Coordinating International Hop MRL Efforts

For the past year, the USHIPPC has formally coordinated with the German hop industry (the German Hop Industry Association (DHVV) and the German Hop Grower Association (VH)) in forming a high-profile issue in key export markets. By speaking as the US and European hop industries, representing over 80% of world hop production, government officials are more likely to respond to requests. This collaboration proved beneficial in meetings with the Korean Brewer’s Association in April, with Japanese and Korean registrants that same month, and with officials in Brussels on EU MRLs. The group also coordinated in a panel in Monterrey at the hop convention.

The advantages to this coordination remain additional resources and perspectives on MRL issues. The German industry has also provided fees that have allowed a reduction of expenses for USHIPPC and additional travel funds to cover anticipated additional trips associated with this coordination. BCI is pleased to continue to work with both industries, and looks forward to future hop MRL successes on behalf of the US and German hop industries.

EU MRL Policies

Recap of EU Pesticide Review Process
As USHIPPC members will recall from previous updates, the European Union adopted in 2009 a new Pesticide Review regulation in which chemicals are evaluated based on a "hazard-based" approach. Products deemed to meet certain "cut-off" hazard criteria are to be withdrawn from the EU market. The "cut-off" criteria can be due to human health concerns (carcinogenic, genotoxic, endocrine disruptor, others), or environmental concerns (persistent organic pollutants, persistent bioaccumulative and toxic, risk to bees, others). Data gaps in submissions can also result in withdrawals.

The 2009 Pesticide Review policy conflicts with the 2005 EU regulation regarding the evaluations for maximum residue levels (MRLs) (summarized below) that require reviews be based on not only hazard, but also on risk. Risk measures how much actual exposure there is to a hazard. The World Trade Organization (WTO), to which EU member states are signatories, requires that scientific evaluations be based on risk as well.

As the EU advances their pesticide re-approval reviews based solely on the hazard-based approach, many currently approved active ingredients in the EU will not be re-approved and are expected to be withdrawn from the EU market – meaning they will not be available to EU farmers. This will have a significant impact for the European hop industry and their efforts to control pests.

For hop exporters to the EU, these withdrawals will also likely lead to the revocation of associated MRLs with those substances, resulting in the EU
EU Pesticide Review Process (continued)

0.01 ppm default tolerance being applied. Some studies estimate that ten to forty percent of currently approved active ingredients could be disallowed in the EU in the near future.

This will not happen at once. The EU evaluation process is based on a schedule, so the determination of whether a chemical is subject to the cut-off criteria will occur when that review is scheduled over the next decade. However, if the chemical is deemed hazardous, the product will be withdrawn at that time. USHIPPC is already seeing key compounds that are being non-renewed with the associated outcome of losing MRLs.

Feeling pressure on the potential international trade impact of this new policy, the EU is considering how to handle import tolerance applications for MRLs for any withdrawn chemical. Originally, the EU stated that if the substance was withdrawn, it would not accept import tolerance applications, but recognizing that such a policy was likely a violation of WTO obligations, the EU is now saying applications for import tolerances can be made. It remains to be seen, however, whether such applications will actually result in import tolerances being approved. It was originally thought that products that failed to be renewed due to environmental issues were more likely to be able to keep import tolerances, but it is now not so clear that this is the case.

As USHIPPC knows from its efforts to seek MRLs in the EU, even before this policy was enacted, often the EU seeks additional studies and finds the information submitted not sufficient to establish an import tolerance MRL.

This issue is not unique to hops. The policy will affect up to 64% of all agriculture imports into the EU according to a 2017 BCI study.

Impact of Cut Off Criteria on Hops Specifically

BCI is monitoring the pesticide review process in the EU. A complete analysis for the active ingredients of interest to the hop industry can be found attached to this Issues Review. Below please find specific active ingredients that have not been renewed in 2018 and may have MRLs withdrawn in 2019/2020.

- Bifenthrin (Brigade)
- Ethopropos (Mocap EC)
- Fenazaquin (Magister)
- Imidacloprid (Admire/Confidor/Provado)
- Malathion (Fyfanon)
- Quinoxyfen (Fortress/Quintec)
- Pymetrozine (Fulfill)
- Thiamethoxam (Actara/Platinum)

This information was presented to the EU Hop Commodity Expert Group (CEG) during its meeting Brussels in March, which caused great concern. Some of the chemicals above, such as imidacloprid, malathion, and quinoxyfen were not renewed due to environmental issues, so there is a chance the MRL may remain, but it is unclear if new EU policies will allow such a situation to remain.

As a result of the discussions in Brussels, the German hop industry has elected to hold a symposium on the MRL issue and its importance to hop growing in Brussels. A Global Hop Summit "Best Hops for Best Beer" – a hop-Symposium and Parliamentary evening on November 18, 2019 will be held in Brussels. The objective of the meeting is to promote understanding of hop’s Integrated Plant Protection needs to ensure market stability and supply security. BCI will participate in the event.

This is a major issue for all EU growers and for exporters to the EU. The hop industry alone is unlikely to change EU policy, but being a voice on how the EU policies are going to affect growers and end users is important and can be coordinated with others. USHIPPC will coordinate closely with the German industry to continue this effort.
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EU MRL Review Process – Separate from the Re-Approval Process
The 2005 EU regulation regarding the evaluations for maximum residue levels (MRLs) requires that MRLs be periodically reviewed in the EU. These are MRL reviews, not chemical renewals.

This review process will usually take 12 to 15 months, when proposed MRL changes are then notified to the WTO, starting a 60-day comment period. However, providing comments that losing the MRL will create a significant trade distortion at this point in the process is too late. The review is complete and the new MRL is months away from being implemented. The system does not work.

After hearing complaints, the EU decided to inform stakeholders at the start of the review process. They encouraged interested parties to contact the registrant and the member state conducting the review to express the importance of the MRL. This is a good idea and a welcome opportunity.

BCI continues to monitor proposed MRLs changes in the EU (and around the world) and does what is possible to establish hop MRLs in the EU. USHPCC’s and BCI’s participation in the European Commodity Expert Working Group (CEG) for hops and coordination with the German hop industry work to coordinate efforts to maintain EU MRLs.

EU Specific MRLs
The European Union has made several MRL changes on hops since January. They include:

- **Fluopyram** (Luna Experience): EU established MRL of 50 ppm, that is harmonized with the Codex level and is more restrictive than the US MRL of 60 ppm.
- **Fosetyl-al** (Alieeta): EU established MRL of 2000 ppm that is less restrictive than the US MRL of 45 ppm. The large disparity between the US and EU MRLs is due to different residue definitions.
- **Pyridaben** (Nexter): EU established MRL of 0.05 ppm will be effective on August 13, 2019. The MRL is more restrictive than the US MRL of 10 ppm.
- **Chlorantraniliprole** (Coragen): EU established MRL of 40 ppm that is harmonized with the US MRL.
- **Fenazaquin** (Magister): EU established MRL of 0.01 ppm, that is more restrictive than the US tolerance of 30 ppm.
- **Clethodim** (SelectMax/Shadow): EU proposed MRL of 0.01 ppm, that is more restrictive than US MRL of 0.5 ppm.
- **Imidacloprid** (Admire/Provado): EU proposed MRL of 15 ppm, that is less restrictive than the corresponding US MRL of 6 ppm.
- **Hexythiazox** (Onager): EU proposed MRL of 3 ppm, that is more restrictive than the corresponding US MRL of 20 ppm.

Korean MRLs
The Korean government implemented its long anticipated new MRL system on January 1. Under this new system, only MRLs that have been established or temporarily established are in effect. The deferral path to Codex or other commodities used by the previous system no longer applies. The default tolerance of 0.01 ppm applies when no MRL has been established. BCI has worked to seek hop MRLs in Korea ahead of the new system’s implementation. BCI has met with registrants in Korea and Japan in April, and with Korean government representatives in May to discuss next steps of implementation.

Prior to the new system’s implementation, in October 2018, the Korean government temporarily established hundreds of MRLs in order to avoid potential trade disruptions due to missing MRLs. The temporary MRLs are set to expire on December 31, 2021, if no submission for a permanent MRL is made. Through this three-year window, Korea allowed more time for stakeholders to work on getting permanent hop MRLs established. Korean MRLs can be obtained through data package submissions to the Korean government.

In January 2019, there were 40 temporary hop MRLs established and since then four hop MRLs have been established and an additional four import tolerances applications have been submitted. This year Korea has
Korean MRLs (continued)
established hop MRLs for 2,4-D, cyazofamid (Ranman), cyflufenamid (Torino), and famoxadone (Tanos).

The USHIPPCC has reviewed the list of temporary MRLs and has selected priorities to focus on seeking permanent MRLs. Because some of the priorities are generic and do not have commitments for submissions from registrants, if MRLs are to be established, USHIPPCC will need to make the submissions directly. To do this, funds are needed to hire an expert to build the applications and pay the review fees. USHIPPCC has been approved for a Washington State block grant to address this issue over the next three years. Finally, USDA approval is expected in July and the grant is scheduled to begin in October. USHIPPCC plans to hire Caroline Harris at Exponent for this work, with BCI managing the effort. Funds should be used to support the ten highest priorities for the hop industry that do not have commitments for submissions.

BCI will continue to work with registrants encouraging the submission of hop MRL data packages for all temporary and missing MRLs. Matt Lantz and Reinhold Kugel will travel to Korea in March or April of 2020 to further work on this issue.

As of June 30, 2019, there are 62 Korean hop MRLs established: 26 permanent hop MRLs, 4 MRL submissions made, and 32 temporary hop MRLs. There are seven hop MRLs at the default level: beta-cyfluthrin, cyfluthrin, endothal, indaziflam, phorate, pyraflufen-ethyl, and pyridaben.

Details of all this information can be found in the Korean MRL ladder Chart and the Traffic Light Chart attached to this Issues Review. Both charts also indicate the compounds for which Korea is currently testing.

Japan MRLs

MRL issues in Japan at this point are largely about ensuring that MRLs are established for needed products. USHIPPCC does this through working with registrants in Tokyo and expressing their needs in order to allow for the hop MRL to be established in Japan. USHIPPCC also works with Japanese chemical registrants on submissions to Korea.

During a meeting with Bayer in Japan, BCI requested that the registrant support harmonization of Japan's MRL for fluopicolide (Presidio) on hops. We also raised for the first time questions about approval of biopesticides in Japan. These products are becoming more important tools for growers and are often exempt from tolerance in the US owing to their natural nature.

The US Embassy confirmed that if the product is used as a pesticide in Japan, it needs to have an approval there, either as a pesticide or on the "exempt from tolerance list." More details are being sought, because BCI is not aware of a products being added to the exempt from tolerance list, but it is clear that simply saying the product is natural is not going to be sufficient for Japan. That being said, Japan does not appear to be testing for these biopesticide products at the moment.

Chinese MRLs

All US commodities are missing many Chinese MRLs. China has slowly been establishing new MRLs, usually harmonized with the Codex tolerance. So far this year China has proposed five hop MRLs, bringing the total established or proposed hop MRLs to 30.

- Cyazofamid: proposed MRL of 15 ppm, harmonized with Codex, less restrictive than US MRL (10 ppm)
- Fenazaquin: (Magister): proposed MRL of 30 ppm, harmonized with Codex and US MRLs
- Flonicamid: (BeLeaf): proposed MRL of 20 ppm, harmonized with Codex and US MRLs
- Metrafenone (Vivando): proposed MRL of 70 ppm, harmonized with Codex and US MRLs
- Pendimethalin (Prowl): proposed MRL of 0.05 ppm, harmonized with Codex and more restrictive than the US MRL (0.1 ppm)
ISSUES REVIEW

Chinese MRLs (continued)

It is important to note that China hosts the annual Codex Committee on Pesticide Residues (CCPR) each year, so their commitment to Codex MRLs is strong. China does not, however, simply defer to Codex MRLs. Chinese MRLs are frequently established at Codex levels.

Even with the new MRLs, there are many Chinese MRLs missing for every commodity, including hops. This will only change when China establishes a system for seeking import tolerances. Currently, all MRLs in China go through a full registration process including field trials in China. With an import tolerance process, the MRL can simply be established if needed.

For several years, China has acknowledged the need for an import tolerance system and committed to developing one. In late 2017, a draft of such a system was circulated to a handful of key stakeholders. Although BCI did not see the draft, reports from those who did say the system proposed was problematic. China has therefore delayed a formal release of the draft, that is now expected for 2019.

Taiwan MRLs

Taiwan has announced new MRLs in 2019, but did not include hop MRLs that are relevant for the US industry. These are the first Taiwan MRLs in several years. The Taiwan MRL system continues to have significant delays. Taiwan does test for pesticide residues. Several US commodities have faced rejections in 2018 as a result of this testing. It is unclear whether hops are tested, as there has never been an issue with hop shipments to the market. Once the MRL system in Taiwan is rectified, additional hop MRLs will be sought. This is a priority for the US and German hop industries. BCI does not understand that hop MRL application can go through the normal Taiwan review process and does not need a special system that was required previously due to its relationship with alcohol. Future applications are similar to all other commodities, which is a positive development.

Australia MRLs

In the last three years USHIPPCC has had huge success in obtaining hop MRLs in Australia through its block grant from the Washington State Department of Agriculture (WSDA). Now there are more than 50 hop MRLs established.

In 2018, USHIPPCC requested harmonization of the cyflufenamid (Torino) hop MRL with the corresponding US MRL at 5 ppm. This was formally established in December 2018. In 2019, USHIPPCC has requested MRL harmonization for ten active ingredients. Results are expected at the end of the year.

Canada MRLs

Canada’s 0.1 ppm general default policy remains in place, which assists with potential trade issues. For new MRLs, Canada continues to seek a residue trial in its southern Ontario growing region. This is burdensome, but the requirement has not been eliminated despite several requests.

Codex MRLs

BCI attended the Codex Committee on Pesticide Residues (CCPR) meeting that was held April 8-13, 2019 in Macau SAR, China. No Codex MRLs were proposed for hop at this year’s CCPR. However, the JMPR recommended a hop MRL in its extraordinary session that took place in May 2019:

- Flupyradifurone (Sivanto): USHIPPCC approached Bayer CropScience in November 2016 to seek their support for a new use review on hops for flupyradifurone at Codex. Bayer agreed to support this effort and hops were included in the JMPR extraordinary session that took place in May 2019. The JMPR-recommended MRL of 10 ppm will be considered at the Codex Committee on Pesticide Residues.
Codex MRLs (continued)  
(CCPR) meeting to be held March 30-April 4, 2020. If approved, it will be in place in the Fall of 2020. The US MRL is 10 ppm.

For Codex Work in 2019-2021  
- **Clofentezine** (Apollo): Codex is currently scheduled to begin reviewing clofentezine in 2019, but the registrant is expected to push the hop review back by one or two years depending on when the approved label is available in the United States. Work is underway to obtain the label, with Dr. Matt Hengel’s analysis and data available in September 2018 and a submission to EPA later this year. To meet the 2019 deadline, information would need to be to Codex by the end of 2018. An update on this issue will be provided at the USHIPPCC meeting. A 2020 or even 2021 review at Codex is more likely once the label is ready. ADAMA, the registrant has pledged to work with USHIPPCC and its consultants in obtaining this MRL at Codex.

- **Famoxadone** (Tanos): This compound was not previously scheduled to be reviewed by JMPR. When the U.S. delegation was seeking nominations this past October, BCI worked with Corteva to add famoxadone to the JMPR schedule for 2021. The nomination was received and is expected to move forward at this time. The U.S. MRL is 80 ppm, the EU MRL is 0.05 ppm, and there is currently no Codex MRL.

**India Medicinal Claim Update**

Work continues to remove a restrictive requirement in India that imported hops be used for medicinal purposes only. This requirement appears in India’s plant quarantine order but there does not appear to be a valid quarantine reason. Moreover, the degree of enforcement is unclear as hop imports from the European Union do not appear to face similar restrictions. Efforts are ongoing with USDA’s Animal and Plant Health Inspection Service (APHIS) to seek amendments to India’s quarantine order to remove this restrictive requirement on US hop exports to India.

In March 2019, Bryant Christie Inc. met with the US Embassy in Delhi to discuss this issue and seek an update on recent discussions between USDA-APHIS and India’s Ministry of Agriculture (MOA) aimed at securing the removal of the requirement. The feedback from the Embassy was positive and according to officials, India’s MOA was receptive to the US request to remove the medical use requirement. However, the process of removing this restriction was expected to be delayed by the Indian election season, which took place from late March to late May, and restricted Indian government ministries from introducing changes to current regulation. Following the end of election season, USDA-APHIS now expects progress on this issue and will continue to raise it in upcoming meetings with India’s MOA.

Of note, Embassy officials highlighted the growth of microbreweries in India and the recent easing of licensing requirements in New Delhi as strengthening the US request. This development was thought to be a response to the growing demand and popularity for microbreweries in urban centers throughout India. The feedback from the Embassy was that they expect a good deal of licenses to be sought in Delhi, which should assist in efforts to remove the restriction and increase US hops exports to India.