U.S Food Quality Protection Act (FQPA)

Overview of Activities in US and Canada

Pest Management Advisory Council
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What is FQPA?

- Food Quality Protection Act - federal statute of the U.S.A
- signed into law August 1996
- significantly amended the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA)

Highlights of FQPA

- a new safety standard “reasonable certainty of no harm” (previously was “no unreasonable risk of adverse effects”)
- consider exposure from all routes - oral (e.g. from food and drinking water), dermal (from the use of household pesticides) and inhalation (from the use of household pesticides)
- consider the cumulative effects of exposure to the pesticide and other substances with “common mechanisms of toxicity”
- heightened health protection for infants and children
- expedited review of new, safer pesticides
- reassessment of all food tolerances (MRL’s) within 10 years
- evaluation of all pesticides for endocrine disruption

Implications for Canada

- need to consider new standards, policies, methodologies?
- need to re-evaluate according to these new standards, policies, methodologies?
- need to consider the outcomes of U.S or Canadian re-evaluations on user groups?

Science Policies

- in the US, the Tolerance Reassessment Advisory Committee (TRAC), a subcommittee of the National Advisory Council on Environmental Policy and Technology (NACEPT) was formed in May 1998 to provide guidance to EPA and USDA on policy options and an implementation strategy
- TRAC consists of more than 50 representatives of affected user, producer, consumer, public health, environmental, states and other interested groups
- identified nine science policy areas key to implementation

Issue: FQPA requires an extra 10-fold safety factor when assessing dietary risk of pesticide to take into account potential pre- and post-natal developmental toxicity and completeness of data with respect to exposure and toxicity to infants and children

US Status:

- SOP for application of 10X to be issued February 1999
- Intra-agency draft document containing guidance on criteria for modifying 10X and on adequacy of data base to be issued February 1999
- currently consider 10X for new products and for re-evaluation

Canada Status:

- although not formalized, PMRA uses additional safety factors for incomplete data bases and/or concerns on severity of endpoint (including consideration of young as well as pregnant women)
- supportive of proposed EPA approach

Issue: Whether and how to use probabilistic analyses in estimating acute dietary risk

US Status:

- draft document on guidance for submission of probabilistic exposure assessments issued in November 1998
- draft document on probabilistic techniques and 99.9th percentile to be issued in December 1998 (delayed)
- currently using probabilistic methodology where appropriate

Canada Status:

- currently implementing the use of probabilistic methodology

Issue: How to incorporate “no residues detected” into exposure assessment

US Status:

- draft document on threshold of regulation issued December 1998
- draft document on assigning values to nondetected/ nonquantified residues issued December 1998
- past practice was to utilize LOQ
- current policy to utilize ½ LOD

Canada Status:

- current practice to utilize LOQ
- supportive of proposed EPA approach

Issue: How to estimate food exposure more realistically

US Status:

- draft document describing National Pesticide Residue Database (NPRD) and EPA methods for assessing acute and chronic dietary exposure to be issued December 1998 (delayed)
- draft of recent USDA food consumption data (including children's consumption) to be issued April 1999
- matrices describing OP usage to be completed December 1998

Canada Status:

- creating residue monitoring database with CFIA; also use NPRD
- use available USDA food consumption data as well as other data (Canadian disappearance data for adults, contemporary UK data on infants and children and Canadian food consumption data)
- surveyed provinces and grower community for OP usage information

Issue: How to estimate drinking water exposure

US Status:

- draft document on estimating drinking water exposure, in particular modeling methodology issued January 1999
- draft document on refinement of assumptions to be issue in May 1999
- guidance document to be issued June 1999

Canada Status:

- currently examining underlying assumptions of models to determine applicability to Canadian scenarios
- currently assess drinking water exposure as part of dietary exposure profile

Issue: How to generate residential exposure data and improve methods for conducting exposure assessments

US Status:

- draft documents on standard operating procedures (SOP) and framework for assessing residential exposure issued in January 1999
- currently assess residential exposure

Canada Status:

- collaborated with EPA on SOP
- collaboration with EPA on post-application exposure guideline
- collaboration with EPA in advising industry on development of major residential exposure databases
- currently assess residential exposure

Issue: How to accurately aggregate exposure (exceptoccupational) from all sources.

US Status:

- ILSI report issued January 1999
- draft documents on guidance and standard operating procedures to be issued April 1999
- currently employ additive method for aggregating exposures

Canada Status:

- providing input to EPA on aggregation approach
- will be considering aggregation of exposure for future assessments

Issue: How to consider the effects of cumulative exposure for products with a common mechanism of toxicity

US Status:

- draft document on guidance for identifying pesticides with common mechanisms was issued August 1998
- draft document on guidance for cumulative risk assessment to be issued in June 1999
- not implemented to date

Canada Status:

- participated in ILSI meeting that was background for August 1998 document
- not currently considered in risk assessment process but will develop an approach for considering cumulative risks

Issue: The role of blood measures in risk assessment of organophosphates

US Status:

- draft document on use of cholinesterase inhibition for risk assessment issued November 1998
- currently use weight of evidence approach that utilizes plasma, red blood cell and brain cholinesterase information in risk assessment

Canada Status:

- supportive of recent international (JMPR) position on use of cholinesterase data that mostly utilizes red blood cell and brain cholinesterase information but maintains flexibility in approach

Issue: How to evaluate endocrine disruption

US Status:

- EPA formed the US Endocrine Disrupting Screening and Testing Advisory Committee to develop a screening and testing program
- draft document issued by EPA on proposed screening program and priority system in December 1998
- revised document to be tabled to SAP/SAB in March/April 1999
- endocrine disruption is routinely assessed through current studies

Canada Status:

- currently examining EPA's proposed screening program
- linked into/contributing to OECD Working Group on Endocrine Disruptors Testing and Assessment
- continue to cooperate with EPA and OECD on new/revised test guidelines and improved harmonized approaches for assessment and management
- endocrine disruption is routinely assessed through current studies

Re-evaluation in Canada

- specifically designed a program to re-examine older products in consideration of FQPA
- conduct Canadian reviews on products that are re-evaluated because of FQPA mandate; specifically focus on organophosphates initially; utilize US reviews as appropriate; provide input into US re-evaluations where possible
- conduct Canadian re-evaluation of products not subject to FQPA re-evaluation (as well as for new products) with a focus on the science issues evolving from the FQPA mandate

Impact of Regulatory Outcomes

- public, consumers, environment
- industry
- users - trade implications of regulatory outcomes in US or Canada
  - Canada and US signed a “Record of Understanding” including an action plan to improve bilateral trade in agriculture; plan calls for continued co-operation between countries with respect to implementation of the FQPA
  - NAFTA Technical Working Group facilitating harmonization
  - Interdepartmental Committee on Trade Policy (DFAIT, Agriculture, PMRA) to flag and resolve potential trade issues
  - use survey results on organophosphates will be important for detecting potential trade implications of US regulatory decisions, for internal decision-making and for priority setting in facilitating the development and registration of alternatives

Conclusion

- FQPA is re-shaping standards, policies and methodologies involved in pesticide regulation
- PMRA is actively involved in addressing these changes within the Canadian context and providing input to EPA
- currently agree in principle with the approaches taken by EPA
- PMRA is handling these challenges by examining policies, re-assessing processes and methodologies, initiating re-evaluation of FQPA affected pesticides, surveying usage of FQPA affected pesticides and proposing regulatory decisions on all pesticides with a consideration of FQPA issues