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# THE CHANGING REGULATORY ENVIRONMENT

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## 1. Background

The Pest Management Regulatory Agency (PMRA) was established in April 1995 in order to consolidate the resources and responsibilities for pest management regulation in Canada under the Minister of Health.

All products designed to manage, destroy, attract or repel pests that are used, sold or imported into Canada are regulated by Health Canada's PMRA. These products include chemicals, devices, and even organisms, and are referred to collectively as pest control products, or simply "pesticides." The federal legislative authority for the regulation of pesticides in Canada is the Pest Control Products Act. The use of pesticides is also subject to regulation under provincial/territorial legislation.

The goal of the PMRA is to protect human health and the environment while supporting the competitiveness of agriculture, forestry, other resource sectors and manufacturing. The PMRA is responsible for providing safe access to pest management tools, while minimizing risks to human and environmental health. The Agency is also dedicated to integrating the principles of sustainability into Canada's pest management regulatory regime.

The PMRA reviews applications for the registration of pest control products; conducts science-based health, environmental and value assessments (including efficacy) of each pesticide before deciding if it should be approved for use in Canada; develops and implements policies and guidelines related to pest management; promotes sustainable pest management; seeks efficiencies in the processing of registration applications through such means as international harmonization and electronic submission and review of pesticide registration data; enforces compliance with the Pest Control Products Act; and disseminates information on pest management issues to the public.

Currently there are over 6000 end use products registered in Canada representing nearly 500 distinct active ingredients. Approximately 2200 submissions are made each year to the PMRA ranging from applications to make simple amendments to existing pesticide labels to applications for new active ingredients. The majority of new active submissions are agricultural in purpose however submissions for new non-agricultural products or amendments to existing products make up approximately 75% of all submissions to the PMRA. The Agency currently approves over 100 applications for research permits each year.

## 2. Challenges and Opportunities

### 2. 1. Harmonization

The PMRA has since 1995 been pursuing an active program of harmonization both within North America (through its work under the NAFTA Technical Working Group on Pesticides), and globally through its work with the OECD and the European Commission. Harmonization will meet one of the Agency's key strategic objectives of strengthening and streamlining the regulatory system in Canada. One of the initial objectives was to minimize trade disruptions caused by dissimilar pesticide registrations in trading countries. By coordinating and harmonizing our regulatory systems we can reduce the likelihood of these events. Harmonization will also result in less duplication of effort and will allow us to share the work of pesticide data review. It will also build our regulatory and scientific capacity as we will have access to the best information and the best expertise to make the best decisions possible. Our goal is have routine joint reviews and worksharing amongst countries globally.

But what do we mean by harmonization? We have defined this as common approaches to doing business that will allow a submission to be accepted for review in another jurisdiction. It does not mean identical decisions in all cases or that all pesticides available in one country will be available in all countries. Our experience to date however (PMRA currently has under joint review or workshare agreement with the U.S.EPA a total of 21 active ingredients) is that joint reviews, with similar timelines in both countries benefit greatly in terms of efficient use of resources but also in having the best science available to discuss problems that arise. These joint reviews most often result in similar decisions in similar timeframes. We have also begun to share reviews with other E.U and OECD countries and we expect this to become routine in the future.

Canada, the United States, and E.U and OECD countries continue to put substantial effort into developing common approaches to data requirements and study protocols, harmonizing submission and review formats, and harmonizing risk assessment policies and methods. Joint reviews with the U.S EPA have been extremely helpful in identifying differences in processes and data requirements and have helped resolve these differences. Much of the focus to date has been on agricultural actives but we are anxious to receive joint submissions for new non-agricultural actives as well to ensure these areas are harmonized to the extent possible.

Canada leads the world in promoting the use of electronic submission formats for industry and recently (October 2002) hosted an OECD IT workshop in Ottawa devoted to this area. The ultimate goal is to have a single, harmonized electronic submission format that can be used by all countries.

## 2. 2. Science

Another challenging area for the future is the science and the implications this has for registrants, the research community and the PMRA as regulator. The introduction of the U.S. Food Quality Protection Act (FQPA) in 1996 resulted in significant changes in the way risk assessments are conducted by the U.S.EPA and this has carried forward into non-food areas as well(e.g. woeker exposure). PMRA has adopted the key policies put forward by the FQPA. Some of the key changes include the requirement to assess the cumulative risks posed by chemicals with a common mode of action. For example organophosphates, which act in a similar manner as cholinesterase inhibitors, have historically been assessed on an individual basis. In addition to an aggregate assessment of exposure (i.e. from all sources such as environment, drinking water, around the home) exposure to multiple chemicals will now be included. This will sometimes pose challenges in fitting these into the 'risk cup'.

The ever increasing complexity of risk assessments and the move from deterministic to probabilistic also has posed challenges, both in keeping up with the science but also in supplying the increasing amounts of data that these models need. In the absence of real world data, potentially overly conservative assumptions will be used. New approaches to risk assessment provide a much more realistic assessment of risk but there is a cost: industry and the research community will be increasingly called upon to provide this data. PMRA is very pleased to be working with a number of industry task forces generating much needed data such as the Outdoor Residential Exposure Task Force (ORETF), the Sapstains Industry Group, and the OECD Emission Scenario for Wood Preservatives. Continued communication and participation amongst industry, the research community, and regulators will ensure that the data generated supports our longterm needs.

## 2. 3. Re-evaluation

The PMRAs re-evaluation program is another area presenting both challenges and opportunities for the future. The current program will see upwards of 400 active ingredients (those registered prior to 1995) re-evaluated by the year 2006. There has been a heavy intial thrust on initiating the re-evaluation of agricultural pesticides such as the organophosphates, primarily to build on (and capitalize) on the reviews conducted by the U.S.EPA. The results of these reviews of acceptability for re-registration in the U.S. and the reassessment of food tolerances has major implications for Canadian growers. PMRA is also in routine contact with the E.C. with respect to the progress of the E.U. re-evaluation program.

The PMRA has also been conducting for quite some time now, in a cooperative program with EPA, re-evaluations of the heavy duty wood preservatives CCA, pentachlorphenol, and creosote. It has been a challenge for the PMRA in terms of timing of reviews and conclusions but also an opportunity to use these reviews to better understand the U.S. process and risk assessment process for antimicrobials such as these. CCA has particular challenges as it is also influenced by the Environment Canada's CEPA SOP process. CCA is also a very good example of how, in spite of all

our best efforts to review and make decisions in a stepwise, harmonized, scientific manner, market forces can ultimately make decisions for us. The antisapstains re-evaluation that has been ongoing for many years should be, after consultation with stakeholders, coming to a close within the next 6-9 months.

### 2. 4. Legislation

Earlier this year Bill C-53 was introduced proposing changes to the Pest Control Products Act. This bill was recently (October 2002) re-introduced as Bill C-8 and is anticipated to receive royal assent within the next 6-9 months. The new legislation proposes much needed modernization of the PCP Act which has not changed since 1970.

The key objectives of the new legislation are to a) strengthen human and environmental health protection, b) to make the registration system more transparent, and c) to strengthen the post-registration control of pesticides. To strengthen human health protection, a number of policies and practices at PMRA would be enshrined into law - such as ensuring an additional 10-fold safety factor is used in assessing the risks to children and taking into account both aggregate and cumulative risks. A key change proposed in the new legislation is to make the system more transparent by providing public access to an electronic registry of information about registered pesticides - this would include access to all non confidential business information including full risk assessments. The public would also be able to view the raw data upon which these assessments were made. Another proposed change is mandatory reporting of adverse effects by industry and for PMRA to make this information public where it represents a serious risk. The new legislation also proposes that all chemicals must, after 15 years of registration, undergo a mandatory re-evaluation. Authority to cancel registrations will also be strengthened where the requested data is not provided..

## 3. Conclusions

The future holds similar challenges and opportunities for pesticide regulation as in the past but perhaps many more opportunities. The ability to receive an electronic submission in the future, together with the ability to jointly review these submissions using similar data and processes will ensure much more equitable access to pest management tools internationally and reduce the potential for this access to introduce trade barriers. PMRA will continue to work closely with stakeholders to ensure the regulation of pesticides is conducted using sound science in an efficient and transparent manner.