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. 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

-

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" 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 <u>Jessica Bowman@fluorocouncil.org</u> 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.