International Agri-Food Network

Coalition for an Enhanced Codex

Case Studies on the Impact of Maximum Residue Limits (MRLs) setting on Farmers Around the World

2017-2018

Introduction

The Coalition for an Enhanced Codex brings together like-minded groups looking to enhance Codex Alimentarius processes for setting Maximum Residue Limits (MRLs) for pesticides and veterinary drugs. Coalition membership encompasses the global agriculture and food value chain. Members represent crop input suppliers, animal health products, agri-commodity traders, famers, and the food and drink manufacturing sector. Coalition members seek effective and impactful Codex reforms to ensure the continued production and trade of safe, high-quality, and diverse food in an economically, environmentally, and socially sustainable way.

The Coalition collected information to document the real-life impact of missing MRLs on farmers and the larger value chain, as well as on farmers' ability to produce sustainable food and access world agricultural markets. A series of three global case-studies were commissioned in 2017 on pesticide MRLs for quinoa, cranberry, and a veterinary drug. These case-studies highlight the importance of a global harmonized process for MRL setting and underline the need for enhancements to Codex Alimentarius MRL-setting processes to achieve greater food safety, facilitate global trade, and improve farmers' livelihoods; in particular, those of smallholder farmers around the world.

These studies outline the problems faced by farmers across the world when rejections at import occur. This happens when shipments either do not comply with MRLs set in the importing country or when there are missing MRLs. Such cases are increasingly common with increased testing and analysis or misaligned MRLs between country of export and import. Two of the cases highlighted involve the production and the export of minor crops whereas the third focuses on the impact on the animal sector of missing and approval delay of MRLs in veterinarian drugs.

Case Study 1: How Non-Compliance with Pesticide MRLs Impacted Peruvian Quinoa Exports to the United States
Case Study 2: Chlorothalonil and Cranberries in Europe: A Cautionary Tale
Case Study 3: Parasite Control in Sheep Farming in the UK and impact of missing MRLs

The IAFN Coalition for an Enhanced Codex represents 30 industry associations across the agri-food chain. Members represent agricultural input industries such as suppliers of seeds, fertilizers, crop protection, animal health, feed and biotechnology-based products, agri commodity traders, farmers, and the food and drink manufacturing sector. Our mission is to help provide sufficient amounts of safe, healthy, high-quality and diverse food at affordable prices to consumers in an economically, environmentally and socially sustainable way. In doing so, we contribute to increased food safety, food security, better nutrition and health, economic growth and development, and poverty reduction

The Coalition is part of the International Agri-Food Network: agrifood.net

Case Study 1: How Non-Compliance with Pesticide Maximum Residue Limits (MRLs) Impacted Peruvian Quinoa Exports to the United States

Background

Quinoa is an annual plant species with grain seeds and leaves as its edible parts. The quinoa grain originated in the Andean region and has been a main food staple of the Andean people for thousands of years.

Quinoa is grown in multiple countries and is in the testing phase for many others around the world. Quinoa grown in the Andean region was a catalyst for the tremendous increase in world demand and it continues to grow in popularity with global consumers as a health food. Table 1 shows the increase in volume of quinoa production in Peru and Bolivia resulting from expansion of the cultivated area.

Table 1. Estimates of Quinoa Production (volume in metric tons)

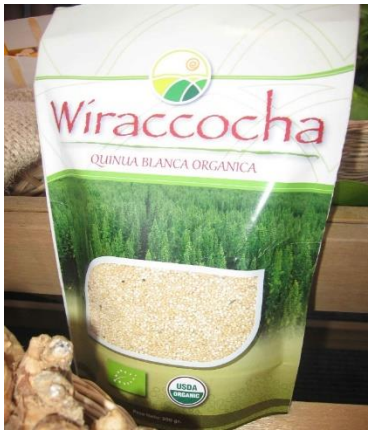
Country	1990	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
Peru	6.3	32.6	30.4	31.8	29.9	39.4	41.1	41.2	44.2	52.1	114.7
Bolivia	16.0	25.2	26.9	26.6	27.2	34.2	36.7	40.9	50.9	63.0	74.4
Other *	0.6	0.7	0.7	0.7	0.7	0.8	0.9	0.8	0.8	0.8	0.8

*Ecuador, United States, China, Chile, Argentina, France, Canada, Spain, United Kingdom, and other countries. Source: FAOSTAT.

The Problem

The rising demand for quinoa resulted in the expansion of quinoa production across Peru into areas with different agro-conditions—especially coastal regions. In lower areas, quinoa is susceptible to heat, humidity and pests migrating from other crops. To protect the crop and minimize economic loss, farmers turned to chemicals not registered or labeled for use on quinoa.

Around 2010, the US Food and Drug Administration (FDA) began testing Peruvian quinoa shipments due to an increase in imports. Prior to December 2015, only one pesticide used on quinoa had an established MRL in the US. Thus, the detection of any other pesticide residue in a shipment of Peruvian quinoa imported led to the detention and rejection of affected shipments by FDA. Once FDA increased monitoring and testing shipments, **38 shipments of quinoa were refused entry between 2012 and September 2017 due to MRL non-compliance.**



The Impact

FDA refusals of Peruvian quinoa shipments alarmed export associations, quinoa growers, and agro-exporters. Reasons for Peru's failure to comply with US MRL regulations include:

- Quinoa farmers and agro-exporters' lack of knowledge of US food safety import requirements prior to treating and exporting their crops.
- Lack of advanced strategic planning and strict control of agricultural practices in the quinoa fields targeted for export.

- Inadequate knowledge of the potential increase in pest populations, pest pressure, and pest damage to quinoa grown in lowland areas.
- Heavy reliance on untrained collection agents (middlemen) that could not ensure that quinoa collected from small- and medium-sized farmers, and provided to agro-exporters, met the US food safety requirements.
- Lack of available technical publications and guidance.
- Lack of public or private training or extension programs for promoting the implementation of Good Agricultural Practices by quinoa farmers.

The Resolution

An intensive nationwide effort in Peru was implemented in 2015 to develop corrective measures. Bulletins and manuals on Good Agricultural Practices for quinoa production were disseminated. Meetings were held between the Minister of Agriculture of Peru and the US FDA and the US Environmental Protection Agency's Office of Pesticide Programs responsible for establishing pesticide MRLs to ensure problem resolution. As a result, there is now stricter control by farmers and agro-exporters on the production of quinoa through the implementation of certification guidelines and sanitary and phytosanitary compliance requirements of the destination export market. The Office of Agricultural Food Safety of the National Agrarian Health Service (SENASA) also amended the Agricultural Food Safety Law to require any agricultural food or animal feed grown in the country and intended for export originate from an establishment with a SENASA sanitary permit.

Lessons Learned

In the race to capture global demand, proper advanced research on meeting regulatory requirements of the export market destination is often overlooked or poorly executed**. Advanced knowledge of the US pesticide MRLs should have been available to quinoa farmers and exporters before they started shipping to the US market**, so that farmers could make more informed pest management decisions.

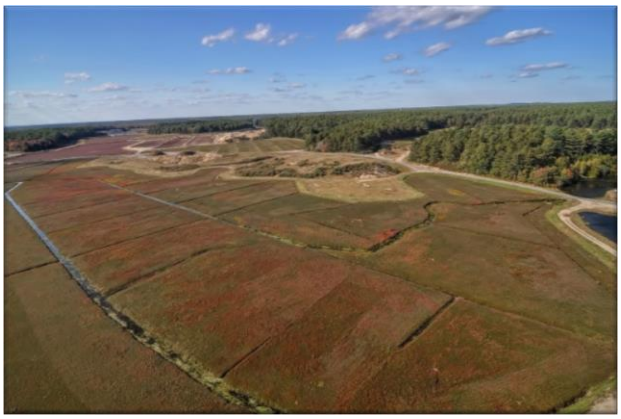
Since the main financial and legal responsibility for the quality of exported agricultural crops still resides with the farmers and the agro-exporters, these groups must have a more complete knowledge of the phytosanitary and sanitary requirements of the intended export market destinations. This is a key component in helping farmers access international markets.

A fully functioning, adequately financed, global Codex MRL system would significantly facilitate trade and make it easier for growers (especially in emerging markets) and exporters to produce compliant crops and to avoid market access risks.

Case Study 2: Chlorothalonil and Cranberries in Europe: A Cautionary Tale

Background

Over the last fifteen years, exports of US cranberry products to Europe have increased significantly. In 2013, the US exported $122 million dollars of cranberry products to the European Union (EU), which included cranberry concentrate (juice), dried cranberries, and fresh cranberries. **Europe is for the US the largest export market for the crop, accounting for almost half of all exports.**



Typical Cranberry Bog

The Problem

On April 4, 2014, the EU issued a World Trade Organization (WTO) Notification in which it proposed lowering the chlorothalonil Maximum Residue Limit (MRL) for cranberry from 2 parts per million (ppm) to 0.01 ppm. Despite the US cranberry industry's active pesticide program, which includes monitoring international MRLs, the industry simply missed the EU announcement and the comment deadline. As a result, the European Commission Standing Committee on Plants, Animals, Food, and Feed voted to lower the MRL to the default 0.01 ppm in July 2014.

The Impact

The US cranberry industry noticed the proposed MRL change in August 2014 and immediately reached out to the US Mission to the EU to see if the proposed MRL could be changed. They were informed that the vote had already occurred. Much of the 2014 crop had been treated with the compound and it would have been difficult to segregate treated from non-treated products. **Over $100 million in exports were threatened.**

The Resolution

Industry officials reached out to the US Trade Representative's office, the US Environmental Protection Agency, and the US Department of Agriculture. These groups worked through the US Mission in Brussels to determine whether the crop produced in 2014 for the EU market could still be exported to the EU. Fortunately, the answer was yes. On October 29, 2014, the EU published in the EU Official Journal *Commission Regulation (EU) No 1146/2014* that crops treated prior to the implementation date of May 18, 2015 would still be allowed to enter under the previous set MRL at 2 ppm.

As soon as it was determined that the 2014 produced crop could be exported to the EU, the industry and the US government started seeking a new import tolerance. Through high-level discussions, it became clear that the only way to address the issue was to submit an import tolerance application through the official EU review process. Circumventing the review system was not possible. However, the US cranberry industry caught a major break. Chlorothalonil cranberry had already been aggregated for the Codex Committee on Pesticide Residues, meaning that an import tolerance application could be drafted and submitted to the EU immediately with the existing data. **Had this information not been available, two years would have been needed to collect the data, delaying the establishment of the chlorothalonil MRL**

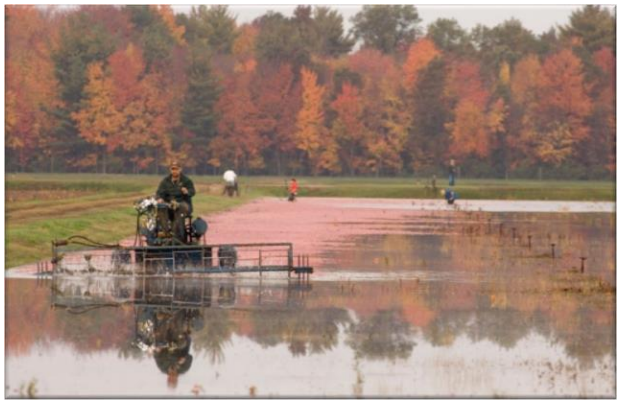
for another two years, stopping trade and leaving farmers without their largest market. On July 10, 2015, the European Food Safety Authority (EFSA) published a recommendation in record time, for the setting of an EU import MRL for chlorothalonil on cranberry. Finally, on September 22, 2015, almost a year after the crisis started, the European Commission Standing Committee on Plants, Animals, Food, and Feed voted to formally adopt EFSA's recommendation of an MRL of 5 ppm on chlorothalonil. The MRL took effect on 11 February, 2016.

Lessons Learned

First, the cranberry industry missed the opportunity to comment on the proposed MRL change. The EU had properly announced the MRL change, but the announcement was overlooked until after the Committee vote had occurred. Because of this oversight, the cranberry industry conducted a thorough review of its MRL monitoring systems and made improvements. There are now weekly reviews of all WTO MRL announcements and monthly summaries of what has been proposed.

Even if the cranberry industry had commented to the EU expressing concern during the WTO announcement process, it is unclear whether such comments would have prevented the proposed change. The WTO announcement process in the EU comes at a very late stage in the overall review process; Rapporteur Member States (RMS) have already made their recommendations to EFSA, and EFSA has already conducted its own review. A better approach is needed to indicate to the RMS and EFSA that imported crops might be affected by a MRL change. To address this issue, in the years since the chlorothalonil cranberry crisis, the EU has started publishing upcoming review schedules and is encouraging commodity groups to approach registrants.

The cranberry industry has met with the US Environmental Protection Agency on the compound, and is tracking chlorothalonil developments throughout the world to make sure it is not caught by surprise with proposed changes in other world areas. Over the past year, the industry commented to maintain the chlorothalonil MRL in Canada, where the product is being proposed for withdrawal from domestic usage on many crops, including cranberries. Finally, timing and flexibility were highlighted throughout this crisis. Such an emergency system might be formalized for future cases. The US cranberry industry is ultimately grateful for how the crisis was handled by the EU, as it saved growers millions of dollars. Still, there is concern that had the data not fortuitously already been available from the Codex review, a further two-year delay would have occurred.



This case highlights the importance of having a CODEX MRL in place and illustrates that an MRL set at the limit of detection can impact any country be it from the Global North or Global South. It also underlines the importance of the WTO notification process involving key stakeholders and giving them the ability to provide comments. Industry and farmer associations spend significant resources tracking MRLs and working with producers to ensure compliance. Having a global database in place, such as the Codex MRLs, alleviates the variances between countries and reduces the risk when growing and selling crops to various markets.

Case Study 3: Parasite Control in Sheep Farming in the United Kingdom and Impact of Missing MRLs

Background

For sheep farmers around the world, the most common health threat facing their flocks is parasites, both ectoparasites (e.g. ticks) and helminths (intestinal worms). Left untreated, parasites can cause weight loss, poor growth and ultimately death – putting the welfare of the animals and the livelihoods of farmers at risk. Sheep farmers have traditionally relied on a class of drugs known as *anthelmintics* to protect sheep from parasites. Without effective worm control, it can take up to three times as long for a sheep to gain weight, while at the same time requiring more feed than a successfully wormed animal: it could take only five weeks for a weaned lamb to put on 10kg if worm control is effective; the sheep then requires 65kg of feed, whereas if worm control is ineffective, the same lamb could take 14 weeks to gain 10kg and it may eat twice the amount of feed.

The Problem

For about 50 years, sheep farmers have relied on three classes of anthelmintics to keep worms at bay. **But the repeated use of a small pool of drugs has led to the rise of anthelmintic resistance, which reduces the efficacy of these drugs.** Answering a call for new anti-parasitic drugs, a product was developed and submitted for regulatory review in its intended primary markets in 2007. The new drug controls roundworm and pole worm in sheep. To facilitate international use and trade in food commodities from treated animals, the drug was also first put on the priority list for review by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in May 2009. The earliest it could have secured a Codex MRL would have been July 2012. However, Codex MRLs were not approved until 2015.

The Impact

The delayed final Codex MRL disadvantaged the application for national approvals for the product and so was seen as a contributing factor to the delayed availability of the drug. **The drug was finally approved nationally in the UK in January 2012 and in Australia in October 2014 – seven years after the initial submissions.** In the UK alone, roundworms are estimated to cost sheep producers £84 million[1] ($112 million) per annum in treatment and lost productivity. The sheep sector is a significant contributor to the UK economy and employment. It directly employs 34,000 people on farms and a further 111,400 in related industries. This contributes around £290 million ($389 million) to employment. As such, delays to a new class of anthelmintic prevented sheep farmers from benefitting from increased choices in worm control and resulting enhanced productivity.

[1] https://www.moredun.org.uk/research/diseases/parasitic-roundworms-sheep

The Resolution
The Acceptable Daily Intake (ADI) safety standard recommended by JECFA in 2011 was the most conservative value reached by any agency reviewing the compound. The proposed ADI was two times lower than approved in Australia, three times lower than in the EU and nearly 17 times lower than suggested by the sponsor in the submitted dossier.

Nevertheless, as the product in question metabolizes very quickly, even this low ADI value was deemed usable for rapidly progressing approval of this veterinary product. The compound is broken down so extensively that violations are likely to be extremely rare, if they occur at all.

However, even with the very conservative ADI, differences in interpretation of the residue data meant that the MRLs recommended by JECFA could not advance and the process was held at stage four (of the eight-step Codex procedure) in 2012. This immediately resulted in a two-year delay in establishing international safety standards for this important new medicine. The drug was later reviewed at a JECFA meeting in 2013, at which the committee reported an error in previously recommended liver MRLs and proposed new levels. These types of errors unnecessarily prolong debate and advancement of Codex standards. Final MRLs were ultimately approved in July 2015.

Streamlining the process for setting MRLs would better facilitate the granting of approvals for veterinary products, which could help get them to market and into the hands of veterinarians and farmers more quickly. One possible way to do this would be to set temporary MRLs based on preliminary evidence that are lower than necessary while tests are completed. This would allow the product to be used in restricted circumstances until the MRLs can be revised accordingly. For drug classes where resistance is growing, this could give farmers an additional option until JEFCA is satisfied it can set final MRL standards.

Lessons Learned
Not only do missing MRLs impact the use of a drug, but they can also impact the very approval of veterinary products in the first instance. While JECFA is in fact not a regulatory body, their recommendations can significantly impact the safety assessment of veterinary medicines undergoing national registration procedures. Conflicts over data interpretation, errors in data and annual or biannual review cycles, which included years without a meeting of JEFCA, all contributed to delays in setting MRLs. This in turn prejudiced applications for national registrations, and therefore, the entry of the product onto the market to support farmers facing the challenge of parasite control.

What is needed is a better and more flexible way to assess veterinary products, particularly in cases of new drugs that, for example, can address the continued concern of anthelmintic resistance while having low safety concern and low risk for residue violations. Use of temporary MRLs, a recognition of safety evaluations conducted by other national regulatory authorities and an equal focus of the importance of Codex standards in facilitating international trade, as well as product safety, should be considered.

This case clearly demonstrates the impact global delays has on national registrations. A streamlined, updated Codex process would facilitate the availability to new tools to farmers.