

International Peer Review of FSANZ GM Food Safety Assessment Process

By Dr. William Yan

Executive Summary

FSANZ has established itself internationally as one of the leading regulatory authorities to regulate and conduct safety assessment of Genetically Modified (GM) foods. A small but knowledgeable, dedicated team of scientists in the Risk Assessment Chemical Safety Section and Product Safety Standards Section of FSANZ routinely conduct robust, risk-based and evidence-based pre-market safety assessment of GM foods. FSANZ has also established an internal working group, the GM team, to assist with ensuring consistency across GM food safety assessments. These safety assessments are performed based on concepts and principles which are developed and recognized internationally through extensive OECD, FAO-WHO and Codex Alimentarius expert consultations. The GM food safety assessment process employed by FSANZ is scientifically rigorous, conducted on a case-by-case basis and is one of the most, if not the most transparent in the world. In addition to completing over 30 GM food approvals to date, FSANZ has also played key roles internationally by participating in and leading a number of expert consultations and task forces as well as numerous capacity building initiatives around the world. These activities have further strengthened the science capacity of FSANZ staff and solidify FSANZ as an international leader in the area of GM food safety assessment.

In addition to the extensive scientific knowledge of the GM team, FSANZ also has access to valuable scientific expertise from the network of distinguished FSANZ Fellows as well as other national and international experts when needed. FSANZ should be commended for the high standard of work it has completed to date in ensuring a safe and nutritious food supply while continuing to keep pace with the innovation of modern food biotechnology. Future food products developed from emerging technologies, such as drought tolerant crops, GM animals, crops with multiple stacked traits as well as GM foods modified for nutritional or health benefits, will undoubtedly create new regulatory challenges and necessitate technical expertise and novel approaches and tools in order to permit effective and timely pre-market safety assessment of these products. To this end, FSANZ is well positioned to build on its strong foundation, to enhance its ability to tap into the pool of scientific expertise available in the FSANZ Fellows and other experts in relevant disciplines, and most importantly, to continue its international efforts in harmonizing and advancing GM food safety assessment approaches as well as strengthening collaborations with other regulatory authorities to meet the challenges posed by the next generation of GM foods.

Recommendations (summary)

1. Maintain a strong scientific GM team and further strengthen expertise to address future challenges associated with the safety assessment of next generation of complex GM foods.
2. Enhance the process of engagement of external scientific expertise as appropriate to address any future knowledge gaps in assessing the safety of GM food.
3. Investigate the feasibility of managing workload associated with the safety assessment of GM food applications.
4. Continue to engage and establish closer working relationship with other Australian and New Zealand regulatory agencies.
5. Continue to build on FSANZ's strong international reputation as leader in GM food safety assessment and explore mechanism(s) to enhance collaboration with international regulatory partners.
6. Continue to provide an open and transparent GM food safety assessment process and enhance the risk communication efforts with key stakeholders.

Introduction

I was invited by Food Standards Australia New Zealand (FSANZ) to conduct an international peer review of the FSANZ GM food safety assessment process. I have extensive knowledge and experience in the regulation and safety assessment of Novel Foods, including GM foods, in Canada. From 1999-2008, I was initially Head of the Office of Food Biotechnology and was later appointed as Chief of the Evaluation Division of the Bureau of Microbial Hazards in the Food Directorate of Health Canada. During this time, my main responsibility was to oversee Health Canada's regulation and pre-market safety assessment of novel foods, including GM foods. I also led the revision of Health Canada's Guidelines for the safety assessment of novel foods in 2007. I have participated in a number of Codex Alimentarius working groups and task forces as well as FAO-WHO expert consultations. From 2002 to 2008, I was the Head of the Canadian delegation for the OECD Task Force on Safety of Novel Foods and Feeds. I was also the Head Delegate for the Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology in 2007. Finally, in collaborations with organizations such as FAO, ILSI, ASEAN and APEC, I conducted a number of international training workshops on the safety assessment of GM foods in various regions around the world including Southeast Asia, Moscow, Latin America and South Africa. My complete *curriculum vitae* is provided in Appendix 1.

From May 15th to May 22nd, 2008 I visited the FSANZ Canberra office in order to obtain a detailed understanding of how FSANZ conducts the safety assessment of GM foods. Prior to the visit, I had examined in details a number of FSANZ reports and publications related to GM food safety assessment. This included relevant sections of the FSANZ Application Handbook, the GM Food Safety Assessment Guidance Document (Updated 2007) as well as a First Review and Final Reports of GM food safety assessments (Amylase modified corn line 3272 and High-lysine corn LY308). On May 16th, I met with FSANZ Chief Scientist (Dr. Paul Brent), FSANZ General Manager, Risk Assessment Branch (Dr. Andrew Bartholomaeus), FSANZ Principal Scientist (Dr. Lisa Kelly) and members of the GM team. The meetings were extremely useful in providing me with operational and scientific details involved in the FSANZ GM food safety assessment process. On May 19th, I attended the Food Regulators' Science Network Forum Workshop on GM Food Safety Assessments and gave the keynote presentation entitled "Regulation and Safety Assessment of Genetically Modified Foods in Canada". The workshop participants included staff members of FSANZ and other government departments, representatives from States and Territories, New Zealand Food Safety Authority, Biotechnology Australia, FSANZ Board members as well as FSANZ Fellows. The main objectives of the workshop were to describe the regulatory framework for GM foods in Australia and New Zealand, to outline the essential elements of the safety assessment of GM foods and their labelling and detection as well as to discuss current and future challenges facing regulatory authorities. On May 20th, I had the opportunity to meet with representatives from Australian and New Zealand government agencies as well as key stakeholders to get a better overall understanding of the complex regulatory system in which GM foods are regulated and approved in the two countries. In the afternoon, I gave a presentation on how novel foods in Canada are regulated to a number of FSANZ staff. The presentation was well received and generated significant amount of information exchange and discussion. On May 21st, I met with FSANZ Board members to discuss my international peer review of the FSANZ GM foods safety assessment process as well as to provide some information on how novel foods are regulated and

assessed in Canada. Following the meeting, I was able to prepare some initial findings from my visit before departing Canberra on May 22nd. Overall, the short visit to FSANZ in Canberra was very productive and provided me with valuable insight and information to supplement the knowledge I had obtained from earlier review of FSANZ documents in order to complete the peer review.

Objective, Scope, and Terms of Reference of the Peer Review

The main objective of the international peer review of FSANZ GM food safety assessment process is to benchmark FSANZ performance in GM food safety assessment against international best practice and identify areas for enhancement of FSANZ's scientific capability.

SCOPE

The review focussed on the FSANZ approach to the safety assessment GM foods, including:

- Technical and scientific aspects, such as the data requirements for safety assessments, concordance of the FSANZ assessment procedures with international best practice for GM foods;
- Procedural and regulatory aspects (to extent that can be accommodated within existing FSANZ legislation), such as the interaction of scientific disciplines within FSANZ to undertake the evaluations, the use of the safety assessment to inform the regulatory decision; and
- Communication aspects, such as documentation of FSANZ GM food safety assessment principles and procedures, presentation of safety assessment reports, interactions with stakeholders.

TERMS OF REFERENCE

Undertake a review of GM food safety assessment procedures used by FSANZ, including the following:

- compare the FSANZ scientific approach with current international best practice;
- review the format, content, presentation and interpretation of GM food safety assessment reports, and other information provided to stakeholders, with a view to making recommendations on possible improvements;
- identify emerging food related issues or developments in methodology relevant to GM food safety assessment that may need to be taken into account by FSANZ in the near to medium term; and

- review the FSANZ approach to communication with stakeholders, including the documentation made available and the nature of interactions, with a view to making recommendations on possible improvements

Key Findings in Peer Review

Regulation of GM Foods in Australia and New Zealand

According to the Australian New Zealand Food Standards Code, GM foods is defined as “a food which has been derived or developed from an organism which has been modified by gene technology (i.e. recombinant-DNA techniques that alter the heritable genetic material of living cells or organisms”. Sale and use of GM foods are prohibited until FSANZ has completed its safety assessment and permitted its listing in Standard 1.5.2 as an approved GM food. This mandatory pre-market assessment of GM foods is consistent with the regulatory requirement for these food products in most regulatory authorities around the world.

General Principles of Safety Assessment of GM Foods

FSANZ’s approach to the safety assessment of GM foods is consistent with the principles outlined in the Codex Principles for the Risk Analysis of Foods Derived from Biotechnology (1) developed by the Codex *Ad Hoc* Intergovernmental Task Force on Foods Derived from Biotechnology. Specifically, FSANZ applies a comparative approach (also known as substantial equivalence) to identify potential new or altered hazards associated with a GM food. The risk-based and evidence-based assessment is conducted on a case-by-case basis and takes into consideration both intended and unintended effects of the genetic modification. Where appropriate, comparisons are made between the GM food and its conventional counterpart to ensure that the GM food is as safe and nutritious as the conventional food. FSANZ’s case-by-case approach to select one or more appropriate comparator for a given GM food as well as its use of a weight of evidence approach to address potential unintended effects associated with the genetic modification are also in line with approaches employed by other international regulatory authorities. Furthermore, FSANZ’s view that profiling techniques, including genomics, proteomic and metabolic profiling, require further research and proper validation before they can be considered as routine data requirement for the safety assessment of GM foods is shared by most other regulatory authorities.

Key Elements of the Safety Assessment of GM Foods

The ultimate goal of FSANZ’s safety assessment of GM foods is to determine if the modified food offers all the expected benefits and risks normally associated with its conventional counterpart. It is important to note that the assessment does not rely on animal toxicity studies

using whole food as test material. Instead, a weight of evidence approach, relying on the following key elements, is employed in the safety assessment:

Molecular Characterization

Detailed molecular characterization information, including description of the transformation system, sequence information on the inserted DNA, rearrangement(s)/transcriptional activation/inactivation as well as the stability of the inserted DNA, is a key component of the overall safety assessment process. It serves to define the intended effect and allow for the assessment of potential food safety issues. Furthermore, molecular characterization can also provide indication of potential unintended effects as a result of the insertion of foreign DNA into the genome of an organism. In some cases, the number of insertions, the locations of the insertions and the possible rearrangement of DNA will directly influence the level of details required in other parts of the safety assessment.

Characterization of the Newly Expressed Substance

Most of the first generation GM crops involve genetic modification resulting in the introduction and expression of a new protein conferring the desired new trait not previously observed in the host plant. Potential toxicity and allergenicity are the key considerations in assessing the safety of the newly expressed protein. Information such as history of safe human consumption, amino acid sequence similarity between the new protein and known toxins, anti-nutrients and allergens, the degree of resistance of the new protein to heat and/or digestion, appropriate animal oral toxicity studies using purified new protein as well as possible serum screening are used by FSANZ to assess the safety of the newly expressed proteins.

Compositional Analysis

The main purpose of FSANZ's compositional analysis is to address any potential unintended effect(s) associated with the genetic modification. Due to the complexity of the food matrix, a targeted approach is taken for the compositional analysis of GM foods whereby the assessment is mainly focused on key nutrients, toxicants and anti-nutrients. While direct comparison to the conventional counterpart is essential, FSANZ also takes into consideration information on key constituents of a number of major crops available in a series of OECD Consensus Documents developed by the OECD Task Force on Safety of Novel Foods and Feeds.

Nutritional Considerations

In the event that a significant compositional change is observed in a GM food resulting in altered levels of nutrient(s), additional nutritional assessment will be warranted. FSANZ may conduct a dietary exposure assessment to determine the potential nutritional impact resulting from the altered nutrient profile of the GM food. In the future, there may be a need to assess GM foods which have been intentionally modified to alter the nutritional property to improve human health. In such cases, other conventional foods rather than the conventional counterpart may be more appropriate as a comparator when assessing the possible nutritional implications associated with the GM food.

All in all, the approach taken by FSANZ and the information required to evaluate the four key safety assessment elements identified above are consistent with those outlined in the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (2) developed by the Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology. The level of detail and quality of the data/information required by FSANZ to conduct a safety assessment is similar to those used by other regulatory authorities to perform similar GM food safety assessments. It should be pointed out that in all cases, the information/data is provided by the applicant, usually in the form of raw data, for review by FSANZ. Similar to other authorities, FSANZ will only accept data generated from internationally accepted protocols and in the case of animal toxicity studies, these must be conducted under Good Laboratory Practice (GLP).

Resource Considerations and Overall Efficiency of the Safety Assessment Process

The FSANZ GM team consists of a small core group of 5 dedicated, knowledgeable scientists who as a team, possess the multidisciplinary scientific expertise required to critically evaluate the data/information submitted by applicants in support of GM food approvals. It is important to note that relevant external scientific advice from FSANZ Fellows as well as other national/international experts is readily available to FSANZ to supplement their knowledge base in assessing highly complex, state of the art GM food applications. This is a key corner stone of FSANZ's science-based GM food assessment process which is essential to be maintained and built upon as FSANZ continues to deal with more and more complex and innovative types of GM food applications.

In addition to the core submission review activities, GM team members are also involved in other duties such as international work, guideline and policy development, outreach activities and perform risk assessments when unauthorized GM plant material is detected in the food supply. While the time taken by the GM team to complete the comprehensive data review is closely monitored, there are other important activities related to the approval of a GM food which are much less predictable in terms of resource implications. Pre-submission consultation with potential applicants, which is a process generally recognized to be key in ensuring the quality and completeness of a submission package, has the potential to add significant amount of work to the GM team. Furthermore, after the GM team has completed its safety assessment of a GM food submission and has reached a regulatory decision, there is still the possibility that resources will be needed to deal with a request by the Ministerial Council for a review of the safety assessment decision. Depending on the nature of the issues raised during the review, this could also lead to significant unplanned workload for the GM team. Due to all the above mentioned work demands, the team has a very heavy workload but currently is able to meet the timelines (9 months for General to 18 months for Major, depending on the complexity of the submission) set for completing the assessment of GM food applications. Nevertheless, it may be worthwhile to explore potential means of improving the predictability and/or effectiveness of both the pre-submission consultation process as well as the response to Ministerial Council review requests in order to reduce the workload stress endured by the small GM team.

Given the complexity of the GM food safety assessment process, significant training and hands-on experience is needed for a new staff member to become proficient in conducting the safety assessment. With the small number of experienced GM team members on staff at the present time, any temporary or permanent loss of any of these individuals will have a significant negative impact on FSANZ's capacity to meet its regulatory and international commitments. It may be in the interest of FSANZ to consider increasing the number of members of the GM team in order to proactively address this potential problem. Alternately, it may be useful to establish a closer working relationship with other groups such as the Office of the Gene Technology Regulator (OGTR) in order to explore opportunities for future work sharing in the safety assessment of GM crops. This may become more feasible as requests to OGTR for environmental release of GM crops become more common. In particular, shared or joint assessment of molecular characterization information of a GM plant may be a prime candidate for a pilot project since the information required would be identical for either environmental or food safety assessment.

Transparency and Risk Communication

The inclusion of a public consultation step in the GM food safety assessment process, combined with the amount of information related to the GM food submission made available on the FSANZ website, results in an overall process which is arguably the most transparent among regulatory authorities worldwide. A number of regulatory agencies have looked to the FSANZ model as a means to enhance the transparency of their respective safety assessment processes. As reported in a presentation by Biotechnology Australia during the Food Regulators' Science Network Forum Workshop on GM Food Safety Assessment held in May 2008, a recent public opinion survey indicated that there has been a significant increase in public acceptance of GM foods in Australia. This is likely due in part to the open and transparent process FSANZ has put in place in its regulation and safety assessment of GM foods. It is imperative that FSANZ continues to ensure public access to information related to its GM food safety assessment activities. In particular, it may consider strengthening its risk communication efforts with representatives from Australian States and Territories and New Zealand as well as key stakeholders. Initiatives such as the Science Network Forum Workshop are invaluable in creating a venue for information exchange and scientific discussion between regulators, scientists and representatives from non-government groups. Better understanding of FSANZ's rigorous scientific risk assessment process will further enhance public confidence and may reduce the number of requests from the Ministerial Council to review GM foods safety assessments completed by FSANZ.

International Activities

FSANZ has established an international reputation as one of the leading authorities in the area of GM food safety assessment. FSANZ staff, particularly members of the GM team, have made key contributions to various FAO-WHO Expert Consultations and other international deliberations by intergovernmental organizations. FSANZ has also played key roles in the work completed by the two Codex *Ad Hoc* Intergovernmental Task Forces on Foods Derived from

Biotechnology. Specifically, FSANZ scientists were instrumental in leading the work in developing Guidelines for the Safety Assessment of Foods Derived from Recombinant-DNA Animals in the most recent Task Force. Australia is also a key member of the OECD Task Force on the Safety of Novel Foods and Feeds established in 1999. Dr. Lisa Kelly of FSANZ's GM team has chaired this Task Force since 2003 and has provided valuable leadership in guiding the work of the Task Force in producing a number of key Consensus Documents which are widely used by regulatory authorities and industries around the world. Finally, FSANZ has successfully led and participated in numerous capacity building workshops around the world in order to share the knowledge and experience it has in the area of GM food safety assessment. In particular, FSANZ's outreach activities in the ASEAN and APEC regions have been instrumental in building up the knowledge base and capacity in a large number of countries to enable them to conduct GM food safety assessment according to harmonized international principles and standards. As regulators around the globe are faced with new challenges associated with the next generation of innovative and complex GM foods, it is critical that FSANZ continues to play a leadership role internationally to develop the necessary regulatory tools to adequately assess the safety of these products.

Future Challenges

FSANZ, in particular the GM team, has put in place the scientific capacity (both internal and external) as well as a transparent, internationally recognized process to conduct pre-market safety assessment of GM foods prior to their introduction into the Australian and New Zealand food supply. It is well recognized that the next generation of GM foods under development will pose new challenges to regulatory authorities in conducting safety assessment of these novel food products. Based on its outstanding international efforts to date, coupled with the expansive network of internal and external scientific experts available to assist the GM team when appropriate, FSANZ is well positioned to tackle any scientific or regulatory gaps triggered by future GM foods including GM animals, drought tolerant crops, crops with multiple stacked traits as well as GM foods modified intentionally to alter their nutritional properties. With these nutritionally-enhanced GM foods, FSANZ may need to explore and investigate the feasibility of conducting post market monitoring and surveillance of potential health impacts (both positive and negative) due to the presence of these products in the food supply. From a broader perspective, it is essential that FSANZ continues to build on its international work and pursue opportunities to enhance its collaboration with international counterparts in order to leverage resources and expertise available from these regulatory partners. Interchange opportunities, shared or joint reviews of GM food applications and ultimately, global review and approval of GM food products are just a few possible short and long term initiatives which may be worthy of consideration in the future.

Recommendations

1. Maintain strong scientific GM team and further strengthen expertise to address future challenges associated with the safety assessment of next generation of complex GM food.

FSANZ should maintain and build on the current strong GM team to ensure that it continues to have the capacity to conduct science-based safety assessment of GM foods. There may be a need to expand the internal expertise to address any scientific gaps associated with the next generation of GM foods such as those posed by GM animals as well as foods modified for nutritional or health benefits. With the nutritionally enhanced GM foods, FSANZ may also consider exploring the feasibility of conducting post market monitoring and surveillance of potential health impacts (both positive & negative) associated with the consumption of these foods. Such efforts may require collaboration with other government and non-government organizations. The availability of a critical mass of internal experts is essential to maintain the high standard of safety assessment currently conducted by FSANZ. From a staff retention standpoint, FSANZ may also consider increasing the size of the GM team given the amount of time it takes to train and develop a scientist to become an independent GM team member capable of conducting a complex GM food safety assessment.

2. Enhance the engagement of external scientific expertise as appropriate to address future knowledge gaps in assessing the safety of GM food.

While it is important to build a GM assessment team with strong scientific capacity, it is not feasible to cover all areas of scientific expertise needed to address potential scientific gaps associated with every future GM food products. Therefore, it is important that FSANZ continues to actively engage its panel of FSANZ Fellows and to periodically assess the need to bring on board additional Fellows as any future scientific gaps emerge. Furthermore, FSANZ should continue to engage international experts and host workshops to address scientific and/or regulatory issues as appropriate.

3. Investigate the feasibility of managing workload associated with the safety assessment of a GM food application.

Through the dedication and hard work of the GM team, FSANZ is currently able to meet the timelines set for the core review of data/information submitted by applicants in support of a GM food approval. However, FSANZ must also conduct important application-related activities such as pre-application consultation with applicants as well as response to Ministerial Council request for reviews of GM food safety assessments completed by FSANZ. In general, the resources needed to perform these tasks is difficult to gauge and often poses significant workload challenges to the team in its effort to adhere to timelines assigned to completing reviews of GM food applications. Therefore, it is important to investigate possible mechanisms to provide more support to these activities and/or reduce the number of request for reviews by the Ministerial Council.

4. Continue to engage and establish closer working relationship with other Australian and New Zealand regulatory agencies.

FSANZ should continue to engage and work closely with other regulatory agencies in Australia. In particular, it may consider establishing a closer working relationship with groups such as the OGTR in Australia and the Environmental Risk Management Authority in New Zealand (ERMA). In the future, as the number of request for environmental release of GM crops increases, there may be valuable work sharing opportunities between FSANZ, OGTR and ERMA in assessing information in support of environmental and food safety of a GM food (for example, molecular characterization information which is similar for both assessments). This will enable better utilization of resources and minimize potential duplication of work.

5. Continue to build on FSANZ's strong international reputation as a leader in GM food safety assessment and explore mechanism(s) to enhance collaboration with international regulatory partners.

FSANZ should continue to build on the outstanding work it has done internationally which has resulted in FSANZ being regarded as one of the leading authorities in GM food safety assessment. This will involve continued key contributions in future intergovernmental scientific consultations, Task Forces and Working Groups. Furthermore, FSANZ should further enhance its collaboration with regulatory authorities in other countries in conducting safety assessment of GM foods. In particular, it should investigate the feasibility of interchange programs, share or joint reviews and ultimately global reviews with other international regulatory partners.

6. Continue to provide an open and transparent GM food safety assessment process and enhance the risk communication efforts with key stakeholders.

FSANZ should take pride in having one of the most open and transparent GM food safety assessment process in the world. It should continue to make relevant information available to the public and involve the public in the GM food safety assessment process. Furthermore, FSANZ should explore mechanisms to enhance its engagement with key stakeholders, particularly government and non-government groups in New Zealand and Australian States and Territories, in order to better communicate its GM food regulatory and safety assessment process. This will likely result in clearer understanding, increased confidence and possibly result in reduced numbers of questions and requests for reviews of FSANZ safety assessment decisions by the Ministerial Council.

References

1. Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (CAC/GL 44-2003), Codex Alimentarius Commission, Rome.
2. Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003), Codex Alimentarius Commission, Rome.

Appendix 1 – *Curriculum Vitae*

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EDUCATION

1990. Ph.D. in Medical Microbiology and Infectious Diseases, University of Alberta, Edmonton, Alberta, Canada

1986. MSc. in Medical Microbiology, University of Alberta, Edmonton, Alberta, Canada

1983. BSc. in Microbiology, University of Alberta, Edmonton, Alberta, Canada

AWARDS

NSERC Visiting Scientist Fellowship, 1992-1994.

Alberta Heritage Foundation for Medical Research Fellowship, 1990-1992.

Alberta Heritage Foundation for Medical Research Studentship, 1987-1989.

Alberta Heritage Foundation for Medical Research Summer Studentships, 1982 and 1983.

REGULATORY EXPERIENCE

01/2008 – Present. Director, Health Effects Division I, Health Evaluation Directorate, Pest Management Regulatory Agency, Health Canada, Ottawa, Ontario.

- \$ Provide professional leadership in multi-disciplinary scientific programs to identify, evaluate and minimize human health effects from chemical pest control products and biopesticides.
- \$ Oversee and direct the evaluation of technical information in industry submissions on pest control products.
- \$ Provide leadership to establish, develop and implement national and international standards, policies and guidelines for the regulation and safety assessment of pest control products.
- \$ Represent Health Canada and participate/chair/head various Committees, Task Forces and Working Groups involving senior industry representatives, national and foreign government officials, research scientists and other relevant stakeholders with respect to harmonization of standards and international collaborations.
- \$ Direct the activities of the Health Effects Division I, including the management of human, financial and material resources and coordination of program delivery strategies for ongoing activities to optimize resources applied against the achievement of the goals and objectives of the Division.
- \$ Act as Media Spokesperson for the Agency on various issues related to pest control products.

02/2002 – 01/2008. Chief, Evaluation Division, Bureau of Microbial Hazards, Food Directorate, Health Products and Food Branch, Health Canada, Ottawa, Ontario.

- \$ Provide professional leadership in multi-disciplinary scientific programs to identify, evaluate and minimize human health effects from microbial contaminated foods, novel foods, food additives and food ingredients.
- \$ Oversee and direct the evaluation of technical information in industry submissions on microbiological and bio-technological aspects related to the safety of food and food additives.
- \$ Provide leadership to establish, develop and implement national and international standards, policies and guidelines for the safety of foods, novel foods, food additives and food ingredients as well as food processing techniques.
- \$ Represent Health Canada and participate/chair/head various Committees, Task Forces and Working Groups involving senior industry representatives, national and foreign government officials, research scientists and other relevant stakeholders with respect to harmonization of standards and international collaborations.
- \$ Direct the activities of the Evaluation Division, including the management of human, financial and material resources and coordination of program delivery strategies for ongoing activities to optimize resources applied against the achievement of the goals and objectives of the Division.
- \$ Act as Media Spokesperson for the Food Directorate on various food safety issues related to microbial contamination and novel foods.

06/1999-02/2002. Head, Office of Food Biotechnology & Policy Coordinator, Antimicrobial Resistance, Food Directorate, Health Protection Branch, Health Canada, Ottawa, Ontario.

- § Coordinate the health and safety assessment of novel food products including genetically modified foods.
- § Provide expert advice on the health and safety assessment of novel foods to industry, media and the Canadian public.
- § Oversee the development of Food Directorate policies on antimicrobial resistance.
- § Provide expert advice on molecular biology to staff members of the Bureau of Microbial Hazards.

11/1996-05/1999. Evaluation Officer, Health Evaluation Division, Pest Management Regulatory Agency, Health Canada, Ottawa, Ontario.

As the Health Evaluation Division's expert on microbiology and molecular biology, primary responsibilities are focussed in the following areas:

- Evaluation of complex toxicology and infectivity study data to determine the human health and safety of microbial pest control products (MPCPs) with naturally occurring and genetically engineered bacteria, fungi, viruses and protozoa as active ingredients
- Determination of potential occupational and bystander exposure as well as food and feed residue risk factors associated with the registration of new MPCPs and application for research permits to perform research trials with experimental products.
- Evaluation of manufacturing processes, quality control and product labels for MPCPs submitted for registration.
- Development and international harmonization of Agency guidelines for the registration and experimental use of new MPCPs.
- Joint reviews, in collaboration with the United States Environmental Protection Agency, of data submissions for registration of MPCPs in the United States and Canada.
- Act as Agency spokesperson and media contact on human health and safety issues associated with the registration and use of MPCPs.
- Act as Agency representative at international meetings on microbial pesticides and related topics.
- Provide expert advice, when requested, on novel foods generated by the use of transgenic plants and/or genetically modified microorganisms.
- Co-organised a workshop on health and safety assessments of microbial products involving regulators and international experts (February 24-25, 1997).

02/1995-11/1996. Research Scientist, Bureau of Microbial Hazards, Food Directorate, Health Protection Branch, Health Canada, Ottawa, Ontario.

- Expertise in molecular biology and biotechnology were applied to perform safety assessment of novel foods involving the use of genetically modified microorganisms and/or transgenic plants.

- Co-organised a workshop on rapid biotechnological methods for detecting bacteria in foods for food industry and government representatives (March 11-15, 1996).

RESEARCH EXPERIENCE

02/1995-11/1996. Research Scientist, Bureau of Microbial Hazards, Food Directorate, Health Protection Branch, Health Canada, Ottawa, Ontario.

Research projects focus on the development of new, rapid methods for the detection and identification of foodborne pathogens such as *Listeria monocytogenes* and *Campylobacter* spp. in various foods. Molecular techniques such as DNA hybridization, HGMF technology as well as conventional and *in-situ* polymerase chain reaction amplifications are utilized. Other responsibilities include the supervision of research technicians, co-op and summer students as well as providing expert advice on molecular biology to other staff members of the Bureau as well as scientists at other government labs.

02/1994-02/1995. Research Associate/Professional Assistant, Reproductive Biology Unit, Loeb Medical Research Institute, Ottawa Civic Hospital, Ottawa, Ontario.

Research projects involved the study of follicular development in the chicken and rat ovary models. Techniques such as *In situ* hybridization studies, northern blot analysis, PCR amplification and DNA sequencing are used to characterize the genes responsible for regulating apoptosis (programmed cell death) in different stages of follicular development. Other responsibilities included laboratory set up and personnel training in molecular biology, the supervision of graduate students and research fellows, manuscript review and assist in the preparation of research grant proposals.

09/1992-02/1994. NSERC Visiting Fellow in the Bureau of Microbial Hazards, Food Directorate, Health and Welfare Canada, Ottawa, Ontario.

Research project involved the development of DNA probe technology to detect food pathogens with the goal of applying this to biotechnology. Techniques employed include DNA hybridizations using Hydrophobic Grid Membrane Filters, PCR technology and pulsed-field gel electrophoresis. Other responsibilities include the co-supervision of research technician, providing expert advice on molecular biology to other staff members in the bureau as well as drafting guidelines for monitoring genetically modified organisms (GMO) in foods.

10/1990-09/1992. Alberta Heritage Foundation for Medical Research postdoctoral fellow in the Department of Molecular Biology and Microbiology, Tufts University Medical School, Boston, MA.

Research was carried out on the regulation of expression of the multiple antibiotic resistance (*mar*) locus in *E. coli* using DNA cloning and sequencing, northern and southern hybridizations and polymerase chain reactions. Responsibilities also included supervising and training technicians in molecular biology.

09/1986-08/1990. Ph.D. student in Medical Microbiology and Infectious Diseases, Department of Medical Microbiology and Infectious Diseases, University of Alberta, Edmonton, Alberta.

Research was carried out on the characterization of erythromycin resistance in *Campylobacter jejuni* and *Campylobacter coli* as well as the use of pulsed-field gel electrophoresis to construct genomic maps of these organisms. Responsibilities included training and supervision of summer students.

09/1983-02/1986. MSc. student in Medical Microbiology, Department of Medical Microbiology and Infectious Diseases, University of Alberta, Edmonton, Alberta.

The transfer regions of the IncIII plasmid pHH1508a was studied using DNA hybridization, restriction mapping, protein purification and electronmicroscopy.

TEACHING EXPERIENCE

01/1995-present. Adjunct Professor, Department of Biochemistry, Microbiology and Immunology, University of Ottawa, Ottawa, Ontario.

Course co-ordinator and lecturer for multiple sessions of the course BAC2100 Microbiology and Immunology for Nursing and Bachelor of Health Sciences students.

09/1998-present. Part-time instructor, Algonquin College, Ottawa, Ontario.

Course co-ordinator and lecturer for Microbiology and Immunology course BIO 2100 for students in the Registered Nurse program (30 students)

01/1995-05/1995. Part-time instructor, Allied Health Programs and Biological Sciences Department, Algonquin College, Ottawa, Ontario.

Responsibilities included designing and teaching a first year Environmental Microbiology Course (28 students) in the Environmental Technology program.

09/1988-08/1990. Laboratory Instructor, Department of Medical Microbiology and Infectious Diseases, University of Alberta, Edmonton, Alberta.

Responsibilities included laboratory course design and supervision of students (15) in a graduate level Medical Microbiology course on bacterial pathogenesis.

09/1986-08/1989. Laboratory Demonstrator, Department of Medical Microbiology and Infectious Diseases, University of Alberta, Edmonton, Alberta.

Responsibilities included laboratory set-up and supervision of nursing students in an undergraduate Medical Microbiology course.

PROFESSIONAL AND INTERNATIONAL ACTIVITIES

Professional Appointment

§ Adjunct Professor, Department of Microbiology and Immunology, University of Ottawa (1995 - present)

International Activities

§ Head of Canadian Delegation for the OECD Task Force on Safety of Novel Foods and Feeds (2002 - 2008)

§ Participated in a number of Codex Alimentarius Workings Groups, Task Forces as well as FAO/WHO Expert Consultation.

§ Head of Canadian Delegation for the Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology (2007).

§ In collaborations with organizations such as FAO, ILSI, ASEAN and APEC, conducted a number of international training workshops on the safety assessment of Genetically Modified Foods in various regions around the world including Southeast Asia, Moscow, Latin America and South Africa.

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- Yan, W. and D. E. Taylor (1987). Characterization of transfer regions within the HII incompatibility group plasmid pHH1508a. *J. Bacteriol.* **169**:2866-2868.
- Taylor, D. E., W. Yan, L.-K. Ng, E. K. Manavathu and P. Courvalin (1988). Genetic characterization of kanamycin resistance in *Campylobacter coli*. *Ann. Inst. Pasteur/Microbiol.* **139**:665-676.
- Yan, W. and D. E. Taylor (1989). Mapping of transfer and pilus coding regions of the IncHII plasmid pHH1508a. *Can. J. Microbiol.* **35**:289-294.
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- Yan, W., N. Chang and D. E. Taylor (1991). Pulsed-field gel electrophoresis of *Campylobacter jejuni* and *Campylobacter coli* genomic DNA and its epidemiological application. *J. Infect. Dis.* **163**:1068-1072.
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- Taylor, D. E., M. Eaton, W. Yan and N. Chang (1992). Genomic maps of *Campylobacter jejuni* and *Campylobacter coli*. *J. Bacteriol.* **174**:2332-2337.
- Cohen, S. P., W. Yan and S. B. Levy (1993). A multidrug resistance regulatory chromosomal locus is widespread among enteric bacteria. *J. Infect. Dis.* **168**:484-488.
- Boone, D. L., W. Yan and B. K. Tsang (1995). Identification of a deoxyribonuclease I-like endonuclease in rat granulosa and luteal cell nuclei. *Biol. of Reproduction* **53**:1057-1065.
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- Li, J., F. Croze, W. Yan, R. J. G. Hache and B. K. Tsang (1997). Up-regulation of urokinase plasminogen activator messenger ribonucleic acid and protein in hen granulosa cells by transforming growth factor alpha in vitro during follicular development. *Biol. of Reproduction* **56**:976-984.
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- Paoletti, C., E. Flamm, W. Yan, S. Meek, S. Renckens, M. Fellous and H. Kuiper (2008). GMO risk assessment around the world: Some examples. *Trends in Food Science & Technology* **19**:S66-S74.

BOOK CHAPTERS AND CONFERENCE PROCEEDINGS

Yan, W. and D. E. Taylor (1990). Characterization of erythromycin resistance in *Campylobacter jejuni*. CAMPYLOBACTER V Proceedings of the Vth International Workshop on Campylobacter Infections. G. M. Ruiz-Palacios, E. Calva and B. R. Ruiz-Palacios (eds.) pp.172-174.

Schneiders, T., H. Haechler and W. Yan (2005). The *mar* Locus. Frontiers in Antimicrobial Resistance. D. G. White, M. N. Alekshun and P. F. McDermott (eds.) pp. 198-208.

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Yan, W. and D. E. Taylor (1989). Characterization of erythromycin resistance in *Campylobacter jejuni* presented at the fifth international workshop on Campylobacter infections in Puerto Vallarta, Mexico.

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Stavric, S., B. Buchanan and W. Yan (1995) Analysis of *V. vulnificus* strains by pulsed field gel electrophoresis presented at the Canadian Society of Microbiologists Conference in Kingston, Ontario.

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