Supporting MRLs and GAP for Minor Use Crops in ACP Countries

BACKGROUND

The COLEACP PIP Programme was developed at the request of the ACP Group of states in response to concerns about changes to EU Sanitary and Phytosanitary (SPS) Regulations, in particular the harmonisation of pesticide maximum residue limits (MRLs). It was recognised that these changes could affect ACP exports and therefore technical assistance was needed to avoid them from becoming market access barriers.

PIP was designed to provide producers and exporters with the necessary information, training, tools, and support so that they could meet the new EU food safety regulations, and the private industry standards that followed. The core activity was capacity building of private sector operators, especially smallholders, to establish and implement food safety management systems. Alongside this, PIP provided technical solutions to ACP suppliers so that they had the tools needed to supply produce that complied with the regulations, while still meeting the quality expectations of EU consumers. This included, in particular technologies and recommendations for the management of pests and diseases.

Pest Management in ACP Horticulture

Compared to other commodities, fresh produce has a short shelf-life and is subject to strict demands in terms of quality attributes. There is very low tolerance, for example, of damage caused by pests and diseases. In tropical countries, where there is high pressure from pest and diseases, it is particularly critical to manage them effectively. However, achieving the necessary control, while meeting the evolving regulatory and market demands, is becoming increasingly challenging.

Growers use a combination of methods: cultural, biological, and inorganic plant protection products (PPPs). A combined approach (Integrated pest management – IPM) is now the norm in many circumstances, and enables the use of PPPs to be kept to a minimum. The use of biological methods has increased in recent years, especially in protected crops (greenhouses). Nevertheless, in field crops, the use of PPPs remains a mainstay in sectors supplying the bulk export markets, allowing them to meet the price, quality, consistency and volumes demanded by buyers. To meet the applicable regulations when using PPPs on export crops, growers must:

- Only use products that are registered in their country
- Only use products that have an MRL in the destination country. The MRL is the maximum amount of residue of a PPP that can remain on the crop when it reaches the destination market. This will vary; some countries (e.g. Japan, EU) set their own MRLs; others use MRLs set by CODEX.
- Meet the relevant MRL by adjusting their production practices (GAP), if possible. This includes the PPP dose rate, frequency of applications, and the pre-harvest interval (PHI – the time between the final application and harvest). Growers supplying the EU must use a different GAP compared to produce destined for local and regional markets, if the MRL is different. If an MRL changes, the GAP will also change, and setting the new GAP accurately generally requires field trials. In cases where there is no MRL, this is set at the limit of determination (LoD) which, in most cases, means that the pesticide cannot be used.

The Minor Use Problem

Crops are called "minor-use" when there is low pesticide usage on a global scale. They include most fruit and vegetables. For these crops there is sometimes no CODEX or other pesticide MRL in force. Without an MRL, trade across borders is difficult. The problem is becoming more serious as the number of PPPs available for these crops is declining, and MRLs are being lost. It is particularly difficult in ACP countries, where little data is generated to support the setting of MRLs. In simplified terms, the reason why there are missing MRLs for minor use crops are:

- Residue trials to support MRL applications are expensive, difficult, and require specialist expertise
- The pesticide industry often does not support the necessary work to get an MRL for a minor use crop as sales potential does not justify the high cost
- IP issues can be a major disincentive for PPP manufacturers to register new products in some countries (which makes it very important not to lose the existing ones)
- When the patent has run out for a PPP, it is referred to as "generic" or "off license". At this stage it can be formulated by any PPP company, not just the manufacturer that developed it. There are many competing companies (notably from Asia as well as ACP) formulating generic products, at a reduced price. They have little interest in funding an MRL that is only needed for export crops, especially if their main market is on crops for local consumption, and the MRL will also benefit their competitors
- Often no individual stakeholder is willing to invest and do the work (on their own)

The situation is most severe in developing countries where the driver for developing an MRL is more public good (development) than commercial. Minor use crops such as horticulture are important generators of income and employment, but small in terms of volume and acreage, and not interesting for PPP companies.

The Impact of EU Regulatory Changes

Many PPPs used in ACP horticulture were older, inexpensive, off-license, and registered in the EU at national Member State level before the start of the Registration Review Programme under Directive EC 91/414. During this review many of these substances were lost because they were either no longer defended or did not pass the new risk assessments. When Regulation EC 396/2005 on MRLs entered into force, national MRLs in the EU Member States were reviewed and harmonised across the EU. New, often lower limits were set for pesticide residues in foodstuffs sold in Europe. When a PPP was lost or when data were lacking to support an existing national MRL during the harmonisation exercise, the MRLs were automatically set at LoD.

The loss of so many products and MRLs poses a particular problem for ACP suppliers. For generic PPPs registered in ACP countries, manufacturers were and are unwilling to invest in obtaining new MRLs if they are reduced to the LoD. Also they are often reluctant to register new products in ACP countries for these minor uses. As a result, ACP producers can no longer use many of their traditional PPPs, and they have not been able to access many of the newer, safer, more environmentally friendly alternatives.

If an MRL changes under the review process, growers need to know the new GAP so that they can adjust their production practices accordingly. Field trials may be needed to establish the new GAP in these circumstances but for ACP minor use crops, neither the manufacturer or local industry/public sector are willing or have the resources to undertake this work.

The review of active substances in the EU is ongoing under Regulation (EC) No 1107/2009, and will continue to create challenges for the fresh produce sector for the foreseeable future. Changes to residue definition, including metabolites, that are being introduced for risk assessment are necessitating additional residue trials and this is exacerbating the problem as it increases the cost of obtaining and defending MRLs.

COLEACP SUPPORT

PIP Phases 1 and 2

To ensure that the EU MRL Harmonisation Programme and Regulation (EC) No 1107/2009 review process did not leave ACP producers without essential PPPs, COLEACP PIP pursued several routes including:

1. Surveys to identify critical crop-pest combinations, where ACP producers risked losing market access
2. Monitoring EU regulatory changes, in particular the review process, so that actions could be put in place well in advance if there was a risk of an important MRL being lost or changed
3. Defending or extrapolating existing EU MRLs, and establishing EU Import Tolerances (ITs), with some parallel work to obtain CODEX MRLs for local and regional trade
    i. Developing, financing and overseeing residue trials according to GLP
    ii. Liaising with accredited analytical facilities (ACP or EU); arranging collection, preparation and transport of samples; financing residue analysis
    iii. Analysing data to develop a proposed MRL
    iv. Preparing the import tolerance dossier and dietary risk assessment, and liaising with the rapporteur member state.
4. With ACP researchers, running trials to establish GAP under local conditions for new MRLs or products. Results were incorporated into technical itineraries (crop protocols and guides), and distributed to producers, SMEs and extension services
5. Facilitating local registration of new products, including biopesticides, with efficacy and residue trials
6. Capacity building of ACP institutions including researcher organisations (to implement residue trials according to GLP), analytical facilities, and regional harmonisation initiatives for registration
7. Identifying alternative solutions, including biological control, through contact with global researchers and companies, and facilitating/conducting local screening trials

COLEACP catalysed the process by bringing on board and coordinating the various stakeholders, by orchestrating the complex series of activities, and by securing the necessary private sector investment. For each PPP, COLEACP had to find a manufacturer who was willing to partner and provide the necessary data on toxicology, crop metabolism, and consumer risk assessment. By undertaking much of the work, COLEACP leveraged the private sector when manufacturers were otherwise unwilling to invest (for a minor use). The work also involved ACP and EU researchers, ACP producers, ACP regulatory authorities, EU raporteur member states and the EC. From 2001-2015, 43 EU ITs were granted as a result of COLEACP activities, and extrapolations for 10 substances (on snow peas, yams, cassava and sweet potato). One further EU ITs and several CODEX MRLs are pending. GAP was established for 140 crop-active ingredient combinations and incorporated into more than 30 crop protocols and guides, covering the main ACP horticultural crops. Some 20 potential biopesticides were identified and production companies supported to test/register locally.

COLEACP took on functions that would generally be fulfilled by the PPP industry, using public funds, to secure benefits of a public good nature. Providing ACP growers with access to crop protection technologies was critical to underpin PIP support, and ensured that export volumes, and the number of small-scale growers in the supply chain, did not decrease despite the challenges posed by the regulations.

Fit for Market

Activities under the new Fir for Market programme will include the monitoring of EU regulatory changes and pest problems in ACP exports, particularly those causing plant health issues. If problems are identified, the programme will inform growers, industry and researchers, and may lobby regulators to raise awareness of impacts in ACP countries. Activities include:

1. Surveys to identify critical crop-pest combinations, where ACP producers risk losing market access

2. Monitoring EU regulatory changes, in particular EU MRLs and the Reg. (EC) 1107/2009 review process to see if there is a risk of important MRLs being lost or changed. Where there is a loss or change, F4M will inform ACP producers and exporters that they may need to stop using the PPP, or change the GAP
3. Monitor the literature to identify alternative solutions, including biological control, and inform research/private sector

REMAINING CHALLENGES

At a global level, the "minor crops issue" is becoming more severe. The lack of an MRLs limits trade across borders, so the loss of an MRLs can become a trade barrier; a workshop at the WTO SPS Committee in October 2016 was dedicated to the problem. The rising cost of reside trials under new guidelines (covering residue definition) will exacerbate the "minor use issue", and further discourage investment by manufacturers in defending MRLs or obtaining import tolerances.

In the context of EU regulations, there is a strong likelihood that more PPPs and MRLs, that are critical for ACP horticultural exports, will be lost under the review process. This includes some of the import tolerances obtained by COLEACP PIP that are coming up for review and need to be defended. It is estimated that at least 9 active substances with ITs on 20 crops obtained by COLEACP (for major ACP export crops including mango, peas and beans with pods) may need to be defended in the near future. The cost of defending these, taking into account the probable need for additional trials due to new residue definitions, is estimated to be 1.5 million Euros. It is unlikely that they will be defended without public funding. It is also unlikely that any one entity will take up the role of "brokering" local registration of new products, or GAP setting in the event of an MRL change. As noted, the driver for these activities in ACP horticulture is more public good than commercial, but they are low priority for most ACP public sector research, which tends to focus scarce resources on staple crops.

COLEACP remains in contact with some global initiatives to address the minor crops issue, including the USDA IR4 project, and the STDF Minor Use Project. Both are attempting to form a global network of programmes, working together to solve the minor use problem through collaborative efforts for data generation to establish CODEX (not EU) MRLs. Data generation under the Minor Use Project has taken place on a small scale, and worked reasonably well in South America and Asia. However, in Africa they found it difficult to get the private sector on board and only one crop-substance was included.

Lack of resources is the key factor limiting data generation and, while these two initiatives try to conserve and rationalise resources through data sharing, the very limited data generation in ACP countries, particularly Africa, will remain critical for the foreseeable future.