FINAL PROPOSED RULE # 19-P74

Administrative Procedures – Final Proposed Rule Filing

Instructions:

In accordance with Title 3 Chapter 25 of the Vermont Statutes Annotated and the "Rule on Rulemaking" adopted by the Office of the Secretary of State, this filing will be considered complete upon filing and acceptance of these forms with the Office of the Secretary of State, and the Legislative Committee on Administrative Rules.

All forms requiring a signature shall be original signatures of the appropriate adopting authority or authorized person, and all filings are to be submitted at the Office of the Secretary of State, no later than 3:30 pm on the last scheduled day of the work week.

The data provided in text areas of these forms will be used to generate a notice of rulemaking in the portal of "Proposed Rule Postings" online, and the newspapers of record if the rule is marked for publication. Publication of notices will be charged back to the promulgating agency.

PLEASE REMOVE ANY COVERSHEET OR FORM NOT REQUIRED WITH THE CURRENT FILING BEFORE DELIVERY!

Certification Statement: As the adopting Authority of this rule (see 3 V.S.A. § 801 (b) (11) for a definition), I approve the contents of this filing entitled:

Chemicals of High Concern in Children's Products Rule

/s/ Michael K. Smith , on 6/24/2020
(signature) (date)

Printed Name and Title:
Michael K. Smith
Secretary
Agency of Human Services

RECEIVED BY: _____

RECEIVED
JUN 25 2020

BY: .....

- ☐ Coversheet
- ☐ Adopting Page
- ☐ Economic Impact Analysis
- ☐ Environmental Impact Analysis
- ☐ Strategy for Maximizing Public Input
- ☐ Scientific Information Statement (if applicable)
- ☐ Incorporated by Reference Statement (if applicable)
- ☐ Clean text of the rule (Amended text without annotation)
- ☐ Annotated text (Clearly marking changes from previous rule)
- ☐ ICAR Minutes
- ☐ Copy of Comments
- ☐ Responsiveness Summary

Final Proposed Coversheet

1. TITLE OF RULE FILING:
   Chemicals of High Concern in Children's Products Rule
2. PROPOSED NUMBER ASSIGNED BY THE SECRETARY OF STATE
   19P-074
3. ADOPTING AGENCY:
   Department of Health
4. PRIMARY CONTACT PERSON:
   (A PERSON WHO IS ABLE TO ANSWER QUESTIONS ABOUT THE CONTENT OF THE RULE).

   Name: David Englander

   Agency: Department of Health

   Mailing Address: 108 Cherry Street, Burlington VT 05401

   Telephone: 802 863 - 7280 Fax: 802 951 - 1275

   E-Mail: ahs.vdhrules@vermont.gov

   Web URL*(WHERE THE RULE WILL BE POSTED)*:
   https://www.healthvermont.gov/about-us/laws-regulations/public-comment
5. SECONDARY CONTACT PERSON:
   (A SPECIFIC PERSON FROM WHOM COPIES OF FILINGS MAY BE REQUESTED OR WHO MAY ANSWER QUESTIONS ABOUT FORMS SUBMITTED FOR FILING IF DIFFERENT FROM THE PRIMARY CONTACT PERSON).

   Name: Brendan Atwood

   Agency: Department of Health

   Mailing Address: 108 Cherry Street, Burlington VT 05401

   Telephone: 802 863 - 7280 Fax: 802 951 - 1275

   E-Mail: ahs.vdhrules@vermont.gov
6. RECORDS EXEMPTION INCLUDED WITHIN RULE:
   (DOES THE RULE CONTAIN ANY PROVISION DESIGNATING INFORMATION AS CONFIDENTIAL; LIMITING ITS PUBLIC RELEASE; OR OTHERWISE EXEMPTING IT FROM INSPECTION AND COPYING?) No

   IF YES, CITE THE STATUTORY AUTHORITY FOR THE EXEMPTION:

   PLEASE SUMMARIZE THE REASON FOR THE EXEMPTION:
7. LEGAL AUTHORITY / ENABLING LEGISLATION:

(THE SPECIFIC STATUTORY OR LEGAL CITATION FROM SESSION LAW INDICATING WHO THE ADOPTING ENTITY IS AND THUS WHO THE SIGNATORY SHOULD BE. THIS SHOULD BE A SPECIFIC CITATION NOT A CHAPTER CITATION).

3 V.S.A. § 801(b)(11), 18 V.S.A. §1776

EXPLANATION OF HOW THE RULE IS WITHIN THE AUTHORITY OF THE AGENCY:

3 V.S.A. § 801(b)(11) states, "'Adopting authority' means, for agencies that are attached to the Agenc[y] of…Human Services…the commissioner of [that] department."

18 V.S.A. § 1776(a) states, "The Commissioner shall, after consultation with the Secretary of Natural Resources, adopt rules as necessary for the purposes of implementing, administering, or enforcing the requirements of this chapter."

8. 18 V.S.A. § 1776 (f)(1)(D) – per Act 75 (2019)§5 – states, "The Commissioner of Health shall adopt by rule the process and procedure to be required when the Commissioner of Health adopts a rule under subsection (b),(c), or (d) of this section. The rule shall provide:…(D)requirements for when and how a manufacturer of a children's product that contains a chemical of high concern to children provides the notice required under subsection 1775(a) of this title when the manufacturer intends to introduce the children's product for sale between the required dates for reporting;"
9. THE FILING HAS CHANGED SINCE THE FILING OF THE PROPOSED RULE.
10. THE AGENCY HAS INCLUDED WITH THIS FILING A LETTER EXPLAINING IN DETAIL WHAT CHANGES WERE MADE, CITING CHAPTER AND SECTION WHERE APPLICABLE.
11. SUBSTANTIAL ARGUMENTS AND CONSIDERATIONS WERE RAISED FOR OR AGAINST THE ORIGINAL PROPOSAL.
12. THE AGENCY HAS INCLUDED COPIES OF ALL WRITTEN SUBMISSIONS AND SYNOPSES OF ORAL COMMENTS RECEIVED.
13. THE AGENCY HAS INCLUDED A LETTER EXPLAINING IN DETAIL THE REASONS FOR THE AGENCY'S DECISION TO REJECT OR ADOPT THEM.

14. CONCISE SUMMARY (**150 WORDS OR LESS**):

This proposal expands the definition of formaldehyde to include "formaldehyde donors", which are the substances that are intentionally added to a product to degrade to and release formaldehyde as a preservative. Per Act 75 (2019)§5, this proposal also establishes the requirements for when and how a manufacturer of a children's product provides the notice required under subsection 1775(a) of this title when the manufacturer intends to introduce the children's product for sale between the required dates for reporting.

15. EXPLANATION OF WHY THE RULE IS NECESSARY:

The rulemaking is necessary in order to satisfy the requirements of 18 V.S.A. § 1776(f)(1)(D), per Act 75 (2019) §5, regarding when and how a manufacturer of a children's product provides the notice required under subsection 1775(a) of this title when the manufacturer intends to introduce the children's product for sale between the required dates for reporting. Additionally, this rule is necessary to ensure that chemicals that are intentionally added to a children's product in order to degrade to the listed chemical formaldehyde be reported on behalf of consumers and the public.

16. EXPLANATION OF HOW THE RULE IS NOT ARBITRARY:

18 V.S.A. § 1776(f)(1)(D), per Act 75 (2019) §5, requires the Department to establish the requirements for providing notice required under subsection 1775(a) of this title when the manufacturer intends to introduce the children's product for sale between the required dates for reporting.

Additionally, formaldehyde donors are intentionally added to a product to release formaldehyde, which is a listed chemical of high concern to children. This amendment clarifies the requirement to report these "formaldehyde donor" substances that will degrade to formaldehyde.

17. LIST OF PEOPLE, ENTERPRISES AND GOVERNMENT ENTITIES AFFECTED BY THIS RULE:

Manufacturers of children's products, Department of Health, children's product retailers, and consumers and users of children's products.

18. BRIEF SUMMARY OF ECONOMIC IMPACT (150 WORDS OR LESS):

This rule imposes a minimally economic burden to the regulated community beyond the existing statutory requirements. There will be a de minimis cost associated with the reporting fee required by statute when a listed chemical is used in children's products. (As of September 2019, the fee is $200 per listed chemical, per manufacturer.) If a manufacturer introduces for sale between reporting periods a product which contains a chemical of high concern to children that has not already been reported by the manufacturer, the cost would be an additional $200 (in total, not annually).

19. A HEARING WAS HELD.

20. HEARING INFORMATION

(THE FIRST HEARING SHALL BE NO SOONER THAN 30 DAYS FOLLOWING THE POSTING OF NOTICES ONLINE).

IF THIS FORM IS INSUFFICIENT TO LIST THE INFORMATION FOR EACH HEARING PLEASE ATTACH A SEPARATE SHEET TO COMPLETE THE HEARING INFORMATION.

Date: 12/4/2019
Time: 01:00 PM
Street Address: 108 Cherry Street, 3rd Fl, Burlington, VT
Zip Code: 05401

Date:
Time: AM
Street Address:
Zip Code:

Date:
Time: AM
Street Address:
Zip Code:

Date:
Time: AM

Street Address:

Zip Code:

21. DEADLINE FOR COMMENT (NO EARLIER THAN 7 DAYS FOLLOWING LAST HEARING):
12/11/2019

KEYWORDS (PLEASE PROVIDE AT LEAST 3 KEYWORDS OR PHRASES TO AID IN THE SEARCHABILITY OF THE RULE NOTICE ONLINE).

Toxics

Toxic Substances in children's products

Children's Products

Chemicals of high concern

Formaldehyde

Formaldehyde donors

VERMONT
DEPARTMENT OF HEALTH

To: Representative Robin Chesnut-Tangerman, Chair of the Legislative Committee on Administrative Rules

From: David Englander, Senior Policy and Legal Advisor for Vermont Department of Health

Re: Chemicals of High Concern in Children's Products Rule

Date: June 22, 2020

Following the filing of the rule for public comment, the Health Department made the following changes to the proposed rule:

These are the specific changes made as a result of comments made during the public comment period:

1. The Department changed the proposed reporting period for products containing chemicals of high concern to children from 30 days after a product is offered for sale to biannual reporting.

2. The Department changed the initial reporting date from August 31, 2020 to January 31, 2022.

Administrative Procedures – Adopting Page

Instructions:

This form must accompany each filing made during the rulemaking process:

Note: To satisfy the requirement for an annotated text, an agency must submit the entire rule in annotated form with proposed and final proposed filings. Filing an annotated paragraph or page of a larger rule is not sufficient. Annotation must clearly show the changes to the rule.

When possible, the agency shall file the annotated text, using the appropriate page or pages from the Code of Vermont Rules as a basis for the annotated version. New rules need not be accompanied by an annotated text.

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1. TITLE OF RULE FILING:
   Chemicals of High Concern in Children's Products Rule
2. ADOPTING AGENCY:
   Department of Health
3. TYPE OF FILING (*PLEASE CHOOSE THE TYPE OF FILING FROM THE DROPDOWN MENU BASED ON THE DEFINITIONS PROVIDED BELOW*):

   - **AMENDMENT** - Any change to an already existing rule, even if it is a complete rewrite of the rule, it is considered an amendment as long as the rule is replaced with other text.
   - **NEW RULE** - A rule that did not previously exist even under a different name.
   - **REPEAL** - The removal of a rule in its entirety, without replacing it with other text.

   This filing is **AN AMENDMENT OF AN EXISTING RULE** .

4. LAST ADOPTED (*PLEASE PROVIDE THE SOS LOG#, TITLE AND EFFECTIVE DATE OF THE LAST ADOPTION FOR THE EXISTING RULE*):

   Chemicals of High Concern in Children's Products Rule, August 15, 2019, Secretary of State Rule Log #19-032.

State of Vermont
Agency of Administration
109 State Street
Montpelier, VT 05609-0201
www.aoa.vermont.gov

[phone] 802-828-3322
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Office of the Secretary

INTERAGENCY COMMITTEE ON ADMINISTRATIVE RULES (ICAR) MINUTES

Meeting Date/Location: October 14, 2019, Pavilion Building, 5th floor conference room, 109 State Street, Montpelier, VT 05609
Members Present: Chair Brad Ferland, Dirk Anderson. Diane Bothfeld, John Kessler, Matt Langham, Steve Knudson, Clare O'Shaughnessy and (via phone) Jennifer Mojo
Members Absent: Ashley Berliner
Minutes By: Melissa Mazza-Paquette

- 2:00 p.m. meeting called to order.
- Review and approval of minutes from the September 9, 2019 meeting.
- Added notes:
    - Louise Corliss in the Secretary of State's office will be out of the office from October 17-22 and on the 28th, therefore there will be limited coverage during that time. Please plan accordingly and contact Louise with any concerns.
    - Shayla Livingston from the Agency of Human Services will be serving as an active committee member in Ashley Berliner's absence from November through February.
- Agenda approved as drafted.
- No public comments made.
- Presentation of Proposed Rules on pages 2-6 to follow.
    1. Chemicals of High Concern in Children's Products Rule, Agency of Human Services, Department of Health, page 2
    2. Medical Necessity for Covered Services, Agency of Human Services, page 3
    3. Early and Periodic Screening, Diagnostic and Treatment (EPSDT), Agency of Human Services, page 4
    4. Non-Emergency Medical Transportation, Agency of Human Services, page 5
    5. Ambulance Services, Agency of Human Services, page 6
- Next scheduled meeting is Wednesday, November 13, 2019 at 2:00 p.m.
- 2:40 p.m. meeting adjourned.

Proposed Rule: Chemicals of High Concern in Children's Products Rule, Agency of Human Services, Department of Health

Presented by David Englander

Motion made to accept the rule by Steve Knudson, seconded by Diane Bothfeld, and passed unanimously with the following recommendations.

1. Proposed Rule Coversheet, page 4, #12 and Economic Impact Analysis, page 1, #3: Explain that the minimal increase is tied to reporting.
2. Proposed Rule Coversheet, page 5, #16: Add 'Formaldehyde' and 'Formaldehyde donors'.
3. Environmental Impact Analysis, page 2, #8: Reword to clarify 'Vermonter's children and parents'.
4. Public Input, page 1, #3, #4 and anywhere else stated incorrectly: Change 'Commissioner' to 'Secretary'.
5. Public Input, page 1, #4: Include information about the meeting that was held if appropriate.

Administrative Procedures – Economic Impact Analysis

Instructions:

In completing the economic impact analysis, an agency analyzes and evaluates the anticipated costs and benefits to be expected from adoption of the rule; estimates the costs and benefits for each category of people enterprises and government entities affected by the rule; compares alternatives to adopting the rule; and explains their analysis concluding that rulemaking is the most appropriate method of achieving the regulatory purpose.

Rules affecting or regulating schools or school districts must include cost implications to local school districts and taxpayers in the impact statement, a clear statement of associated costs, and consideration of alternatives to the rule to reduce or ameliorate costs to local school districts while still achieving the objectives of the rule (see 3 V.S.A. § 832b for details).

Rules affecting small businesses (excluding impacts incidental to the purchase and payment of goods and services by the State or an agency thereof), must include ways that a business can reduce the cost or burden of compliance or an explanation of why the agency determines that such evaluation isn't appropriate, and an evaluation of creative, innovative or flexible methods of compliance that would not significantly impair the effectiveness of the rule or increase the risk to the health, safety, or welfare of the public or those affected by the rule.

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1. TITLE OF RULE FILING:

   Chemicals of High Concern in Children's Products Rule

2. ADOPTING AGENCY:

   Department of Health

3. CATEGORY OF AFFECTED PARTIES:

   LIST CATEGORIES OF PEOPLE, ENTERPRISES, AND GOVERNMENTAL ENTITIES POTENTIALLY AFFECTED BY THE ADOPTION OF THIS RULE AND THE ESTIMATED COSTS AND BENEFITS ANTICIPATED:

   Children's product manufacturers: This rule imposes no increase to the economic burden on the regulated community beyond the existing statutory requirements and legislative directives regarding reporting.

   Children's product retailers: Same as above.

   Consumers and users of children's products: Consumers and users of products may use disclosed information to

make purchasing and usage decisions in order to protect their health.

4. IMPACT ON SCHOOLS:
INDICATE ANY IMPACT THAT THE RULE WILL HAVE ON PUBLIC EDUCATION, PUBLIC SCHOOLS, LOCAL SCHOOL DISTRICTS AND/OR TAXPAYERS CLEARLY STATING ANY ASSOCIATED COSTS:

None.

5. ALTERNATIVES: *CONSIDERATION OF ALTERNATIVES TO THE RULE TO REDUCE OR AMELIORATE COSTS TO LOCAL SCHOOL DISTRICTS WHILE STILL ACHIEVING THE OBJECTIVE OF THE RULE.*

None.

6. IMPACT ON SMALL BUSINESSES:
INDICATE ANY IMPACT THAT THE RULE WILL HAVE ON SMALL BUSINESSES (EXCLUDING IMPACTS INCIDENTAL TO THE PURCHASE AND PAYMENT OF GOODS AND SERVICES BY THE STATE OR AN AGENCY THEREOF):

None.

7. SMALL BUSINESS COMPLIANCE: *EXPLAIN WAYS A BUSINESS CAN REDUCE THE COST/BURDEN OF COMPLIANCE OR AN EXPLANATION OF WHY THE AGENCY DETERMINES THAT SUCH EVALUATION ISN'T APPROPRIATE.*

Any business may be exempt from reporting requirements by adopting a chemical control program.

8. COMPARISON:
COMPARE THE IMPACT OF THE RULE WITH THE ECONOMIC IMPACT OF OTHER ALTERNATIVES TO THE RULE, INCLUDING NO RULE ON THE SUBJECT OR A RULE HAVING SEPARATE REQUIREMENTS FOR SMALL BUSINESS:
No rule would be contrary to the requirements of statute.

9. SUFFICIENCY: *EXPLAIN THE SUFFICIENCY OF THIS ECONOMIC IMPACT ANALYSIS.*
Act 75 (2019) mandates that the rule include requirements for when a manufacturer shall submit notice when intending to introduce a product for sale between the required reporting dates. If a product which contains a chemical of high concern to children is introduced for sale between the required dates of reporting, which has not already been reported by the manufacturer, the cost would be an additional $200 (in total, not annually) to the manufacturer. This cost is weighted against a consumer's ability to avoid

purchasing children's products whose use may result in substantial health care costs (e.g. lessening exposure to a carcinogen).

Administrative Procedures – Environmental Impact Analysis

Instructions:

In completing the environmental impact analysis, an agency analyzes and evaluates the anticipated environmental impacts (positive or negative) to be expected from adoption of the rule; compares alternatives to adopting the rule; explains the sufficiency of the environmental impact analysis.

Examples of Environmental Impacts include but are not limited to:

- Impacts on the emission of greenhouse gases
- Impacts on the discharge of pollutants to water
- Impacts on the arability of land
- Impacts on the climate
- Impacts on the flow of water
- Impacts on recreation
- Or other environmental impacts

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1. TITLE OF RULE FILING:

   Chemicals of High Concern in Children's Products Rule

2. ADOPTING AGENCY:

   Department of Health

3. GREENHOUSE GAS: *EXPLAIN HOW THE RULE IMPACTS THE EMISSION OF GREENHOUSE GASES (E.G. TRANSPORTATION OF PEOPLE OR GOODS; BUILDING INFRASTRUCTURE; LAND USE AND DEVELOPMENT, WASTE GENERATION, ETC.):*
   None.

4. WATER: *EXPLAIN HOW THE RULE IMPACTS WATER (E.G. DISCHARGE / ELIMINATION OF POLLUTION INTO VERMONT WATERS, THE FLOW OF WATER IN THE STATE, WATER QUALITY ETC.):*
   None.

5. LAND: *EXPLAIN HOW THE RULE IMPACTS LAND (E.G. IMPACTS ON FORESTRY, AGRICULTURE ETC.):*
   None.

6. RECREATION: *EXPLAIN HOW THE RULE IMPACT RECREATION IN THE STATE:*
   None.

7. CLIMATE: *EXPLAIN HOW THE RULE IMPACTS THE CLIMATE IN THE STATE:*
   None.

8. OTHER: *EXPLAIN HOW THE RULE IMPACT OTHER ASPECTS OF VERMONT'S ENVIRONMENT:*

The intention of the rule is to require that manufacturers of children's products disclose the use of chemicals of high concern to children. In addition, such disclosure may move manufacturers to safer alternatives. If that latter objective is successful, there will be fewer carcinogens, endocrine-disrupting, and otherwise harmful chemicals in the hands of Vermont consumers, in the waste stream and in the environment generally.

9. SUFFICIENCY: *EXPLAIN THE SUFFICIENCY OF THIS ENVIRONMENTAL IMPACT ANALYSIS.*

The analysis provides what information is available.

Administrative Procedures – Public Input

Instructions:

In completing the public input statement, an agency describes the strategy prescribed by ICAR to maximize public input, what it did do, or will do to comply with that plan to maximize the involvement of the public in the development of the rule.

This form must accompany each filing made during the rulemaking process:

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1. TITLE OF RULE FILING:

   Chemicals of High Concern in Children's Products Rule

2. ADOPTING AGENCY:

   Department of Health

3. PLEASE DESCRIBE THE STRATEGY PRESCRIBED BY ICAR TO MAXIMIZE PUBLIC INVOLVEMENT IN THE DEVELOPMENT OF THE PROPOSED RULE:

   Prior to filing with ICAR, the Department convened the CHCCP Working Group and hosted a public Workshop on September 5, 2019, per 18 V.S.A. § 1776(g), and accepted written comments through September 20th, 2019. The Department also consulted with the Secretary of Natural Resources, as required by 18 V.S.A. §1776(a). The Department will continue to involve stakeholders to seek input on the rule, post the rule on the website and hold a public hearing.

4. PLEASE LIST THE STEPS THAT HAVE BEEN OR WILL BE TAKEN TO COMPLY WITH THAT STRATEGY:

   Per 18 V.S.A. § 1776(g), that requires additional consultation with stakeholders prior to filing a rule, the Department held a workshop on September 5, 2019.

   A public workshop was held on September 5, 2019, per 18 V.S.A. § 1776(g).

   The Department also consulted with the Secretary of Natural Resources, as required by 18 V.S.A. §1776(a).

   Department's website will also host the proposal throughout the rulemaking process until adoption:

Public Input

http://www.healthvermont.gov/about-us/laws-regulations/public-comment

Hard copies of the rule were provided to any requestor by calling 802-863-7280.

5. BEYOND GENERAL ADVERTISEMENTS, PLEASE LIST THE PEOPLE AND ORGANIZATIONS THAT HAVE BEEN OR WILL BE INVOLVED IN THE DEVELOPMENT OF THE PROPOSED RULE:

- Seventh Generation
- Global Foundries
- American Chemistry Council
- Consumer Specialty Products Association
- Wal-Mart Corporation
- Vermont Conservation Voters
- Vermont Teddy Bear
- Associated Industries of Vermont
- Cradle to Cradle Products Innovation Institute
- Toy Industry Association
- Consumer Specialty Products Association
- Vermont Public Interest Group
- Chemicals of High Concern Working Group
- Vermont Agency of Natural Resources

VERMONT
DEPARTMENT OF HEALTH

Public Comment Responsiveness Summary
Chemicals of High Concern in Children's Products Rule

The Department of Health (Department) held a public hearing on December 4, 2019 in Burlington, Vermont, regarding the proposed rule regarding Chemicals of High Concern in Children's Products and accepted written comments through December 11, 2019. The following is summary of comments received from the public and the Department's response to each comment. Comments of a similar or consistent nature have been consolidated and responded to accordingly.

1. **Comment:** One commenter recommended that the proposed language in Section 5.0 be amended to: "(1) Formaldehyde, ~~and substances that are intentionally added~~ including formaldehyde intended to be released by one of the following donor chemicals if that donor chemical has been intentionally added to release for the purpose of releasing formaldehyde including: 5-Bromo-5-nitro-1,3-dioxane, Bronopol, Diazolidinyl urea, DMDM hydantoin, Imidazolidinyl urea, Methanol, (phenylmethoxy), Methenamine, Quaternium-15, and Sodium N-(hydroxymethyl) glycinate.

   Another commenter recommended the following language: "(1) Formaldehyde, including formaldehyde intended to be released by one of the following substances if that substance has been intentionally added for the purpose of releasing formaldehyde: 5-Bromo-5-nitro-1,3-dioxane, Bronopol, Diazolidinyl urea, DMDM hydantoin, Imidazolidinyl urea, Methanol, (phenylmethoxy), Methenamine, Quaternium-15, and Sodium N-(hydroxymethyl)glycinate."

   Response: The Department believes that the existing proposed language is clear, and that the commenters' suggested language does not clarify this requirement.

2. **Comment:** One commenter requested the proposed language be amended to: "Any chemical that is added for a specific function (not a contaminant), which degrades to or releases a chemical listed in [section 5]," as opposed to focusing exclusively on formaldehyde.

   Response: The Department had previously proposed similar language in a prior rulemaking. Under advisement from the Legislative Committee on Administrative Rules, the Department reconsidered this language and determined it to be too broad to be practicable.

3. **Comment:** One commenter requested that the language proposed in Section 5.0 be removed and stated that the proposed language will not provide for "consistent or accurate information" to the Department. The commenter further notes that "the amount of formaldehyde released…will vary and is dependent on a variety of factors, including temperature, the acidity or basicity of the solution, and time;" and that "the amount of formaldehyde detected from some formaldehyde-releasing substances can vary greatly based on the analytic method used to quantify emissions.

   Response: The Department will provide guidance for manufacturers with regards to reporting formaldehyde released from the degradation of these substances. As with existing reporting requirements under this rule, appropriate testing methodology and accurate reporting are the responsibility of manufacturers.

4. **Comment:** One commenter expressed concern that the proposed language in Section 5.0 only addressed chemicals that have been intentionally added and requested that "intentionally" be removed from the proposed language in Section 5.0.

Response: The purpose of this rule is to require the disclosure and reporting of toxic substances that are intentionally added to a children's product. The inclusion of "intentionally" in Section 5.0 is consistent with this purpose.

5. **Comment:** Several commenters noted appreciation that the formaldehyde donors are specifically listed in Section 5.0.

   Response: The Department acknowledges these comments.

6. **Comment:** One commenter requested additional details in the rule that would clarify that formaldehyde is the chemical of high concern to children that is required to be reported and not the specific list of donor chemicals that degrade to and release formaldehyde as a preservative.

   Response: Formaldehyde is the chemical of high concern to children that is required to be reported. The inclusion of the "formaldehyde donor" chemicals in the definition of formaldehyde, rather than being listed separately, is intended to clarify this distinction. The Department will provide additional clarification for manufacturers in a published guidance document.

7. **Comment:** Several commenters stated that reporting "within 30 days of a product being offered for sale or distribution in Vermont" is not a realistic timeframe for manufacturers. One commenter asked for the basis of the Department's proposed reporting period of 30 days from being offered for sale or distribution. Several commenters stated that a reporting period of six months from being offered for sale was reasonable, pragmatic and preferred over the proposed 30-day reporting period. One commenter stated that a 30-day reporting period was too long and may preclude the reporting of some seasonal products which may not be offered for sale for more than that period of time.

   Response: The Department agrees that biannual reporting provides a clear and consistent requirement that may facilitate greater compliance from manufacturers. The Department has revised this proposed rule accordingly.

8. **Comment:** One commenter requested that the proposed language for section 8.0 be revised to require reporting only at the existing annual reporting period and that no interim reporting be required.

   Response: This request is inconsistent with 18 V.S.A. § 1776 (f)(1)(D), which requires the Department to provide, "requirements for when and how a manufacturer of a children's product that contains a chemical of high concern to children provides the notice required under subsection 1775(a) of this title when the manufacturer intends to introduce the children's product for sale between the required dates for reporting."

9. **Comment:** One commenter asked how "offered for sale" is defined. Several commenters stated this phrase is ambiguous and that manufacturers may not know when a product would be "offered for sale."

   Response: "Offered for sale" means the date on which a consumer is able to buy the product in Vermont. The phrase "offered for sale" is found in 18 V.S.A. § 1774, 18 V.S.A. § 1776, and 18 V.S.A. § 1776 (f)(1)(D). The Department notes that it requested from manufacturers language that would help clarify the meaning of this but received no responses to that request. Importantly, the updated proposal requires biannual reporting, which provides manufacturer's with up to 6 months from when a product is offered for sale to report CHCCs.

10. **Comment:** Several commenters requested the removal of "distribution" from Section 9.0. One commenter stated that this inclusion is confusing to manufacturers.

Response: This language addresses intends to eliminate any potential ambiguity of the phrase "offered for sale." 18 V.S.A. § 1776(d)(1) states, "The Commissioner…may adopt a rule to regulate the sale or distribution of a children's product containing a chemical of high concern to children…" Accordingly, the inclusion of "distribution" is within the authority granted to the Commissioner, and will ensure disclosure of a product that contains a chemical of high concern to children whether "sold" or "distributed" in Vermont.

11. **Comment:** One commenter asked whether there would be one fee per year per chemical reported.

    Response: There will continue to be an assessment of one fee per year per chemical.

12. **Comment:** One commenter requested that the Department provide guidance as to whether reporting fees are required per product or per chemical.

    Response: The Department has already published this guidance. Reporting fees are per chemical not per product. The Department notes that this is outside the scope of the rulemaking.

13. **Comment:** One commenter asked whether the reporting requirement can be delegated by the manufacturer to another party.

    Response: A manufacturer may delegate reporting to another entity. However, the manufacturer, as defined by 18 V.S.A. § 1772, is responsible for ensuring compliance. The Department notes that this is outside the scope of the rulemaking.

14. **Comment:** One commenter asked how the Department would track children's products that come into the state.

    Response: The Department does not track which products are offered for sale in Vermont. It is the responsibility of the manufacturer to ensure compliance with this regulation. The Department notes that this is outside the scope of the rulemaking.

15. **Comment:** One commenter asked whether the rule would apply to food.

    Response: The rule does not apply to food. A definition of products regulated by this rule are included in 18 V.S.A. § 1772. The Department notes that this is outside the scope of the rulemaking.

16. **Comment:** One commenter asked whether the Department is able to provide website data that to show how and how often the website is utilized by the public.

    Response: The Department does not have this information. The Department notes that this is outside the scope of the rulemaking.

17. **Comment:** One commenter requested that the Department amend Section 10.0 to ensure risk-based rather than hazard-based evaluations of chemicals. The commenter further requested the Department to conduct "margin of exposure assessments" for chemicals that meet the requirements for listing in this rule.

    Response: These requests are outside the scope of this rulemaking.

December 11, 2019

Mr. David Englander
Vermont Department of Health
Agency of Human Services
108 Cherry Street
Burlington, VT 05401

Submitted via email to: ahs.vdhrules@vermont.gov

Re: Vermont Chemicals of High Concern in Children's Products Rule and Proposed Amendments to Expand the Definition of Formaldehyde

Dear Mr. Englander:

The American Chemistry Council's Formaldehyde Panel (the Panel) appreciates the opportunity to provide comments on the Vermont Department of Health's (DOH) proposed amendments to the Chemicals of High Concern in Children's Products Rule to expand the definition of formaldehyde to include formaldehyde donors. Specifically, the DOH proposes the following additional language: *"and substances that are intentionally added to release formaldehyde, including 5-Bromo-5-nitro-1,3-dioxane, Bronopol, Diazolidinyl urea, DMDM hydantoin, Imidazolidinyl urea, Methanol, (phenylmethoxy), Methenamine, Quaternium-15, and Sodium N-(hydroxymethyl)glycinate."* Given that the intent of the rule is to regulate the disclosure and reporting of substances that are intentionally added to a children's product at a level above established levels, the addition of this proposed language will not provide consistent or accurate information to the DOH.

The DOH appears to make the incorrect assumptions that all substances that are intentionally added to release formaldehyde will do so at the same levels and concentrations over time or that the amount of formaldehyde released results in some adverse effect. However, substances that intentionally release formaldehyde generally do so because of formaldehyde's preservative or antimicrobial properties. The amount of formaldehyde released from these applications will vary and is dependent on a variety of factors, including temperature, the acidity or basicity of the solution, and time.[1] It is unclear from the DOH's proposed amendments how any of these factors will be considered in collecting emission information on the formaldehyde-releasing substances or how the DOH will assess the variable emissions data that will likely be seen over time during the annual reporting periods. Furthermore, the amount of formaldehyde detected from some formaldehyde-releasing substances can vary greatly based on the analytic method used to quantify emissions. This is due to the fact that formaldehyde being emitted from these sources is not continuous and is highly dependent on the water content of the matrix. Thus, analytical

[1] Lv, C., J. Hou, W. Xie, and H. Cheng. "Investigation on formaldehyde release from preservatives in cosmetics." International journal of cosmetic science 37, no. 5 (2015): 474-478.

approaches that rely on gas chromatography or high performance liquid chromatography may provide inaccurate results if not properly validated.[2,3] The DOH must assess and evaluate these possible inaccuracies in the data collection methods, and provide guidance on acceptable data collection/analytical methodologies, before finalizing any proposed amendments to the rule.

In addition to these specific comments on the proposed amendments, the Panel also strongly encourages the DOH to re-evaluate Section 10 "Evaluation of Chemicals for Listing as a Chemical of High Concern to Children" of the rule and modify the process for adding a chemical to ensure the process is risk-based versus based only on hazard. Ensuring the safety of children's products and addressing the potential risks from possible exposure to chemicals is important, however, the mere presence of a chemical in a children's product does not mean that the product is harmful to human health. This is particularly relevant for formaldehyde, since it is metabolically produced by all cells and naturally present in the environment.

We also urge the DOH to revise the rule and its process for identifying chemicals so that the approach incorporates current knowledge about hazard and relevant human exposures. One way to accomplish this would be for the DOH to conduct margin of exposure assessments for the chemicals that have been identified as meeting the criteria established in Section 9.1.1. The DOH could compare the toxicity values associated with those specific adverse health endpoints to publicly available biomonitoring, environmental sampling or monitoring data in accordance with Section 9.1.2. Using this approach would provide the DOH and the public with relevant information about both the hazard and exposure needed to result in adverse health impacts and increased health risk.

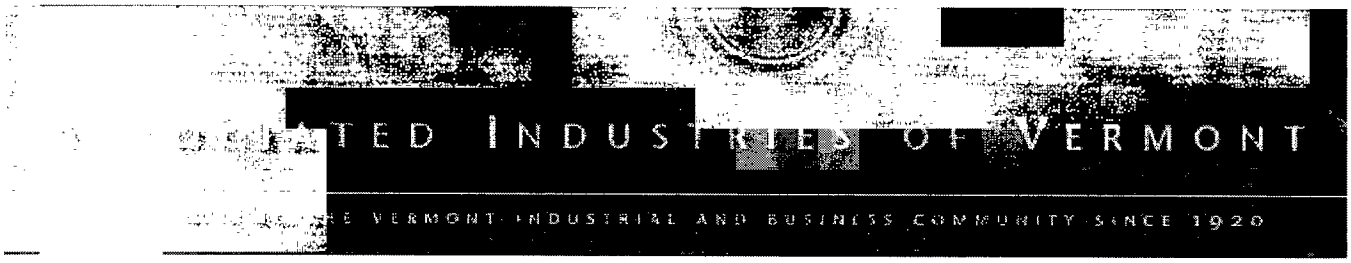
The Panel thanks the Vermont DOH for consideration of these comments and requests that the DOH: (1) not expand the definition of formaldehyde under the list of chemicals of high concern to children; and (2) update Section 10 "Evaluation of Chemicals for Listing as a Chemical of High Concern to Children" of the rule to include the conduct of a margin of exposure estimate to determine if any adverse health impact is anticipated associated with the chemicals identified in Section 5 of the rule. If you have questions regarding this submission, please feel free to contact me by phone: 202-249-6707 or email: Kimberly_White@americanchemistry.com.

Sincerely,

Kimberly Wise White, Ph.D.
American Chemistry Council (ACC)
Senior Director, Chemical Products and Technology Division
On Behalf of the ACC Formaldehyde Panel

[2] Brandão, Pedro Francisco, Rui Miguel Ramos, and José António Rodrigues. "GDME-based methodology for the determination of free formaldehyde in cosmetics and hygiene products containing formaldehyde releasers." Analytical and bioanalytical chemistry 410, no. 26 (2018): 6873-6880.

[3] Lv, Chunhua, Jiannan Sun, and Heyong Cheng. "Determination of formaldehyde residue in cosmetics by short-column high performance liquid chromatography with mass spectrometric confirmation." Analytical Methods 7, no. 4 (2015): 1630-1634.



December 11, 2019

Mark Levine, MD
Commissioner, Department of Health
Department of Health
108 Cherry Street
Burlington, VT 05402

Re: Proposed Rule Changes to Implement 18 VSA Chapter 038A: Chemicals of High Concern to Children

Dear Dr. Levine:

AIV appreciates the opportunity to provide comments on behalf of Vermont manufacturers on proposed rule changes to implement 18 VSA Chapter 038A: Chemicals of High Concern to Children.

Formaldehyde

With regard to revisions to the proposed rule regarding formaldehyde circulated and discussed at the December 4 public hearing, AIV appreciates the intent that the rule would list specific formaldehyde donors that would trigger reporting if intentionally added for the purpose of releasing formaldehyde, rather than create an open ended requirement triggered by unspecified donors. We also understand the intent to be that formaldehyde, not the donor, would be reported, and that the listing of donors in this section would not mean that the donors themselves are being designated Chemicals of High Concern to Children (CHCCs).

Nevertheless, we are concerned that the revised proposed language remains ambiguous on these points. In particular, the use of "including" might still be interpreted as open ended, and the structure of the language might be interpreted to mean that the donors are themselves CHCCs.

We would recommend the following further revision of this language to better clarify that 1) formaldehyde and not the donor is to be reported, 2) the donor must be added for the purpose of intentionally releasing formaldehyde, 3) the donors covered are specifically listed, and 4) the donors themselves are not being designated as CHCCs:

(1) Formaldehyde, including formaldehyde intended to be released by one of the following substances if that substance has been intentionally added for the purpose of releasing formaldehyde: 5-Bromo-5-nitro-1,3-dioxane, Bronopol, Diazolidinyl urea, DMDM hydantoin, Imidazolidinyl urea, Methanol, (phenylmethoxy), Methenamine, Quaternium-15, and Sodium N-(hydroxymethyl)glycinate

Reporting Periods

Act 75 (S.55) requires the Department to implement a rule by January 1, 2020, that provides for "when and how" companies are to report CHCCs in products that are introduced between the regular reporting deadlines, which will be changing from biennially to annually under the new law. Although this provision addresses products introduced between regular reporting deadlines, the provision does not itself require that reporting occur between regular reporting periods. AIV continues to recommend that the "when and how" be that new products should be included in the regular annual reports that follow their introduction.

- Providing for a uniform deadline for reporting on all products is most efficient for compliance in terms of cost and administrative burdens, as opposed to having to conduct testing, obtain certificates of compliance, make filings, address any compliance verification or other related communication between manufacturers, distributors, and retailers, etc., on an ad hoc, rolling basis.

- It should be noted that having new products addressed as part of the regular annual reporting cycle is consistent with the policy direction in 18 VSA §1771(2) that, when possible, Vermont conform with other states. The other states with reporting programs similar to Vermont, Washington and Oregon, do not require reporting of new products outside of the regular reporting cycle. Should those states change this, it would be consistent with the statutory policy direction for Vermont to work with them to seek a common approach.

- Some supporters of more frequent or timely reporting for new products argue that it is needed for informed consumer decisions based on health, and some have cited the policy direction in 18 VSA §1771(1) that the state reduce exposure to toxic chemicals. However, the reporting required does not provide health or exposure information, and more frequent reporting in and of itself does not provide for meaningfully informed health-based consumer decisions or exposure reduction.

Recommendations Should Interim Reporting be Required

Although AIV does not support requiring reporting between the regular annual deadlines, we appreciate the discussion during the December 4 public hearing regarding more or less reasonable timeframes and the merits of a deadline based on the date a product is offered for sale or, instead, based on a fixed date in the calendar.

There are several factors to consider. First, there are different time demands based on the nature of the product, including its components, the resources of the manufacturer, etc. There is also the uncertainty for manufacturers as to when a deadline based on the date a product is offered for sale would begin if the manufacturer does not control and might not have sufficient notice of that offering, however "offered for sale" might be defined. There are also the administrative and cost burdens of testing and reporting for multiple products on a rolling basis throughout the year.

No one approach might address all of these concerns fully. Nevertheless, AIV believes that the optimal approach should interim reporting be required would be to set a fixed date for semi-annual reporting. Specifically, the optimal approach would be to require that new products offered for sale after August 31 but before March 1 be reported prior to March 1, and those offered for sale after this period be reported by the next regular deadline of before August 1. Subsequent reports would be based on the regular August 1 deadline.

Although the approach outlined above could still create time constraint issues for some products and manufacturers, the semi-annual timeframe should provide some reasonable accommodation, and the regularity of a fixed date should help facilitate compliance planning. This should also facilitate consolidating testing and reporting for multiple new products.

NOTE: The proposed rule in 9.1 sets a deadline based on a product begin offered for sale "or distribution". The current rule and the provision in Act 75 addressing this issue address sale, not distribution. Further, the informal discussion draft of the rule did not include distribution and subsequent discussion at the December 4 public hearing focused on the definition of "offered for sale". Including distribution in addition to sale would seem conflicting, confusing, and unwarranted. We would strongly recommend that any language addressing new products not include "distribution".

Conclusion

Again, AIV very much appreciates the opportunity provide these comments and requests made above. Please do not hesitate to contact us with any questions or to otherwise continue discussions.

Sincerely,

William Driscoll
Vice President

From:	White, Kimberly
To:	AHS - VDH Rules
Subject:	Comments Submitted on proposed amendments to the Chemicals of High Concern in Children"s Products Rule
Date:	Wednesday, December 11, 2019 12:10:41 PM
Attachments:	ACC Formaldehyde Panel Comments on Proposed Amendments to Vermont Chemicals of High Concern in Childrens Products Rule - Final- 12 11 19.pdf

Dear Mr. Englander,

Please find attached, comments submitted on behalf of the American Chemistry Council's Formaldehyde Panel related to proposed amendments to the Chemicals of High Concern in Children's Products Rule.

Kind Regards,

Kimberly Wise White, Ph.D. | American Chemistry Council
Senior Director, Chemical Products & Technology Division
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700 2nd Street NE | Washington, DC | 20002
O: (202) 249-6707 C: (202) 341-7602
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December 11, 2019

Mark Levine, MD,
Commissioner of Health
Department of Health
108 Cherry Street
Burlington, VT 05402

Re: Comments on Act 188 Chemicals of High Concern to Children – Chapter 6 Proposed Rule Changes

Dear Dr. Levine,

I am writing as a member of the Act 188 Working Group and on behalf of the Juvenile Product Manufacturers Association (JPMA) to provide comments on the proposed Act 188 Chapter 6 Rule revisions. I appreciate this opportunity to provide comments and appreciate that the Department is now actively utilizing the Working Group – as a means for discussing changes and critical issues with this law.

The following comments provide specific feedback on the new changes contained in the draft Chapter 6 rule proposal that was presented to the Working Group during a meeting on September 5th:

1. **Chemicals of High Concern to Children – Section 5.0 Degradation & Formaldehyde Releasers**

We appreciate that the Department has provided greater specificity regarding formaldehyde, which is an improvement over the previous draft, however, additional clarity is needed. The concept of a chemical "degrading and releasing another" is a highly technical concept and all chemicals and materials have the potential to degrade under certain conditions, even if they are intentionally added, but not to release a chemical. JPMA is not specifically commenting on the chemicals suggested for inclusion in this rulemaking as "formaldehyde releasers". However, we are concerned about the current language still lacking clarity with regard to chemicals that release formaldehyde. Therefore, we request that the rule be amended as follows:

(1) Formaldehyde, ~~and substances that are~~ <u>including formaldehyde intended to be released by one of the following donor chemicals if that donor chemical has been</u> intentionally added ~~to release~~ <u>for the purpose of releasing</u> formaldehyde ~~including~~<u>:</u> 5-Bromo-5-nitro-1,3-dioxane, Bronopol, Diazolidinyl urea, DMDM hydantoin,

JUVENILE PRODUCTS MANUFACTURERS ASSOCIATION, INC.

1120 Route 73, Suite 200 • Mt. Laurel, NJ 08054
TEL: 856.638.0420 • FAX: 856.439.0525
jpma@jpma.org • www.jpma.org

Imidazolidinyl urea, Methanol, (phenylmethoxy), Methenamine, Quaternium-15, and Sodium N-(hydroxymethyl)glycinate

It is critical to limit reporting under these circumstances to where the donor chemical is known and intended to "functionally" release formaldehyde for a specific purpose. This is the only way to ensure clarity and provide that the rule is consistent with the letter and intent of the statute.

2. Reporting New Products - Section 9.1

Reporting periods and consistency are a critical element to implementing the policy direction in 18 VSA §1771(2) that, state that when possible, Vermont conform with other states. Further, this care is necessary to ensure that both consumer and manufacturers have the time to understand and provide accurate information. This Department has already established requirements that vary greatly from states like Washington and Oregon, which rely on a higher level of reporting and are consistent enough to allow the potential for uniform reporting.

Vermont's move to annual reporting under S.55, passed this year already constitutes a significant new requirement for companies to ensure compliance. The requirement in Section 9.1 that a company report, *"no later than 30 days of the product being offered for sale or distribution in Vermont"* is not consistent with Washington and Oregon, which do not have a rolling registration system, not do they mention distribution. Further, such a requirement is incredibly burdensome for companies that do not control when a product is offered for sale in Vermont. This is typically determined within the supply chain and depended upon retailers can vary greatly.

Therefore, this provision should be removed, or at a minimum, **a company should be provided 180-days or a mid-year, 6-month date certain interim reporting date such as February 28th of each year**. Such an approach would be the minimum necessary to ensure reporting within supply-chains, especially for small companies and small retailers that may not have sophisticated inventory control reporting systems.

Additionally the inclusion of **the language "or distribution" must be deleted.** This language is confusing to a product manufacturer and retailer – as it refers to two different points in time in the supply-chain process. "Offered for sale" and "offered for distribution" are two very different points in time as a product is brought to market and would start the reporting clock ticking at very different points in time. Further, this language was **not** included in the initial rule, proposed in September 2019. JPMA strongly believes that this language must be removed for this rule to be workable for the supply-chain for juvenile products.

Once again, I appreciate the opportunity to provide these comments and to serve on the Act 188 Working Group. We appreciate that the Department has accepted some of the

recommendations from previous comments and that this proposed rule seeks to ensure greater consistency with other states and similar laws.

Respectfully Submitted,

Andrew R Hackman
Principal Lobbyist
Serlin Haley LLP

CC: Mr. David Englander, Senior Policy and Legal Advisor
Kelly Mariotti, Executive Director, Juvenile Products Manufacturers Association

December 11, 2019

Brendan Atwood
Department of Health
108 Cherry Street
Burlington, VT 05402

Re: Comments on Act 188 Chemicals of High Concern to Children – Proposed Rule Changes

Dear Mr. Atwood,

Below please find comments from the Toy Association (TA) on the Vermont Department of Health's proposed changes to the administrative rules for Act 188 related to chemical disclosure. TA appreciates the opportunity to provide comments and it is our hope that the Department continues to utilize the Working Group and hold public workshops to have interactive discussions on these proposed rule changes.

The Toy Association is the not-for-profit trade association for manufacturers, importers and retailers of toys and youth entertainment products sold in North America. The Association represents more than 950 companies – both large and small in size. The Toy Association and its members have long been leaders in toy safety. The Toy Association's mission is to bring fun and joy to children's lives and in that mission the safety of young consumers is paramount – it is our industry's number-one priority.

The following comments provide specific feedback on the proposed amendments to the Chemicals of High Concern in Children's Products Rule:

Reporting Years and Periods - Section 8.0

The Department's proposal would require annual reporting as well as reporting in between reporting periods. The proposal to require reporting for products "within 30 days of the product being offered for sale or distribution in Vermont," is not a realistic timeframe for companies to collect information from suppliers, conduct product testing (if needed), and process other necessary information internally and through their supply chains. For manufacturers who sell to national retailers, they often don't know what states their products will be sold in. It takes time and resources to determine where the product was sold. Further, the Toy Association respectfully seeks clarification or removal of the term "distribution". If a product is not offered for sale in Vermont, it is unclear how reporting on a distributed product would further the goal of the Act.

During the public hearing on December 4, 2019, the Department had asked for consideration of a six-month reporting period for new products. The Department has already added new reporting requirements such as a UPC code requirement, additional HPCCs and a switch to annual reporting this year that have increased the resource and administrative burden for business to comply with the law. However, a six-month reporting period would be an improvement over a 30-day reporting period. Due to the varied launch timing of products a six-month period would reduce the reporting burden on companies

needing to update the database compared to monthly updates. It would be rare for the person inputting information in the database to do this without placing a request into the organization for the updated SKU list, which is not just new products but all products and requires a fair bit of data management prowess, and thus, having requests twice a year is much more pragmatic. Product launches use to be much more regular, but with partner IP constraints, movie releases and customer exclusives it has become more varied, thus a six-month schedule would be easier to capture the prior six months of activity. A fixed six-month period would provide predictability for companies to gather the data necessary to fulfill the reporting requirements.

Chemicals of High Concern – Section 5.0

The Department proposes to add "substances that are intentionally added to release formaldehyde, including 5-Bromo-5-nitro-1,3- dioxane, Bronopol, Diazolidinyl urea, DMDM hydantoin, Imidazolidinyl urea, Methanol, (phenylmethoxy), Methenamine, Quaternium-15, and Sodium N-(hydroxymethyl) glycinate" to the list of Chemicals of High Concern to Children (CHCC) which are required to be reported in children's products. It is unclear what products the Department believes necessitate adding this new requirement.

Harmonization with Other States

Additionally, the statute includes language indicating that Vermont should harmonize with other states:

> ***"(6) Other states and countries, including Maine, Washington, California and the European Union, are already taking a more comprehensive approach to chemical regulation in consumer products, and chemicals regulation in Vermont should harmonize with these efforts."***

The rule proposal further separates the Vermont program from the approach taken by states with similar programs such as Washington state, Oregon and Maine. It continues a trend of creating a patchwork of state regulatory schemes that make it very difficult for manufacturers to comply with. The Toy Association and its members urge the agency to work with its counterparts in the other states to align standards. This alignment with other states will yield better and more accurate information and further drive supply chain clarity when it comes to reporting. Alignment will start a more consistent message to supply chain partners and consumers alike and will advance the goals of all these transparency programs more quickly and efficiently.

The Toy Association appreciates the opportunity to provide these comments and offer our perspective as the Department evaluates changes to the program rule. Please feel free to contact TA if you have any questions or concerns about these comments or would like to discuss in more detail. We look forward to working with the Department as the rulemaking process moves forward.

Respectfully Submitted,

Matthew Lenz
Director, State Government Affairs
The Toy Association

VERMONT'S VOICE

Comments of the Vermont Public Interest Research Group regarding the Chemicals of High Concern in Children's Products Rule

December 11, 2019

The Vermont Public Interest Research Group (VPIRG) offers the following comments on the Chemicals of High Concern in Children's Products Rule.

Regarding **Section 5(1)**, VPIRG supports the more comprehensive language used in an earlier CHCC draft rule, which stated that it applied to "Any chemical that is added for a specific function (not a contaminant), which degrades to or releases a chemical listed in [section 5]," as opposed to focusing exclusively on formaldehyde.

Further, we are concerned that this section applies only to chemicals that have been intentionally added and later degrade into a chemical of high concern. If degradation of a chemical results in a children's product that contains a chemical threat to a child, there must be accountability regardless of whether there is proof of intention. Therefore, we recommend the word "intentionally" be removed from section 5(1).

With respect to **Section 9: 9.1,** VPIRG has provided a full explanation of our thinking on this matter in past comments. Suffice to say, we believe that when Vermont legislators passed this law, they intended to provide consumers with an opportunity to learn what toxins may be present in a toy or other product before purchasing it for a child. Initial guidelines from the Department of Health were very much in line with this intent as they made clear that manufacturers were to report to the Department any children's product containing a chemical of high concern to children before it was offered for sale here.

The current rule allows products to be sold for thirty days before reporting is required. We recognize that this is a significant improvement over earlier drafts of the rule, which could have allowed a product to be on store shelves for nearly two years before a reporting requirement was triggered. Of course, new legislation has since been passed requiring annual reporting, and this rule ensuring that no product will be sold for more than thirty days without reporting goes a long way toward closing the reporting loophole.

However, VPIRG remains convinced that legislative intent and consumer protection is best served by requiring reporting before products containing chemicals of high concern to children are sold here.

Furthermore, for some products such as seasonal toys, the shelf-life is barely over thirty days. For these types of products in particular, thirty days may be too long a wait to provide meaningful information to consumers.

For manufacturers, the thirty day period would also seem to make compliance challenging. They may not know precisely when their products make their way to store shelves. Enforcement could be similarly difficult. It's much cleaner to simply say that reporting must happen before the products in question hit store shelves. As manufacturers are preparing a product for sale, they will be aware of this reporting requirement. They will have the ability to build into their schedule time for reporting compliance. As the ultimate goal is to protect children and families, the best course of action is to require the reporting to be before the product enters the marketplace.

VPIRG appreciates the opportunity to make these comments.

Annotated Text

Chapter 6 – Environmental Health Rules
Subchapter 7

CHEMICALS OF HIGH CONCERN IN CHILDREN'S PRODUCTS RULE

1.0 Authority

This rule is adopted pursuant to 18 V.S.A § 1776.

2.0 Purpose

This rule provides the requirements for the disclosure and reporting of toxic substances that are intentionally added to a children's product at a level above the PQL produced by the manufacturer or are present in a children's product produced by the manufacturer as a contaminant at concentrations of 100 parts per million or greater. This rule also establishes the process by which a chemical may be added or removed from the list of Chemicals of High Concern to Children and the process by which a chemical might be banned for sale or distribution.

3.0 Scope

This rule applies to manufacturers of children products as defined by 18 V.S.A. § 1772(7) offered for sale in the State of Vermont.

4.0 Definitions

Any terms used in this rule but not defined in this section shall have the meaning found in 18 V.S.A. §1772. Whenever used in this rule, the following terms shall be construed as follows:

4.1 "Department" means the Vermont Department of Health.

4.2 "Commissioner" means the Commissioner of Health.

4.3 "Chemical of high concern to children" means a chemical listed under section 18 V.S.A. §1773 or designated by the Department as a chemical of high concern by this rule.

4.4 "Manufacturer" means any person who manufactures a children's product or whose name is affixed to a children's product or its packaging or advertising, and the children's product is sold or offered for sale in Vermont; or any person who sells a children's product to a retailer in Vermont when the person who manufactures the children's product or whose name is affixed to the children's product or its packaging or advertising does not have a presence in the United States other than the sale or offer for sale of the manufacturer's products.

4.5 "Practical quantification limit (PQL)" means the lowest concentration that can be

reliably measured within specified limits of precision, accuracy, representativeness, completeness, and comparability during routine laboratory operating conditions.

4.6 "Product component" means the uniquely identifiable material or coating (including ink or dye) that is intended to be included as part of a finished children's product.

4.7 "Product model" means the specific product name used by the retailer or assembler to place the product into the stream of commerce.

4.8 "Contaminant" means a trace amount of a chemical or chemicals that is incidental to manufacturing and serves no intended function in the children's product or component of the children's product, including an unintended by-product of chemical reactions during the manufacture of the children's product, a trace impurity in feed-stock, an incompletely reacted chemical mixture, and a degradation product.

5.0 Chemicals of High Concern to Children

The following chemicals are designated as chemicals of high concern to children:

(1) Formaldehyde and substances that are intentionally added to release formaldehyde, including 5-Bromo-5-nitro-1,3-dioxane, Bronopol, Diazolidinyl urea, DMDM hydantoin, Imidazolidinyl urea, Methanol, (phenylmethoxy), Methenamine, Quaternium-15, and Sodium N-(hydroxymethyl)glycinate

(2) Aniline

(3) N-Nitrosodimethylamine

(4) Benzene

(5) Vinyl chloride

(6) Acetaldehyde

(7) Methylene chloride

(8) Carbon disulfide

(9) Methyl ethyl ketone

(10) 1,1,2,2-Tetrachloroethane

(11) Tetrabromobisphenol A

(12) Bisphenol A

(13) Diethyl phthalate

(14) Dibutyl phthalate

(15) Di-n-hexyl phthalate

(16) Phthalic anhydride

(17) Butyl benzyl phthalate (BBP)

(18) N-Nitrosodiphenylamine

(19) Hexachlorobutadiene

(20) Propyl paraben

(21) Butyl paraben

(22) 2-Aminotoluene

(23) 2,4-Diaminotoluene

(24) Methyl paraben

(25) p-Hydroxybenzoic acid

(26) Ethylbenzene

(27) Styrene

(28) 4-Nonylphenol; 4-NP and its isomer mixtures including CAS 84852-15-3 and CAS 25154-52-3

(29) para-Chloroaniline

(30) Acrylonitrile

(31) Ethylene glycol

(32) Toluene

(33) Phenol

(34) 2-Methoxyethanol

(35) Ethylene glycol monoethyl ether

(36) Tris (2-chloroethyl) phosphate

(37) Di-2-ethylhexyl phthalate

(38) Di-n-octyl phthalate (DnOP)

(39) Hexachlorobenzene

(40) 3,3'-Dimethylbenzidine and Dyes Metabolized to 3,3'-Dimethylbenzidine

(41) Ethyl paraben

(42) 1,4-Dioxane

(43) Perchloroethylene

(44) Benzophenone-2 (Bp-2); 2,2',4,4'-Tetrahydroxybenzophenone

(45) 4-tert-Octylphenol; 4 (1,1,3,3-Tetramethylbutyl) phenol

(46) Estragole

(47) 2-Ethylhexanoic acid

(48) Octamethylcyclotetrasiloxane

(49) Benzene, Pentachloro

(50) C.I. Solvent yellow 14

(51) N-Methylpyrrolidone

(52) 2,2',3,3',4,4',5,5',6,6'-Decabromodiphenyl ether; BDE-209

(53) Perfluorooctanyl sulphonic acid and its salts; PFOS

(54) Phenol, 4-octyl

(55) 2-Ethyl-hexyl-4-methoxycinnamate

(56) Mercury and mercury compounds including methyl mercury (22967-92-6)

(57) Molybdenum and molybdenum compounds

(58) Antimony and Antimony compounds

(59) Arsenic and Arsenic compounds, including arsenic trioxide (1327-53-3) and dimethyl arsenic (75-60-5)

(60) Cadmium and cadmium compounds

(61) Cobalt and cobalt compounds

(62) Tris (1,3-dichloro-2-propyl) phosphate

(63) Butylated hydroxyanisole; BHA

(64) Hexabromocyclododecane

(65) Diisodecyl phthalate (DIDP)

(66) Diisononyl phthalate (DINP)

(67) Bisphenol S

(68) Dicyclohexyl phthalate

(69) Diisobutyl phthalate

(70) Triphenyl phosphate

(71) Tris (2,3-dibromopropyl) phosphate

(72) Tri-n-butyl phosphate

(73) Dipentyl phthalate

(74) Perfluorooctanoic acid

(75) Bisphenol F

(76) Ethylhexyl diphenyl phosphate

(77) Tricresyl phosphate

(78) Tris (1-chloro-2-propyl) phosphate

(79) Bis (2-ethylhexyl) tetrabromophthalate

(80) Bis (chloromethyl) propane-1,3-diyl tetrakis-(2-chloroethyl) bis (phosphate)

(81) Isopropylated triphenyl phosphate

(82) Decabromodiphenyl ethane

(83) Short-chain chlorinated paraffins; Chlorinated paraffins

(84) 2-ethylhexyl-2,3,4,5-tetrabromobenzoate

(85) Lead and lead compounds

(86) Di-(2-methoxyethyl) phthalate

6.0 Disclosure Notice

6.1 Any notice submitted under 18 V.S.A. § 1775 shall contain the following information:

6.1.1 The name of the chemical used or produced and its chemical abstracts service registry number (18 V.S.A. § 1775(b)(1));

6.1.2 A description of the product or product component containing the chemical. This description must include Global Product Classification (GPC) product brick description;

6.1.3 The brand name, product model, and the universal product code (UPC) if the product has such a code (18 V.S.A. § 1775(b)(2));

6.1.4 The amount of the chemical contained in each unit of the product or product component, reported by weight or parts per million as authorized by the Commissioner (18 V.S.A. § 1775(b)(3));

6.1.5 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 (18 V.S.A. § 1775(b)(4));

6.1.6 Any other information the manufacturer deems relevant to the appropriate use of the product (18 V.S.A. § 1775(b)(5));

6.1.7 The function of the chemical in the product;

7.0 Reporting Ranges

7.1 A manufacturer may report ranges of the amount of a chemical in a children's product, rather than the exact amount, provided that if there are multiple chemical values for a given component in a particular product category, the manufacturer shall use the largest value for reporting.

7.2 The ranges are as follows:

7.2.1 Equal to or more than the PQL but less than 100 ppm (0.01%).

7.2.2 Equal to or more than 100 ppm (0.01%) but less than 500 ppm (0.05%).

7.2.3 Equal to or more than 500 ppm (0.05%) but less than 1,000 ppm (0.1%).

7.2.4 Equal to or more than 1,000 (0.1%) ppm but less than 5,000 ppm (0.5%).

7.2.5 Equal to or more than 5,000 ppm (0.5%) but less than 10,000 ppm (1.0%).

7.2.6 Equal to or more than 10,000 ppm (1.0%).

8.0 Reporting Years and Periods

8.1 On or before January 31, 2022, and annually thereafter, a manufacturer of a children's product offered for sale or distribution in Vermont shall submit to the Department the notice described in Section 6.0 of this rule.

~~On or before August 31, 2020 and annually thereafter, a manufacturer of a children's product or a trade association representing a manufacturer of children's products, shall submit to the Department the notice described in Section 6.0 of this rule. The submission schedule is:~~

~~**8.1.1** Submission on or prior to August 31, 2020 for products offered for sale between September 1, 2018 and August 31, 2020;~~

~~**8.1.3** Submissions shall continue annually thereafter.~~

8.2 ~~Any manufacturer required to submit notices to the Department pursuant to 18 V.S.A. § 1775, must provide notices prior to August 31 of each year.~~

9.0 Reporting Between Annual Reporting Periods

9.1 On or before July 31 of every year, a manufacture of a children's products shall report all products introduced for sale or distribution in Vermont between January 31 and July 31 of that year in accordance with Section 6.0 of this rule

10.0 Evaluation of Chemicals for Listing as a Chemical of High Concern to Children

10.1 Adding a Chemical

The Commissioner may by rule add additional chemicals to the list of chemicals of high concern to children, provided that the Commissioner of Health, on the basis of credible, scientific evidence, including peer-reviewed studies, has determined that a chemical proposed for addition to the list meets both of the following:

10.1.1 An authoritative governmental entity or accredited research university has demonstrated that the chemical:

9.1.1.1 Harms the normal development of a fetus or child or causes other developmental toxicity;

9.1.1.2 Causes cancer, genetic damage, or reproductive harm;

9.1.1.3 Disrupts the endocrine system;

9.1.1.4 Damages the nervous system, immune system, or organs or causes other systemic toxicity; or

9.1.1.5 Is a persistent bioaccumulative toxic as defined in 18 V.S.A. § 1772 (14).

10.1.2 The chemical has been found through:

9.1.2.1 Biomonitoring to be present in human blood, umbilical cord blood, breast milk, urine, or other bodily tissues or fluids;

9.1.2.2 Sampling and analysis to be present in household dust, indoor air, drinking water, or elsewhere in the home environment; or

9.1.2.3 Monitoring to be present in fish, wildlife, or the natural environment.

10.2 Removing a Chemical

The Commissioner may by rule remove a chemical from the list of chemicals of high concern to children established under 18 V.S.A. § 1773 and this rule if the Commissioner determines that the chemical no longer meets the criteria found therein.

10.3 Process and Procedure to Add or Remove a Chemical

The Commissioner shall prepare a summary of evidence on the basis of credible, scientific evidence, including peer-reviewed studies. The summary shall reference all sources and shall be available to the public. The Commissioner may consult with the Chemicals of High Concern to Children Working Group for feedback on the summary of evidence.

11.0 Prioritization for Chemical Review

11. 1 Beginning on July 1, 2017 and biennially thereafter, the Commissioner of Health shall recommend at least two chemicals of high concern to children in children's products for review by the working group.

11.2 The Commissioner may recommend chemicals for review based on the degree of human health risks, exposure pathways, and impact on sensitive populations presented by a chemical of high concern to children, including but not limited to the following criteria:

11.2.1 Whether the chemical has been listed as a chemical of concern in statute or regulation or otherwise restricted by other states, the federal government, other countries, or other governmental bodies;

11.2.2 The disclosure data submitted to the Department of Health for the chemical.

12.0 Regulation of Sale or Distribution

12.1 The Commissioner, after consultation with the Chemicals of High Concern to Children Working Group, may adopt a rule to regulate the sale or distribution of a children's product containing a chemical of high concern to children upon a determination that:

12.1.1 Children may be exposed to a chemical of high concern to children in the children's product; and

12.1.2 There is a possibility that, due to the degree of exposure or frequency of exposure of a child to a chemical of high concern to children in a children's product, exposure could cause or contribute to one or more of the adverse health impacts listed under subsection 9.1.1.

12.2 In determining whether children may be exposed to a chemical of high concern in a children's product, the Commissioner shall review available, credible information regarding:

12.2.1 The market presence of the children's product in the State;

12.2.2 The type or occurrence of exposures to the relevant chemical of high concern to children in the children's product;

12.2.3 The household and workplace presence of the children's product; or

12.2.4 The potential and likelihood of exposure of children to the chemical of high concern to children in the children's product.

12.3 A rule adopted under this section may:

12.3.1 Prohibit the children's product containing the chemical of high concern to children from sale, offer for sale, or distribution in the State; or

12.3.2 Require that the children's product containing the chemical of high concern to children be labeled prior to sale, offer for sale, or distribution in the State.

12.4 In any rule adopted under this subsection, the Commissioner shall adopt reasonable time frames for manufacturers, distributors, and retailers to comply with the requirements of the rules. No prohibition on sale or manufacture of a children's product in the State shall take effect sooner than two years after the adoption of a rule adopted under this section unless the Commissioner determines that an earlier effective date is required to protect human health and the new effective date is established by rule.

13.0 Notice of Removal of Chemical

A manufacturer that submitted the notice required by law may at any time submit to the Department notice that a chemical of high concern to children has been removed from the manufacturer's children's product or that the manufacturer no longer sells, offers for sale, or distributes in the State the children's product containing the chemical of high concern to children. Upon verification of a manufacturer's notice, the Commissioner shall promptly remove from the Department website any reference to the relevant children's product of the manufacturer, for data that is reported prior to the offer for sale.

14.0 Disclosure of Information on Chemicals of High Concern

Notice of chemical of high concern to children. A manufacturer of a children's product or a trade association representing a manufacturer of children's products shall submit notice to the Department for each chemical of high concern to children in a children's product if a chemical of high concern to children is:

(1) intentionally added to a children's product at a level above the PQL produced by the manufacturer; or

(2) present in a children's product produced by the manufacturer as a contaminant at a concentration of 100 parts per million or greater.

Clean Copy

Chapter 6 – Environmental Health Rules
Subchapter 7

CHEMICALS OF HIGH CONCERN IN CHILDREN'S PRODUCTS RULE

1.0 Authority

This rule is adopted pursuant to 18 V.S.A § 1776.

2.0 Purpose

This rule provides the requirements for the disclosure and reporting of toxic substances that are intentionally added to a children's product at a level above the PQL produced by the manufacturer or are present in a children's product produced by the manufacturer as a contaminant at concentrations of 100 parts per million or greater. This rule also establishes the process by which a chemical may be added or removed from the list of Chemicals of High Concern to Children and the process by which a chemical might be banned for sale or distribution.

3.0 Scope

This rule applies to manufacturers of children products as defined by 18 V.S.A. § 1772(7) offered for sale in the State of Vermont.

4.0 Definitions

Any terms used in this rule but not defined in this section shall have the meaning found in 18 V.S.A. §1772. Whenever used in this rule, the following terms shall be construed as follows:

4.1 "Department" means the Vermont Department of Health.

4.2 "Commissioner" means the Commissioner of Health.

4.3 "Chemical of high concern to children" means a chemical listed under section 18 V.S.A. §1773 or designated by the Department as a chemical of high concern by this rule.

4.4 "Manufacturer" means any person who manufactures a children's product or whose name is affixed to a children's product or its packaging or advertising, and the children's product is sold or offered for sale in Vermont; or any person who sells a children's product to a retailer in Vermont when the person who manufactures the children's product or whose name is affixed to the children's product or its packaging or advertising does not have a presence in the United States other than the sale or offer for sale of the manufacturer's products.

4.5 "Practical quantification limit (PQL)" means the lowest concentration that can be

reliably measured within specified limits of precision, accuracy, representativeness, completeness, and comparability during routine laboratory operating conditions.

4.6 "Product component" means the uniquely identifiable material or coating (including ink or dye) that is intended to be included as part of a finished children's product.

4.7 "Product model" means the specific product name used by the retailer or assembler to place the product into the stream of commerce.

4.8 "Contaminant" means a trace amount of a chemical or chemicals that is incidental to manufacturing and serves no intended function in the children's product or component of the children's product, including an unintended by-product of chemical reactions during the manufacture of the children's product, a trace impurity in feed-stock, an incompletely reacted chemical mixture, and a degradation product.

5.0 Chemicals of High Concern to Children

The following chemicals are designated as chemicals of high concern to children:

(1) Formaldehyde and substances that are intentionally added to release formaldehyde, including 5-Bromo-5-nitro-1,3-dioxane, Bronopol, Diazolidinyl urea, DMDM hydantoin, Imidazolidinyl urea, Methanol, (phenylmethoxy), Methenamine, Quaternium-15, and Sodium N-(hydroxymethyl)glycinate

(2) Aniline

(3) N-Nitrosodimethylamine

(4) Benzene

(5) Vinyl chloride

(6) Acetaldehyde

(7) Methylene chloride

(8) Carbon disulfide

(9) Methyl ethyl ketone

(10) 1,1,2,2-Tetrachloroethane

(11) Tetrabromobisphenol A

(12) Bisphenol A

(13) Diethyl phthalate

(14) Dibutyl phthalate

(15) Di-n-hexyl phthalate

(16) Phthalic anhydride

(17) Butyl benzyl phthalate (BBP)

(18) N-Nitrosodiphenylamine

(19) Hexachlorobutadiene

(20) Propyl paraben

(21) Butyl paraben

(22) 2-Aminotoluene

(23) 2,4-Diaminotoluene

(24) Methyl paraben

(25) p-Hydroxybenzoic acid

(26) Ethylbenzene

(27) Styrene

(28) 4-Nonylphenol; 4-NP and its isomer mixtures including CAS 84852-15-3 and CAS 25154-52-3

(29) para-Chloroaniline

(30) Acrylonitrile

(31) Ethylene glycol

(32) Toluene

(33) Phenol

(34) 2-Methoxyethanol

(35) Ethylene glycol monoethyl ether

(36) Tris (2-chloroethyl) phosphate

(37) Di-2-ethylhexyl phthalate

(38) Di-n-octyl phthalate (DnOP)

(39) Hexachlorobenzene

(40) 3,3'-Dimethylbenzidine and Dyes Metabolized to 3,3'-Dimethylbenzidine

(41) Ethyl paraben

(42) 1,4-Dioxane

(43) Perchloroethylene

(44) Benzophenone-2 (Bp-2); 2,2',4,4'-Tetrahydroxybenzophenone

(45) 4-tert-Octylphenol; 4 (1,1,3,3-Tetramethylbutyl) phenol

(46) Estragole

(47) 2-Ethylhexanoic acid

(48) Octamethylcyclotetrasiloxane

(49) Benzene, Pentachloro

(50) C.I. Solvent yellow 14

(51) N-Methylpyrrolidone

(52) 2,2',3,3',4,4',5,5',6,6'-Decabromodiphenyl ether; BDE-209

(53) Perfluorooctanyl sulphonic acid and its salts; PFOS

(54) Phenol, 4-octyl

(55) 2-Ethyl-hexyl-4-methoxycinnamate

(56) Mercury and mercury compounds including methyl mercury (22967-92-6)

(57) Molybdenum and molybdenum compounds

(58) Antimony and Antimony compounds

(59) Arsenic and Arsenic compounds, including arsenic trioxide (1327-53-3) and dimethyl arsenic (75-60-5)

(60) Cadmium and cadmium compounds

(61) Cobalt and cobalt compounds

(62) Tris (1,3-dichloro-2-propyl) phosphate

(63) Butylated hydroxyanisole; BHA

(64) Hexabromocyclododecane

(65) Diisodecyl phthalate (DIDP)

(66) Diisononyl phthalate (DINP)

(67) Bisphenol S

(68) Dicyclohexyl phthalate

(69) Diisobutyl phthalate

(70) Triphenyl phosphate

(71) Tris (2,3-dibromopropyl) phosphate

(72) Tri-n-butyl phosphate

(73) Dipentyl phthalate

(74) Perfluorooctanoic acid

(75) Bisphenol F

(76) Ethylhexyl diphenyl phosphate

(77) Tricresyl phosphate

(78) Tris (1-chloro-2-propyl) phosphate

(79) Bis (2-ethylhexyl) tetrabromophthalate

(80) Bis (chloromethyl) propane-1,3-diyl tetrakis-(2-chloroethyl) bis (phosphate)

(81) Isopropylated triphenyl phosphate

(82) Decabromodiphenyl ethane

(83) Short-chain chlorinated paraffins; Chlorinated paraffins

(84) 2-ethylhexyl-2,3,4,5-tetrabromobenzoate

(85) Lead and lead compounds

(86) Di-(2-methoxyethyl) phthalate

6.0 Disclosure Notice

6.1 Any notice submitted under 18 V.S.A. § 1775 shall contain the following information:

6.1.1 The name of the chemical used or produced and its chemical abstracts service registry number (18 V.S.A. § 1775(b)(1));

6.1.2 A description of the product or product component containing the chemical. This description must include Global Product Classification (GPC) product brick description;

6.1.3 The brand name, product model, and the universal product code (UPC) if the product has such a code (18 V.S.A. § 1775(b)(2));

6.1.4 The amount of the chemical contained in each unit of the product or product component, reported by weight or parts per million as authorized by the Commissioner (18 V.S.A. § 1775(b)(3));

6.1.5 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 (18 V.S.A. § 1775(b)(4));

6.1.6 Any other information the manufacturer deems relevant to the appropriate use of the product (18 V.S.A. § 1775(b)(5));

6.1.7 The function of the chemical in the product;

7.0 Reporting Ranges

7.1 A manufacturer may report ranges of the amount of a chemical in a children's product, rather than the exact amount, provided that if there are multiple chemical values for a given component in a particular product category, the manufacturer shall use the largest value for reporting.

7.2 The ranges are as follows:

7.2.1 Equal to or more than the PQL but less than 100 ppm (0.01%).

7.2.2 Equal to or more than 100 ppm (0.01%) but less than 500 ppm (0.05%).

7.2.3 Equal to or more than 500 ppm (0.05%) but less than 1,000 ppm (0.1%).

7.2.4 Equal to or more than 1,000 (0.1%) ppm but less than 5,000 ppm (0.5%).

7.2.5 Equal to or more than 5,000 ppm (0.5%) but less than 10,000 ppm (1.0%).

7.2.6 Equal to or more than 10,000 ppm (1.0%).

8.0 Reporting Years and Periods

8.1 On or before January 31, 2022, and annually thereafter, a manufacturer of a children's product offered for sale or distribution in Vermont shall submit to the Department the notice described in Section 6.0 of this rule.

9.0 Reporting Between Annual Reporting Periods

9.1 On or before July 31 of every year, a manufacture of a children's products shall report all products introduced for sale or distribution in Vermont between January 31 and July 31 of that year in accordance with Section 6.0 of this rule.

10.0 Evaluation of Chemicals for Listing as a Chemical of High Concern to Children

10.1 Adding a Chemical

The Commissioner may by rule add additional chemicals to the list of chemicals of high concern to children, provided that the Commissioner of Health, on the basis of credible, scientific evidence, including peer-reviewed studies, has determined that a chemical proposed for addition to the list meets both of the following:

10.1.1 An authoritative governmental entity or accredited research university has demonstrated that the chemical:

10.1.1.1 Harms the normal development of a fetus or child or causes other developmental toxicity;

10.1.1.2 Causes cancer, genetic damage, or reproductive harm;

10.1.1.3 Disrupts the endocrine system;

10.1.1.4 Damages the nervous system, immune system, or organs or causes other systemic toxicity; or

10.1.1.5 Is a persistent bioaccumulative toxic as defined in 18 V.S.A. § 1772 (14).

10.1.2 The chemical has been found through:

10.1.2.1 Biomonitoring to be present in human blood, umbilical cord blood, breast milk, urine, or other bodily tissues or fluids;

10.1.2.2 Sampling and analysis to be present in household dust, indoor air, drinking water, or elsewhere in the home environment; or

10.1.2.3 Monitoring to be present in fish, wildlife, or the natural environment.

10.2 Removing a Chemical

The Commissioner may by rule remove a chemical from the list of chemicals of high concern to children established under 18 V.S.A. § 1773 and this rule if the Commissioner determines that the chemical no longer meets the criteria found therein.

10.3 Process and Procedure to Add or Remove a Chemical

The Commissioner shall prepare a summary of evidence on the basis of credible, scientific evidence, including peer-reviewed studies. The summary shall reference all sources and shall be available to the public. The Commissioner may consult with the Chemicals of High Concern to Children Working Group for feedback on the summary of evidence.

11.0 Prioritization for Chemical Review

11. 1 Beginning on July 1, 2017 and biennially thereafter, the Commissioner of Health shall recommend at least two chemicals of high concern to children in children's products for review by the working group.

11.2 The Commissioner may recommend chemicals for review based on the degree of human health risks, exposure pathways, and impact on sensitive populations presented by a chemical of high concern to children, including but not limited to the following criteria:

11.2.1 Whether the chemical has been listed as a chemical of concern in statute or regulation or otherwise restricted by other states, the federal government, other countries, or other governmental bodies;

11.2.2 The disclosure data submitted to the Department of Health for the chemical.

12.0 Regulation of Sale or Distribution

12.1 The Commissioner, after consultation with the Chemicals of High Concern to Children Working Group, may adopt a rule to regulate the sale or distribution of a children's product containing a chemical of high concern to children upon a determination that:

12.1.1 Children may be exposed to a chemical of high concern to children in the children's product; and

12.1.2 There is a possibility that, due to the degree of exposure or frequency of exposure of a child to a chemical of high concern to children in a children's product, exposure could cause or contribute to one or more of the adverse health impacts listed under subsection 9.1.1.

12.2 In determining whether children may be exposed to a chemical of high concern in a children's product, the Commissioner shall review available, credible information regarding:

12.2.1 The market presence of the children's product in the State;

12.2.2 The type or occurrence of exposures to the relevant chemical of high concern to children in the children's product;

12.2.3 The household and workplace presence of the children's product; or

12.2.4 The potential and likelihood of exposure of children to the chemical of high concern to children in the children's product.

12.3 A rule adopted under this section may:

12.3.1 Prohibit the children's product containing the chemical of high concern to children from sale, offer for sale, or distribution in the State; or

12.3.2 Require that the children's product containing the chemical of high concern to children be labeled prior to sale, offer for sale, or distribution in the State.

12.4 In any rule adopted under this subsection, the Commissioner shall adopt reasonable time frames for manufacturers, distributors, and retailers to comply with the requirements of the rules. No prohibition on sale or manufacture of a children's product in the State shall take effect sooner than two years after the adoption of a rule adopted under this section unless the Commissioner determines that an earlier effective date is required to protect human health and the new effective date is established by rule.

13.0 Notice of Removal of Chemical

A manufacturer that submitted the notice required by law may at any time submit to the Department notice that a chemical of high concern to children has been removed from the manufacturer's children's product or that the manufacturer no longer sells, offers for sale, or distributes in the State the children's product containing the chemical of high concern to children. Upon verification of a manufacturer's notice, the Commissioner shall promptly remove from the Department website any reference to the relevant children's product of the manufacturer, for data that is reported prior to the offer for sale.

14.0 Disclosure of Information on Chemicals of High Concern

Notice of chemical of high concern to children. A manufacturer of a children's product or a trade association representing a manufacturer of children's products shall submit notice to the Department for each chemical of high concern to children in a children's product if a chemical of high concern to children is:

(1) intentionally added to a children's product at a level above the PQL produced by the manufacturer; or

(2) present in a children's product produced by the manufacturer as a contaminant at a concentration of 100 parts per million or greater.

VERMONT **GENERAL ASSEMBLY**

The Vermont Statutes Online

Title 3 : Executive

Chapter 025 : Administrative Procedure

Subchapter 001 : General Provisions

(Cite as: 3 V.S.A. § 801)

§ 801. Short title and definitions

(a) This chapter may be cited as the "Vermont Administrative Procedure Act."

(b) As used in this chapter:

(1) "Agency" means a State board, commission, department, agency, or other entity or officer of State government, other than the Legislature, the courts, the Commander in Chief, and the Military Department, authorized by law to make rules or to determine contested cases.

(2) "Contested case" means a proceeding, including but not restricted to rate-making and licensing, in which the legal rights, duties, or privileges of a party are required by law to be determined by an agency after an opportunity for hearing.

(3) "License" includes the whole or part of any agency permit, certificate, approval, registration, charter, or similar form of permission required by law.

(4) "Licensing" includes the agency process respecting the grant, denial, renewal, revocation, suspension, annulment, withdrawal, or amendment of a license.

(5) "Party" means each person or agency named or admitted as a party, or properly seeking and entitled as of right to be admitted as a party.

(6) "Person" means any individual, partnership, corporation, association, governmental subdivision, or public or private organization of any character other than an agency.

(7) "Practice" means a substantive or procedural requirement of an agency, affecting one or more persons who are not employees of the agency, that is used by the agency in the discharge of its powers and duties. The term includes all such requirements, regardless of whether they are stated in writing.

(8) "Procedure" means a practice that has been adopted in writing, either at the election of the agency or as the result of a request under subsection 831(b) of this title. The term includes any practice of any agency that has been adopted in writing, whether or not labeled as a procedure, except for each of the following:

(A) a rule adopted under sections 836-844 of this title;

(B) a written document issued in a contested case that imposes substantive or procedural requirements on the parties to the case;

(C) a statement that concerns only:

(i) the internal management of an agency and does not affect private rights or procedures available to the public;

(ii) the internal management of facilities that are secured for the safety of the public and the individuals residing within them; or

(iii) guidance regarding the safety or security of the staff of an agency or its designated service providers or of individuals being provided services by the agency or such a provider;

(D) an intergovernmental or interagency memorandum, directive, or communication that does not affect private rights or procedures available to the public;

(E) an opinion of the Attorney General; or

(F) a statement that establishes criteria or guidelines to be used by the staff of an agency in performing audits, investigations, or inspections, in settling commercial disputes or negotiating commercial arrangements, or in the defense, prosecution, or settlement of cases, if disclosure of the criteria or guidelines would compromise an investigation or the health and safety of an employee or member of the public, enable law violators to avoid detection, facilitate disregard of requirements imposed by law, or give a clearly improper advantage to persons that are in an adverse position to the State.

(9) "Rule" means each agency statement of general applicability that implements, interprets, or prescribes law or policy and that has been adopted in the manner provided by sections 836-844 of this title.

(10) "Incorporation by reference" means the use of language in the text of a regulation that expressly refers to a document other than the regulation itself.

(11) "Adopting authority" means, for agencies that are attached to the Agencies of Administration, of Commerce and Community Development, of Natural Resources, of Human Services, and of Transportation, or any of their

components, the secretaries of those agencies; for agencies attached to other departments or any of their components, the commissioners of those departments; and for other agencies, the chief officer of the agency. However, for the procedural rules of boards with quasi-judicial powers, for the Transportation Board, for the Vermont Veterans' Memorial Cemetery Advisory Board, and for the Fish and Wildlife Board, the chair or executive secretary of the board shall be the adopting authority. The Secretary of State shall be the adopting authority for the Office of Professional Regulation.

(12) "Small business" means a business employing no more than 20 full-time employees.

(13)(A) "Arbitrary," when applied to an agency rule or action, means that one or more of the following apply:

(i) There is no factual basis for the decision made by the agency.

(ii) The decision made by the agency is not rationally connected to the factual basis asserted for the decision.

(iii) The decision made by the agency would not make sense to a reasonable person.

(B) The General Assembly intends that this definition be applied in accordance with the Vermont Supreme Court's application of "arbitrary" in *Beyers v. Water Resources Board*, 2006 VT 65, and *In re Town of Sherburne*, 154 Vt. 596 (1990).

(14) "Guidance document" means a written record that has not been adopted in accordance with sections 836-844 of this title and that is issued by an agency to assist the public by providing an agency's current approach to or interpretation of law or describing how and when an agency will exercise discretionary functions. The term does not include the documents described in subdivisions (8)(A) through (F) of this section.

(15) "Index" means a searchable list of entries that contains subjects and titles with page numbers, hyperlinks, or other connections that link each entry to the text or document to which it refers. (Added 1967, No. 360 (Adj. Sess.), § 1, eff. July 1, 1969; amended 1981, No. 82, § 1; 1983, No. 158 (Adj. Sess.), eff. April 13, 1984; 1985, No. 56, § 1; 1985, No. 269 (Adj. Sess.), § 4; 1987, No. 76, § 18; 1989, No. 69, § 2, eff. May 27, 1989; 1989, No. 250 (Adj. Sess.), § 88; 2001, No. 149 (Adj. Sess.), § 46, eff. June 27, 2002; 2017, No. 113 (Adj. Sess.), § 3; 2017, No. 156 (Adj. Sess.), § 2.)

VERMONT **GENERAL ASSEMBLY**

The Vermont Statutes Online

Title 18 : Health

Chapter 038A : Chemicals Of High Concern To Children

(Cite as: 18 V.S.A. § 1776)

§ 1776. Rulemaking; additional chemicals of concern to children; prohibition of sale

(a) Rulemaking authority. The Commissioner shall, after consultation with the Secretary of Natural Resources, adopt rules as necessary for the purposes of implementing, administering, or enforcing the requirements of this chapter.

(b) Additional chemicals of concern to children. The Commissioner may by rule add additional chemicals to the list of chemicals of high concern to children, provided that the Commissioner of Health, on the basis of credible, scientific evidence, including peer-reviewed studies, has determined that a chemical proposed for addition to the list meets both of the following criteria in subdivisions (1) and (2) of this subsection:

(1) The Commissioner of Health has determined that an authoritative governmental entity or accredited research university has demonstrated that the chemical:

(A) harms the normal development of a fetus or child or causes other developmental toxicity;

(B) causes cancer, genetic damage, or reproductive harm;

(C) disrupts the endocrine system;

(D) damages the nervous system, immune system, or organs or causes other systemic toxicity; or

(E) is a persistent bioaccumulative toxic.

(2) The chemical has been found through:

(A) biomonitoring to be present in human blood, umbilical cord blood, breast milk, urine, or other bodily tissues or fluids;

(B) sampling and analysis to be present in household dust, indoor air, drinking water, or elsewhere in the home environment; or

(C) monitoring to be present in fish, wildlife, or the natural environment.

(c) Removal of chemical from list. The Commissioner may by rule remove a chemical from the list of chemicals of high concern to children established under section 1773 of this title or rules adopted under this section if the Commissioner determines that the chemical no longer meets both of the criteria of subdivisions (b)(1) and (2) of this section.

(d) Rule to regulate sale or distribution.

(1) The Commissioner, after consultation with the Chemicals of High Concern to Children Working Group, may adopt a rule to regulate the sale or distribution of a children's product containing a chemical of high concern to children upon a determination that:

(A) children may be exposed to a chemical of high concern to children in the children's product; and

(B) there is a possibility that, due to the degree of exposure or frequency of exposure of a child to a chemical of high concern to children in a children's product, exposure could cause or contribute to one or more of the adverse health impacts listed under subdivision (b)(1) of this section.

(2) In determining whether children may be exposed to a chemical of high concern in a children's product, the Commissioner shall review available, credible information regarding:

(A) the market presence of the children's product in the State;

(B) the type or occurrence of exposures to the relevant chemical of high concern to children in the children's product;

(C) the household and workplace presence of the children's product; or

(D) the potential and likelihood of exposure of children to the chemical of high concern to children in the children's product.

(3) A rule adopted under this section may:

(A) prohibit the children's product containing the chemical of high concern to children from sale, offer for sale, or distribution in the State; or

(B) require that the children's product containing the chemical of high concern to children be labeled prior to sale, offer for sale, or distribution in the State.

(4) In any rule adopted under this subsection, the Commissioner shall adopt reasonable time frames for manufacturers, distributors, and retailers to comply with the requirements of the rules. No prohibition on sale or manufacture of a children's product in the State shall take effect sooner than two years after the adoption of a rule adopted under this section unless the Commissioner determines that an earlier effective date is required to protect human health and the new effective date is established by rule.

(5) The Chemicals of High Concern to Children Working Group may, at its discretion, submit to the House Committees on Natural Resources, Fish, and Wildlife and on Human Services and the Senate Committees on Natural Resources and Energy and on Health and Welfare the recommendations or information from a consultation provided to the Commissioner under subdivision (1) of this subsection.

(e) Exemption for chemical management strategy. In adopting a rule under this section, the Commissioner may exempt from regulation a children's product containing a chemical of high concern to children if the manufacturer of the children's product is implementing a comprehensive chemical management strategy designed to eliminate harmful substances or chemicals from the manufacturing process.

(f) Additional rules.

(1) The Commissioner of Health shall adopt by rule the process and procedure to be required when the Commissioner of Health adopts a rule under subsection (b), (c), or (d) of this section. The rule shall provide:

(A) all relevant criteria for evaluation of the chemical;

(B) criteria by which a chemical, due to its presence in the environment or risk of harm, shall be prioritized for addition or removal from the list of chemicals of high concern to children or for regulation under subsection (d) of this section;

(C) time frames for labeling or phasing out sale or distribution;

(D) requirements for when and how a manufacturer of a children's product that contains a chemical of high concern to children provides the notice required under subsection 1775(a) of this title when the manufacturer intends to introduce the children's product for sale between the required dates for reporting; and

(E) other information or process determined as necessary by the Commissioner for implementation of this chapter.

(2) The Commissioner may, by rule, authorize a manufacturer to report ranges of the amount of a chemical in a children's product, rather than the exact amount, provided that if there are multiple chemical values for a given component in a particular product category, the manufacturer shall use the largest value for reporting.

(3) Notwithstanding the required reporting dates under section 1774 of this title, the Commissioner may adopt by rule phased-in reporting requirements for chemicals of high concern to children in children's products based on the size of the manufacturer, aggregate sales of children's products, or the exposure profile of the chemical of high concern to children in the children's product.

(g) Additional public participation. In addition to the public participation requirements of 3 V.S.A. chapter 25 and prior to submitting a rule authorized under this section to the Secretary of State under 3 V.S.A. § 838, the Commissioner shall make reasonable efforts to consult with interested parties within the State regarding any proposed prohibition of a chemical of high concern to children. The Commissioner may satisfy the consultation requirement of this section through the use of one or more workshops, focused work groups, dockets, meetings, or other forms of communication. (Added 2013, No. 188 (Adj. Sess.), § 2, eff. June 10, 2014; amended 2019, No. 75, § 5, eff. June 19, 2019.)

VERMONT

Proposed Rules Postings
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Search Rules

Deadline For Public Comment

Deadline: Dec 11, 2019

Please submit comments to the agency or primary contact person listed below, before the deadline.

Rule Details

Rule Number:	19P074
Title:	Chemicals of High Concern in Children's Products Rule.
Type:	Standard
Status:	Proposed
Agency:	Department of Health, Agency of Human Services
Legal Authority:	3 V.S.A. § 801(b)(11); and 18 V.S.A. § 1776.
Summary:	This proposal expands the definition of formaldehyde to include "formaldehyde donors", which are the substances that are intentionally added to a product to degrade to and release formaldehyde as a preservative. Per Act 75 (2019) § 5, this proposal also establishes the requirements for when and how a manufacturer of a children's product provides the notice required under subsection 1775(a) of this title when the manufacturer intends to introduce the children's product for sale between the required dates for reporting.
Persons Affected:	Manufacturers of children's products, Department of Health, children's product retailers, and consumers and users of children's products.
Economic Impact:	This rule imposes no economic burden to the regulated community beyond the existing statutory requirements and legislative directive. There is a de minimis cost associated with the reporting fee required by statutes when a listed chemical is used in children's products. (as of October 2019, the fee is $200 per listed chemical, per manufacturer.) If a manufacturer introduces for sale between

reporting periods a product which contains a chemical of high concern to children that has not already been reported by the manufacturer, the cost would be an additional $200 (in total, not annually).

Posting date: Oct 30,2019

Hearing Information

Information for Hearing # 1

Hearing date: 12-04-2019 1:00 PM ADD TO YOUR CALENDAR

Location: Vermont Department of Health, Room 3B
Address: 108 Cherry Street
City: Burlington
State: VT
Zip: 05401
Hearing Notes:

Contact Information

Information for Contact # 1

Level: Primary
Name: David Englander
Agency: Department of Health, Agency of Human Services
Address: 108 Cherry Street
City: Burlington
State: VT
Zip: 05401
Telephone: 802-863-7280
Fax: 802-951-1275
Email: ahs.vdhrules@vermont.gov
SEND A COMMENT
Website Address: http://www.healthvermont.gov/about-us/laws-regulations/rules-and-regulations
VIEW WEBSITE

Information for Contact # 2

Level: Secondary
Name: Brendan Atwood
Agency: Department of Health, Agency of Human Services
Address: 108 Cherry Street
City: Burlington
State: VT
Zip: 05401
Telephone: 802-863-7280
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Email: ahs.vdhrules@vermont.gov
SEND A COMMENT

Keyword Information

Keywords:

Toxics
Toxic sub[Back]children's products
Children's products
Chemicals of high concern
Formaldehyde
Formaldehyde donors

19-P94

OFFICE OF THE SECRETARY OF STATE

VERMONT STATE ARCHIVES & RECORDS ADMINISTRATION

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	The Islander (islander@vermontislander.com)	Tel: 802-372-5600 FAX: 802-372-3025
	Vermont Lawyer (hunter.press.vermont@gmail.com)	Attn: Will Hunter

FROM: Louise Corliss, APA Clerk **Date of Fax:** November 7, 2019

RE: The "Proposed State Rules " ad copy to run on **November 7, 2019**

PAGES INCLUDING THIS COVER MEMO: **2**

NOTE **8-pt font in body. 12-pt font max. for headings - single space body. Please include dashed lines where they appear in ad copy. Otherwise minimize the use of white space. Exceptions require written approval.**

If you have questions, or if the printing schedule of your paper is disrupted by holiday etc. please contact Louise Corliss at 802-828-2863, or E-Mail louise.corliss@vermont.gov, Thanks.

PROPOSED STATE RULES

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By law, public notice of proposed rules must be given by publication in newspapers of record. The purpose of these notices is to give the public a chance to respond to the proposals. The public notices for administrative rules are now also available online at https://secure.vermont.gov/SOS/rules/ . The law requires an agency to hold a public hearing on a proposed rule, if requested to do so in writing by 25 persons or an association having at least 25 members.

To make special arrangements for individuals with disabilities or special needs please call or write the contact person listed below as soon as possible.

To obtain further information concerning any scheduled hearing(s), obtain copies of proposed rule(s) or submit comments regarding proposed rule(s), please call or write the contact person listed below. You may also submit comments in writing to the Legislative Committee on Administrative Rules, State House, Montpelier, Vermont 05602 (802-828-2231).

Chemicals of High Concern in Children's Products Rule.

Vermont Proposed Rule: 19P074

AGENCY: Agency of Human Services, Department of Health

CONCISE SUMMARY: This proposal expands the definition of formaldehyde to include "formaldehyde donors", which are the substances that are intentionally added to a product to degrade to and release formaldehyde as a preservative. Per Act 75 (2019) § 5, this proposal also establishes the requirements for when and how a manufacturer of a children's product provides the notice required under subsection 1775(a) of this title when the manufacturer intends to introduce the children's product for sale between the required dates for reporting.

FOR FURTHER INFORMATION, CONTACT: David Englander, Department of Health 108 Cherry Street, Burlington, VT 05401 Tel: 802-863-7280 Fax: 802-951-1275 Email: ahs.vdhrules@vermont.gov URL: http://www.healthvermont.gov/about-us/laws-regulations/rules-and-regulations.

FOR COPIES: Brendan Atwood, Department of Health, 108 Cherry Street, Burlington, VT 05401 Tel: 802-863-7280 Fax: 802-951-1275 Email: ahs.vdhrules@vermont.gov. ----------

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Combined Newspaper Advertisement for AHS Administrative Rulemaking

The four rules below are being promulgated by the Agency of Human Services (AHS) which has requested the notices be combined to facilitate a savings for the agency. When contacting AHS about these rules, please note the title and rule number of the rule(s) you are interested in.

Amended:

- Ambulance Services : **19P075**
- Non-Emergency Medical Transportation : **19P076**
- Medical Necessity for Covered Services: **19P077**
- Early and Periodic Screening, Diagnostic and Treatment: **19P078**

AGENCY: Agency of Human Services

(802) 828-2863

MEMORANDUM OFFICE OF THE SECRETARY OF STATE

Primary Contact: David Englander, Department of Health 108 Cherry Street, Burlington, VT 05401 Tel: 802-863-7280 Fax: 802-951-1275 Email: ahs.vdhrules@vermont.gov

Secondary Contact: Brendan Atwood, Department of Health, 108 Cherry Street, Burlington, VT 05401 Tel: 802-863-7280 Fax: 802-951-1275 Email: ahs.vdhrules@vermont.gov.

URL: http://www.healthvermont.gov/about-us/laws-regulations/rules-and-regulations

From: Louise Corliss, APA Clerk

RE: Chemicals of High Concern in Children's Products Rule.

Date 10/23/2019

We received Proposed Rule on 10/22/2019
Final Proposed Rule on
Adopted Rule on
We have assigned the following rule number(s):
Proposed Rule Number: 19P074
Adopted Rule Number:
(Final Proposals are not assigned a new number; they retain the Proposed Rule Number.)

The following problems were taken care of by phone/should be taken care of immediately:

We cannot accept this filing until the following problems are taken care of:

The ad for this proposed rule appeared/will appear in newspapers of record on 11/07/2019 & / / .

This rule takes effect on
Adoption Deadline: 06/22/2020

Please note: URL was missing the last 2 characters, SOS staff added the characters and tested the URL for functionality.

If you have any questions, please call me at 828-2863. OR
E-Mail me at: louise.corliss@vermont.gov

cc: Charlene Dindo