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Homologa™, The Global Crop Protection Database of MRLs and current product registrations

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ABSTRACT

Spotting risks in the food chain is a daily challenge faced by growers, importers, producers, retailers, laboratories and regulators. It is a task made all the more difficult by having to wade through endless reports, often in foreign languages, and trying to compare the results of this search cross-country just to find the bits that might apply to you. The regulatory framework concerning the occurrence of pesticide residues (MRLs) is changing. The standardization of the MRLs for EU members helps but the problem with registered versus expired agrochemicals remains (last use/expiry date). For some active ingredients (ai) no MRL exists but there are still agrochemicals with this ai in use. Homologa™ is set to change all that by providing agronomic information including the current pesticide product approval status of over five dozen countries together with the associated MRLs to support the development of business strategies and to ensure compliance within the prevailing regulatory frameworks. It facilitates the access to regulatory data and hence saves important resources to its subscribers. There are numerous examples in which Homologa has been used to resolve critical problems. Subscribers can search online for expired and registered crop protection products as in several countries in a single report allowing side-by-side comparisons. There is also the possibility to receive alert e-mails when registrations or MRLs change. In addition, the new version of Homologa™ provides access to product label information for many countries and companies. The database can communicate with other user platforms using a Webservice. The Homologa™ Team and its global collaborators constantly update the database. Today the mark of 7 000 000 lines of registration data is passed and will continue to increase further.

Keywords: Database, Crop Protection, MRLs, Agrochemicals, Webservice, Biopesticides, France

1. INTRODUCTION

Homologa is a plant protection database containing information on plant protection products from over 60 OECD and non-OECD countries. It lists 34 information items: national product name, registration number, company name, active ingredients, concentration, formulation, product group, toxicity class, bee toxicity, flammability, safety and environmental restrictions, links to labels and MSDS sheets, method of application, time of application, pest/problem, dose rates, amount of water, maximum number of treatments, PHI, national MRLs, upcoming changes in MRLs, regulations, common crop name, crop name, crop group, production site, common pest name, scientific pest name, export/import markets, EU registration status

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whenever these are available for that country. The data are updated monthly, bi-monthly or yearly depending on the frequency of updates in the respective countries.

Access to this database opens a new dimension of opportunities for pest management, IPM, international trade, control of invasive species, scientific research, data generation, market studies, registration of pesticides, and the international harmonization of all of the above. It is the first database that allows access to information that so far has either not been available on the web or was not accessible because the majority of the countries do not publish their information in English or only translate part of their information.

2. SOLUTIONS AND STRATEGIES BASED ON DATA

Agricultural production and distribution require a constant flow of current information about plant production products, their availability, regulatory status and accepted residue limits. Access to this information provides the industry with the tools to prevent or overcome pre- and post-harvest losses, and to trade commodities to countries that wish to import them.

2.1 Crop production

The crop production industry consists of growers, crop/pest specialists, processors, marketers, retailers and shippers. All of them have clearly defined responsibilities that require precise and timely information. Most crops grow seasonal and time is critical. Due to the effects of globalization information needs to be internationally available. The lack of information leads to yield loss, non-tariff trade barriers, crop destruction, rising commodity prices and, in the worst case, food crisis. Homologa has often been used to prevent or resolve such issues.

2.1.1 Hay for export

The Canadian hay industry produces high quality feed for Japanese cattle and dairy producers. Every year, Japanese buyers provide a list of active ingredients in plant protection products that Canadian growers are allowed to apply to their crop intended for export to Japan. Canadian growers now have to identify products that contain these ingredients and are approved for use in Canada. If they find an adequate product, they then have to determine the use pattern (application rate, method, frequency and intervals) that is (i) approved in Canada and (ii) remains below the Japanese MRL for this active ingredient on hay.

The Canadian regulator does not set MRLs for hay and it is therefore impossible for Canadian growers and Japanese buyers to directly compare MRLs to use patterns. Growers are forced to take samples from single bales and to have these tested by a GLP certified laboratory to demonstrate residue levels to their customers. As this requirement by Japanese authorities is not likely to go away, growers need to make sure that they apply plant protection products in a way that leaves residue levels below the Japanese MRLs.

This task can be achieved through Homologa. Growers can compare the MRLs between different countries, select countries that have MRLs for hay that are similar to those in Japan,

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look up the use patterns that are approved in these countries and follow those that are acceptable under Canadian regulations. This approach takes about one hour compared to years of scientific research, regulatory reviews and government lobbying. In addition, this approach provides a flexibility that allows growers to adjust to regulatory developments either in Canada or in Japan.

2.1.2 Change of an MRL

Governments frequently change MRLs for specific active ingredients and crops. These changes are communicated to the regulators in other countries and to the World Trade Organization (WTO) in an effort to avoid non-tariff trade-barriers.

The worst case scenario for a grower is the lowering of an MRL in an importing country mid-season. The products that he has applied until this moment can't be wiped off the plants and will prevent him from further use of the same product during the remainder of the season.

In such situations, Homologa provides growers with the information on use patterns with residue levels that remain below the newly set MRL in the importing country. The database allows the identification of these use patterns in countries that have MRLs similar to those permitted in the importing country and will either indicate to growers that it is safe to continue with the treatments they had intended or will provide them with options for treatments with other ai.

2.1.3 New plant varieties

A particularly difficult situation is that of the highly competitive ornamental industry because serves customers that are used to a constant flow of new varieties. Varieties change a lot faster than regulatory adjustments to approved product labels can be accomplished. The situation is further complicated by the fact that crop tolerance differs between plant varieties and any damage to the flowers or foliage of the plants would be unacceptable to customers. Growers in the ornamental industry therefore run small trials on a subsection of their crops before treating the main crop.

Crop tolerance trials are carefully planned based on the biology of plant and pest. To a certain extend use patterns (rate, method, timing and frequency) can be deducted from similarities between plant species. The precision of the protocols increases with the amount of information that feeds into the establishment of the use patterns and this way reduces the cost of trials.

Homologa provides such information in thousands of lines of spreadsheets that can be systematically analyzed to determine which products and use patterns have the best chance to protect the high value crops from pests without causing damage to the plants.

2.2 Science

2.2.1 Replacing chemistry

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Plant protection products and their respective active ingredients can remain on the market for decades. Eventually however, they are withdrawn due to growing pest resistance or due to changes in a company's business interests. When such a product becomes unavailable to the growers and needs to be replaced, a search of the Homologa database shows which products are used by growers in other countries. The spreadsheets can be searched for crop/pest/product combinations that are authorized in other countries. Typically that means that these combinations have been tested for efficacy and crop tolerance.

From the same spreadsheets scientists can identify the companies that hold the registrations in the different countries and can contact them to request the reports of studies that were conducted to obtain registrations in their countries. Scientists can then provide the regulator with copies of these studies and scientific rationales that bridge the potential differences in climate or use patterns. This approach saves the time for years of trial work that would just be a repetition of what has already been done elsewhere and it potentially provides the regulators with a far larger amount of data than would otherwise be made available to them.

2.2.2 New active ingredients

One of the most important steps in the development of a new active ingredient is the determination of the use rates, the application methods and the intervals between treatments that are adequate for the plant to be protected and the pest to be controlled. Both organisms effect each other and therefore require large numbers of efficacy trials that result in treatment effects ranging from 'no effect' to 'plant destroyed'. The investments in time and money are significant expenses even for large R&D companies.

Homologa allows the development of study protocols that considerably narrow the range of possibilities based on crop, pest and ai comparison to already approved uses. In a first step the user generates a spreadsheet that shows crop/pest/production combinations and their use patterns for a specific product type (e.g. fungicide) in all countries. This spreadsheet can then be analyzed by type of ai, of crop or of pest resulting in a range of rates, application timing, application methods and application frequency that have shown to provide the efficacy required by growers and regulators.

2.3 Manufacturers

2.3.1 Expanding a data package

Prior to the commercialization of a plant protection product it has to undergo a risk assessment by governmental regulators and the proposed use patterns need to be approved. Most manufacturers first apply for the approval of uses in high value markets such as wheat or cotton. Other uses (minor uses) are gradually submitted to the regulators in the following years. For many crops this means that new plant protection products only become accessible to them ten to twenty years after the product has been launched.

Manufacturers have recently made a slight change to their process. Some of them have used Homologa to generate a spreadsheet that consolidates all the uses for which approvals were

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granted in at least one country. This sheet is then provided to all grower organizations in a country where the manufacturer intends launch his product. Crop/pest specialists in the grower organizations or the growers themselves indicate on this spreadsheet which of the listed uses are of interest to them.

Based on this information manufacturers can then compile data packages that apply for the approval of uses that are requested by growers rather than being pushed by the manufacturer who now deals with a 'pull market' that requires a lot less marketing expenses than a 'push market'. The best example so far is a case where a manufacturer increased his application from four to over 120 uses.

2.3.2 Building a data package from existing data

Growers, scientists, regulators and consumers have become increasingly aware of the health and environmental concerns associated with the use of plant protection products. Consequently the demand for reduced risk and low risk products has been on the rise worldwide. One way to reduce risk is the use of known ais in new formulations and with new application methods.

A good example is the use of sulfur. While the active ingredient and its effects are well known, its applications raise concerns of worker protection in greenhouses. A safe and efficient application is the use of vaporizers that burn the sulfur at a temperature low enough to prevent the development of highly toxic fumes. The amount of sulfur used in these burners is so very small, that it would be impossible to raise the necessary funds for new data generation trials. Therefore, a group of growers and scientists collaborated in building a data package from existing scientific and technical reports that were either publicly available or in the hands of growers, scientists and manufacturers in other countries. The working group identified the companies and grower associations in other countries by using Homologa. Potential gaps between the information that they obtained and the information required by the regulator were bridged by scientific rationales.

2.2 Regulators

2.4.1 International Harmonization

The review of a data package includes the assessments of hundreds of studies with thousands of scientific methods and acceptable endpoints depending on the scientific discipline and the newest findings in the associated field of science. It is crucial that regulatory scientists are at all times aware of the newest scientific developments. There are two ways to accomplish this: the regular study of scientific publications and the direct communication with colleagues in other countries.

Homologa allows regulators the search for uses of active ingredients that have been approved in other countries. With this information they can identify the regulatory agencies that have approved these uses. The comparative spreadsheets from Homologa facilitate the communication between regulators. It allows discussions to rapidly get to the point and to strategize for next steps.

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2.4.2 Avoiding differences in MRLs

As mentioned above, maximum residue limits (MRLs) of active ingredients (ai) on specific crops often create non-tariff trade barriers that can't be resolved by scientific data and interpretations. Prior to the availability of Homologa, regulators assessed the data provided to them by manufacturers of plant protection products and then calculated national MRLs. Differences in MRLs between countries were only noticed after they had been set and legalized.

With the availability of Homologa regulatory scientists can now compare the values they reach with those that have been set in other countries. It is an easy step that allows regulators to flag potential issues to the authorities within their own government for potential resolution. This is the first step in the efforts to the global harmonization of MRLs.

3. CONTENTS

The information provided by Homologa is searchable in three categories of 13 reports:

Product Registrations

MRLs

Food Trade Statistics

The reports can be downloaded into Excel spreadsheets where individual reports can be combined. This is especially an advantage for users who need reports that are longer than the 10,000 lines limitation of online searches of Homologa. These users compile successive reports

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by product type, geographic region or crop group and then copy/past these reports into a single sheet from where they continue to work with Excel autofilters.

Reports comprise up to 34 columns of information that is difficult to analyze further in an online format. The Excel download allows users to select the columns of information that are essential for their task at hand.

4. DATA SUPPLY

4.1 Feeding the database

Agrobase is a team of agronomists and programmers. The core is located in Southern France where the information from countries that publish on their information on the web and in English is coded and uploaded into the company's database. For countries that either do not have such websites or do not publish in English, national consultants obtain the information from government offices, translate it into English and code it before uploading it.

4.2 Online Access

Homologa is an online querying service. Users access data at www.homologa.com. Through the same site users can request data on-demand, record their reports to be automatically completed at pre-selected intervals and then sent by email. Reports can be exported in ".csv" format from the Homologa platform.

4.2 Export Facility for Metadata Supply

A Web Service is available for automated data supply to external platforms in any desired format. From the listing of new and forthcoming products to the sending of incremental updates all the relatively complicated reports can be performed within a single system.

5. CONCLUSION

Worldwide, Homologa the only database that allows to access this type information in its completeness and in a single language. Until the development of this database the information contained in it was not accessible because

- several of the countries included do not have pesticide information available on the internet
- of the over 60 countries only 11 publish their Webpages in English
- countries that offer an English version of their webpage translate only part of the information
- terminology differs even among English speaking countries and has only now been coded by Agrobase.

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Without access to this information the international harmonization of the development, registration, manufacture and use of plant protection products is not possible.

Homologa updates its information in regular intervals. These intervals range from monthly to annually and depend on the frequency of the respective national updates. The goal is to update Homologa as often as the individual countries update their own information. Any efforts by another organization to deliver the same information update would cost over 2 million dollars annually, costs that Homologa covers through its national and international customers who buy not only subscriptions but also reports and analysis of an even larger group of information items than those provided in the database.

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