Update on MRL Harmonization Situation for Hops

IHGC Harmonization Commission

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Specific EU Hop MRL Updates

As we continue to closely monitor MRL changes in the European Union, the following MRLs have been established in the past few months:

Established MRLs:

- **Cyflumetofen** (Nealta): 30 ppm EU MRL established as of July 26, 2021; recently established U.S. MRL (30 ppm).
- **Pymetrozine** (Fulfill/Plenum): 0.1 ppm EU MRL established as of September 2, 2021; U.S. MRL (6 ppm).
- **Cyflufenamid** (Torino): 5 ppm EU MRL established as of November 3, 2021; U.S. MRL (5 ppm).
- Oxathiapiprolin (Orondis): 8 ppm EU MRL established as of November 3, 2021; U.S. MRL (5 ppm).
- **Fluopicolide** (Presidio or Profiler): 0.15 ppm EU MRL established as of November 6, 2021; U.S. MRL (15 ppm).
- Ametoctradin (Zampro): 90 ppm EU MRL went into effect January 27, 2022. U.S. MRL 100 ppm.
- **Fenazaquin** (Magister): 0.05 ppm EU MRL went into effect January 27, 2022. U.S. MRL (30 ppm). Gowan planned to submit the import tolerance application by the end of 2021.
- Imidacloprid (Provado, Admire, Confidor): U.S. MRL (6 ppm); new EU MRL (15 ppm) went into effect on May 16, 2022. However, Bayer expects the MRL to be lowered to LOQ in 2022.
- **Hexythiazox** (Onager Optek/Ordovol): current EU MRL harmonized with U.S. MRL at 20 ppm, new EU MRL at 3 ppm will go into effect on August 9, 2022.

Within Europe the hazard-based evaluation of active ingredients and the so called "Green Deal" with its "Farm-to-Fork" part for farming remains the most pressing condition for plant protection issues. Although recently new discussions on potential mitigation of these regulation have arisen in the context of producing more food to compensate failures in Ukraine, we need to expect further reductions of active ingredients on a chemical synthetic basis. EU politics intends to promote organic farming and organic plant protection means.

It might be considered as a curiosity that even within the EU there are different situations concerning the use of plant protection products by hop farmers. While the same MRLs apply to all EU member states some national authorities permit more products and other do not.

Korean MRLs

Korea has implemented its new MRL system on January 1, 2022. All temporary Korean MRLs have been withdrawn and only the permanent national Korean MRLs are in effect. If no Korean MRL exists, a 0.01 ppm default tolerance applies.

In efforts to ensure Korean hop MRLs are at acceptable levels relative to US hop MRLs, USHIPPC has been working with BCI to establish permanent MRLs in Korea through a Washington State Block grant. The

industry identified the highest priority substances to pursue import tolerances in Korea. BCI has worked to seek these MRLs by approaching the Korean government and registrants and working with Caroline Harris at Exponent UK.

Korea has established 8 hop MRLs in the past months:

- Acetamiprid (Mospilan): Established MRL (0.5 ppm) is less restrictive than EU MRL (0.05 ppm).
- **Cyclaniliprole** (Harvanta): Established MRL (2 ppm) is less restrictive than EU MRL (0.05 ppm). Substance is exempted from a tolerance in the US.
- **Deltamethrin** (Decis): Established MRL (0.5 ppm) is less restrictive than EU MRL (0.1 ppm).
- Fenpyroximate (FujiMite): Established MRL (15 ppm) is harmonized with EU and proposed US MRLs.
- Flutriafol (Topguard/Rhyme): Established MRL (20 ppm) is harmonized with EU and U.S. MRLs.
- **Hexythiazox** (Onager Optek/Ordovol): Established MRL (20 ppm) is harmonized with the U.S. and current EU MRLs.
- Oxathiapiprolin (Orondis Gold): Established MRL (5 ppm) is harmonized with U.S. MRL and is more restrictive than EU MRL (8 ppm).
- **Sulfoxaflor** (Transform): Established MRL (0.5 ppm) is less restrictive than EU MRL (0.05 ppm).

As of January 1, 2022, there are **55** established MRLs or where the default is acceptable, including **six** covered by the Block grant; and **five** submissions have been made and are currently under review in Korea.

Great Britain's Pesticide and MRL Regulation post Brexit

As Great Britain is no longer a Member of the European Union as of January 1, 2021 new EU MRLs will no longer be automatically adopted into the GB regulatory system and will require separate regulatory petitions.

From now on, any EU pesticide (non)approval/(non)renewal related changes will not be applicable to GB. BCI will continue to closely monitor this new system and any changes that may occur as Great Britain continues to work through the policy development process. The US is currently working with registrants to seek GB MRLs for four compounds that are no longer harmonized with the EU: cyflumetofen, cyflufenamid, oxathiapiprolin, and fenazaquin.

In 2022, the following MRL was established in Great Britain:

• Flupyradifurone (Sivanto): Established MRL (4 ppm) harmonized with EU and more restrictive than US MRL (10 ppm)

Chinese MRLs

Since China's announcement last summer there have been **seven** new hop MRLs established and **four** proposed. In total there are now **35** relevant hop MRLs established in China. In general, China announces large MRL updates every one to two years as part of their MRL review process. While China frequently sets their national MRLs at Codex levels; they do not defer to Codex.

One of the new 2021 MRLs sets a level of 0.01 ppm for acequinocyl (specifically on the Beverages category), which is out of alignment with the US and EU MRLs of 15 ppm. We have been exploring avenues to address this issue, but an easy solution to addressing the situation has not been identified.

There are many Chinese MRLs missing for hops. This gap in MRLs is correlated with the absence of China's long-promised Import Tolerance System for maximum residue levels, which would allow foreign industries to seek import tolerances in China. The hop MRLs established in 2021 are based on China's internal MRL review process. This is separate from import tolerance requests. Currently, all MRLs in China must go through a full registration process including field trials in China. Should an import tolerance process be established in China, a MRL would be established without having to register the product in China.

In discussions with the US Embassy in Beijing the second week of July, it appears that such an import tolerance system has been permanently delayed and is unlikely to be established in the near future. The US Embassy recommends seeking Codex MRLs as the most efficient way to seek Chinese MRLs. They moreover informed BCI that China tends to test against established MRLs in China.

Codex MRLs

The Codex Committee on Pesticide Residues (CCPR) met in early July to consider the MRL recommendations made by the FAO/WHO Joint Meeting on Pesticides Residues (JMPR). Due to the pandemic, the JMPR and CCPR work have been delayed, which will continue to impact the review schedule in the next couple of years.

In the latest CCPR, the following actions are relevant to hops:

- Clofentezine (Apollo): 7 ppm MRL will now be considered by the Codex Commission in its meeting in November and is likely to be in place by 2023. The new MRL is harmonized with the U.S. MRL and is less restrictive than the EU MRL (0.05 ppm). Unfortunately, the EU introduced a reservation, pending the outcome of the current evaluation in the EU. For this reason, we do not expect the EU to adopt this MRL going forward.
- **Metalaxyl-M** (Ridomil Gold): 10 ppm MRL will remain in place while registrant develops new data to support this MRL. No changes at this time.