Establishing MRLs for Minor Crops in ACP Countries: The Example of COLEACP


The Organisation

COLEACP (Europe–Africa–Caribbean–Pacific Liaison Committee) was established in 1973 as a not-for-profit private sector association representing the interests of EU importers, and ACP (Africa–Caribbean–Pacific) producers and exporters of fruit, vegetables, flowers and plants. Its overall goal is to facilitate the flow of trade between ACP countries and the EU, and within the ACP region. COLEACP provides a range of services to members in support of horticultural import and export activities including market intelligence, communication, business development, technical assistance, innovation brokerage, lobbying, and advocacy.

In 2001, COLEACP extended its activities into the field of development cooperation with the implementation of European Union–funded technical assistance programmes. Since this time COLEACP has channelled support to both public and private sectors in the ACP agrifood industry, with a poverty and sustainability focus that is aligned with the MDGs and SDGs. Activities have included the flagship PIP Programme (Phases 1 and 2), which ran from 2001 to 2015. PIP was conceived and developed by COLEACP in the late 1990s in response to concerns from its members about changes to EU Sanitary and Phytosanitary (SPS) Regulations, in particular the harmonisation of pesticide maximum residue limits (MRLs). They feared that these changes would create barriers for ACP exports and affect their access to EU markets.

PIP and the EU MRL Harmonisation Programme

PIP was designed to provide producers and exporters with the necessary information, training and support so that they could meet the new EU food safety regulations and private industry standards. The core activity was capacity building of private sector operators, especially smallholders, to establish and implement food safety management systems. Alongside this, through innovation and brokerage, PIP provided technical solutions to ACP suppliers so that they had the tools and advice to comply with the regulations and standards. Central to this was ensuring that growers had access to available, affordable and permitted crop protection products, and recommendations for Good Agricultural Practice (GAP) to use them under local conditions.

The EC Maximum Residue Level (MRL) Harmonisation programme set new limits for pesticide residues in foodstuffs sold in Europe. It posed a particular problem for ACP suppliers as many plant protection products (PPPs) used in horticulture were old, inexpensive, off-license, and registered before there was a requirement for MRLs. When a PPP had no existing MRL this was automatically set at the Limit of Determination (LoD), which was often not possible or practicable to meet. As a result, ACP producers could no longer use many of their existing PPPs, while at the same time few new products were being registered locally for minor crops. The problem was compounded by the loss of a large number of substances through the review process under Regulation (EC) No 1107/2009. Furthermore, for the substances remaining, growers had to adapt production practices to comply with new MRLs.
To ensure that the EU MRL Harmonisation Programme did not suddenly leave ACP producers without effective and affordable methods of pest management, COLEACP pursued several routes including setting new MRLs, extrapolating existing MRLs, and establishing Import Tolerances. It took up these normally industry-led functions where the manufacturers were unwilling to invest because of a lack of expected return on investment due to low production volumes, or generic active ingredients. Instead, with public funds, and using its position and contacts as a private sector association, COLEACP took on the role of innovation broker to put the necessary actions in place.

A Public Private Partnership

COLEACP began with surveys to identify the most critical crop-pest combinations, where ACP producers faced a real risk of losing market access. For these cases it then facilitated the various stages required to obtain EU Import Tolerances (ITs). An IT request must contain data on residues, crop metabolism, toxicology, and dietary consumer risk; an authorisation for use in the relevant third country; and a proposed MRL. The completed dossier is submitted to the rapporteur member state for evaluation, prior to transfer to EFSA. It is a complex process involving many stakeholders.

For each active substance supported, COLEACP had to find a PPP manufacturer who was willing to be a partner. The IT application process requires that a manufacturer is involved to provide the necessary data on toxicology and crop metabolism, as well as the data required to complete a consumer risk assessment. In most cases the manufacturer also provided the active ingredient, and covered the dossier evaluation fee. To encourage manufacturers to make this investment, COLEACP in effect took over the all remaining elements of the process. This included:

i. Identifying (and sometimes training) local researchers to implement residue trials according to GLP; identifying partner farmers with suitable trial sites; developing the trial specifications; financing and overseeing trial implementation.

ii. Identifying suitable accredited analytical facilities (ACP or EU); arranging sample collection, preparation and transport; and financing residue analysis.

iii. Analysing data to develop a proposed MRL. (A CODEX MRL can be used under some circumstances, if available, but in many cases a CODEX MRL was also lacking).

iv. Preparing the IT dossier and dietary risk assessment (in consultation with the manufacturer), and liaising with the rapporteur member state.

v. Working with local researchers to implement efficacy and residue trials for local registration; preparation and submission of registration applications, again in collaboration with a manufacturer, and liaising closely with local regulatory authorities

COLEACP also applied for new MRLs and extrapolations, which involve similarly complex procedures and partnerships. In collaboration with African regulators, parallel work was done to obtain CODEX MRLs with the aim of facilitating local and regional trade. Alongside this, 140 crop-active ingredient combinations were tested in ACP fruit and vegetables to define the pre-harvest interval for compliance with EU and Codex MRLs, and to develop GAP recommendations for local conditions. These were incorporated into technical itineraries that were used to draft crop protocols and guides. Using EU and ACP experts, COLEACP developed more than 30 crop protocols and guides covering the main ACP horticultural crops.

Between 2001 and 2015, a total of 43 EU ITs were granted as a result of the activities of COLEACP under the PIP Programme. Extrapolations were obtained for more than 10 substances on crops that included snow peas, yams, cassava and sweet potato. One further EU ITs is awaited. Data has also been submitted for several CODEX MRLs, but progress is delayed pending registration extensions, and changes in residue definition.

EU funding for this work by COLEACP ended on completion of PIP Phase 2 in December 2015.
**The Role of Innovation Broker**

While COLEACP was responsible for implementing much of this work, its most important function here was not the research and development itself, but its role as broker. COLEACP catalysed the process by bringing on board and coordinating the many stakeholders needed, by orchestrating the complex series of activities required, and by securing the necessary private sector investment.

COLEACP was in a good position to play this role as it had long-established relationships with the key players in both EU and ACP public and private sectors including regulatory authorities, PPP manufacturers, researchers, and horticultural supply chain operators. It was able to coordinate and bring on-board stakeholders that were not familiar with each other, or had diverging positions, but who were all essential to the process.

**Conclusions and Future Prospects**

COLEACP, a producer–exporter–importer association, took on functions that would generally be fulfilled by the PPP industry, and using public funds. It was an unusual scenario, but it succeeded in securing benefits of a public good nature. The ITs, and the choice of active substances targeted, ensured that ACP growers (including small-scale) maintained access to necessary PPPs for use on export crops. This, combined with the delivery of training that covered an estimated 80% of ACP–EU horticultural exports, helped to ensure that export volumes, and the number of small-scale growers in the supply chain, did not decrease over the period covered by the PIP programme, despite the challenges posed by the new regulations and market requirements.

There is a pressing need for continued support for MRLs in ACP horticulture, but any follow-up to this work in the future would be operating in a more challenging environment. It would be affected by the continued loss of active substances, but also by the changes that have been introduced in residue definition. These changes are not only likely to result in the loss of some existing ITs, but in many cases would considerably increase the cost of supporting future MRL/IT applications. Already, towards the end of the PIP Programme, these changes in residue definition restricted the number of active substances that could be supported.

One of the key learnings from the PIP experience was that, in the context of ACP horticulture, there was a clear benefit – and a need – for a dedicated actor to fulfil the role of broker in obtaining these ITs and extrapolations. Now that the Programme has ended, it is not clear how or whether the process will continue without one.