Mycotoxins by Chemical Analysis Workgroup

Completed Work to Date

Over the 3 months of meetings specifically dedicated to Mycotoxin via chemical analysis and its associated instrumentation was able to produce two motions; one passed and one pending. The first motion was to (Appendix A) apply the adapted USDA PDP validation procedures to analysis of Mycotoxins using Liquid Chromatography Tandem Mass Spectroscopy.

Defined Challenges, Gaps and Actions Needed

The following gaps were identified as needing further resolution to continue method development. These challenges and gaps should be addressed by the ICT. These do not include all potential gaps needed in order for accreditation to occur. It is important to note, that since there is some overlap with the work of the Microbiology Workgroup's scope: that workgroup's thoughts and recommendations must also be considered with these thoughts and recommendations by the ICT when continuing their work on Mycotoxin analysis.

Validation of the ELISA kits on Cannabis material with >0.3% THC

1. The currently available ELISA kits are NOT validated on Cannabis plant material and extracts that contain >0.3% THC. Although many kits are available, they have been, at best, only validated on Hemp (plant material and extracts that contain <0.3% THC). It is yet unclear if the presence of THC (or other cannabinoids) in the tested material is a significant interference. However, the workgroup (as well as the PT workgroup) believes that this is likely since cannabinoids and mycotoxins are both extracted utilizing similar procedures that the significant concentrations of cannabinoids could create interferences with the mycotoxin identification by the instrument/analyst. It is important to note that it is highly likely that there will eventually be an ELSIA Kit validated on Cannabis material/products. However, that has not yet happened.
2. Some of the available ELISA Kits recommend confirmation from a Liquid Chromatograph Tandem Mass Spectrometer (LC-MS MS) for positives results. If this is the case, it seems to suggest that the ELISA kits are not producing a quantitative number and are only providing a rough estimate. The data-user should be aware of this level of risk for bias in the data. For example, if only positive detections are sent to another laboratory with an LC-MS MS for confirmation: false negatives could be slipping through the cracks and reaching the retail market.

Movement of samples between laboratories

1. Since the laboratories that are utilizing the ELISA kits are likely doing so because they do not have the financial resources to purchase an LC-MS MS, they would need to sub out their "confirmation samples." At the time of the workgroup's work on Mycotoxins, the traceability system for Cannabis did not allow laboratories to sub-out samples for this type of LC-MS MS confirmation analysis and maintain traceability of the material.

Incorporation of Mycotoxins into the USDA PDP

1. Fortunately, in order to incorporate Mycotoxins into the USDA, not much effort is required. In the view of the workgroup, the Summary of Adaptations to the USDA PDP (Appendix A of the 2020 Task Force report) simply needs the following:
    a. Wherever the term, "client" is used; replace with "ICT"
    b. Wherever the word(s), "pesticide" or "pesticides" is used; replace with "and/or Mycotoxin" or "and/or Mycotoxins"

Background

ELISA methodologies vs LC-MS MS Analysis

Mycotoxin analysis in the state of Washington is in a bit of a complicated state. Although the test has defined analytes and limits of quantitation outlined in WAC 314-55-102, there is a divide in methodologies utilized by the laboratories to meet these standards. The first option, which is the most common due to initial start-up cost and ease of use, is utilizing an Enzyme-Linked Immunoassay (ELISA) methodology. Since this analytical approach falls more into a microbiologist's area of expertise: those recommendations were to come from the Micro-workgroup led by Raymond Gee of the Washington State Department of Health if his group was able to complete their other work in time. The other option to test for the required Mycotoxins is to develop a Liquid Chromatograph Tandem Mass Spectrometer (LC-MS MS) analytical method.

Only a few laboratories currently employ the LC-MS MS methodology. This is primarily due to the significant initial investment to procure the LC-MS MS. Based on discussions with the workgroup, analysis of Mycotoxins can be with the same instrument utilized for pesticide analysis. Although it is theoretically possible to analyze pesticides and mycotoxins concurrently, none of the members of the workgroup does so at this time. It is important to note, that unless/until pesticide analysis become more widespread, the recommendation we provided (following the USDA PDP), will not be widely employed.

Appendix A: Motion #1

October 1, 2021

Motion #1: APPLICATION OF THE ADAPTED USDA PDP VALIDATION PROCEDURES TO ANALYSIS OF MYCOTOXINS USING LIQUID CHROMATOGRAPHY TANDEM MASS SPECTROSCOPY

When laboratories are analyzing mycotoxins via Liquid Chromatography Tandem Mass Spectrometry technology, they must follow the CSTF adapted USDA PDP protocols when developing and running an LCMSMS method for Mycotoxin analysis. Further modification of the PDP might be necessary to incorporate mycotoxins.