FluoroCouncil
Global Industry Council for FluoroTechnology

July 12, 2018

Dr. Brian Penttila
Washington State Department of Ecology
Hazardous Waste & Toxics Reduction Program
Reducing Toxic Threats Section
PO Box 47600
Olympia, WA 98504-7600

Re: Comments on Ecology's Implementation of HB 2658

Dear Dr. Penttila:

Under recently enacted HB 2658, Washington State Department of Ecology (Ecology) has been given the responsibility of preparing an alternatives assessment (AA) for food packaging that contains intentionally-added PFAS chemicals.[1] As a result of this AA, it is possible that consumers and businesses in Washington State may be deprived of a number of packaging options that have been reviewed by the US Food and Drug Administration (FDA) and proven safe and effective. Because of this, it is essential that the AA is conducted in a manner that is sound, transparent, and faithful to the requirements set forth by the legislature in HB 2658. FluoroCouncil[2] offers the comments contained in this letter to help ensure the integrity and legitimacy of the AA being undertaken by Ecology.

Interstate Chemicals Clearinghouse Guidance

HB 2658 directs Ecology to "follow[] the guidelines for alternatives assessments issued by" the Interstate Chemicals Clearinghouse (IC2), which are set forth in the IC2 Alternatives Assessment Guide (IC2 Guide).[3] The IC2 Guide provides a flexible framework for conducting an AA, which allows the assessor to pick and choose appropriate modules. However, the Guide also identifies several core principles,[4] as well as four specific modules that "should be included in all AAs."[5]

---

[1] For purposes of HB 2658, the term "PFAS chemicals" is defined in Section 1(5) to mean "a class of fluorinated organic chemicals containing at least one fully fluorinated carbon atom."
[2] FluoroCouncil's member companies are Archroma Management LLC, Arkema France, AGC Inc., Daikin Industries, Ltd., Solvay Specialty Polymers, The Chemours Company LLC, Dynax (associate), and Tyco Fire Products LP (associate).
[3] Interstate Chemicals Clearinghouse Alternatives Assessment Guide, Interstate Chemicals Clearinghouse, January 2017, version 1.1, 183 pages, available at: http://www.theic2.org/alternatives_assessment_guide (hereinafter "IC2 Guide").
[4] IC2 Guide at 3-4.
[5] *Id*. at 3.

Stakeholder Participation

Among the core principles identified in the IC2 Guide is the need for transparency, which is linked to stakeholder involvement in the AA process. According to the IC2 Guide, the assessor should determine "whether stakeholder involvement would improve the process and, if so, to what degree [level] stakeholders will be involved."[6] With respect to HB 2658, stakeholder involvement is essential to ensuring the integrity and reliability of the AA. In particular, because the AA may result in the elimination of packaging options that have been available to Washington State consumers and business for decades, input from those stakeholders is critical to forming a fair and accurate assessment of the suitability, cost, and availability of potential alternatives to those packaging options. It is difficult to conceive of an adequate assessment that does not include input from these stakeholders.

Similarly, without stakeholder participation, it will be impossible for Ecology to conduct an accurate hazard evaluation. For example, the PFAS chemicals that are used in food packaging today have been reviewed by FDA (and, in many cases, the US Environmental Protection Agency (EPA), as well) and they are supported by numerous toxicity and exposure studies. These studies, which conform with OECD and/or FDA or EPA guidelines and good laboratory practice (GLP) standards, have been reviewed and accepted by federal regulatory authorities; however, for confidentiality or other reasons, these studies may not be available in the published literature. Any hazard assessment that fails to take into account such data would be inherently flawed and unreliable. Adequate opportunities for stakeholder participation will be essential to ensuring that these highly relevant data are included in the AA.

Because adequate stakeholder involvement is crucial to conducting a valid AA under HB 2658, we urge Ecology to ensure that stakeholders have opportunities to provide comment on: (i) the alternatives being considered as part of the AA and the specific packaging and PFAS chemical(s) against which those alternatives are being compared; (ii) the specific data being used to characterize the hazards associated with the alternatives and the PFAS chemicals against which they are being compared; (iii) the exposure information being used to characterize exposures to alternatives and the PFAS chemicals against which they are being compared; and (iv) the parameters used to compare the performance of the alternatives against the performance of the PFAS chemicals being assessed. In addition, after a draft AA has been prepared, Ecology should make that draft AA available for public comment – to ensure that all appropriate, relevant information has been adequately considered. Finally, if the peer review required under HB 2658 results in any recommended changes to the draft AA, those recommendations should also be subject to public comment.

Hazard Assessment

[6] *Id.* at 7.

The universe of PFAS chemicals is comprised of several thousand distinct substances with widely varying chemical and physical properties and toxicities.[7] Importantly, only a handful of these substances (less than three dozen) are allowed to be used in food packaging. These substances (termed "food contact substances" under the Federal Food Drug and Cosmetics Act (FFDCA)) have been rigorously reviewed by FDA and are supported by extensive data demonstrating their safety.

The IC2 Guide explains that the hazard assessment module of the AA is intended to allow the assessor to determine what hazards exist "for the chemical of concern in a product or process."[8] Consistent with this guidance, the hazard assessment conducted by Ecology as part of the AA must focus on the specific PFAS chemicals that are actually used in food packaging. It would be inappropriate and scientifically unjustifiable for the AA to examine hazards that may be associated with any of the thousands of PFAS chemicals ***other than*** those specific chemicals that have been reviewed by FDA and can lawfully be used in food packaging. Cherry-picking data on substances ***other than*** the handful of substances specifically allowed for use in food packaging would be especially egregious, given the large body of scientific data that has been developed on those FDA-reviewed substances.

Materials Management and Life Cycle Considerations

The IC2 Guide provides for the inclusion of two additional "modules" when appropriate: the Materials Management Module and the Life Cycle Module. The Materials Management Module "evaluates how a potential alternative will impact natural resources and generate . . . waste." The Life Cycle Module is used "to gather information about the entire product life cycle" and can "help avoid the shifting of impacts across the life cycle."[9] Given the large volume of waste generated each year that is associated with food and food packaging, the inclusion of these two modules in the AA conducted by Ecology is essential to understanding the true health and environmental impacts associated with any alternatives to current packaging options.

For example, cellulose fiber packaging, including paper, board, and molded pulp, has many benefits, including being derived from a renewable resource, sequestering carbon, being recyclable, as well as being light and strong. One of the key engineering challenges in utilizing cellulose fiber packaging stems from the complete lack of this substrate's ability to resist oil and grease penetration that is required in many food packaging applications. Several chemical and physical barriers exist that can be incorporated into cellulose-fiber food packaging to overcome this performance flaw; however, some of these add-on barriers remove the ability of this type of packaging to meet the above-stated goals. A specific example of this is crystalline PET (CPET) film that is frequently applied to either molded pulp or board food packaging. The CPET creates a physical barrier against oil and grease, but the finished package is no longer recyclable or compostable and is only suitable for landfill. The PFAS chemicals permitted for use on food

---

[7] *See* Department of Ecology, Interim Chemical Action Plan for Per- and Polyfluorinated Alkyl Substances, April 2018 at 1.
[8] *Id.* at 8 (emphasis added).
[9] *Id.* at 9.

packaging provide superior oil and grease resistance while preserving the life cycle and materials management benefits of fiber-based packaging – including recyclability and compostability.

Thus, consideration of life cycle and materials management impacts as part of the AA is crucial to understanding the full environmental and fiscal impacts of all alternatives, allowing Ecology to make the most appropriate recommendation to the legislature and avoiding "regrettable substitutes" for current, environmentally conscious packaging.

Exposure

Any scientifically valid, risk-based evaluation of alternatives to current packaging must include consideration of ***exposure*** as well as hazard, with respect to the alternatives being considered and the PFAS chemicals to which they are being compared. As indicated previously, the PFAS substances that are allowed for use on food packaging in the US are reviewed by FDA prior to being allowed on the market. Specifically, FDA employs a regulatory process referred to as the Food Contact Notification (FCN) program to provide a formal review of components of food packaging that may come into contact with food. The FCN process is rigorous in its examination of all aspects of safety and potential toxicity of food contact substances. FDA allows a food contact substance onto the market based on a maximum allowable exposure to the food contact substance, as specified in the FCN for that substance. The AA being conducted by Ecology must match these maximum FDA-permitted exposure levels to the exposures associated with any alternatives being assessed.

Other Requirements Imposed by HB 2658

In addition to directing that Ecology "follow the guidelines" contained in the IC2 Guide in performing its alternatives assessment, HB 2658 also requires Ecology to evaluate several specific factors beyond those contained in the IC2 Guide in order to determine whether "safer alternatives to PFAS chemicals in specific applications of food packaging are available for each assessed application."[10] The law goes on to specify that:

> In order to determine that safer alternatives are available, the safer alternatives must be readily available in sufficient quantity and at a comparable cost, and perform as well as or better than PFAS chemicals in a specific food packaging application. If an alternative is a chemical, it must have previously been approved for food contact by the [FDA]. . . .[11]

Thus, in addition to conducting an AA, Ecology must make several determinations in order to find that a "safer alternative" exists. Importantly, these determinations cannot be based on generalized comparisons; they must be made for each "specific food packaging application" being examined. In particular, for each specific food packaging application, Ecology must determine as follows, in order to conclude that a "safer alternative" exists:

---

[10] HB 2658, Section 2(3).
[11] *Id.*

- The alternative must be "readily available." In order to be considered "readily available," the alternative ***must*** be approved by FDA for use in the specific food contact application being evaluated, or otherwise permitted for that food contact use under the FFDCA. Unless an alternative satisfies this requirement, it cannot lawfully be distributed or used in the US for that food contact use. For example, an alternative for a particular food packaging application that may be available in countries other than the US cannot be considered "readily available" under the law unless that alternative has successfully completed FDA review for the particular packaging application being evaluated. Ecology cannot simply *assume* that a material that is available outside of the US (or that is available in the US for a different type of application) will satisfy the rigorous requirements of FDA review for the particular food packaging application being evaluated.

- The alternative must be available "in sufficient quantities and at comparable cost." In order to ascertain whether a given alternative will be available in sufficient quantities and at comparable cost, Ecology cannot rely on price and/or production volume projections offered by the supplier of that alternative or other anecdotal evidence. Instead, Ecology must rely on real-world data and valid economic modeling. In addition, it is essential for Ecology to solicit public comment on these issues from the stakeholders who will be most directly impacted by these determinations, including, specifically, the Washington State consumers and businesses that may be forced to deal with the elimination of packaging options that have been available and successfully used by them for decades.

- The alternative must perform "as well as or better than" approved PFAS chemicals used in the "specific food packaging" application being evaluated. The law provides that an alternative cannot be deemed a "safer alternative" unless the alternative performs at least as well as the PFAS chemical(s) used in the particular food packaging application being evaluated. In order to ascertain whether a given alternative performs as well as, or better than, an approved PFAS chemical, it is unacceptable for Ecology to rely on marketing claims from the manufacturer or distributor of the alternative or other forms of anecdotal evidence. Instead, Ecology must use objective, scientific data to demonstrate the performance of the alternative as compared to the approved PFAS chemical. Specific test methods have been widely adopted within the food industry to assess the performance requirements of different food packaging applications. These tests are standardized through such industry associations as the Technical Association of the Pulp & Paper Industry (TAPPI). The most commonly used oil and grease resistance tests are commonly referred to as the Kit test (TAPPI T559) and turpentine test (TAPPI T454, which does not actually use turpentine). Ecology must use verified data from these types of scientific tests to determine whether an alternative performs as well as, or better than, an approved PFAS chemical for a particular application. In addition, Ecology must take into account the fact

that, for certain packaging applications, the performance of approved PFAS chemicals is based not only on oil and grease repellency, but other factors as well – such as permeability. For example, theater and microwave popcorn bags have combined requirements of being able to have good vapor and grease resistance.

* * *

As a global organization representing the world's leading manufacturers of products based on PFAS substances, FluoroCouncil and its member companies have a deep and sophisticated understanding of the specific PFAS substances that are approved for use in food packaging applications, and the scientific data supporting the safety of those substances. We encourage Ecology to take advantage of this expertise, and the expertise of other stakeholders, by ensuring a robust opportunity for stakeholder participation – including opportunities for submitting comments – both prior to and following completion of the draft AA. For the reasons outlined above, stakeholder participation is essential to assure the integrity and reliability of the AA process and the conclusions drawn from that process.

We look forward to ongoing participation in this effort. Please contact me at 202-249-6737 or jessica_bowman@fluorocouncil.org with any questions.

Sincerely,

Jessica S. Bowman
Executive Director

cc: Maia Bellon, Washington Department of Ecology
Denise Clifford, Washington Department of Ecology
Rob Duff, Office of the Governor