FluoroCouncil
Global Industry Council
for FluoroTechnology

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Ken Zarker
Washington State Department of Ecology
Section Manager
Pollution Prevention and Regulatory Assistance Section
PO Box 47600
Olympia, WA 98504-7600

Re: Comments on Ecology's PFAS in Food Packaging AA Project Summary

Dear Mr. Zarker:

FluoroCouncil appreciates this opportunity to provide comments on Washington State Department of Ecology's (Ecology's) PFAS in Food Packaging Alternatives Assessment Project Summary ("Project Summary"). FluoroCouncil is a global organization representing the world's leading manufacturers of products based on PFAS. FluoroCouncil has a fundamental commitment to product stewardship and rigorous, science-based regulation, and, as part of its mission, addresses science and public policy issues related to PFAS.

Under RCW 70.95G, 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. Otherwise, it may not be administratively or technically feasible, thereby raising serious administrative and legal issues.

FluoroCouncil[2] offers the below comments on the Project Summary to help ensure the integrity and legitimacy of the AA being undertaken by Ecology.

1. Interstate Chemicals Clearinghouse Guidance

RCW 70.95G.070(2)(b) directs Ecology to "follow[] the guidelines for alternatives assessments issued by" the Interstate Chemicals Clearinghouse (IC2), which are set forth in the IC2

[1] For purposes of RCW 70.95G.010, 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).

Alternatives Assessment Guide (IC2 Guide or 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]

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 RCW 70.95G.070, stakeholder involvement is essential to ensuring the integrity and reliability of the AA.

While we appreciate the opportunities identified in the Project Summary where stakeholder input will be sought, from subject matter experts in the identification and assessment of alternatives, through the PFAS Chemical Action Plan Advisory Committee updates, and the Peer Review process, the plan does not go far enough in seeking appropriate stakeholder input.

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. In several aspects of the AA, the Project Summary calls for seeking input only from purchasers, users and manufacturers of potential alternative products (including ability to be practicably and economically substituted and availability in sufficient quantity and at comparable cost). It is critical that the contractor also seek input from those stakeholders that continue to manufacture and use PFAS-based products to understand the potential challenges associated with switching to an alternative product. In this regard it is important for Ecology to recognize that not all packaging applications require the functionality provided by PFAS chemicals; therefore, Ecology cannot fairly judge the adequacy or feasibility of non-PFAS alternatives ***unless*** information is obtained from current users of PFAS-containing packaging to elucidate what factors may cause available non-PFAS alternatives to be infeasible in certain applications.

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;

[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.
[6] *Id*. at 7.

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.

Finally, because adequate stakeholder involvement is crucial to conducting a valid AA, 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 RCW 70.95G.070 results in any recommended changes to the draft AA, those recommendations should also be subject to public comment.

Hazard Assessment

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, arbitrary and capricious, 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. Utilizing 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.

Furthermore, Ecology should clarify why, in Table 1 of the Project Summary, any potential alternative with a GreenScreen benchmark of 2 or higher would be considered improved from a hazard standpoint. This implies that the specific PFAS chemicals used in food packaging have a GreenScreen benchmark of 1; however no further explanation is provided to support this

[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).

implication. Without further explanation and justification by Ecology, the use of this benchmark value would be arbitrary and capricious.

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 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

[9] *Id*. at 9.

base its dietary exposure assessment for PFAS chemicals on these maximum FDA-permitted exposure levels, and these levels should be evaluated against the dietary exposure levels associated with any alternatives being assessed.

While the Project Summary includes an assessment of exposure, the described module is rather cursory in its execution, calling only for a "narrative explanation of primary exposure from food contact packaging to food, other use-phase exposures, and end-of-life exposures." A narrative description, alone, is an inadequate and scientifically invalid basis upon which to assess dietary exposures to food contact substances and would fly in the face of Federal law governing the safety of foods and food contact substances.

The Project Summary also notes that additional exposures, past those associated with the intended use of PFAS-based food packaging, will be analyzed. If Ecology deems it appropriate to track exposures throughout the product's entire life-cycle, the agency should be consistent in its analysis of alternatives. Consequently, it would be appropriate to include the two modules described above: the Materials Management Module and the Life Cycle Module. Similarly, the Project Summary asserts at page 9 that packaging chemicals or their degradation products may enter the food cycle from compost. If Ecology decides to assess this possibility as part of the AA, Ecology must consider data that have been generated on the *actual PFAS chemicals used in food packaging* which demonstrate that these food-packaging chemicals do not biodegrade in the environment in any meaningful way. Failure to consider these data would be arbitrary and capricious.

2. Other Requirements Imposed by RCW 70.95G

In addition to directing that Ecology "follow the guidelines" contained in the IC2 Guide in performing its alternatives assessment, RCW 70.95G 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, and they must be based on the specific PFAS chemicals approved for use in those food packaging applications. In particular, for each specific food packaging application, Ecology must determine as follows, in order to conclude that a "safer alternative" exists:

[10] RCW 70.95G.070(3).
[11] *Id.*

- The alternative must be "readily available in sufficient quantities and at comparable cost."

  In order to ascertain whether a given alternative will be readily 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, including how forcing a significant shift in purchasing could affect future cost and availability of PFAS-free food packaging alternatives. 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. Furthermore, it is inappropriate to correlate the use of PFAS-free food packaging with the food service industry's apparent willingness to purchase PFAS-free products, as not all food service applications require the unique attributes of PFAS-based food packaging.

  Finally, 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 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 or subjective opinion. 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.

Finally, it is arbitrary, capricious, and contrary to its legislative mandate for Ecology to state in the Project Summary that "[a]lternatives do not need to achieve levels [of performance] beyond application requirements in order to meet the law's criteria for safer alternatives." As written, the law sets the baseline performance standard as that of the PFAS chemicals used in the specific food packaging application. Therefore, any safer alternative, ***at the very least***, must perform as well as the PFAS-based food packaging for a particular application, even if Ecology determines, for whatever reason, that superior performance is not required for a particular application and inferior performance by an alternative is "good enough."

- <u>The alternative "must have previously been approved for food contact by the [FDA]."</u>

  In order to be considered a "safer alternative," the law clearly requires that an alternative ***must*** have been previously approved by FDA for use in the specific food contact application being evaluated, or otherwise permitted for that food contact use under the FFDCA. Footnote 1 of the Project Summary is arbitrary, capricious, and clearly in contradiction to this legislative mandate when it notes that the contractor may consider alternatives that have ***not*** been previously approved by FDA, rationalizing that the two-year transition period before any ban could allow for such a product to be successfully introduced into the US market. However, as noted above, Ecology cannot simply assume that a material available in foreign markets will satisfy the rigorous requirements of FDA review for the particular food packaging application being evaluated. Therefore, the only alternatives that should be assessed are those that are currently approved by FDA for use in the pertinent food contact application.

Finally, language used in the "Summary" section is misleading, as it implies that finding a safer alternative to PFAS-based food packaging is a foregone conclusion. Nowhere does the document address the process to be employed in a scenario where no safer alternative is found for the use of PFAS in a particular food application being evaluated, nor does it note that such a process may need to be developed in the future to meet the iterative requirements of the law.

3. General Comments - Background

The Project Summary "Background" section over-generalizes PFAS chemistry on several points:

- We are unaware of concerns Ecology and the Department of Health have identified for the entire class of PFAS chemicals. While numerous documents have been drafted related to the Chemical Action Plan for PFAS currently under development by Ecology and Health, none of those documents identify concerns related to all PFAS, including fluoropolymers. Fluoropolymers are high molecular weight polymers that are stable, inert, and not bioavailable, thus they do not present toxicity concerns.
- This section also states that "PFAS…can change into substances of concern…" This statement is inaccurate for all PFAS, including fluoropolymers, which do not degrade into smaller molecules. Moreover, as discussed above, data on the *actual PFAS chemicals used in food packaging* demonstrates that these food-packaging chemicals do not biodegrade in the environment.
- PFAS are also over-generalized in that they are not all water soluble, including fluoropolymers.

These concerns illustrate, again, why Ecology's AA must focus on the **specific** PFAS chemicals that are actually used in food packaging and the large body of data that has been generated on those specific chemicals. Any other approach would be arbitrary and unreasonable.

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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.

Thank you for your consideration of these comments. 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