Children's Safe Product Act – Reporting Rule – WAC 173-334
Reporting Guidance – Reporting Contaminants and Due Diligence

December 3, 2012

The purpose of this guidance is to provide clarification on what Ecology will look for in the event that the agency must evaluate the sufficiency of manufacturer efforts to minimize the presence of contaminants in their products (proposed WAC 173-334-080(1)(c)).

Contaminant is defined as follows in WAC 173-334-040 as follows:

> "Contaminant" means trace amounts of chemicals that are incidental to manufacturing. They serve no intended function in the product component. They can include, but are not limited to, unintended by-products of chemical reactions during the manufacture of the product component, trace impurities in feed-stock, incompletely reacted chemical mixtures, and degradation products.

The party responsible for reporting data has one of two options for contaminants:

1) Report them if they are above 100 ppm, or
2) Rely on the quality of their manufacturing control program to eliminate the need to report the concentration of contaminants. The rule allows manufacturers who have a manufacturing program to minimize contaminants in their products, and who use due diligence to ensure the effectiveness of the program, the option of not reporting the presence of contaminants.

If the agency determines that a chemical present in a product category was not reported, the reporting party will be contacted. If the manufacturer has relied on the use of an effective manufacturing program – in place **at the time of manufacturing** – the manufacturer will need to demonstrate the sufficiency of such a program to the agency.

A manufacturer of children's products is responsible for knowing the amount of CHCCs in its children's products. To control the amount of any contaminants present in its final children's product, the manufacturer may choose to establish and conduct a manufacturing control program. At a minimum, a reasonable manufacturing control program includes those methods and procedures required to comply with federal regulations for children's products and may include recognized industry best manufacturing practices, e.g., compliance with: relevant International Standards Organization (ISO) requirements, American Society for Testing and Materials (ASTM) standards, or other widely established certification or standards programs.

Actions demonstrating diligence **may** include, but are not limited to:

- Use and enforcement of contract specifications.
- Procedures to ensure the quality/purity of feedstock (whether raw or recycled).
- Use and enforcement of contract specifications for manufacturing process parameters (e.g., drying and curing times when relevant to the presence of high priority chemicals in the finished children's product components).
- Periodic testing for the presence and amount of CHCCs.
- Auditing of contractor or supplier manufacturing processes.
- Use of a chemical educational outreach program for members of supply chain.
- Other practices reasonably designed to ensure the manufacturer's knowledge of the presence, use, and amount of CHCCs in its children's product components.

As stated in the rule, the agency's compliance assurance efforts would include an investigation prior to any formal enforcement actions. As part of this investigation the agency will make a good faith effort to provide notice to the responsible party and an opportunity to respond to any agency concerns. It is during this response period that the responsible party can present their justification for relying on their manufacturing control program.

While the agency can't provide the specifics of a "one size fits all" manufacturing control and due diligence program, any person wishing to demonstrate compliance with this provision must establish both the presence and implementation of the appropriate actions listed above when evaluating submitted information. Ecology will begin any investigation by looking first at the lowest attainable concentration obtained by manufacturers of similar products. There is no value or set of actions, however, that will be appropriate or applicable to all circumstances. If a manufacturer does not have confidence in its ability to demonstrate an appropriate manufacturing control and due diligence program they should report all CHCCs that are present as contaminants above a concentration 100ppm.

Ecology anticipates that there will be situations where the same chemical in the same product category or component could be considered a contaminant in one situation and intentionally added in another. Below are a few examples to illustrate this point.

> **Example 1:** A manufacturer makes a variety of shirts. Some are designed to be wrinkle free and others that are not. Where Chemical Z is added to help the shirt remain wrinkle-free, Ecology would consider Chemical Z to be intentionally added and the manufacturer would have to report any amount above the PQL. For shirts where Chemical Z is not added intentionally, but there is some present in the final product anyway, the manufacturer has one of two options:
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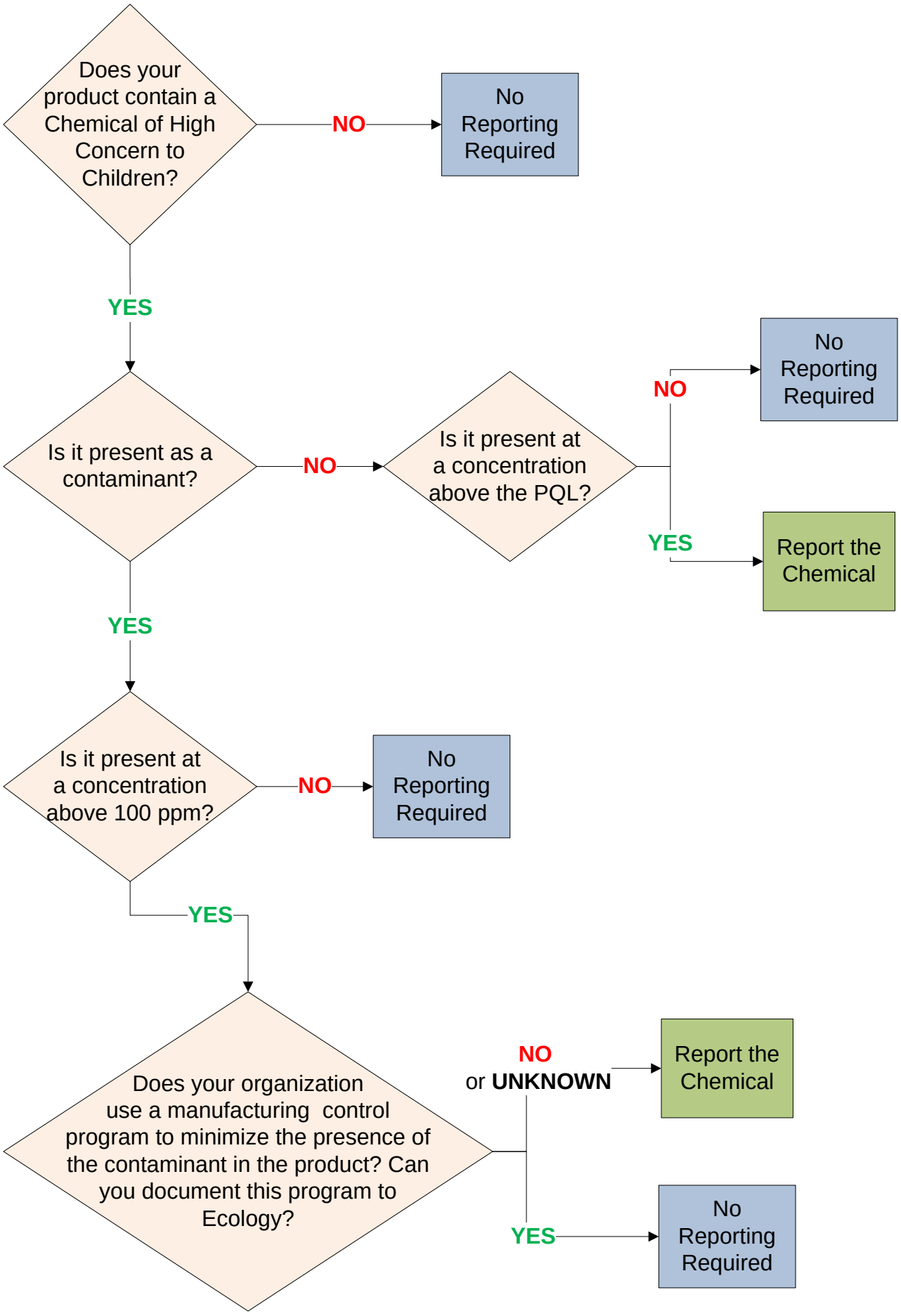
> 1) Report the presence of Chemical Z if its concentration is above 100 ppm.
> 2) Rely on their ability to demonstrate to the agency that a manufacturing control and due diligence program was in place that minimized the presence of Chemical Z.

Example 2: If Metal Y is used to provide malleability in a metal used in jewelry, the concentration of Metal Y added to products would need to be reported at any concentration above the practical quantification limit. But if Metal Y is present in jewelry due to small amounts inadvertently being transferred from the mold to the jewelry, it would be considered to be a contaminant. The manufacturer again has one of two options:

1) Report the presence of Metal Y if its concentration is above 100 ppm. OR
2) Rely on their ability to demonstrate to the agency that a manufacturing control and due diligence program was in place that minimized the presence of Metal Y.

Example 3: A manufacturer is making a material to be molded into a plastic toy. Chemical A is combined with Chemical B to make Plastic Material C that has essential properties needed to produce the plastic toy. Some trace amounts of Chemicals A and B remain in plastic material C. Chemicals A and B would be considered contaminants, per the definition in WAC 173-334-040. The manufacturer has one of two options:

1) Report the presence of Chemicals A and B if the concentration of either chemical is above 100 ppm.
2) Rely on their ability to demonstrate to the agency that a manufacturing control and due diligence program was in place that minimized the presence of Chemicals A and B.


Does your product contain a Chemical of High Concern to Children?
NO
No Reporting Required
YES
Is it present as a contaminant?
NO
Is it present at a concentration above the PQL?
NO
No Reporting Required
YES
Report the Chemical
YES
Is it present at a concentration above 100 ppm?
NO
No Reporting Required
YES
Does your organization use a manufacturing control program to minimize the presence of the contaminant in the product? Can you document this program to Ecology?
NO or UNKNOWN
Report the Chemical
YES
No Reporting Required