

POSITION PAPER

Pesticide Solutions for Minor Uses

CropLife International's Position, established September 2015

Pesticides for Minor Uses – a global challenge.

The provision of pest and disease control solutions for minor uses, i.e. specialty/minor crops and low volume uses in major crops, is recognised as a challenge both nationally and globally. The broad ranging and complex challenges are currently being defined and addressed by national and regional governments, international organizations, e.g. Organisation of Economic Co-operation and Development (OECD) and CODEX Alimentarius (CODEX), and through international initiatives, e.g. Global Minor Use Summits (GMUS) and resulting Global Minor Use Steering Committee. Within the last decade positive steps have been made to recognise the extent of minor use gaps, harmonise practices and procedures, share best practices, and in the development of databases. These initiatives and activities include:

- Promotion of successful models/processes established for minor use programmes (USA and Canada)
- Increasing transparency through the development of databases at national and regional level, as well as global proposals (GMUS)
- OECD guidance documents and OECD MRL Calculator.
- CODEX electronic working group recommendations on minor crops
- Harmonization of crop grouping (via International Crop Grouping Consulting Committee (ICGCC))
- USDA – FAS (Foreign Agricultural Service) capacity building program
- EU minor use fund and coordination facility agreed
- Mechanisms to facilitate registrations for minor uses, e.g. extrapolations from major crop data
- GMUS – 5 year plan, establishment of the Minor Use Steering Committee and subsequent working groups

CropLife International (CropLife) supports these activities and encourages all stakeholders to work together, as partners, to maintain the momentum in the effective and efficient provision of crop protection solutions. This paper provides a review of some of the activities mentioned above, the major challenges ahead, and highlights where industry can engage as a stakeholder in the processes.

What are the major challenges?

Economics, trade, coordinated approach (stakeholder engagement)

Sustainable agriculture is a key factor for global food security and represents a complex matrix of environmental/human health and socio/economic factors. To provide high quality, marketable produce and a sustainable income, grower communities require a set of tools to protect crops from pests and diseases. Management solutions based on chemical pesticides are a key part of the “tool kit” and are highly regulated to ensure environmental and human safety. Research and data generation required to obtain and maintain an authorisation for the use of a plant protection product is costly and time/resource intensive; although solutions are widely available for major crops, minor uses have limited options.

Growers of minor crops from both developed and emerging economies face similar challenges, i.e. gaining recognition of the problem and insufficient data. Data generation to support a registration for minor uses may require extensive costs and resource inputs, and are unlikely to be economically viable for industry to pursue due to the diversity of crops, low volume sales and inherent liabilities. Markets in the emerging economies are especially demanding and growers in those countries face additional socio-economic challenges through the loss of traditional labour to cities, resulting in a greater need for technologies/solutions.

A second major challenge, even when a solution has been identified, is the freedom to trade the resulting commodities. Trading requires the establishment of Maximum Residue Levels (MRLs) for each pesticide/commodity combination both nationally/regionally and in the importing countries. Where no MRL is established there is risk that a traded commodity can be rejected by an importing country.

Both the lack of availability of products for minor uses and the challenges associated with trade reduce grower competitiveness and negatively impact national/regional economies. The overall value of minor crops is high having an estimated global value of \$500bn, ca.

approximately \$70bn in the USA and €70bn in the EU (ca, 22% of the plant protection value¹). However the number of crops under the definition *minor* and the associated agricultural practices is highly diverse. This diversity and complexity of the registration process, e.g. lack of harmonization and mutual acceptance means it is unlikely that any one of the stakeholders (such as growers, extension services², industry, exporters) within the minor use value chain would have the necessary knowledge and resources to individually deliver a complete solution. The elements required to provide a solution include: awareness of a problem and its extent, its value, knowledge of the trade routes and associated regulatory requirements, funding to generate data and make the submissions, and the resources to manage the project. Bringing all the interdependent elements together requires that all stakeholders work together in managed projects which have the support of knowledge management tools, regulatory incentives, and funding.

How can solutions for minor use growers be recognised and prioritised?

Problem recognition, prioritisation processes, funding, tools for knowledge management and partnering (stakeholder engagement)

A pest or disease pressure in a minor crop, or a minor use in a major crop, is unlikely to be a research priority for researchers or manufacturers due to its low direct value. If however it can be shown that the problem is wider, i.e. pest or disease present on several similar crops or is a wider problem at the national or global level, then the weight and value of the project is increased and is more likely to receive greater recognition, prioritisation, and potential funding.

A number of national and regional minor use schemes/programmes are currently in place, some with extensive funding and facilities (e.g. Inter-Regional Project No. 4 (IR-4)) and some which simply facilitate routes to authorisations, e.g. Brazil (Joint Instruction (INC 01/2014)).

The most extensive programmes are exemplified by the processes in USA and Canada which include a “bottom up” approach to collate the needs of the growers, prioritise through annual planning meetings, gain stakeholder engagement and manage the projects. The processes are similar in both countries, being managed by a central body (e.g. IR-4 Project and Pest

¹ REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL on the establishment of a European fund for minor uses in the field of plant protection Products, Brussels, 18.2.2014 COM(2014) 82 final

² Agricultural Extension Services provide knowledge in agronomical techniques and skills to improve production, income and quality of life.

Management Centre, (PMC)) and supported, in part, by federal funding, e.g. IR4 receives annual funding of ca. \$18m from government and industry grants and based on its submissions, 793 permanent tolerances were established at EPA over the period 2010-2014. A simplified representation of the process used is shown diagrammatically in Figure 1. Pesticide manufacturers are key stakeholders in the process through their support for label expansion and/or inclusion of minor uses as part of the initial new product registration, as well as providing guidance on the relevance of the active ingredient database for the proposed use, e.g. are the appropriate plant metabolism studies available or any risk cup implications. In addition, the company representatives need to retain a global perspective when considering minor use projects, i.e. global company strategy. The manufacturers' role in the process (outlined in Figure 1) may include making minor use additions to the master label, requesting State registrations for amended product labels, and managing registrations including annual renewals and maintenance fees.

The generation and submission of data (for risk assessment and setting trading standards (MRL) and, where needed, efficacy data) for the authorisation of a minor use needs to be rigorous because both are costly (in excess of €200,000¹ for a minor use registration and evaluation) and time consuming. These data need to meet the regulatory requirements nationally and also consider the needs of importing countries. Funding for project management, data generation, dossier preparation and submissions needs to be available and secured; these are exemplified by USA and Canada where funding is available via the IR-4 Project and PMC. USA and Canada also maximise the utility of the data generated by data sharing for minor crop authorisations.

An example of a national minor use scheme exists in the Netherlands where, in recognition of the value of minor uses to the Dutch economy, the Netherlands Expert Centre for Speciality Crops was established in 2010. The objective of this virtual network is to deliver a reduction in the number of minor use gaps in the Netherlands through effective national and international cooperation. The process involves capturing needs, prioritisation, comparison with other minor use platforms (EU), identifying solutions, and where necessary, funding trials and submitting an application for approval. The fund is financed by the Ministry of Agriculture and Industry. Manufacturers are active within the process in checking for available data and supporting the submission through document preparation.

Within the EU it is estimated that approximately €8m of funding is made available at the national level to support minor crops. This funding is used to support research and development, primarily at the national level.

Under Regulation (EC)1107/2009³ the Commission was required to make proposals to the European Parliament for an EU fund on minor uses. Following a publication of a report¹ in 2014, the Commission has agreed to establish a fund of €0.35m/year, as partial funding, to set up a EU Minor Use Coordination Facility. The role of the Coordination Facility is to promote synergies and avoid duplication. Primary activities will include: coordinating minor use work between Member States and stakeholders, the maintenance of a database, and the promotion of harmonisation, including crop groupings, definitions, and developing guidance. The Commission did not support the provision of funding for data generation and dossier evaluation, viewing it to be outside the scope of Article 76³ of the Regulation. It did however encourage more efficient use of national funding and agreed to monitor progress and effectiveness of the Coordination Facility over time. The Commission also encouraged the Coordination Facility to make use of the European Research Area Network IPM ERA NET⁴ to allow Member States to coordinate research activities and jointly fund projects.

- ***CropLife welcomes the establishment of the EU Minor Use Coordination Facility and its objectives of promoting synergies and avoiding duplication. The lack of funding to conduct trials, make submissions, and the short/medium term nature of the funding commitment however creates a level of uncertainty.***
- ***The Coordination Facility is encouraged to promote strong project management to ensure stakeholder commitment, consistent protocols, consistent product supply, and the appropriate paperwork for legal positions and letters of access to facilitate data sharing.***
- ***CropLife would encourage the establishment of programmes similar to those currently proving successful in USA, Canada, and Holland using a bottom up approach, stakeholder involvement, and more sustainable funding.***

³ REGULATION (EC) No 1107/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

⁴ <http://c-ipm.org/what-is-c-ipm/what-is-era-net/>

The knowledge management tools to collate needs, priorities, activities, data and authorisations are critical and are being actively used in some countries; however, the ultimate goal of common databases at regional or global level have yet to be fully realised. These databases provide transparency and increase the awareness, for all stakeholders, of where a solution is needed and could lead to efficiencies in data provision. Databases include, e.g. European Minor Use Database (EUMUDA⁵), IR4 Food Crops Database⁶, US Grower Priority database⁷, United States-Canada Grower Priority Database⁸, and East Africa Phytosanitary Information Committee-Pest information Management System (EAPIC-PIMS)⁹

- ***CropLife supports the development of databases and encourages that they are appropriately funded, regularly updated and managed in a sustainable manner. To facilitate global sharing and increase the utility of the databases, the goal should be to have a standard global format and definitions (such as the efforts underway by the Global Minor Use Steering Committee database working group).***

How can global minor use challenges be addressed?

Harmonised guidelines and processes, databases and communication between stakeholders

Challenges associated with minor uses are common to both developed and emerging economies, i.e. the need for pest control solutions and the establishment of appropriate MRLs to minimise trade barriers. Capacity building is also particularly important in the emerging economies and a considerable level of funding has been made available through the World Bank, FAO, USDA FAS, and European Development Fund.

Groups actively working on developing international cooperation include OECD, CODEX and GMUS-Global Minor Use Steering Committee.

The OECD expert group on Minor Crops (EGMU) works on identified issues around the authorisation of minor uses in member countries. It has published several documents

⁵ <http://www.eumuda.eu/Apps/WebObjects/PSInfoEU.woa>

⁶ www.IR4.rutgers.edu/food.html

⁷ <http://www.mrlpriority.com/>

⁸ www.uscanadagrowerprioritydatabase.com

⁹ <http://www.eapic.org/index.php/pest-database>

defining minor uses¹⁰ and regulatory incentives¹¹, and is currently preparing guidelines for addressing minor use gaps, data exchange, as well as the selection of a crop/pest for a pilot process.

- **CropLife support efforts by OECD EGMU to develop harmonisation in the authorisation of minor uses.**

The Global Minor Use Summits (GMUS) are co-organised by Food and Agriculture Organisation of the United Nations (FAO), US Department of Agriculture (USDA), US Environmental Protection Agency (EPA), Canadian Pest Management Centre (PMC), and IR-4, and event participants include a range of stakeholders representing 50+ countries, industry and extension services. Priority actions include, improving communications (GMU portal) and information exchange (databases and global priority setting), incentives, capacity building in developing countries, harmonisation of data requirements (including crop grouping, study protocols for the conduct of residue and efficacy trials), engaging with CODEX for better support for minor uses, and collaborative pilot projects. During the second summit (GMUS II), industry expressed ongoing concerns relating to potential liability resulting from minor uses. The term liability encompasses commercial/economic liability due to lack of efficacy and/or crop safety, trade issues because of the lack of a MRL or MRL exceedance, as well as liability for worker safety and the environment due to the diverse agricultural practices in minor crops. Actions from this summit included scrutiny of existing liability waivers and the need to bring together legal experts from industry and governments to provide advice relating to the standing of the waivers and of other liability issues.

- *CropLife supports the work themes prioritised by GMUS and encourage stakeholder groups to maintain the momentum behind activities.*
- *CropLife also encourages the joint legal discussions on liability issues.*

¹⁰ Publication of the OECD Guidance Document on Defining Minor Uses of Pesticides Series on Pesticides No. 49 [ENV/JM/MONO/\(2009\)39](#)

¹¹ Guidance Document on Regulatory Incentives for the Registration of Pesticide Minor Uses Series on Pesticides No. 63 [ENV/JM/MONO\(2011\)16](#)

How are incentives and mechanisms to facilitate authorizations used to increase minor uses?

Increasing the indirect value of the minor use; maximising the utility of datasets and data extrapolation

Some Authorities have provisions for incentives for manufacturers to include minor uses in submissions, e.g. extended data protection, expedited review or reduced fees. In the USA, an exclusive data use period of 10 years following registration can be extended by 1 year for the addition of 3 minor uses to the label, up to a maximum of 3 years. Similar provisions are available in Canada, with up to 5 additional years of data protection (3 minor uses for each additional year), and in Europe where 3 extra months data protection is available for each minor use up to a maximum of 3 additional years.

Incentives are widely supported by industry, providing an indirect increase in value and sometimes faster introduction of new and reduced risk technologies to growers. An industry survey conducted by CropLife in 2012 questioned which regulatory incentives were the most attractive for companies. The two most frequently mentioned incentives were extension of exclusive use of regulatory data, and lower fees; other incentives mentioned included faster authorization or shorter review time, reduced data requirements, and support for data generation. The top priority is clearly an extension of the data protection period, during which secondary applicants will have to provide their own registration data for market entry or pay for the use of existing data in countries with compensatory data protection systems.

The use of data extrapolation and international datasets to facilitate the estimation of MRLs for minor uses represents an efficient use of available data and is encouraged, when based on sound science and where safety is not compromised. The use of crop groupings, i.e. where crops are grouped based on taxonomic or agronomic similarities, is a pragmatic solution in estimating MRLs and is very applicable for minor crops. Within the methodology, MRLs can be estimated, following scientific scrutiny, from residue data for representative crops i.e. the most significant crops in the group (from an economic standpoint) or those likely to have the highest residues. The use of crop groups and representative crops is an accepted methodology in many regulatory arenas, even though there is a lack of global harmonisation of definitions and requirements (representative crops and numbers of trials). The International Crop Grouping Consulting Committee (ICGCC) is working to revise and harmonise crop groupings at the International level with inputs from 40 countries. These

crop groups are simultaneously considered in updating the CODEX Classification of Foods and Feeds. All countries will be encouraged to adopt the new groupings.

In Brazil, extrapolation for minor uses was established in 2010 and is based on crop groupings. The groups are based on broad, botanical characteristics using extrapolations of the data from representative crops to minor crops in the same groups. Restriction on the ability to extrapolate include products in re-evaluation, with low ADI (<0.005mg/kg/day) or those restricted to back pack uses¹².

- ***CropLife encourages the use of incentives and global harmonisation of crop groupings and representative crops to facilitate the provision of minor use authorisations.***

Generation of trial data represents a major cost and greater use of global data, where scientifically defensible, is encouraged when making country and/or regional registration submissions. Where trial data are generated in one country, consideration should be given of its applicability for other country registrations provided the proposed GAP and agricultural practices are similar. Directly pertinent to this point is work ongoing by US EPA, Canada's PMRA and CropLife America's Residue Expert Working Group to investigate if systematic differences in pesticide residue levels exist amongst trials performed with similar GAPs at difference geographic locations. The current statistical analysis of thousands of trials from US, Canada, EU (North and South), South. America and Asia provides compelling evidence that the residue levels are not statistically different. It is hoped the results of this work will open the way for residue data from various zones, conducted under the same or sufficiently similar application scenarios, to be combined to provide larger data sets for MRL setting, especially amongst minor crops.

- ***CropLife encourages the use of International datasets, where scientifically defensible, to support minor use authorizations.***

¹² http://www.agricultura.gov.br/arq_editor/file/vegetal/agrotoxicos/CSFI - Minor Crops/Manual da INC de CSFI_Final.pdf

How can trade barriers be minimised for commodities resulting from minor uses?

MRLs established for all countries within the trade route, capacity building in exporting countries

Another major challenge is the minimisation of trade barriers through the establishment of MRLs nationally and in importing countries. An understanding of the trade flows of minor crop commodities is necessary when planning the establishment of MRLs in importing countries. If there is no MRL, or the MRL is exceeded, then the shipment may be rejected in the monitoring process. MRLs may be established via a domestic use registration, adoption of a CODEX MRL (CXL) or through the setting of an import tolerance MRL.

The role of CODEX is to develop harmonised international food standards, guidelines and codes of practice to protect health of consumers and ensure fair practices in food trade. It has 185 member countries and its standards are an important reference in food trade disputes. It is therefore a logical vehicle for the global harmonisation of MRLs and trade facilitation; however CXLs are not necessarily accepted by all member countries. Some countries and regions will defer to CXLs, (e.g. Chile, Kenya, Myanmar) while others consider adopting a CXL into legislation providing they meet national/regional requirements, e.g. each year the EU considers the adoption of CXLs into Legislation 396/2005 as EU MRLs. The CXL may not however be accepted due to differences in risk assessment policies, definition of the residue (DOR), data requirements or crop grouping differences. More and more countries are setting up their own national registries and moving away from deferral to CXLs if no national MRL exists, e.g. Korea will not defer to CXLs once the first phase of its Positive List System is introduced, starting Jan 2017.

The CODEX process can take in excess of 18 months from the submission of the dossier, and since JMPR will not currently review a package until a national registration is in place it can impact the provision of CXLs for new technologies and therefore the availability of reduced risk solutions to growers of minor crops.

In recognition of the economic value, health implications and challenges associated with minor uses, CODEX has initiated several activities, i.e. established an Electronic Working Group (EWG) to make recommendations for the establishment of CXLs for minor crops and specialty crops, as well as crop groupings. The EWG commenced in 2008 and based on the significant challenges in deriving an overall international definition of a minor crop, has

focused on the number of trials required to support a CXL; this is based on a global, FAOSTAT database and regional dietary intake (Global Environment Monitoring System (GEMS) Food Clusters diets). The current draft guidance¹³ is based on assigning the minor crop commodity to one of 3 categories, 1) commodities where no consumption data exists – case by case basis for the number of trials required, 2) percentage diet is <0.5% both globally and all clusters – requires a minimum of 4 trials; 3) percentage diet represents <0.5% globally and >0.5% in one or more clusters, minimum of 5 trials.

The minimum number of trials only refers to individual crops and not for crop groups. In the case of minor crops it is also recommended that the acceptance of field trials data with no formal label be formalised, i.e. the acceptance of an official letter from the government agency of the country where the chemical is being used, including the details of the chemical's use pattern. Particularly for minor crops, the use of global datasets (provided they reflect the use pattern), together with the principles of proportionality and extrapolation are encouraged.

The EWG also has a role in identifying problems and in finding solutions to facilitate the establishment of CXLs for minor crops based on CODEX schedules and priority lists. In a pilot project the EWG have requested that members populate a spreadsheet to collect needs, existing labels GAP and available residue data. Although members of the GMU Steering Committee were consulted on the design of the spreadsheet, it should be an opportunity to promote the concept of a single global database. CODEX is also updating their own crop classifications based on the work of the ICGCC which will facilitate the establishment of minor crop CXLs.

Where no MRL exists for the commodity in the importing country and where application procedures are in place, an import tolerance submission may be appropriate, i.e. EU, USA, Canada, Hong Kong, South Korea, Taiwan, Japan and Russia. However the processes are not harmonized with some countries requiring exporting country registrations prior to review and some requiring efficacy data, i.e. Taiwan. This lack of harmonization further complicates the challenges for minor uses and can impede trade.

¹³ Annex 1, Discussion paper on Guidance to facilitate the Establishment of Maximum Residue Limits for pesticides for minor crops/speciality crops. 47th Session Codex Committee on pesticide Residues April 2015. CX/PR 15/47/11 March 2015.

- ***CropLife encourages all member countries to consider deferral or inclusion of CXLs into their national registers and for CODEX to consider its procedures to facilitate more efficient estimation of CXLs for minor uses.***

Two examples of capacity building initiatives are the Europe-Africa-Caribbean-Pacific Liaison Committee - Pesticide Initiative Programme (COLEACP-PIP) and USDA FAS. COLEACP-PIP was initially rolled out in 2001 (Phase 1) and a second phase launched in October 2009, having a proposed duration of 5 years: The scheme received funding of ca. €30m from the European Development Fund; its objectives included addressing safety concerns from EU consumers, sustainability, overcoming international barriers and minimizing pesticide residues. Through its information systems, COLEACP-PIP has published Crop Production Protocols, explained EU food safety regulations, provided regular updates on new regulations and active substance approvals, and withdrawals. The programme has developed the capacity of African-Caribbean-Pacific (ACP) regulatory authorities to provide ‘in-country’ registration of plant protection products and also facilitated their participation in international trade decisions and standards setting. Where EU or Codex MRLs are not available COLEACP-PIP performed residues trials, working with national governments and manufacturers to develop and submit dossiers for import tolerances. Over 30 import tolerances and one Codex MRL have been obtained by the programme¹⁴.

The United States Department of Agriculture Foreign Agricultural Services (USDA FAS) initiative on trade facilitation through capacity building, has worked in collaboration with PIP. Its objective is to facilitate global trade by reducing technical barriers (e.g. establishing MRLs), and promoting communications between global regulatory authorities. It has developed capacity in overall technical knowledge and skills in the area of pesticide management (risk assessment) and analysis through its extensive training courses and workshops. Following the GMUS it has incorporated minor use issues into the outreach programmes.

- ***CropLife supports sustainable capacity building programmes and would encourage that these include minor uses issues where feasible.***

¹⁴ Global Minor Use Summit 2. FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS (FAO) HEADQUARTERS Rome, 21–23 February 2012, FOR SUSTAINABLE DEVELOPMENT OF THE ACP HORTICULTURAL TRADE – COLEACP PIP A European Cooperation Programme for the ACP horticultural industry
Christine Moreira

What do manufacturers believe are the key challenges to a successful provision of solutions for minor uses?

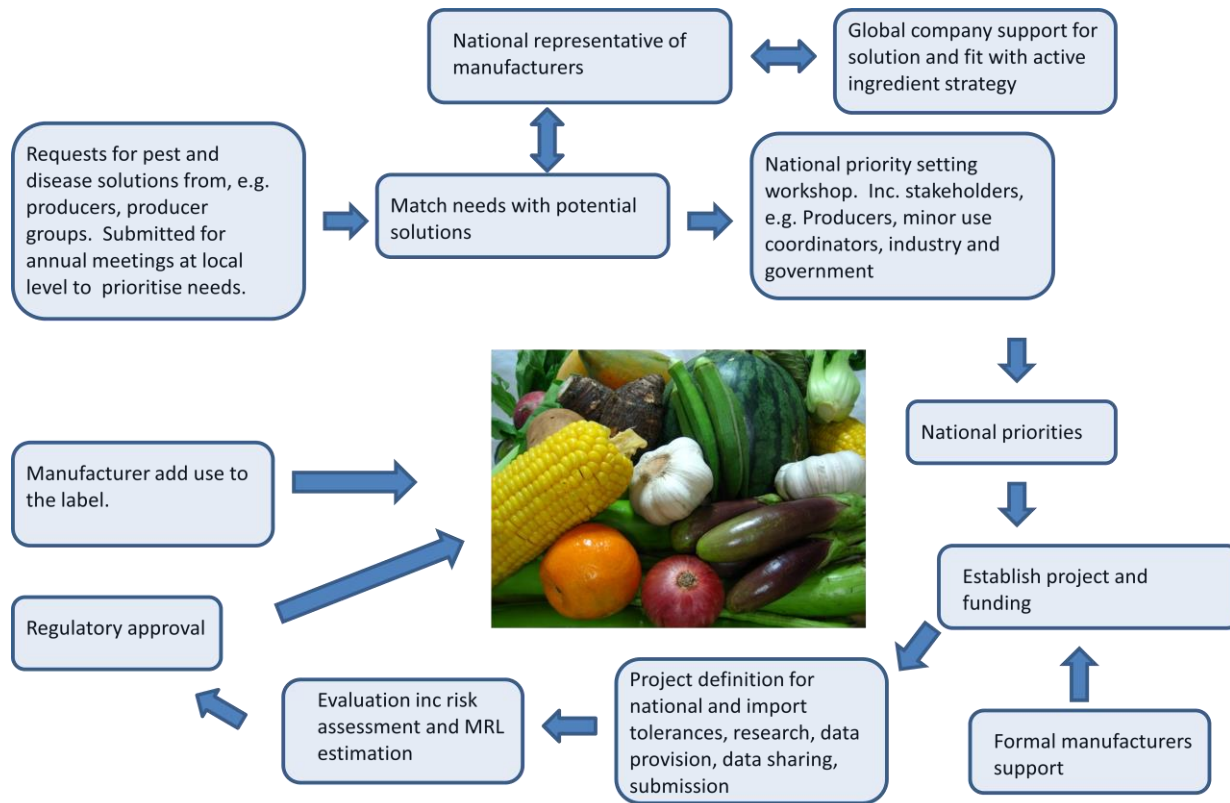
The recognition of the value of minor crops to a nation's economy and the need to minimise trade barriers has resulted in a significant amount of funding and activities at the national/regional level and more recently at a global level. Many pieces of this complex matrix are available but lack cohesion and harmonisation. CropLife encourages the activities associated with:

- Recognition, transparency, and wider sharing of the need and extent of pest and disease pressures, to enable more efficient solutions (e.g., one pesticide product to cover multiple needs/or same need in multiple geographies)
- Globally harmonized procedures and practices
- The use of managed databases along with globally harmonised formats
- Stakeholder involvement (partnering) and strong project management
- Appropriate, sustainable funding for national and regional processes
- Incentives for manufacturers to include minor uses on labels
- Use of facilitation mechanisms (data extrapolation and international data sets, harmonized crop groupings) for authorisation of minor uses
- Resolution of liabilities
- Deferral to CODEX or inclusion of CXLs into national registers where feasible.

Where can industry be more proactive?

- As stakeholders in minor use programmes, to provide clear commitments if the use is globally supported by the company
- Continue to provide insights into novel innovations, as well as knowledge sharing of overall crop protection solutions / systems
- To use the available databases to review minor use needs and where feasible, build these into overall active ingredient strategies for data generation for the initial submissions
- Share regulatory knowledge on how to prepare and submit dossiers; tracking of minor use regulatory schemes globally
- Engage in legal discussions on liability concerns.

Figure 1: Schematic representation* of a typically successful Minor Use programme.



* Representation based on successful processes used in USA, Canada, and EU.