Examining toxicological reviews

When a product undergoes rigorous testing to meet the NSF/ANSI standards, extraction testing is also required. The extraction testing protocol varies in length, and the type of water used to conduct the test is based on various factors. The type of product that is being certified as well as the standard to which the product, component or chemical is being certified will dictate the precise protocol to be followed for extraction testing. However, the general concept that all extraction tests follow—regardless of product or standard type—remains the same.

By Pauli Undesser

What toxicological reviews are required and what are their purposes?

An extraction test is described as the soaking of a product in water and analyzing the extraction water to ensure that the product itself does not introduce any harmful contaminants into the water.

A formulation review is required before extraction testing can be conducted. This is the first toxicological review that is required for NSF/ANSI extraction testing. The formulation review investigates all materials in a product to determine the analytical test battery that will appropriately evaluate the product for public health and safety. While an initial toxicological review dictates analysis of some specific compounds based on the product composition, much of the chemical analysis is conducted by performing general scans of regulated chemicals.

The Environmental Protection Agency (EPA) method 524.2, for example, is a volatile organic compound (VOC) scan that is used to target hundreds of thousands of organic compounds. Other scans used are the EPA method 625 for semi-volatile compounds and the EPA 200.8 for regulated metals.

The NSF/ANSI standards include lists of acceptable levels for many of the chemicals that are evaluated within these scans; however, these scans can detect compounds that are present in the extraction water but are not included on the NSF/ANSI lists. These compounds are referred to as tentatively identified compounds (TICs) or unknown compounds.

In order to identify the compounds, their results are compared against results for hundreds of thousands of known compounds contained in libraries compiled from scientists across the world. If the compound scan matches a known compound scan in the library with high certainty, then the compound is tentatively identified as that known compound. If a match cannot be determined through this search, then the unidentified compound is classified as an unknown.

When TICs are present in analytical scans, the need for an additional toxicological review for risk assessment may arise. Before sending the TIC to a toxicologist for review, the analytical chemists must verify that the compounds are matched to a known compound with a high level of certainty. Once the certainty has been determined, the TIC will be compared against the lists of TICs in the NSF/ANSI standards or the lists of cleared TICs for the certification body that conducted the testing.

If the TICs are found on one of those lists and it is below the level that has already been set by a toxicologist, no further action will be taken. If the TIC is not on the established cleared TIC lists, or if it was present at a level higher than the clearance set for that compound, then further risk assessment is required. Either the TIC must undergo further evaluation by a qualified toxicologist to determine if a higher safe level can be established for the TIC; flushing conditions can be altered during a retest to reduce the effective concentration of the TIC; or the source of the TIC can be found and eliminated from the product and further testing may be required.

After the extraction testing is conducted, analysis is complete and any TICs have been cleared to acceptable levels, then a final toxicological review will be conducted. The final review verifies that all analysis dictated by the formulation review was conducted and that all target analytes meet the levels set in the standards. This review will also summarize any additional toxicological work that was required for TICs or unknowns. The final review will indicate whether the extraction test passed or failed the requirements of the standard.

Author's Note: The procedures noted in this article may not represent the precise process each certification agency uses when TICs are detected. These procedures accurately reflect the procedures used by the Water Quality Association (WQA). Currently, Thomas Palkon, director of product certification for the WQA, is chairing a committee to work with all certification agencies and public health officials to develop a single procedure for all certification agencies to use regarding TIC extractants. In addition, a task group is working to clarify section 4 of the Drinking Water Treatment Unit Standards to facilitate a cohesive procedure across all certification bodies. *wqp*

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