IHGC Commission on Regulatory Harmonization
10 November 2017 – Prague, Czech Republic

The Commission on Regulatory Harmonization works closely with the US Hop Industry Plant Protection Committee and the European Union Commodity Expert Group for Hops on the harmonization of issues impacting the international trade of hops, particularly in the area of chemical (pesticide) residue Maximum Residue Levels (MRLs). Information from around the world is summarized and provided to IHGC delegates, to ensure that all hop producing countries are aware of regulatory issues impacting the trade of hops.

MRL Tracking Chart

The US Hop Industry Plant Protection Committee maintains a database comparing hop MRLs in several key hop producing and customer countries, as well as the international Codex Alimentarius Commission. This database is posted on the USA Hops website and updated monthly:
https://www.usahops.org/growers/plant-protection.html

International Conference on Plant Protection

A successful International Conference on Plant Protection was held on 2 August 2017, in conjunction with the IHGC Congress in Yakima, WA, USA, in conjunction with the Congress of the IHGC. We appreciate the sponsorship of this event by by the **German Federal Ministry of Food and Plant Protection** and the **Association of German Hop Growers**. Many high-level government and university officials attended to discuss regulatory and scientific challenges related to hop plant protection. An excellent foundation was established for ongoing cooperation between German and US regulatory officials.

Sustainability and Best Practices Platforms

The GLOBALG.A.P. Hop Sub-scope was approved and launched in time for 2017 hop harvest. As this was the first year for the new certification program, some revisions and clarifications are now being made to improve the sub-scope. The program is available internationally.

US Food Safety Modernization Act

As discussed at the May 2017 meeting of the IHGC Executive Committee, the US Food and Drug Administration has included hops in the new Food Safety Modernization Act. US hop grower and merchant representatives met with FDA officials in early September to discuss the application of FSMA rules to hops, and to provide educational material and a tour of harvesting operations to the group. As a result, FDA has agreed to assist the hop industry in preparing a petition to the Agency that would request reconsideration of the classification of hops, exempting the crop as "rarely consumed raw". This petition will be submitted in 2018, the earliest date the agency will consider such requests.

European Union MRLs

USHIPPC contractor Matthew Lantz attend a MRL conference and meeting with the US Mission to the EU, the European Commission, and European Food Safety Authority (EFSA) in mid-October. The following discussion is taken from his notes during these meetings.

According to Mr. Lantz, as an industry, there are essentially two sets of issues we need to be concerned about highlighted below: 1. Review of Existing EU Chemicals/MRLs and 2. The Cut Off Criteria Situation.

1. **Review of Existing EU Chemicals/MRS**
    - **Background on EU MRLs:** The EU has had community-wide MRLs for nine years. This standardized list has helped trade. These EU MRLs were gathered from member states' national lists and previous EU MRLs. MRLs in the EU must be renewed at least every 15 years. The EU is in the

process of reviewing all existing active ingredients. As part of this review, MRLs are evaluated and can be adjusted as needed. So far since 2011, they have reviewed 200 of 350 compounds.

- **Will an MRL Change in a Review?** Just because an active ingredient is reviewed, does not mean the MRL will change. Something must be new to adjust a MRL. Perhaps a lower acute reference dose is determined. Perhaps the review finds that there is no information supporting an MRL. These types of situations may cause the MRL to be reduced.
- **What is the Review Process?** Data is submitted by the registrant to the rapporteur member state (RMS). The RMS conducts the review and makes recommendations to the European Food Safety Authority (EFSA). EFSA then reviews the RMS recommendation and forwards their own recommended MRLs to the European Commission, which then votes. From there, the European Parliament approves and about five months later the MRL is formally implemented. The whole process takes about two years. Renewals are normally begun three years before a chemical is set to expire. Registrants typically initiate the review.
- **Weighing In Now:** The announcement of a pending EU MRL change to the World Trade Organization (WTO) occurs after all the RMS and EFSA reviews are completed, but just before the commission votes. This creates a challenge for industry groups who may wish to comment. At that point, it is really too late to change the MRL. You can weigh in at that point and express concerns about trade effects, and the Commission may consider potentially delaying a new MRL, but that is not a time for new data to be submitted. If you don't weigh in at all, they were unsympathetic to any proposed changes. If a health issue is identified, no change will occur regardless of trade impact. The only option then is to submit new data that addresses the health issue at the beginning through an import tolerance.
- **Weighing In Going Ahead:** All people at the conference and in our meetings agreed there has to be a better way, so we don't get to the end of a review, and only then identify a trade issue. EFSA and the Commission are considering ways to improve transparency. In the last year, EFSA has started publishing upcoming reevaluations that they plan to undertake. This list will be published quarterly. EFSA stressed that this is the time to submit comments. They need good agriculture practice (GAP) data associated with the commodity and the compound. This can be submitted by the registrant who is starting to work with the RMS or by commodity groups themselves. The important thing is to provide the GAP information as the review is underway. This signifies the MRL is needed and important. The RMS will review the GAP and if they identify it is a critical GAP, then more information may need to be provided. A critical GAP is one of those examples where a reference dose is changed or information is not available to support the MRL. At that point more data may need to be submitted. This will allow the RMS to make decisions and start a dialogue on what is needed.
- **Practical Steps on Weighing In:** We had started to look at the EFSA review schedule in the last six months, and even sent emails to registrants saying that a MRL was important for an upcoming review, but we didn't really have details on what information the RMS was needing and timing. From these meeting, that is clearer. We need to adjust our thinking on EU MRLs and increase our efforts on the EFSA regulatory review schedule (in addition to reviewing WTO announcements). Doing this should give us our best chance to influence EU MRLs as they are being evaluated.

2. Cut Off Criteria

- **What is the Cut Off Criteria?** In 2009, the European Parliament passed legislation that said chemicals could not be sold in the European market if they posed a hazard to the community. There were several categories that cause an active ingredient to be deemed hazardous. It could be a mutagen, a carcinogen, toxic for reproduction, or an endocrine disruptor. (We have been focused on the endocrine disruptor issue to date, but a chemical can be withdrawn for these other reasons

too.) If a chemical falls into one of these categories, EFSA will recommend its removal from the European market. Growers will not be able to use it and EU MRLs will be withdrawn.

- **What is Hazard vs. Risk:** The 2009 legislation is based on hazard. Is a chemical potentially dangerous? Risk seeks to determine how likely a person is to be affected by such a hazard. i.e. Will you be exposed to it? The analogies used are a lion is dangerous, but if it's in a zoo the risk is low. Or 1000's of people die in car wrecks every year so it is hazardous, but people drive all the time, because the risk is low. The EU legislation looks at hazard and only minimally considers risk. This is at odds with the principle of the World Trade Organization's SPS Agreement, which requires scientific assessments based on risk. Therefore, the EU is potentially facing a WTO case on this policy.
- **What happens if a chemical is deemed to be subject to the Cut Off Criteria?** The active ingredient will be removed from use in the European Union. Growers will no longer be able to apply that compound to their crops. Moreover, the MRLs will also be removed.
- **If a compound is withdrawn from the EU, what happens to the Import MRLs?** There was a lot of discussion on this at the conference and meeting with the European Commission. The current answer is the Commission is not sure. There are some very limited circumstances where an import tolerance might be allowed to stay, such as negligible exposure from residues, but that is not likely to happen often. European farmer groups at the conference were vocal that they do not want to be at a competitive disadvantage, so they are arguing that if they lose the ability to use a compound, all MRLs should be revoked. Even if the compound remains legal in a foreign country, food entering the EU should not be allowed to carry residues of that compound. This is a competitiveness and fairness argument, although its wrapped up in the hazard discussion. i.e. If it's a hazard on our food, it's a hazard on theirs too. The commission has not made a decision on import tolerances, but announced in the conference and in our meetings today, they are leaning toward not allowing import tolerances for such chemicals. If that occurs, we were told it would not be worth seeking import tolerances for compounds in question.
- **What happened on October 4, 2017 and what are the consequences?** On July 4, 2017, the European Commission put forward a position on how it planned to handle the endocrine disruptor issue in reviews. It uses the hazard based approach, and only if there was negligible likelihood of exposure would a chemical be maintained. It was a conservative approach that would likely result in many active ingredients being withdrawn in the future. This proposal needed European Parliament approval. In a surprise move, the European Parliament on October 4 rejected the Commission's recommendation. As a result, the Commission is considering its next steps. This will take some time (at least months). It should be noted the Parliament's rejection was NOT because the commission's recommendation was too conservative and might affect trade. Essentially, concerns from the Parliament were that things had been omitted from the Commission's recommendation. (So, we got the vote we wanted, but not for the right reason.) The Commission will regroup, and a new proposal is likely.
- **If a chemical is declared an ED, will we lose all the MRLs at once?** No. According to the Commission's proposal, the consideration on whether a product is an endocrine disruptor (or meets the other cut off criteria) will be made during the regular reevaluation review described above. When a compound is up for its normal review, a determination will be made it it's an ED. If so, the compound is likely to be withdrawn.
- **If an MRL is Eliminated, how much time do we have?** From a calendar perspective, once the Commission vote is taken to remove an MRL, it takes about nine months for it to be implemented and enforced. After the vote, there is a period of translation into EU languages, an EU Parliament vote, and publication in the EU journal, and then another six months after that. IMPORTANTLY though - and this was stressed several times by the Commission - food treated when the compound was legal remains legal in the EU. It does not matter how long it is stored.

- **Which Chemicals might be Endocrine Disruptors and therefore subject to this process?** There is no official list, but groups have attempted to put together lists. Some of the chemicals that have been included on prospective lists are: 2,4-D, boscalid, cypermethrin, flumioxazin, folpet, glufonisate, iprodione, maneb/mancozeb, myclobutanil, propiconzaole, pendemethalin, spirodiclofen, tebuconazole, thiophanate-methyl, and thiabendazole Again, these are not declared endocrine disruptors and this is a subset of a larger list, but these are chemicals I work with when seeking foreign MRLs, so they could be important.
- **What can be done?** If a chemical is deemed to trip the cut off criteria, it will be removed from the EU, and depending on the future EU position, import MRLs are likely to be revoked. Options for success in seeking new import tolerances on such a compound are highly unlikely. It is likely that this entire cut off criteria/hazard approach issue needs to be raised by foreign governments with the EU at the World Trade Organization (WTO). This is a big issue and has the potential to seriously affect ag trade to the EU. Even the Commission recognizes this, but they are mandated to follow the rules handed to them by the European Parliament, including the hazard- based approach.

Next Steps:

- **On Review of Existing MRLs**: Expand our system of tracking when chemicals are being reviewed using the EFSA schedule and provide GAP information to the RMS, so we are weighing in early in the process. Continue to monitor all WTO announcements in case something is already in the works at EFSA. Comment as needed.
- **On Cut Off Criteria**: Continued engagement with the US Mission and USDA/FAS on this issue. Track developments on Commission policy, especially how the respond to the European Parliament rejection. Continue to determine which actives could be considered subject to the cut off criteria generally, or endocrine disruptors specially.t
- **REFIT:** The commission today said they are going through a comprehensive evaluation process of their MRL system called REFIT. It will look to see whether the EU pesticide/MRL policies are meeting their objectives. A third part is conducting the review, and there will be an opportunity for public comment for six weeks starting in November.

Respectfully submitted,
Ann George, Hop Growers of America
ageorge@wahops.org