

August 26, 2019

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: Ecology's PFAS Food Packaging Alternatives Assessment Process

Dear Dr. Penttila:

The undersigned organizations are writing to express several concerns regarding the effort by the Department of Ecology (Ecology) to prepare an alternatives assessment (AA) for food packaging that contains intentionally-added PFAS chemicals. Given the impact this process could have on companies and products sold in Washington State, as well as the precedent this could set for regulatory action in other jurisdictions across the country, it is essential that the AA is conducted in a manner that is scientifically sound, transparent, and adheres to the requirements outlined in the enacting statute.

On February 13, 2019, Ecology released an updated Statement of Work, Deliverables, and Timeline, in addition to announcing its selection of SRC, Inc. (SRC) as the independent contractor responsible for assisting Ecology in carrying out the AA.¹ However, since that time, several issues that may undermine the integrity of the AA and render it arbitrary and capricious have arisen and are outlined below.

1. Insufficient transparency and inadequate opportunities for meaningful stakeholder input.

Thus far, the process carried out by Ecology and SRC has suffered from a concerning lack of transparency and inadequate opportunities for meaningful stakeholder input. For example, the initial selection of the proposed PFAS "base case" is an illustration of this problem. Following Ecology's publication of the AA Project Summary in November 2018, a stakeholder, the FluoroCouncil, sought to provide information and expertise that could assist in the assessment of PFAS-based food contact substances to Ecology and SRC on multiple occasions. The FluoroCouncil's member companies manufacture the vast majority of PFAS substances used in food contact materials and could provide substantive input on considerations for the selection of a PFAS "base case." However, rather than seeking input from industry experts intimately

¹ This update and associated documents can be found online here:
<https://www.ezview.wa.gov/?alias=1962&pageid=37105>.

familiar with the PFAS chemistries that are available in the market, it appears SRC relied solely on non-industry sources to make their first “base case” PFAS product selection.² As a result, SRC initially selected as its proposed “base case” a PFAS chemical that has not been commercialized for food packaging applications and is not available in any food packaging.³ Simply engaging manufacturers in the selection process would have provided an opportunity for prompt and meaningful feedback from knowledgeable stakeholders, and as a result, an inappropriate product would not have been selected as the proposed base case and the AA process would not have been unnecessarily delayed.

Following SRC’s acknowledgment that the initial base case selection was inappropriate, FluoroCouncil reached out again and identified for the contractor multiple PFAS products that are approved by FDA for use in food packaging applications and are currently commercialized for that use. While Ecology did publicly announce the selection of a new “base-case” in a stakeholder email on July 25, 2019, none of the manufacturers of the provided PFAS products has been individually contacted by SRC or Ecology for any additional information regarding those products – including information (such as the availability of toxicity or exposure data) that should be of central importance in selecting a base case.

In order to complete a sufficiently robust and scientifically valid AA, Ecology and SRC should constructively engage with, solicit information from, and allow for timely feedback from knowledgeable stakeholders. Regular dialogue and interactions will keep stakeholders engaged in the process to assist in the AA.

2. Unjustified limitation of industry expert participation in the peer review process.

In a July 25, 2019 stakeholder email, Ecology announced that it was in discussions with the Washington State Academy of Sciences (Academy) to manage and perform the AA’s statutorily-required peer review. While Ecology describes the Academy as a “nonprofit entity independent of government,” a review of its membership list⁴ reveals the organization to be primarily composed of individuals in academia or non-profits. While this is an improvement over the announcement made during the May 15, 2019 public webinar that the peer review would only include individuals in academia, it is still a great concern, as it would not include any scientists or other experts associated with the food packaging industry. The decision to exclude from the peer review process industry scientists and experts who are among the most knowledgeable about the subject matter is arbitrary, unjustified, and inconsistent with achieving an objectively sound and scientifically valid result. The peer review process must include all pertinent stakeholders with requisite technical expertise and an in-depth knowledge of the products being evaluated, including relevant industry experts.

² In a PowerPoint presentation explaining the basis for their selection of the PFAS “base case,” SRC cites as references various organizations such as the Environmental Defense Fund and the Green Science Policy Institute; however not a single industry expert was cited – which may help explain why an inappropriate substance was proposed as the “base case.” See

https://www.ezview.wa.gov/Portals/_1962/Documents/PFAS/PFAS%20AA%20Webinar_05152019.pdf

³ The substance, (CAS No. 1071022-26-8) is a Chemours product that Chemours has acknowledged is not commercially available.

⁴ <http://www.washacad.org/wp-content/uploads/2019/04/2018-19-Membership-Directory.pdf>

3. Arbitrary selection of “decision rules” that will form the basis of the AA.

In its Statement of Work, Ecology has selected several arbitrary parameters or “decision rules” that will form the basis of the AA. For example, the decision to use a “Level 2” Green Screen assessment to evaluate hazard was not adequately justified nor publicly vetted by Ecology. Similarly, the use of a “Level 1” exposure assessment – including “a narrative explanation of exposure” – was not adequately explained by Ecology and no scientific justification for this approach was offered. In evaluating the safety of food additives, including food contact substances, the decision to rely on a purely qualitative assessment of exposure and a broad screening-level hazard assessment is scientifically invalid and wholly inappropriate from a public health perspective. Yet stakeholders, including the public, and experts in food safety assessment, were not given the opportunity to provide input on these critical decisions that have a real potential to impact the health and safety of Washington State residents.

Similarly, Ecology’s assertion in its Statement of Work that an alternative with inferior performance can be acceptable for purposes of the AA as long as the alternative performs “well enough,” and the reliance on subjective or anecdotal evidence of performance, is squarely at odds with the legislative intent and plain words of RCW 70.95G that requires that an acceptable alternative must “perform as well as or better than PFAS chemicals.” An alternative cannot be deemed acceptable if, by objective measurements, it demonstrates inferior performance as compared to the PFAS substance being evaluated.

In short, Ecology must sufficiently justify and submit to public scrutiny its basis for selecting the “decision rules” that will govern the AA process to ensure that those decision rules are not arbitrary and that they fulfill the legislative intent of RCW 70.95G.

4. AA does not appear to be evaluating individual food packaging applications.

RCW 70.95G.070 requires that “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.” (emphasis added) At this point, it is not clear whether SRC or Ecology is conducting or is intending to conduct separate assessments for “specific applications of food packaging” as set forth under the law. Indeed, SRC’s recently-distributed “PFAS Food Packaging Scoping Survey”⁵ suggests that the contractor is contemplating *not* conducting separate assessments for different food packaging applications. Furthermore, as Ecology moves forward with this process, it is important for the agency to keep in mind that the law requires that any proposed alternative chemical must have “previously been approved for food contact by the United States Food and Drug Administration, such as through the issuance of a determination that the chemical has a reasonable certainty of causing no harm.” Before proceeding further in the AA process, Ecology and SRC should clearly outline how they intend to address these imperative requirements of the law.

* * *

⁵ The survey is available online here: <https://www.surveygizmo.com/s3/5092489/PFAS-Food-Packaging-Scoping-Survey>.

Please contact Jessica Bowman (Executive Director, FluoroCouncil) at 202-249-6737 or Jessica_Bowman@fluorocouncil.org with any questions. We look forward to our ongoing participation in this effort.

Sincerely,

American Forest & Paper Association
FluoroCouncil
Foodservice Packaging Institute
Washington Retail Association

cc: Ken Zarker, Washington Department of Ecology
Denise Clifford, Washington Department of Ecology
Rob Duff, Office of the Governor
Cathy Rudisill, SRC, Inc.



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DEPARTMENT OF ECOLOGY

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September 25, 2019

Jessica Bowman
FluoroCouncil
700 Second Street NE
Washington, DC 20002

Dear Jessica Bowman,

Thank you for your letter of August 26, 2019, and for bringing concerns from the FluoroCouncil and other interested industry groups forward regarding the PFAS in Food Packaging Alternatives Assessment. We value relevant and timely input from all interested parties and are committed to working with you to address your concerns.

Your letter identifies four main topics, and we address them here in the order of your letter:

1. Project Transparency and Interested Party Input

Your letter contends that our process has not been sufficiently transparent and has not allowed for sufficient input from interested parties. As an example of this, you cite our decision to identify and then change the initial PFAS Base-Case selection. We conducted a records review in order to clarify and document the facts.

The project contractor, SRC, Inc. (SRC), is coordinating communications with interested parties. We have communicated extensively with interested parties through one-on-one phone calls, one-on-one email correspondence, a public webinar, a conference call, and multiple online surveys. We have maintained and updated a website and sent listserv messages on the project's progress to over two hundred recipients. FluoroCouncil member company representatives have been participants in each of these communications and via in-person engagement. Since the outset of the project work in January 2019, we have routinely invited FluoroCouncil members and interested parties to contact us at any time with comments or suggestions.

The development of the initial PFAS Base-Case began with both email and phone communications with the FluoroCouncil regarding commercially relevant PFAS used in food

packaging. The FluoroCouncil indicated in these communications that C6-methacrylate polymers were the most widely used PFAS in food packaging. We also reviewed documents made available by the Environmental Defense Fund, cited as a “non-industry source” in your letter. These documents included over 1,000 pages of industry food contact submissions to the Food and Drug Administration (FDA) obtained through a Freedom of Information Act request. For reasons described in our May 15 webinar, we selected Food Contact Notifications (FCNs) 885 and 1027.

Following the announcement of the PFAS Base-Case at our May 15 webinar, The Chemours Company (Chemours) contacted us by email. In a follow-up May 22 phone conference with Bob Buck and Kai-Volker Schubert of Chemours, they informed us that FCNs 885 and 1027 were being withdrawn from the market and that inventory would be exhausted in the coming weeks. These FCNs are both C6-methacrylate polymer products in the class recommended by the FluoroCouncil as relevant for our assessment work. During that May 22 conversation with Chemours, we discussed the possibility of engaging the FluoroCouncil to survey members for information on suitable PFAS products as replacements for FCNs 885 and 1027. SRC followed up with a request to that effect with the FluoroCouncil by email on May 28, 2019. The FluoroCouncil responded with input on relevant FCNs on June 11, 2019. We appreciate the cooperation of the FluoroCouncil and its members in providing this input.

Following additional analysis of options, we updated the PFAS Base-Case to FCN 604 (599). These substances are further identified on the FDA website as referring to Chemical Abstracts Service Registry Numbers (CASRN) 863408-20-2 and 1225273-44-8. We have not made formal requests to the FluoroCouncil or its members for further information and data on these products because we have not yet finalized what specific data are needed for our assessment work. We know that requests of this nature will likely involve significant effort both to gather the data and to obtain the necessary permissions to share that data with our project. We want to minimize this burden by making one complete request for data. Unfortunately, we need to develop our thinking further on the decision rules before we can appropriately specify data needs (discussed further below). We will contact the FluoroCouncil as soon as we have completed our data needs assessment.

In summary:

- The suggestion that only “non-industry sources” were used and that we did not involve industry experts is incorrect. We directly sought input on the PFAS Base-Case from the FluoroCouncil and its member representatives prior to our initial base-case selection and supplemented that input with industry food contact substance notification documents from the FDA.

- SRC initiated contact with the FluoroCouncil to obtain assistance in selecting a new base-case candidate. The idea for a survey of FluoroCouncil member companies was developed in our call with Chemours.
- We have not yet finalized the specifics of our assessment data needs. It would be premature to contact the FluoroCouncil or its members for specific additional data at this time. By waiting until our needs are clearly defined, we can avoid inefficiencies and burdensome multiple data requests.

2. Peer Review Process

Your letter contends that our peer review process must include all pertinent stakeholders. We believe that Ecology has the discretion to select the Washington State Academy of Sciences (WSAS or Academy) members or other scientists, as needed, for the peer review process. The law does not identify the peer review process as a stakeholder or interested party review process.

WSAS members either are members of the National Academies of Sciences, Engineering, and Medicine, or are elected directly to the WSAS by their peers. The large majority of WSAS members are professors or scientists at highly regarded universities and research institutions, and their election to the Academy is a testament to their strong professional reputations.

While professionals employed by food packaging makers or suppliers would have relevant experience to conduct a peer review, they might also have a financial interest in the outcome of the assessment. Avoiding or promoting a ban on PFAS in a particular packaging application could directly affect markets for products sold or promoted by their employers. It might be difficult then for these industry employees to be objective in their review.

3. Decision Rules

Your letter contends that we have selected arbitrary parameters or “decision rules,” and that we have not explained the basis for these selections. Ecology is required to use the AA process identified in the Interstate Chemicals Clearinghouse Alternatives Assessment Guide (IC2 Guide). The IC2 Guide states that “...decisions...should be documented and explained.” The use of decision rules and our proposal to develop them are further specified in the Statement of Work released in January 2019:

Ecology will propose decision rules for comparisons between PFAS-based and PFAS-free alternative products. The Contractor will interview experts and knowledgeable parties, and engage interested parties (see Interested Parties Outreach and Engagement below) to develop data on cost comparability,

performance measures, and other assessment criteria (Table 1). The contractor will provide input and feedback on Ecology's proposed decision rules.¹

Ecology has not finalized any of the decision rules, including decision rules addressing performance. The Legislature directed that Ecology should make the safer alternative determinations. Ecology is not required to solicit approval from interested parties on any of these decisions. Ecology will report the basis for the final decision rules and assessment levels in our published findings.

4. Individual Food Packaging Applications

Your letter contends that we are contemplating *not* conducting separate assessments for different food packaging applications. That is incorrect. The Statement of Work describes the need to address specific applications and other requirements for PFAS-free alternative products as identified in the RCW 70.95G. Ecology has the discretion to select which products it will address in this first phase of food packaging assessment. SRC's Product Scoping Survey was an information gathering exercise intended to gain insights into how to properly define and address "specific food packaging applications."

The specific applications that Ecology selects for this assessment will depend on a variety of factors. For example, Ecology may choose to assess a chemical alternative treatment that provides functional oil and grease resistance in a number of different, specific applications. In this way, we may achieve economies in the hazard assessment, since the chemical components of alternatives used in different applications might be identical. This would be a prudent use of State resources and in no way violates the requirement to address specific applications.

Ecology may focus its assessment work on products or markets for other reasons, such as the potential size of the market, or for environmental justice considerations. Understanding the market for a specific application also helps to enrich the assessment by, for example, supporting the need for specific application performance requirements. While we must address specific applications, we have the discretion to consider other factors that we find useful in selecting products for assessment.

Summary

We thank the American Forest & Paper Association, the FluoroCouncil, the Foodservice Packaging Institute, and the Washington Retail Association for taking the time to document your concerns. As the project progresses further, there will be many opportunities for interested

¹ https://www.ezview.wa.gov/Portals/_1962/Documents/PFAS/PFAS_Food_Pckg_AA_Statement_of_Work.pdf

Jessica Bowman
September 25, 2019
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parties to provide feedback and information, primarily through group engagement processes such as surveys, webinars, and conference calls.

In order to improve communications, we are planning to develop a separate Ecology website for the food packaging assessment work. We will provide additional information and responses in a Frequently Asked Questions (FAQ) section or document on the website. Please contact us at any time should you have additional suggestions or concerns.

Best regards,

A handwritten signature in black ink, appearing to read "Ken Zarker". The signature is stylized with a large, sweeping "K" and a long horizontal stroke at the end.

Ken Zarker, Manager
Pollution Prevention and Regulatory Assistance Section
Hazardous Waste and Toxics Reduction Program

By certified mail: 9489 0090 0027 6021 5211 31

cc: Renée Lani, FluoroCouncil



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Ken Zarker, Manager
Pollution Prevention and Regulatory Assistance Section
Hazardous Waste and Toxics Reduction Program

By certified mail: 9489 0090 0027 6021 5211 31

cc: Renée Lani, FluoroCouncil