

U. S. - Canada MRL Harmonization Database

(April 2008)

Introduction—What Is The Database and How Will It Be Used?

The U.S. - Canada MRL Harmonization Database is an information source for U.S. and Canadian growers, registrants, and regulatory officials. The database can be found at www.mrlharmonization.com. The database captures grower identified priorities for resolving differences in available crop protection tools and MRLs in the United States and Canada. It is anticipated that the database can be expanded in the future to include Mexican priorities.

Ideally, the database will allow users to go to one place to identify:

- Potential trade barriers—situations where an active ingredient or use site is available in one country but not the other;
- Potential trade irritants—situations where the two countries have different MRLs (or no MRL) for corresponding use sites; and
- Growers' priorities for addressing these discrepancies.

The database, while not directly regulatory in nature, is designed to provide support for the orderly and expedited consideration and removal of potential trade issues that may exist in the NAFTA Region. Each of the stakeholders involved in the development, generation and verification of data for the database has the opportunity to extract value from the information contained in the database. It will also serve to monitor progress in removal of potential trade impediments.

- Regulatory Agencies: The information in the database will assist the regulatory agencies in more systematically identifying and addressing grower priorities for MRL harmonization and establishment. Historically, these issues have been identified and addressed in a more ad hoc way, often on a commodity basis, and outside of the regular work processes of the Agencies. This is very resource intensive. A major goal of this effort is for the regulatory agencies to be able to readily identify *priority* issues so that they may be addressed when work is being done on a chemical in the regular work processes, for example, when new uses are being added or during the re-evaluation process. The resources required to address MRL harmonization issues are significantly reduced when the work is done in conjunction with other regulatory work on the chemical.

In order for the database to be an effective mechanism, it will be important for the growers:

- to develop an effective priority system that allows the regulatory agencies to identify what are truly the *top priorities* for work
- to develop an effective mechanism to keep the priorities up-to-date

In addition, as the regulatory agencies and the registrants continue to move toward a multi-national perspective on registration of chemicals and uses, the information in the database will allow everyone to clearly understand the grower level priorities for registrations that will address trade barriers that exist as the result of a lack of registration in one country versus another. Finally, the database should serve as a reminder to all of the benefits of harmonization from the beginning.

As experience is gained in using the database it is expected that it will become clearer exactly how the information can be used by all participants in the process. In particular, it will be necessary for all stakeholders in both the U.S. and Canada to work together because, in many cases, what is a problem to a grower in one country can only be resolved by an action in the other country.

- Growers: The grower community can use the database to define their priority needs for crop production tools that can then be utilized by the regulatory agencies and the registrants to best and most efficiently deal with potential trade issues before they actually become barriers. This is especially true as the United States and Canada move through the registration review process on the US side of the border and the revocation of the 0.1 general maximum MRL (tolerance) level on the Canadian side of the border. The ongoing debate over the economic value of obtaining a NAFTA-wide registration can be informed through the identification of needs by growers. The database will allow for a cooperative effort to develop market incentives to obtain comparable use spectrums and regulatory thresholds in both countries.
- Registrants: Both stewardship and business benefits exists for registrants. The MRL database allows a quick and easy source for registrants to check where there are trade irritants and trade barriers. The registrant then has an opportunity to talk with the commodity group(s) about possible resolutions. This will help prevent problems for users of crop protection materials, which is good stewardship. There is also a business benefit to registrants. By reviewing this quick and easy source, registrants will be able to prioritize business opportunities. A market that might seem small could become much larger when it is made clear; 1) how great the need is for products when there are no or few MRLs for that crop, or 2) how many multiple smaller use sites need a particular product.

Why and How Was the Database Developed?

The current database is an outgrowth of issues identified at the NAFTA Pesticide Technical Working Group (TWG) Meetings that are held annually among the government and stakeholders in the United States, Canada, and Mexico. The primary objective of the NAFTA TWG is to develop easier and less expensive pesticide regulation and trade among the three countries and meet the environmental, ecological and human health objectives of NAFTA. The database is expected to further these

objectives by facilitating MRL harmonization for priority chemicals as well as addressing the desire by growers in both countries for access to the same or similar crop protection tools for the same crops.

The database, as initially rolled out, is a project of the Minor Crop Farmer Alliance and is currently being supported by a Technical Assistance to Specialty Crops (TASC) Grant from the United States Department of Agriculture's Foreign Agriculture Service. Additional funding that was necessary to develop the password protected priority section of the database was generated from the crop protection industry and member organizations of the Minor Crop Farmer Alliance. As a result of the TASC funding base there are currently limits on the use of the database. The current funding was for development and the initial support necessary for maintenance of the database for specialty crops (as defined under the USDA grant guidelines) through the end of the first years funding cycle, September 2008. Additional support will have to be identified and secured to allow input of Canadian grower priorities and any non-specialty crops (as defined by the USDA FAS Grant guidelines).

What Data Are Currently in the Database?

The current database was populated with information that was initially solicited from members of the Minor Crop Farmer Alliance Technical Committee. It was verified for accuracy by the consultant developing the database, Bryant Christie, Inc. (BCI). The information was also distributed to the U.S. registrants for the identified active ingredients and products for verification. The majority of the contacted registrants reviewed and corrected information on their products as necessary.

Information was requested using a specific guidance document that directed the commodity group or submitter to identify those products that were important from a production perspective. For the active ingredients in the products, the corresponding U.S. and Canadian MRLs in the existing USDA-EPA MRL Database (which is also maintained by Bryant Christie, Inc.) were identified. For those products without MRLs in Canada or where differences in MRLs were apparent, the commodity group was asked to identify the relative importance of the active ingredient. Based on that input a relative priority of High, Medium or Low was assigned in the database. For commodities that have regional differences in production needs the highest priority identified for an individual active ingredient was included in the database. This information was then forwarded to CropLife America for distribution to pesticide registrants identified in the initial data submission. Once the information was verified to the extent possible, it was placed into the database as currently posted on the website.

The database as currently configured may be sorted in multiple ways and contains the following information (information in bold is password protected):

- commodity (use site)
- active ingredient, brand name, and registrant of the product
- US MRL

- Canadian MRL
- **grower priority (this information is password protected and is accessible only by the grower or commodity groups that provided data, the government Agencies, and the registrants that hold pesticide registrations in Canada and the U.S.)**
- **Grower/Registrant/Regulatory Agency comments that have been entered into the database**

What is the Process for Inclusion of New Data?

The following process, which is still under consideration, has been developed for submission and review of data:

The public portion of the database contains directions for how to submit information to be added to the database. The gatekeeper for information input is Bryant Christie, Inc. in consultation with Screening Committees in each country which will be responsible for verifying the data to the extent possible. There will be two separate screening committees, one for U.S. grower supplied data and one for Canadian grower supplied data. The U.S. screening committee includes: Lois Rossi, Kathy Monk, and Jane Smith from EPA; Dan Kunkel from IR-4; John Jachetta the U.S. co-chair of the NAFTA Industry Working Group; Ray McAllister from CropLife America; and Daniel Botts from Florida Fruit and Vegetable Association (MCFA). In addition, the U.S. will add representatives from some of the major commodities when these commodities are added to the database. Canada is currently determining the composition of their screening committee.

Solicitations for additional data submissions will be directed to regional and national commodity groups. It is not anticipated that an individual grower's priorities will be included without some type of regional or national sponsor for the information. Mark Rasmussen from FAS will lead the effort to contact the trade associations for the non-specialty crop groups and Daniel Botts will continue to lead the effort for outreach to specialty crop groups which are not currently included in the data base.

The input spreadsheet and accompanying instructions should be used to guide submissions. At this point, the input instructions are based on the U.S. grower defined input parameters. It is anticipated that for direct input from Canadian commodity groups a similar spread sheet, (if not the exact same one) will be used by Canadian data providers. Any differences in how priorities are assigned or other process differences for Canadian information will need to be clearly identified and documented for inclusion on the website. This will allow the priorities to be clearly understood by all users of the data base.

Data submitters will receive acknowledgement of their submission and the information will be sent to the appropriate Screening Committee for verification and completeness

review. If any changes are made to the information the initial submitter will be contacted to verify and agree to any changes to their submissions.

At the point that information is added to the publicly accessible portion of the website the data submitter will be issued a password to allow access to those portions of the database that are password protected. Passwords will be managed as part of the on-going maintenance of the database.

What Database Enhancements are Expected and What Issues Remain to be Addressed?

To fully realize the potential of the database, several issues and potential enhancements need to be more fully considered. Many of these enhancements will require additional input and funding sources beyond those currently available. Among the issues to be considered and resolved as the database becomes publically available are:

Database Oversight:

The original database development oversight committee, headed by Dan Botts, was drawn from members of the MCFA technical committee, USDA Foreign Agriculture Service, CropLife America, the Canadian Horticultural Council, and EPA with recent additions of members from PMRA and CropLife Canada. In anticipation of needing a broader range of participants on the committee, efforts have been made to expand its membership. The attached listing provides the currently proposed membership of the MRL Harmonization Database Oversight and Development Committee, all of whom were invited to the last meeting on March 31, 2008. At that meeting it was decided that EPA will chair the committee. This committee will serve in an advisory role to ensure the database meets the needs identified in the NAFTA Pesticide Technical Working Group's work plans as well as the needs of all of the stakeholders involved. MCFA is anticipating continuance of its role regarding the Specialty crops industry in the U. S. as directed by its membership. This role is anticipated for at least the next two years in response to conditions and guidelines associated with Technical Assistance to Specialty Crops (TASC) funding.

Database Funding:

The current database is being developed on a time limited and process specific grant from USDA FAS under its Technical Assistance to Specialty Crops (TASC) grant funds. It is anticipated that funds under this program will be requested by the Florida Fruit & Vegetable Association on behalf of the Minor Crop Farmer Alliance to continue to allow specialty crop input, review and maintenance (at least for the next two funding cycles – FAS has a three year funding life for any specific TASC project).

Other countries and non-specialty crop commodity groups will have to identify and secure funding their own funding to cover those portions of the database maintenance and support necessary to input, review, and maintain their entries in the database. The MRL

Harmonization Database Oversight and Development Committee will develop a scoping document for possible enhancements to the database which will aid in defining the funding needs that go beyond those initially funded by the TASC grant. Once the scoping document is developed, additional funding sources will be identified and attempts to secure continued support for the expanded database will be initiated.

Questions regarding specific funding issues associated with the database and its possible expansion should be directed to the primary contacts managing the current database development (see below for contact information).

On-going Database Support and Maintenance:

To date, most of the work on the database has been in the development and testing phase. The on-going support necessary to adequately maintain the database can only be estimated at this time. It is assumed that the database will continue to be managed and the direct maintenance and oversight provided in the private sector. To adequately plan and estimate the ongoing budgetary requirements for the long term operation of the database it will be necessary to fully define the individual processes envisioned by the data entry, review maintenance and scheduled updating of the database. These parameters will become more clearly defined after the database becomes publically available.

Scheduled Review and Update of Included Information:

Again this process has not yet to been fully defined. It is anticipated that the commodity groups represented in the database will review their submitted information, at least semi-annually. This would be accomplished by the Screening Committee going back to the original data submitters to determine if priorities have changed or if additional information needs to be added. It is also anticipated the regulatory agencies in each country would have access to the contact information for individual commodity groups to address concerns or questions directly to the data submitter.

The actual process to implement this phase of database management has not been fully discussed. It will be part of discussions of the MRL Harmonization Database Oversight and Development Committee and will be included in the scoping document.

Who Should be Contacted for More Information?

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