Final Report
of the
Workshop on National Surveillance of Veterinary Drugs in Foods

Government Conference Center, Ottawa, Ontario, March 30, 2004

Sponsored by:
Veterinary Drugs Directorate, Health Products and Food Branch, Health Canada
Food Directorate, Health Products and Food Branch, Health Canada

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Executive Summary

Canada does not possess a national system to coordinate food surveillance activities or share data on chemical contaminants in foods among federal, provincial and territorial organizations. Participants at the Workshop on National Surveillance of Potentially Hazardous Chemicals in Foods, held in Ottawa on March 10-12, 2003 clearly favoured establishing some means of data sharing and improving the level of coordination between government organisations. Progress updates on several recommendations from that workshop were presented at Health Canada's Workshop on National Surveillance of Veterinary Drugs in Foods on March 30, 2004 including: the development of a web-based database to facilitate collaboration and coordination of food surveillance activities, an initial evaluation of the US electronic laboratory exchange network (eLEXNET), and a pilot study of veterinary drugs in foods to identify and provide solutions to issues related to increased coordination of surveillance activities.

Following plenary presentations on results from the Veterinary Drug Surveillance Questionnaire, the Pocket eLEXNET Pilot Project and a National Food Surveillance Activity Database, participants were divided into three breakout groups and asked to complete the following tasks:

- Identify issues related to access, cost, quality, ownership and use of a database
- Assess database use and identify its most important features
- Review the following database scenarios involving federal, provincial, and territorial organisations:
  - connect directly to the US electronic laboratory exchange network (eLEXNET) with no Canadian data sharing network.
  - share information through a Canadian Laboratory Information Network (CANLINE)
  - share data through a CANLINE which is also a portal to eLEXNET.

Conclusions

Participants unanimously agreed that the preferred scenario was a CANLINE used as a portal to eLEXNET. To offset some of the drawbacks to this scenario that include the possibility of higher costs, confusion over different sets of data, longer start-up time, future integration with other systems, participants suggested the following:

- Build on experience of eLEXNET to keep costs down
- Work towards developing a Memorandum of Understanding on future use and integration of systems
- Develop synchronization, training and communication strategies to coordinate data between the Canadian portal, CANLINE and eLEXNET
- Make clear decisions on which authority takes ownership for training, maintenance, on-line help, communications, privacy and system abuse issues.

Next Steps

The following items were identified from the breakout sessions as the next steps in the establishment of a national food surveillance system:

- Seek approval from the US FDA to enter Canadian data for veterinary drugs in food into the pocket eLEXNET trial currently underway

- Scan existing database and data sharing systems in Canada to assess what is available and determine feasibility of building on these resources
- Determine costs for each proposed scenario
- Respond to privacy and ownership issues
- Leave channels of communication open with US federal health authorities.

Introduction

In March 2003, federal, provincial and territorial participants at the Workshop on National Surveillance of Hazardous Chemicals in Foods discussed possible means of sharing data and improving collaboration and co-ordination of Canadian food surveillance activities. The Workshop on National Surveillance of Veterinary Drugs in Foods, March 30, 2004 facilitated further consultations with more than 40 scientists, statisticians, computer specialists and other stakeholders from federal and provincial agencies to examine options for the next steps in establishing a national food surveillance system. Participants were provided with progress updates on recommendations from the previous workshop including:

- The development of a web-based national food surveillance activity database, as a registry of "who does what" in Canadian food surveillance programs
- The selection of veterinary drugs as the pilot project for examining issues associated with exchanging data, coordinating activities and sharing a database
- A preliminary evaluation of eLEXNET, the US electronic exchange network for data sharing among Canadian and US participants.

Participants divided into three breakout groups following plenary presentations on results from the Veterinary Drug Surveillance Questionnaire, the Pocket eLEXNET Pilot Project and a National Food Surveillance Activity Database. In their breakout sessions, participants were asked to complete the following tasks:

- Identify issues related to access, cost, quality, ownership and use of a database
- Assess database use and identify its most important features:
- Review the following database scenarios involving federal, provincial, and territorial organisations:
    - connect directly to the US electronic laboratory exchange network (eLEXNET) with no Canadian data sharing network
    - share information through a Canadian Laboratory Information Network (CANLINE)
    - share information through CANLINE which is also a portal to eLEXNET.

Participating organizations' responses to Health Canada's surveillance questionnaire on veterinary drug residues guided the preparation of the database scenarios for the workshop.

Opening Remarks

The workshop chair, Dr. Samuel Benrejeb, Associate Director, Bureau of Chemical Safety, Health Canada asked participants to suggest ways to improve collaboration, coordination and information sharing between federal, provincial and territorial agencies and develop partnership opportunities.

In his opening remarks, Paul Mayers, Director General, Food Directorate, Health Canada stated that the objective of the workshop was "to develop recommendations on how to move forward" on tasks set at the previous year's Workshop on the National Surveillance of Potentially Hazardous Chemicals in Food (WNSPHCF). These recommendations were to establish a web-based database of food surveillance and monitoring activities and experts, develop a pilot study examining "who is doing what" in surveillance and monitoring in the area of veterinary drug residue analysis, and communicate the results of a national survey.

Further, suggestions on "partnering surveillance of chemicals in our food supplies" will improve the risk assessment and policy development work of Health Canada's Food Directorate to better serve Canadians.

Results from the Veterinary Drug Surveillance Questionnaire(link to workshop2004presentations.pdf)

Dr. Sheryl Tittlemier, Food Research Division, Bureau of Chemical Safety, Health Canada presented the results of the Veterinary Drug Surveillance Questionnaire that was sent to organizations across Canada involved in surveillance and monitoring of veterinary drugs. The questionnaire built on WNSPHCF's recommendations in 2003 to better utilize resources, use Web-based technology, and implement a national pilot study on the surveillance of veterinary drug residues in food.

The National Veterinary Drug Residue Monitoring and Surveillance in Food Pilot Study Survey attempts to find the answers to the following questions:

- Who does what?
- Who is analyzing what compounds?
- What methods are used?
- How are results coordinated?

Seven of the ten attending organizations responded to the questionnaire. Of these, six conduct tests in their own facilities. The Aquaculture Division of the Nova Scotia Department of Agriculture and Fisheries requests testing from the Canadian Food Inspection Agency (CFIA) or the New Brunswick aquaculture laboratory when residue analysis is required before processing. Most provinces have their own laboratory facilities for analysis.

The key findings of the Veterinary Drug Surveillance Questionnaire were:

- Antibiotics and anti-bacterials are key analytes in veterinary drug surveillance and monitoring activities
- The methods for testing drug residues vary, including instrumental techniques (HPLC, LC-MS/MS and GC-MS) as well as rapid screening of immunochemical assays and microbial inhibition assays and TLC
- Most of the food products tested were derived from animal products: dairy products, meat, eggs, fish, seafood, and poultry
- A wide range of foods was tested, from raw milk to cooked food products, to reflect what Canadians consume.

The surveillance and monitoring activities are undertaken for the following reasons:

- To determine compliance and ensure safe levels of residues
- To provide support to industry
- To conduct research and risk assessment
- To provide information to consumers.

Data is stored in different formats including in-house LIMS and Oracle databases and Lotus 123 and Excel spreadsheets.

Results are shared widely with other federal government divisions, federal and provincial organizations, industry and producer associations, and representatives of the scientific community and the public. A number of vehicles are used to share survey results:

- Web sites
- Reports, industry/producer conferences and workshops
- Peer reviewed journals and articles
- Scientific conferences and workshops.

eLEXNET-An Update on the Pocket eLEXNET Pilot (link to workshop2004presentations.pdf)

Dr. Xu-Liang Cao, Food Research Division, Bureau of Chemical Safety, Health Canada and Dr. Colin Broughton, Regional Director, Ontario and Nunavut Region, Health Products and Food Branch, Health Canada, described the objectives and function of eLEXNET as:

- A seamless, integrated, secure system that allows multiple government agencies engaged in food safety activities to compare, communicate, and co-ordinate laboratory analysis findings
- Providing the necessary infrastructure for an early-warning system that identifies potentially hazardous foods and enables health officials to assess risks and analyse trends.

eLEXNET is funded by the US Food and Drug Administration and has been joined by 100 federal, state and local laboratories in the US. Contained in it are analysis results of over 100 marketed food products. The US Department of Homeland Security (DHS) requires all US federal departments to use the system when reporting analytical work carried out during a food emergency.

The Pocket version of eLEXNET is a fully functional eLEXNET with information only for and from Canadian sources. The purpose of the Pocket version is to test the functionality and utility of the main system and to determine whether Canada should join. In the Pocket version, Canadian health authorities cannot access data in the main eLEXNET system. Similarly, US health organizations, with the exception of the US FDA, cannot access Canadian data.

In 2002 the US FDA invited Health Canada and the Mexican Health Authority (HA) to join eLEXNET. In July 2003, Health Canada decided to participate in eLEXNET to test its functionality and utility. In November 2003, training for Health Products and Food Branch staff was approved, and Health Canada and US FDA decided to enter the results of its recent infant formula survey. In March 2004, Health Canada received a password and accessed Pocket eLEXNET. Implementation of sample data from Health Canada's infant formula studies began.

The next steps:

- Complete manual entry of infant formula data, a time-consuming process
- Consider options to input data automatically from spreadsheets
- Continue evaluation of the system's "functionality and utility"
- Decide whether to join the main eLEXNET.

Workshop participants received 'a tour' of the eLEXNET system and were shown how food product test samples are coded, data entered and reports structured.

The National Food Surveillance Activity Database (NFSAD): An Update (link to workshop2004presentations.pdf)

Dr. Don Forsyth, Food Research Division, Bureau of Chemical Safety, Health Canada described the background and progress to date on a national food surveillance database, future goals and directions that could be undertaken.

The NFSAD database is a key recommendation from WNSPHCF. Its purpose is to promote collaboration and coordination of food monitoring/surveillance activities through the development of a registry of "who does what."

The goals for NFSAD are fourfold. It will be used to:

- Collect information on federal, provincial and territorial food surveillance activities
- enhance awareness of areas of expertise and food surveillance activities in Canada among federal and provincial colleagues
- Increase collaboration and coordination of Canadian food surveillance activities
- Leverage existing resources to improve efficiency of operations during normal or emergency situations.

Dr. Forsyth outlined a number of features of NFSAD. The database will contain contact information, food surveillance activity profiles and research interests of food surveillance experts. Participants can update their own information profiles. Health Canada will load information into the NFSAD. Searches will examine all data fields using Boolean logic operators. The database will be bilingual.

Describing the use of NFSAD, Dr. Forsyth said federal, provincial and territorial participants would first provide information using NFSAD's Web-based questionnaire. After participants submit the completed questionnaire, Health Canada would verify contact information, translate the information and place it into the NFSAD database. Registered participants would then be able to view the provided information.

Short-term goals include completing current database development, beta testing and encouraging participation through regional liaison officers, the Federal/Provincial/ Territorial Committee on Food Safety Policy, presentations and the Health Canada Web site.

A longer term goal is to add program enhancements to NFSAD including:

- data sharing capacity so laboratories can report contaminant levels and commodities
- manual and automated data entry
- additional reporting formats to facilitate comparison and communication of laboratory results
- bulletin board discussion group.

NFSAD with the described program enhancements would become the Canadian Laboratory Information Network (CANLINE). Dr. Forsyth described three database-sharing scenarios for participants' consideration:

- Federal, provincial and territorial organizations connect directly to eLEXNET with no Canadian data-sharing network
- Federal, provincial and territorial organizations share information through CANLINE
- Federal, provincial and territorial organizations share data through CANLINE, which is also a portal to the US main system eLEXNET.

Key issues for consideration include short and long-term costs of each scenario and questions such as with whom to share the data, what data and when to share it.

Plenary Panel Discussion

Participants raised the following issues during the plenary discussion:

- Sovereignty and security issues related to sharing sensitive data with international partners
- Proper accreditation of data sources
- Legal protection and access to legal and financial compensation if research data is cited inappropriately
- Economic and financial implications for Canadian companies if US organizations have access to Canadian research data
- Legal implications and ability to back out of an agreement with the US FDA if the system is not considered functional or useful
- Usefulness of applying an early warning system for chronic exposure to chemicals in food
- Timeliness of including sensitive data
- Integrating existing Health Canada data surveillance systems such as the Laboratory Information Management System (LIMS) and Laboratory Data Management System (LDMS).

Dr. Broughton told participants a food surveillance database for North American partners could prevent costly communication errors exemplified by the Californian strawberry and Guatemalan raspberry mishap a few years ago. He suggested that a North American database would provide health risk managers access to clusters of incidences. "It's a way of bringing together information for an early resolution of safety issues." Although costly, eLEXNET has helped prevent millions of dollars in health fraud in the US and Canada.

Provincial representatives of Quebec, Ontario and Manitoba expressed support in principle for the notion of a national surveillance database; however, cost, rapid publication of results and sharing of sensitive information with international partners before sharing results in Canada were considerations that were noted among participants.

Breakout Sessions

Following the plenary presentations and discussion, three breakout session groups with more than 12 participants each, reviewed and made recommendations on three themes: data issues, database features, and assessing database scenarios.

Data Issues-Summary of Discussion

How would organizations use a database?

Participants agreed their organizations would use CANLINE to do the following:

- Plan for future testing
- Enhance risk assessment through identification of clusters
- Improve sampling size and population studies
- Harmonize sampling methodologies and standards
- Promote transfer of technology and studies between Canadian laboratories
- Identify gaps in research
- Find out "who's doing what?"
- Reduce duplication in research and "leverage" existing research resources.

What should go into a database?

Participants agreed that a database should include:

- A definition of terms
- Agreement on "analytical" methods used
- Information on screening and method performance characteristics
- Maximized linkages to other existing databases e.g. in-house databases, eLEXNET.

Other suggestions included the following:

- Tested commodities and matrices
- Only summaries of screened testing results to be entered
- An automated interface to import/export data
- A legal agreement with registered users is required.

How to evaluate a database's usefulness

Participants considered the following criteria important indicators of a database's utility:

- The number of buy-ins by registered users
- How data are shared and used

- Whether or not laboratories are using the data
- Whether it influences an organization's planning and contributes to business decisions
- Whether regional health and safety officers endorse it.

Who should have access to data?

Federal, provincial, and territorial governments and their respective agencies should have access to data. Participants agreed industry, the public, trading partners, and non-governmental organizations should have limited access to data. Data that identifies products, companies and individuals should be excluded from the database. There should be a distinction between compliance data and exploratory data.

Cost Concerns

Provincial representatives indicated costs of the database were a concern and that every effort should be made to maximize existing resources and reduce costs. It was suggested that data contributors should receive a discount if a user fee system is adopted.

Data Quality

Participants agreed that quality management of data is required. One group recommended defining the quality control measures used in the analyses and using the ISO 17025 format. Another group emphasized the importance of the ability to remove data.

Data Ownership

Participants agreed legal agreements and other guidelines should be established to control ownership issues related to data. To address ownership concerns, participants suggested the following:

- Authors provide explicit permission for publication of research and that the database appropriately credits publications
- Authors be able to seek recourse if their work is published without consent or not credited
- Federal, provincial, and territorial departments and agencies control ownership of the database.

One group suggested that authors prepare to relinquish ownership of research once it enters the database. This was a minority opinion.

Database Features-Summary of Discussion

The breakout sessions provided a wide range of complementary suggestions for "most important" database features. All participants agreed the database should be user-friendly, accessible and relevant. Participants considered the following features essential: search, report, import/export and data storage. One group suggested the search features identify foods by group, tissue type, analytes, time, and geography. The database also requires a high level of automation, speed, security, data transfer capacity by DBF, Oracle, and Excel software, online help, use of passwords, and the ability to phase-in upgrades without substantial increases to the initial cost outlay.

Other Issues and Concerns

Participants raised the issue of who owns and operates the database on behalf of organizations and Canadians. If the database crashes who is responsible for technical repairs and maintenance? Some workshop members expressed concerns about the length of time it takes to input data manually. Participants recommended that the database have flexible input features with options for manual and automated programming. Speed and security are other issues.

Assessing Database Scenarios-Summary of Discussion

Participants unanimously agreed to the third scenario suggesting CANLINE be used as a portal to eLEXNET. To offset some of the drawbacks to this scenario that include the possibility of higher costs, confusion over different sets of data, longer start-up time, future integration with other systems, participants suggested the following:

- Build on experience of eLEXNET to keep costs down
- Work towards developing a Memorandum of Understanding on future use and integration of systems
- Develop synchronization, training and communication strategies to coordinate data between the Canadian portal, CANLINE and eLEXNET
- Make clear decisions on which authority takes ownership for training, maintenance, on-line help, communications, privacy and system abuse issues.

Workshop Conclusions and Next Steps

Dr. Samuel Benrejeb said participants had met most of the objectives on how to move forward with a national surveillance process on veterinary drugs in food considered as a pilot for a National Surveillance of Chemicals in food**.** "The level of buy-in from participants to project initiatives was very high, if not unanimous," he said. Health Canada has been given the mandate to participate in the evaluation of eLEXNET. Next steps can be summarized as follows:

- Seek approval from the US FDA to enter Canadian data on veterinary drugs in food into the pocket eLEXNET pilot project underway
- Scan existing database and data sharing systems in Canada to assess what is available and determine feasibility of building on these resources
- Determine costs for each proposed scenario
- Study a response to privacy and ownership issues.

Appendix A. Evaluation of the Main eLEXNET System to the Needs of Food Directorate, Health Canada

Xu-Liang Cao and Samuel Ben Rejeb, Bureau of Chemical Safety, Food Directorate, April 2004

This evaluation is based on the use of the Pocket eLEXNET system which has the full functionality of the main eLEXNET system but has very limited data from Health Canada and US FDA and thus some features of the main eLEXNET system (e.g., mapping) could not be evaluated.

The eLEXNET (electronic Laboratory EXchange NETwork) is a seamless, integrated, secure system that allows multiple US government agencies engaged in food safety activities to compare, communicate, and coordinate laboratory analysis findings. It provides the necessary infrastructure for an early-warning system that identifies potentially hazardous foods and enables health officials to assess risks and analyse trends. This program is funded by the US FDA, and supported by the US Dept. of Agriculture and Dept. of Defence. eLEXNET has been designated by the US Dept. of Homeland Security as the system to be used by all US federal departments when reporting analytical results generated during food emergency.

The main eLEXNET system is fully functional in the US, and currently has the microbiological and/or chemical results of over 100,000 marketed food products submitted by 100 US federal, state, and local laboratories, thus joining this system will provide Health Canada with immediate access to these data. Over 80 attributes were designed to capture the information of samples and tests, even though most of these are not mandatory. Among the attributes, product code, which contains at least three components (industry code, class code, and group code), is unique to describe the product precisely and thus minimize the possibility of incorrect sample identity. Although it has not been tested while inputting data to the Pocket eLEXNET system, it is claimed that data can be imported to the eLEXNET system directly from the spreadsheet, which will save time significantly considering the fact that the option of manual data entry is very time-consuming.

However, the current version of the main eLEXNET system presents the following limitations:

1. Language

Since this is a US-based database, it is available only in English. Some users in Canada may prefer to use French. Both data entry and displays of results on a web-based application have to comply with the official languages act.

2. Tedious manual data entry

Manual data entry of the current version of eLEXNET system appears extremely tedious. This is in part due to the exhaustive list of attributes for samples and tests. Another reason is related the design of the database itself since it uses the multi-screen approach to capture information of samples and tests. No less than 10 screens are needed to capture the information for the sample

itself, and additional 15 screens are required to capture the information for each test of the sample. If a sample was analysed for 10 chemicals (10 tests), this would translate into 160 screens in order to enable the capture of all information needed for the sample and the tests. A single-screen approach would be preferred for this task.

The eLEXNET system is claimed to enable the direct transfer of data from spreadsheets. However, this approach has not been explored yet, and it is unknown if additional manual entry is required to complete the direct data importing process.

3. Exporting format

Some uses of the database (e.g., risk assessment, comparison of contaminant levels in foods from different regions, countries, etc.) require frequent manipulation of the data in the database. This requires that the data be exported in a format (e.g., sample information tabulated in a spreadsheet style contained in an Excel file) that allows further manipulation.

Data in the current main eLEXNET system can only be exported in a *text* format and in a *PDF* file. This makes data manipulation almost impossible without further text processing. An improvement of the current version of eLEXNET system should be recommended in order to include an alternative "data exporting" format (in spreadsheets: Excel file, Lotus and others).

4. Dietary intake data

This database contains the concentrations of chemical contaminants (and also microbiological) in foods, but does not contain the actual dietary intake data of the contaminants.

While it appears extremely valuable to be part of the evaluation and possible utilisation of the e-LEXNET system, it is highly recommended that a similar application (possibly a licensed version) be made available for Canadian users. This can then serve as a portal to a North American database with a better coordination of the input of Canadian data.

Several approaches were presented at the last workshop on coordination of veterinary drug surveillance activities (March 30th, 2004) and will be investigated by the Food Directorate in collaboration with other organisations (F/P/T).