourage examples to illustrate particular points; and
- as your submission may be photocopied, please use good-quality type, or make sure the comments are clearly hand-written in black or blue ink.

You can make your submissions by either:

- **Sending comments to:**

Morag Cameron

Administration Co-ordinator

MAF Food: Dairy & Plants

PO Box 2526

Wellington

Phone: 04 474 4143

Fax: 04 474 4196

E-mail: cameronm@maf.govt.nz; or

- **Completing the document feedback form available on the MAF website.** You can access the form by clicking on the button at the bottom of the Publications page.

Please note that your submission is public information. If any information in your submission is commercially sensitive, or if you do not wish it to be released to other interested parties, please state this clearly.

8.2 THE NEXT STEPS

A summary of submissions will be prepared and posted on the Dairy & Plants website (www.maf.govt.nz/Dairy) at the end of the consultation period. Based on the submissions, a paper will be presented to the DPSAC for consideration at its 10 December 2001 meeting.

9. References

- Agreement between the European Community and New Zealand on sanitary measures applicable to trade in live animals and animal products. Agreement 297A0226(02), Official Journal L 057, 26/02/1997, p. 0005 - 0059. http://europa.eu.int/eur-lex/en/lif/dat/1997/en_297A0226_02.html
- *Agricultural Chemicals and Veterinary Medicines Act 1997*
- *Animal Products Act 1999*
- *Australian Food Standards Code*
- *Australia New Zealand Food Standards Code*
- Council Directive 92/46/EEC of 16 June 1992, laying down the health rules for the production and placing on the market of raw milk, heat-treated milk, and milk-based products. http://europa.eu.int/eur-lex/en/lif/dat/1992/en_392L0046.html
- Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC. http://www.europa.eu.int/eur-lex/en/lif/dat/1996/en_396L0023.html
- *Dairy Industry Act 1952*
- *Dairy Industry Regulations 1990*
- *Dairy Industry Restructuring Act 2001*
- *Food Act 1981*
- *Food Regulations 1984*
- *Food Administration in New Zealand. A risk management framework for food safety.* Joint Ministry of Health and Ministry of Agriculture and Forestry Food Harmonisation Project. Wellington New Zealand, June 2000
- *Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application*, Supplement to Volume 1B, Annex to CAC/RCP 1-1969, Rev 3 (1997). Codex Alimentarius Commission, 1997
- *Hazardous Substances and New Organisms (HSNO) Act 1996*

- MAF Standard D115, *Raw Milk Acceptance*. MAF Food: Dairy and Plant Products Group, Wellington New Zealand, 2001
- MAF Standard D107, *Dairy Product Safety*. MAF Food: Dairy and Plant Products Group, Wellington New Zealand, 1999
- MAF Standard D109, *Dairy Product Conformance*. MAF Food: Dairy and Plant Products Group, Wellington New Zealand, 1999
- MAF Standard D206, *Dairy Sanitary and Related Export Certification*. MAF Food: Dairy and Plant Products Group, Wellington New Zealand, 2000
- *NZCP 5 Dairy Product Safety Standards Code of Practice*. New Zealand Dairy Board Quality Section, Wellington New Zealand, 1992
- *Policy for the Resolution of Regulatory Non-compliances and the Application of Sanctions*. MAF Food: Dairy and Plant Products Group, Wellington New Zealand, 2000
- *Risk Management of New Zealand Dairy Products*. Discussion Paper No 14, MAF Food: Dairy and Plant Products Group, Wellington New Zealand, July 1999

Appendix: Background for the development of the NCCP for Dairy

HISTORY

Prior to 1990, MAF was directly involved in testing finished product and supervising laboratories testing raw milk and finished product. Thus, MAF had a detailed knowledge of the level and types of chemical contamination in raw milk and dairy products.

With the introduction of the *Dairy Industry Regulations 1990*, the management and demonstration of product safety became the manufacturer's responsibility in accordance with the requirements of a MAF-approved Product Safety Programme (PSP). Industry codes of practice, e.g. NZCP 5, were approved by MAF as a resource for the PSPs development.

In 1996, the New Zealand signed veterinary agreement with the EU, covering access standards for bilateral trade. This agreement recognised the equivalence of New Zealand's dairy industry regulations and programmes to the EU standards, however it recognised some additional requirements relating to raw milk, including surveillance of raw milk for residues of veterinary medicines and other contaminants.

Residues in raw milk

MAF Standards MRD 12 "Acceptance Standards for Raw Milk" and MRD 13 "Actions to be Taken for Non-complying Results for Raw Milk used for the Manufacture of Dairy Products to the European Union" were issued in 1996 and 1997, respectively, and the National Milk Residue Programme commenced in 1997. In 2001, MAF Standards MRD 12 and 13 were replaced by MAF Standard D115, "Raw Milk Acceptance". In June 2002, this Standard fully comes into force.

National Monitoring Programme for Residues in Raw Milk

MAF Dairy Newsletter 37 briefly outlines that for the continued trade access into EU markets surveillance programme is required to detect and control residues of both animal remedies and pesticides in milk at the time of collection from farm dairies.

The programme was developed by an industry working group, and is funded by export-aligned co-operative dairy companies, via the New Zealand Dairy Board. AgriQuality New Zealand Ltd (AgriQuality) has a five-year contract for operating the programme. All farm dairies supplying cow's milk to dairy companies are listed on its database. Each season, 300 farms are sampled by AgriQuality samplers, with the milk being tested for approximately 65 contaminants. Test results are provided to the dairy companies concerned, the New Zealand Dairy Board, and MAF Dairy. If the result is non-compliant, a relevant dairy company is required to trace back on the contamination, and report to MAF and the programme manager at AgriQuality. Contaminated milk and product is required to be segregated.

In the past two seasons this programme has been extended to include monitoring for aflatoxins and chemical elements. In addition, targeted sampling has investigated potential sources of contamination.

Contaminants in finished products

In December 1999, MAF issued two MAF Standards D107, “Dairy Product Safety”, and D109, “Dairy Product Conformance”. These standards define, respectively, the criteria for safe dairy product, and the means for demonstrating the finished product’s conformity to regulatory requirements, specifically sampling and testing. These Standards were derived from the export-aligned co-operative dairy companies’ *NZCP 5 Dairy Product Safety Standards Code of Practice* and the *Food Regulations 1984*, which include criteria for wholesomeness and foreign matter, pathogenic micro-organisms, residues of pesticides and veterinary medicines, fortified nutrients, toxic trace metals, and radionuclides.

CURRENT STATUS

Current programmes for managing contaminants

Currently, all data relating to finished product testing are held by the manufacturer, and are available to MAF at its request. There is no single database of information on the contaminant status of finished dairy products. Similarly, there is no feedback to the regulatory organisations that authorise contaminants conditions of use and limits (e.g. MRLs).

Residues of pesticides and veterinary medicines

The MAF AVCM Group, in accordance with the *Agricultural Chemicals and Veterinary Medicines Act 1997*, registers veterinary medicines and pesticides (agricultural compounds). The registration process examines the efficacy and safety of the active ingredients in trade-name products, works with the MoH to establish MRLs where required. If there is an acceptable level of risk, the trade-name product and its label are registered, and a withholding period (WHP) is set. Application of pesticides or veterinary medicines by veterinarians and farmers must comply with the label directions and WHP.

Raw milk

Dairy milk-processors’ PSPs are required to demonstrate that the milk being used is safe. The minimum criterion for chemical contaminants is that the milk used for manufacturing dairy products for sale in New Zealand and Australia complies with the New Zealand MRLs. Milk used for export (other than Australia) must comply with the Codex MRLs, unless there is an overriding importing country’s requirement.

The PSP must also contain requirements for sampling and testing of milk collected from farms for manufacturing dairy products. Raw milk must be randomly sampled and tested for inhibitory substances at least three times per month. The principal inhibitory substances likely to be detected in raw milk are antibiotics, although there is a possibility of other naturally occurring and contaminant inhibitory substances present in milk.

Some manufacturers also operate programmes for testing for other residues, the most notable being AnchorMilk's programme for managing DDT residues.

Contaminated milk is managed as non-conforming dairy produce or withheld milk when it is located on the farm or in the on-farm silo. Contaminated milk in tankers or processed milk is managed as non-conforming produce.

Finished product

Dairy product manufacturers, stores, and transporters must have, as part of their PSP, a HACCP plan to control the food safety hazards in their operation. Dairy products for sale in New Zealand or Australia must comply with the New Zealand MRLs, while export dairy products comply with the Codex MRLs. Manufacturers are required to perform conformance testing (multi-residue analysis) of each type of finished product at least once a month. The requirements for the multi-residue analysis have not been defined. Contaminated dairy products are managed as non-conforming produce.

Nutrient fortification

As mentioned above, dairy product manufacturers, stores, and transporters must have, as part of their PSP, a HACCP plan to control the food safety hazards in their operation. Infant and follow-on formulae that undergo nutrient fortification must comply with the Codex limits. Manufacturers must undertake conformance testing of one sample each from four lots per month.

Toxic trace metal contaminants

As mentioned above, dairy product manufacturers, stores, and transporters must have, as part of their PSP, a HACCP plan to control the food safety hazards in their operation. Dairy products must comply with Regulation 257 of the *New Zealand Food Regulations 1984* for the maximum permissible levels for elements. Where a dairy product is manufactured using ingredients, additives, processing aids etc., which might contain metal residues, a manufacturer must perform monthly conformance testing of one randomly selected sample of each product. Contaminated dairy products are managed as non-conforming produce.

Radionuclides

Dairy products should not exceed one tenth of the limits specified by Codex guideline levels for radionuclides in food following accidental nuclear contamination. The National Radiation Laboratory undertakes environmental surveillance, and MAF co-ordinates additional product surveillance. Manufacturers are not required to undertake sampling and testing for radionuclides as part of their PSP.

National Milk Residue Programme

The existing National Milk Residue Programme (refer Section 3.1.1.1) comes to the end of its tenure in May 2002, when the contract between the New Zealand Dairy Board and AgriQuality comes to the end of its term. This programme consists of statistical random and targeted monitoring of selected residues and environmental contaminants in raw milk. Samples are taken by independent samplers, and tested at independent laboratories. Testing results are reported by AgriQuality to the companies' nominated person, the Dairy Board, and MAF Dairy. In the event of a violation or an unusual result, the company must undertake an investigation and follow-up, and—if there is a violation—isolate affected produce and manage it as non-conforming.

This programme provides information on the incidence of inhibitory substances in raw milk, thus making it possible to monitor the effectiveness of the relevant ACVM registration process and PSP management procedures. This programme also assesses the level of risk from other contaminants, the effectiveness of existing control procedures, and takes corrective actions where violations are detected.

NEW ZEALAND'S LEGAL REQUIREMENTS

Briefly, the law deals with the requirements for raw milk to ensure its suitability for manufacturing dairy products that are safe and fit for human consumption, and to ensure it is not adulterated.

The requirements for the production, supply, manufacture, transport, storage, sale, and export of dairy produce, including milk, are contained in the *Dairy Industry Act 1952*. The *Dairy Industry Regulations 1990* provide regulations for the production, supply, manufacture, transport, storage, sale, and export of dairy products (for human consumption).

The *Dairy Industry Regulations 1990* and MAF standards apply to all manufacturers of dairy products, with the exception of those covered by the harmonisation project. The *Dairy Industry Regulations 1990* include requirements for:

- excluding milk that may be contaminated with extraneous substances, toxic substances, or pesticides capable of rendering milk unsafe, from sale to dairy factories;
- excluding adulterated milk from sale;
- safe dairy produce (raw milk) to be used for manufacturing dairy products.

Recent amendments to *Dairy Industry Act 1952* provide for monitoring of residues in dairy produce.

In addition, dairy products sold as food in New Zealand or Australia must comply with the requirements of *Food Act 1981*, the associated New Zealand food standards, and one of the following: the *Food Regulations 1984*, the *Australian Food Standards Code*, or the joint *Australia New Zealand Food Standards Code*. However, under the provisions of *Trans-Tasman Mutual Recognition Act 1997*, matters relating to health and safety of persons in New Zealand (such as MRLs for agricultural compounds) may differ from those applying in Australia.

INTERNATIONAL STANDARDS AND GUIDELINES

Codex Alimentarius Commission

The SPS Agreement seeks to further the use of harmonised sanitary measures on the basis of international standards, guidelines, and recommendations developed by the relevant international organisations, including the Codex Alimentarius Commission (Codex). Codex has developed a comprehensive work plan for incorporating principles of risk analysis within its activities wherever possible. The use of Codex standards as a benchmark for national standards is rapidly increasing worldwide.

Consequently, Codex standards and guidelines need to be incorporated in the design and development of programmes managing chemical contaminants. Specific Codex documents that need to be taken into consideration include:

- CAC/RCP 001-1969 Recommended International Code of Practice of General Principles of Food Hygiene
- CAC/GL 005-1989 Guideline Levels for Radionuclides in Foods Following Accidental Nuclear Contamination for Use in International Trade
- CAC/GL 006-1991 Guideline Levels for Vinyl Chloride Monomer and Acrylonitrile in Food and Packaging Material
- CAC/GL 026-1997 Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems
- List of Codex Extraneous Maximum Residue Limits in Food
- List of Codex Maximum Residue Limits for Pesticides Residues in Food
- CAC/GL 016-1993 Guidelines for the Establishment of a Regulatory Programme for Control of Veterinary Drug Residues in Foods
- CAC/RCP 038-1993 Recommended International Code of Practice for Control of the Use of Veterinary Drugs
- List of Codex Maximum Residue Limits for Veterinary Drugs
- CODEX STAN 192-1995 Preamble to the General Standard for Food Additives
- CODEX STAN 193-1995 Preamble to the General Standard for Contaminants and Toxins in Foods

International Dairy Federation (IDF)

IDF has a number of publications on contaminants in milk and milk products, e.g. S.I. No. 9701, 1977. Monograph on Residues and Contaminants in Milk and Milk Products.

The IDF Standing Committee on Residues and Chemical Contaminants collects and presents information on risk assessment of residues and contaminants, and advises on risk management.

IMPORTING COUNTRY REQUIREMENTS

European Union

Milk and Milk Products Directive (92/46/EEC)

The EU/NZ Veterinary Agreement does not provide for equivalence for the National Milk Residues Programme due to its non-existence at the time of signing the agreement. Consequently, the requirements of Council Directive 92/46/EEC of 16 June 1992 laying down the health rules for the production and placing on the market of raw milk, heat-treated milk, and milk-based products apply.

Article 15 of the Directive requires that competent authorities have implemented national measures to comply with the requirements of Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products.

Article 15 also requires

“that tests are carried out to detect any residues of substances having a pharmacological or hormonal action, and of antibiotics, pesticides, detergents and other substances which are harmful or which might alter the organoleptic characteristics of milk or milk-based products or make their consumption dangerous or harmful to human health, insofar as those residues exceed the permitted tolerance limits. If the milk or milk-based products examined show traces of residues which exceed the permitted tolerances, they must be excluded from human consumption.”

This is further and specifically reinforced by the following requirement in Annex A, Chapter III:

“Milk must not be used for human consumption if it contains antibiotic residues in a quantity which, in respect of any one of the substances referred to in Annexes I and III to Regulation (EEC) No 2377/90 (1), exceeds the levels authorized therein”

Residue Monitoring Directive (96/23/EC)

This Directive sets up specific requirements for the design and operation of programmes administered by the competent authority to monitor certain substances and residues in live animals and animal products, including milk. The programme specifies the compounds to be monitored, the number of samples required, the means by which samples are taken, handled, and reported, and follow up actions. Annually, the competent authority of each member state is required to submit to the Commission for its approval the plan for the coming year, and the results from the preceding year.

Third countries such as New Zealand, authorised to import animals and animal products into the EU are also required to submit annual plans for authorisation by the Commission. These plans must provide guarantees at least equivalent to those contained in the Directive, and, in particular, meet the requirements of Article 4, specify the particulars laid down in Article 7, and meet the requirements of Article 11 (2) of Directive 96/22/EC. (Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stock-farming of certain substances having a hormonal or thyrostatic action and of β -agonists)

EU audit 2000

In May 2000, the European Commission's Food and Veterinary Office audited the New Zealand's programmes for residues in meat, honey, and milk programmes, and identified a number of defects relating to the milk residues programme. Corrective actions have been undertaken to eliminate these defects. MAF has indicated that it is redesigning New Zealand's dairy residue programme, and will be seeking equivalence for the new programme (the NCCP).

USA

Memorandum of Understanding between the USA FDA and MAF states that,

“MAF agrees to inspect each lot of dry milk product produced in New Zealand for and offered for export to the United States of America to assure that the lot is....penicillin negative.”

Brazil

Brazil and New Zealand signed Memorandum of Understanding. On its basis, a technical agreement (including sanitary certification) for exporting animal products, including dairy products, from New Zealand to Brazil is currently being negotiated. The proposed sanitary certificate states:

“The product is safe and fit for human consumption and does not contain harmful levels of additives or contaminants.”

Other countries

A range of assurances relating to chemical contaminants in dairy produce is provided to competent authorities in other countries through attestations in sanitary and related export certificates. These assurances include:

- residues of veterinary medicines (including antibiotics);
- residues of pesticides (including organochlorines, organophosphates);
- environment contaminants (including PCBs, dioxins, heavy metals, radionuclides);
- aflatoxins;
- antiseptics
- harmful substances.