ARTICLE

Are distributed chemicals still certified?

Guidance for water administrators — procurement of third-party treatment chemicals

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Procuring NSF/ANSI/CAN 60 certified drinking water treatment chemicals for use in water systems has become increasingly more challenging as it relates to the complexity of the chemical distribution chain. Third-party distribution of treatment chemicals, as opposed to the sale of products directly from supplier to customer, continues to be a growing trend.

Distributors, repackagers or transfer facilities may rely on the NSF/ANSI/CAN 60 certification of their supplier, rather than obtaining their own certification, and water system administrators must determine if this is acceptable. System administrators may reach out to state and local administrators for direction regarding third-party sources of water treatment chemicals.

This article is intended to provide guidance to state and local administrators by examining clauses in NSF/ANSI/CAN 60 and NSF/ANSI 223, which apply to transfer processes for certified chemicals. NSF/ANSI/CAN 60 addresses the health effects of treatment chemicals primarily as related to initial certification assessments, whereas the newer NSF/ANSI 223 standard directs conformity assessment requirements for certification bodies that certify products pursuant to NSF/ANSI 60. NSF/ANSI 223 specifically defines inspection activities at certified facilities, as well as the frequency of surveillance audits and product testing. The standard also contains criteria for consideration of an increased inspection frequency in cases where specific program deficiencies are identified. Both standards address potential questions related to processes such as blending, diluting, dissolving, relabeling and general transfer of certified drinking water chemicals, with the main question being, "If a chemical is certified prior to additional transfer processes by an unlisted seller, is it still considered certified after?"

Let's look at the standard

There is no single clause in NSF/ANSI/CAN 60 or NSF/ANSI 223 that directly provides the answer to this question.

However, upon reading these standards in full, the answer becomes evident: blended, diluted, dissolved, relabeled and transferred products are no longer certified if the final provider is not certified.

The following clauses are from NSF/ANSI/CAN 60 – 2019 or NSF/ANSI 223 – 2015.

> *NSF/ANSI/CAN 60, Section 2 Definitions, Clause 2.8: "certified product: A single product or trade designation that appears in the public listings of a NSF/ANSI/CAN 60 certification agency."*

If there is no listing, then the product is not certified. The purchaser should use caution and if in doubt, contact the specific certifier.

> *NSF/ANSI 223, Section 2 Definitions, Clause 2.10: "original product: A NSF/ANSI 60 certified product prior to being blended, dissolved, diluted, repackaged, or re-labeled."*

The words "prior to" indicate that chemicals having undergone these processing steps are no longer considered certified afterward without additional evaluation.

> *NSF/ANSI 223, Section 4, Product Testing: "For a blended, diluted, dissolved, re-packaged or transferred certified product, a minimum of one product sample per facility shall be tested annually."*

From this clause, it is evident that even facilities that are processing certified products are required to have at least one product sampled and tested annually. That will not happen if the facility is not certified and under an inspection program.

> *NSF/ANSI/CAN 60, Section 3 General Requirements, Clause 3.9 Product Security: "Appropriate, effective measures shall be made to control access to products at all points of manufacturing, blending, diluting, packaging, repackaging, storage, shipping and handling..."*

Facility security requirements

This audit of facility security and tamper evidence cannot occur if the certifier is not doing annual inspections at the final facility. Uncertified facilities have a potential risk of intrusion and tampering with process equipment and the final product.

> *NSF/ANSI/CAN 60, Section 6 Disinfection and oxidation chemicals, Clause 6.3.3.2 Production dates and repackaging dates: "For sodium hypochlorite products, the manufacturing date and, if applicable, the repackaging date for the product shall be included on the documentation supplied with any shipment."*

Sodium hypochlorite is particularly sensitive to repackaging, as two contaminants of concern increase in concentration with decomposition. The concentrations of chlorate and perchlorate can be expected to be higher in a repackaged sample than in a sample obtained from the original manufacturer because of the additional time added. Thus, Clause 6.3.3.2 was added in an effort to give the user better insight into the true age of the product.

> *NSF/ANSI 223, Section 2 Definitions, Clause 2.18: "unannounced facility audit: A site audit of a facility as part of surveillance of a product manufacturer, a blender, a diluter, a dissolver, a re-labeler, a re-packager or a transfer facility without prior notice, that includes a written record of the determination of compliance with NSF/ANSI 60 in conjunction with this Standard."*

NSF/ANSI/CAN 60 certifications are facility site-specific. Only facilities under continuous surveillance, as directed in NSF/ANSI 223, are authorized to designate a chemical as being certified, regardless of whether the facility is the original manufacturer or a blender, diluter, dissolver, relabeler, repackager or a transfer facility for originally certified product.

> *NSF/ANSI 223, Section 5.2 Facility audits during surveillance, Clause 5.2.3: "If the country in which the manufacturing, blending, diluting, dissolving, re-packaging, re-labeling, or product transferring facility is located has a score less than 50 or lacks a Corruption Perceptions Index on Transparency International's most recent Corruption Perceptions Index (TI CPI), then the audit frequency for a facility shall be increased to at least twice per calendar year."*

This clause provides further evidence that facilities altering originally certified products in any way are expected to be under prescribed surveillance, or products from these facilities cannot be considered as meeting the requirements of the standard.

Ongoing surveillance audits

All transfer processes for chemicals have the potential to add contaminants from any equipment that comes into contact with the chemical. Even the source water for dilution and dissolving processes is a consideration, as additional testing specific to the water source may be required. This is the reason all certifications are facility-specific and processes other than original manufacturing also require ongoing surveillance audits by the certification body.

During surveillance audits, certifiers verify all of the following:

- Authorized sources are used
- Previously certified raw materials remain certified and to the same maximum use level
- There have been no changes in production equipment or process
- A quality management system is in place
- Processes are in place to segregate nonconforming raw materials and products
- Processes are in place to prevent commingling and contamination of materials
- Traceability records exist from raw materials to shipping destination
- The facility is secure against intentional tampering
- Tamper-evident measures are in place for product packaging
- Certified products are labeled as required, including instructions for maximum dose

In the case of relabeling, documentation from the certifier will indicate that the production process is relabeling only, and the inspector will verify that the seal on the containers is never broken. All of this surveillance is in addition to annual product testing of samples selected randomly by the certifier.

In the United States, the American National Standards Institute (ANSI) accredits certification bodies to certify products to NSF/ANSI/CAN 60, ensuring that the certification is done according to industry-accepted criteria established in ISO/IEC 17065 requirements for bodies certifying products, processes and services. Each accredited certifier maintains a directory of products certified with their organization. The lack of an online certification listing for a procured product means that no ANSI-accredited certifier is conducting the aforementioned surveillance for the final processing steps of a third-party distributor, and no annual verification testing is occurring. In addition to transporting and selling treatment chemicals to end users, distributors provide additional value by offering services such as diluting, blending, packaging, managing inventories, waste removal, etc. Larger operations frequently distribute treatment chemicals from several manufacturers. This third-party activity introduces the potential for distribution of products from suppliers that have never been tested to NSF/ANSI/CAN 60, as well as cross-contamination of the final product. In one such incident, a water system received a drum of sodium hypochlorite that had previously been labeled formaldehyde. The seller was a repackager that did not have certification to NSF/ANSI/CAN 60 but represented the product as certified.

Supplier certification

Even if certification for the previous supplier can be confirmed, a product from a seller that does not have a certification listing of their own is no longer considered certified. The seller does not have the authorization to use the mark of the certification agency, as the certifier does not have eyes on the process and cannot vouch that the final product still meets the requirements of NSF/ANSI/CAN 60. Choosing to use uncertified products in drinking water treatment is assuming the risk of a product that potentially picked up contamination during additional processing steps outside of the watch of the original product certifier.

Conclusion

The complex and fragmented chemical distribution system can create a challenge for water system administrators trying to ensure procurement of only NSF/ANSI/CAN 60-certified drinking water treatment chemicals. The direction contained herein provides state and local administrators with guidance directly from the standards that will hopefully prove beneficial for assisting water system administrators with difficult circumstances related to third-party distribution. Certifiers encourage administrators to reach out for answers wherever there is any doubt about the certification status of a drinking water treatment chemical.

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