

# Vermont Department of Health

CHEMICAL DISCLOSURE PROGRAM GUIDANCE DOCUMENT

*FEBRUARY 16, 2016*

**CONTACT INFORMATION:**

[Chemical Disclosure Program Website](#)

Tel: 1-800-439-8550

Email: [AHS.VDHChemicalDisclosureProgram@vermont.gov](mailto:AHS.VDHChemicalDisclosureProgram@vermont.gov)

# Table of Contents

1. INTRODUCTION.....	2
2. WHAT ARE CHEMICALS OF HIGH CONCERN TO CHILDREN? .....	2
3. WHO NEEDS TO REPORT? .....	2
4. REPORTING .....	3
(A) HOW DOES A MANUFACTURER KNOW WHETHER TO REPORT A PRODUCT?.....	3
(B) HOW DOES A MANUFACTURER REPORT? .....	3
(C) WHAT TYPES OF PRODUCTS SHOULD MANUFACTURERS REPORT? .....	3
(D) ARE REPORTING REQUIREMENTS DIFFERENT FOR CHEMICALS THAT ARE INTENTIONALLY ADDED VERSUS CHEMICALS PRESENT AS CONTAMINANTS? .....	3
(E) WHAT TYPE OF INFORMATION ABOUT A PRODUCT IS REQUIRED TO BE REPORTED?.....	4
(F) HOW OFTEN MUST MANUFACTURERS REPORT? .....	5
(G) WHAT IS THE SIX-MONTH REPORTING PERIOD? .....	5
(H) WHAT IF A MANUFACTURER REPORTS IN 2016, AND STARTS SELLING A NEW PRODUCT IN 2017?.....	5
(I) DO MANUFACTURERS REPORT PRODUCTS THAT HAVE BEEN OFFERED FOR SALE PRIOR TO THE REPORTING DATES, BUT ARE NO LONGER ON THE MARKET? .....	5
5. EXEMPTIONS.....	6
(A) CHEMICAL CONTROL PROGRAM.....	6
(B) CERTIFICATE OF COMPLIANCE .....	7
(C) PRODUCTS FOR SALE OUT OF STATE .....	7
(D) APPLICATION OF SECTION .....	7
6. OTHER .....	8
(A) DATA SHARING .....	8
(B) NOTICE OF REMOVAL OF A CHEMICAL.....	8
(C) WILL THE DEPARTMENT BAN THE SALE OF CHILDREN’S PRODUCTS WITH CHEMICALS OF HIGH CONCERN IN THEM? .....	8

## 1. INTRODUCTION

Manufacturers are required to report to the Vermont Department of Health (Department) when their children's products contain one or more chemicals of high concern to children. This document provides guidance to the manufacturers responsible for reporting to the Department as required by the statute (18 V.S.A. Chapter 38A) and the chemicals of high concern to children rule (CHCC Rule). This document defines and explains key terms and concepts relating to the statute and rule. References to the statute and rule are in bold.

## 2. WHAT ARE CHEMICALS OF HIGH CONCERN TO CHILDREN?

There are 66 chemicals of high concern to children listed in statute. Click [HERE](#) to view the list of chemicals. These chemicals may be intentionally added to a children's product to serve a particular function, or they may be present as contaminants. The list will be reviewed and updated every two years; beginning in 2017.

## 3. WHO NEEDS TO REPORT?

Manufacturers of children's products are required to report the use of chemicals of high concern to children to the Department. The term "manufacturer" usually means the entity whose name is affixed to the product, if that entity has a physical presence in the US. If the entity whose name is affixed to the children's product does not have a physical presence in the US, then the entity who sells the product in Vermont is considered the manufacturer. Therefore, "manufacturer" may include other entities that may not technically fabricate a product, but rather assemble product components or import a final product for sale in the US. The definition of a manufacturer, and the reporting requirements of the manufacturer, apply only to products offered for sale in Vermont, not products that are given away for free. It is only necessary for one entity to provide notice with respect to a particular children's product.

**18 V.S.A. §1772 (12) (A) and (B)**

### **EXAMPLES:**

These examples apply to children's products that are not exempt from reporting, are offered for sale in Vermont and contain one or more chemicals of high concern to children:

1. A children's toy is fabricated or assembled (manufactured) in the US by FUNTOY and sold by KidToyInc, under the FUNTOY brand.
  - FUNTOY is considered the manufacturer and is responsible for reporting.
2. A children's toy is fabricated or assembled (manufactured) in the US by FUNTOY and sold by KidToyInc, under the KidToyInc brand.
  - KidToyInc is considered the manufacturer and is responsible for reporting.
3. A children's toy is fabricated or assembled (manufactured) in Europe by EuroFUNTOY, and imported and sold by KidToyInc, under the EuroFUNTOY brand. EuroFUNTOY is located in Europe and does not have a physical presence in the United States.
  - KidToyInc is considered the manufacturer and is responsible for reporting.
4. A children's toy is fabricated or assembled (manufactured) in Europe by EuroFUNTOY, and imported and sold by KidToyInc, under the KidToyInc brand. EuroFUNTOY is located in Europe and does not have a physical presence in the United States.
  - KidToyInc is considered the manufacturer and is responsible for reporting.
5. KidToyInc fabricates or assembles (manufactures) a product using components from both inside the US and outside the US, and then sells the product. The product is labeled with

KidToyInc's name.

- KidToyInc is considered the manufacturer and is responsible for reporting.
6. A children's product is fabricated or assembled (manufactured) by an individual using materials or supplies that were purchased at a local craft store. The individual does not know if the materials and supplies purchased at the craft store were made in the US or outside the US. The final product is sold at a craft fair in Vermont.
    - The individual who crafted the product is considered the manufacturer and is responsible for reporting.
  7. Children's products are fabricated or assembled (manufactured) in the US by FUNTOY. FUNTOY distributes those products to vending machines where the products are sold without a brand name.
    - FUNTOY is considered the manufacturer and is responsible for reporting.
  8. Children's products are fabricated or assembled (manufactured) in Europe by EuroFUNTOY and imported by USA Imports. USA Imports distributes those products to vending machines, where the products are sold.
    - USA Imports is considered the manufacturer and is responsible for reporting.

#### 4. REPORTING

*(a) How does a manufacturer know whether to report a product?*

See the reporting chart, which helps determine if a chemical in a children's product(s) should be reported.

*(b) How does a manufacturer report?*

The online reporting system will be accessible from the Health Department website. Specific instructions on reporting will also be available on the website in spring 2016.

*(c) What types of products should manufacturers report?*

Manufacturers must submit a report when their children's product contains a chemical of high concern to children. A children's product means a consumer product marketed for use by, or marketed to children. Specific exemptions are listed in section 6(e).

**18 V.S.A. §1772 (7)(A)**

*(d) Are reporting requirements different for chemicals that are intentionally added versus chemicals present as contaminants?*

Reporting is different for chemicals that are intentionally added to products, versus chemicals that are present as contaminants. Chemicals that are present as contaminants must be reported when present in a component at a concentration of 100 ppm or greater. The 100 ppm threshold was established by the legislature. Chemicals that are intentionally added to a product, usually to serve a specific function, must be reported when present above the practical quantification level (PQL) for that chemical. To download the PQL Document from the Department of Health website, click [HERE](#).

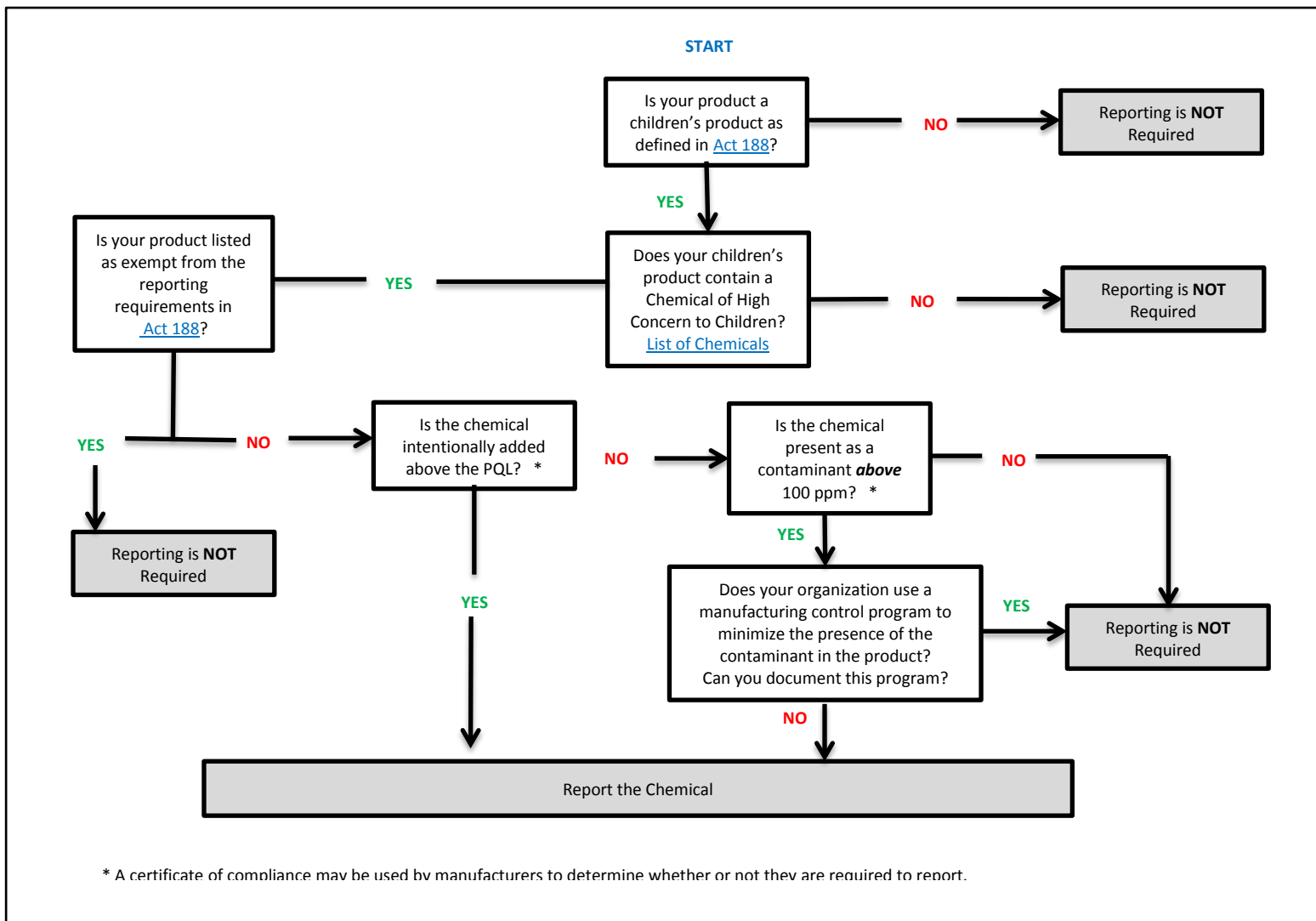
If a product releases one of the 66 chemicals as a post-production byproduct, and the chemical has not been intentionally or unintentionally added to the product during production, the chemical does not need to be reported.

**18 V.S.A. §1772 (9), (11); 18 V.S.A. §1775 (a)(1), (2)**

*(e) How much does it cost to report?*

The fee for reporting is \$200 per chemical. The maximum amount that could potentially be paid by one entity is \$13,200 if all 66 chemicals are reported.

**18 V.S.A. §1775 (j)**



(e) *What type of information about a product is required to be reported?*

1. The name of the chemical and its chemical abstracts service (CAS) registry number.
  2. The Global Product Classification (GPC) product brick description.
  3. The product component containing the chemical.
    - (a) The product component means the uniquely identifiable material or coating (including ink or dye) that is intended to be included as part of a finished product.
- CHCC Rule Section 4.6**
4. The amount of the chemical contained in each unit of the product or product component, reported by weight or parts per million. The concentration in parts per million should be the concentration in the product component; not the concentration in the final children's product.
- 18 V.S.A. §1775(b)(3)**
5. The name and address of the manufacturer of the children's product and the name, address, and telephone number of a contact person for the manufacturer.
  6. The function of the chemical in the product.

7. The brand name and product model.

(a) The brand name and product model must be descriptive enough so that the product can be easily located, online or in a store, based on the product information reported to the Department. The brand name and product model is determined by the manufacturer or responsible party, such as the supplier or retailer, prior to placing the item into the stream of commerce. The product model may be the description associated with the PLU or SKU number.

(b) In some limited cases, products may be sold without a brand name and/or product model. In those cases, the brick cannot be used as a replacement for product model. The manufacturer responsible for reporting must provide a description of the product model beyond the brick level, even if no brand name is available. A brick description has insufficient information for consumers to make retail choices.

(c) Manufacturers will report the brand names and product models of their products that contain chemicals. The brand names and product models are associated only with a chemical, and not with function, concentration, component or brick information for that chemical.

**18 V.S.A. §1775(b)(1) – (5) and CHCC Rule 6.1.6 – 6.1.7**

*(f) How often must manufacturers report?*

Manufacturers are required to report biennially, beginning in July 1, 2016. Each report is based on a chemical; thus a manufacturer can submit a maximum of 66 reports per reporting year. Products can be added to reports throughout the two-year period.

*(g) What is the six-month reporting period?*

The Department established a six-month reporting period for each reporting year, in order to streamline the process of receiving reports. The six-month reporting period will open January 1 of each reporting year, beginning in 2016 and biennially thereafter, and all reports must be submitted by July 1. Every product that meets the reporting criteria should be reported at the time that it is placed on the market or before. The six-month reporting period means that by end of the six month period, all products that are offered for sale and all products that are planned to be offered for sale until December 31, 2017, should be reported.

As additional children's products become available before December 31, 2017, they must be reported when they are offered for sale, or before.

*(h) What if a manufacturer reports in 2016, and starts selling a new product in 2017?*

If the product contains a chemical for which a manufacturer has already created a report, the new product should be added to the appropriate existing chemical report. If the product contains a new chemical that has not been reported, this would be considered a new report, resulting in a new fee. The product should be reported at the time that it is placed on the market; or before.

**CHCC Rule 8.3**

*(i) Do manufacturers report products that have been offered for sale prior to the reporting dates, but are no longer on the market?*

No, only items that are currently offered for sale need to be reported.

*(j) How will manufacturers report chemicals that are Trade Secret?*

It is the burden of the manufacturer to assert that information submitted under §1775 is a trade secret, confidential business information, or is otherwise designated confidential by law. When a manufacturer asserts that the specific identity of a chemical is a trade secret, the generic class or category of the chemical in the children's product and the potential health effect of the specific chemical will be displayed to the public. The function, concentration, component, and brick are all required for products with trade secrets; however, product model and brand name are not.

**18 V.S.A. §1778**

*(k) Will the Department allow for small manufacturers to seek a waiver or variance from the initial reporting deadline if they can demonstrate that they have taken all reasonable measures to obtain testing and other data necessary to comply, but still require additional time to prepare and file their disclosures?*

There are no additional waivers for small businesses. It is beyond the scope of this rule to create additional waivers other than what are included in the statute.

*(l) Will the Department consider a phase-in reporting schedule?*

No, there is not a phased-in schedule for reporting.

## 5. EXEMPTIONS

*(a) Chemical Control Program*

Manufacturers are exempt from reporting to the Department chemicals that are present as contaminants if the manufacturer implements a manufacturing control program and exercises due diligence to minimize the presence of the contaminant. A chemical control program is a program that includes industry best practices for the minimization of a chemical in a children's product. These practices may include, but are not limited to: methods and procedures for meeting relevant federal regulations; International Standards Organization (ISO) requirements; ASTM International standards; and other widely established certification or standards programs.

Actions demonstrating due diligence in ensuring the effectiveness of a manufacturing control program may include the following: the use and enforcement of contract specifications, procedures to ensure the quality/purity of feedstocks (whether raw material or recycled); the use and enforcement of contract specifications for manufacturing process parameters (e.g. drying and curing times when relevant to the presence of chemicals of high priority chemicals in the finished children's product components); periodic testing for the presence and amount of chemicals; auditing of contractor or supplier manufacturing processes; and other practices reasonably designed to ensure the manufacturer's knowledge of the presence, use, and amount of chemicals in its children's product components. Manufacturers who rely on their chemical control program to exempt themselves from reporting chemicals present as contaminants should provide the Department with a summary of their chemical control program.

**18 V.S.A. §1775(e)**

*(b) Certificate of Compliance*

A certificate of compliance is a document certified by a competent authority stating that the supplied good or service it covers meets the agreed-upon or required specifications. The certificate of compliance would be expected to state that the product or component does or does not contain a chemical of high concern to children. A certificate of compliance is one way that manufacturers may evaluate whether they are required to report. If a manufacturer is certain that their manufacturing process does not involve the use or addition of a chemical to a children's product due to the availability of the certificate of compliance, there is no need to report. A manufacturer who relies on the certificate of compliance to negate the need to report should provide a copy of the certificate of compliance to the Department.

**18 V.S.A. §1775 (g)**

*(c) Products for sale out of state*

Act 188 applies to products for sale within Vermont. Products for sale outside of the state of Vermont are not within the scope of this legislation.

**18 V.S.A. §1775 (h)**

*(d) Application of section*

Product exemptions are listed below:

- Batteries
- Snow sporting equipment including skis, poles, boots, snow boards, sleds, and bindings
- Inaccessible components of a consumer product that during reasonably foreseeable use and abuse of the consumer product would not come into direct contact with a child's skin or mouth
- Used consumer products that are sold in second-hand product markets
- A product primarily used or purchased for industrial or business use that does not enter the consumer product market or is not otherwise sold at retail
- A food or beverage or an additive to a food or beverage
- A tobacco product
- A pesticide regulated by the U.S. Environmental Protection Agency
- A drug, or biologic regulated by the U.S. Food and Drug Administration (FDA), or the packaging of a drug, or biologic that is regulated by the FDA, including over the counter drugs, prescription drugs, dietary supplements, medical devices, or products that are both a cosmetic and a drug regulated by the FDA
- Ammunition or components thereof, firearms, air rifles, hunting or fishing equipment or components thereof
- An aircraft, motor vehicle, vessel
- Consumer electronic products, including personal computers, audio and video equipment, calculators, wireless telephones, game consoles, and hand-held devices incorporating a video screen used to access interactive software intended for leisure and entertainment and their associated peripherals
- Interactive software, intended for leisure and entertainment, such as computer games, and their storage media, such as compact discs
- The packaging in which a product is sold, offered for sale, or distributed
- Soap



- Dietary supplements
- Food and drugs approved by the FDA

**18 V.S.A. §1772 (7)(B), 18 V.S.A. §1772 (8), 18 V.S.A. §1772 (10), 18 V.S.A. §1775 (k)**

## 6. OTHER

### *(a) Data sharing*

For the first reporting period beginning in 2016, Vermont will not be in a reciprocal data-sharing agreement with Washington State. Chemical data that have been disclosed to Washington must be disclosed separately to the state of Vermont, if the products meet Vermont's requirements. Once Vermont begins accepting disclosures, the Department will evaluate the ability of the program to work with other states to share data.

**18 V.S.A. §1775(c)**

### *(b) Notice of removal of a chemical*

A manufacturer who submitted a report may notify the Department that the chemical has been removed from the product or that the product is no longer for sale. A form to notify the Department will be available on the website. Upon receipt of the form, the Department will remove the reported information from the website.

**18 V.S.A. §1775 (f)**

### *(c) Will the Department ban the sale of children's products with chemicals of high concern in them?*

Beginning in July 2017, and biennially thereafter, Health will review disclosure data to suggest chemicals for review for regulation by the Working Group. More information on this process will be available as the July 2017 date approaches. See the Health Department website for more information on the working group, including, members, meeting dates, agendas and minutes, when the information becomes available.

**18 V.S.A. §1776(b), 18 V.S.A. §1774**

### *(d) Will the Department accept petitions for removal of chemicals from the Chemicals of High Concern to Children List?*

Under 3 V.S.A. §805 any person may request that the Commissioner add or remove a chemical from the list of high concern to children.

**18 V.S.A. §1773 (d)**