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Academy of Sciences
Science in the Service of Washington State

PFAS IN PLANT FIBER-BASED FOOD PACKAGING COMMITTEE DELIVERABLES

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Dr. Elaine Faustman is a toxicologist and Professor and Director of the University of Washington (UW) Department of Environmental & Occupational Health Sciences. She is also Adjunct Professor in the UW Evans School of Public Policy and Governance. Dr. Faustman's research focuses on identifying biochemical mechanisms of developmental neurotoxicity and to develop new approaches for the evaluation and characterization of health risks from environmental agents. Her expertise is in risk assessment of chemical hazards and neurodevelopmental toxicology. Dr. Faustman received the 2019 Merit Award from the International Union of Toxicology and was elected to the Washington State Academy of Sciences. Dr. Faustman earned a PhD in Toxicology from Michigan State University.

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Dr. Simona Balan, Senior Environmental Scientist in the California Department of Toxic Substances Control. Dr. Balan is leading the Safer Consumer Products team on perfluoroalkyl and polyfluoroalkyl substances (PFASs). Dr. Balan previously managed international projects on the use of flame retardants and PFASs in consumer products. She was recognized by the Collaborative on Health and the Environment as one of 20 Pioneers under 40 in Environmental Public Health. Dr. Balan has a PhD in Environmental Science, Policy and Management from the University of California, Berkeley.

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Dr. Lauren Heine is Senior Science Advisor at Northwest Green Chemistry and is adjunct faculty at Gonzaga University. Dr. Heine applies green chemistry, green engineering, and multi-stakeholder collaboration to the development of products and processes. She led development of GreenScreen® for Safer Chemicals, a method for chemical hazard assessment increasingly used worldwide. Dr. Heine drafted Policy Principles for Sustainable Materials Management for the OECD, and she helped develop criteria for the Design for the

Environment (DfE) Safer Choice and Alternatives Assessment Programs for the EPA. Dr. Heine was technical advisor to the development of the Interstate Chemicals Clearinghouse (IC2) Alternatives Assessment Guide and the WA Alternatives Assessment Guide. She serves on the Apple Green Chemistry Advisory Board, and previously served on the California Green Ribbon Science Panel. Dr. Heine earned a PhD in Civil and Environmental Engineering from Duke University.

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Dr. Patricia A. Hunt is Meyer Distinguished Professor in the School of Molecular Bioscience at Washington State University. Her primary research interest lies in human aneuploidy, mammalian germ cells and meiosis, and she is best known for showing the adversary effect of Bisphenol A and replacement bisphenols (BPS, BPF, BPAF, Diphenyl sulfone) on the reproductive system of mammalians. Dr. Hunt's current work centers on the reproductive effects of exposure to chemicals with estrogenic activity. She was elected to the Washington State Academy of Sciences. Dr. Hunt earned a PhD in Reproductive Biology from the University of Hawaii.

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Dr. Donatien Pascal Kamdem is Professor in the School of Packaging at Michigan State University and works with Global Packaging Solutions, LLC. His research interests include the chemical, physical, and mechanical properties of packaging made from wood, paper, and natural fibers, and technology to improve the performance and reduce cost of those products. Dr. Kamdem is an elected fellow of the International Academy of Wood Science. He has served as a witness expert, consultant, and reviewer on many projects regarding wood products. Dr. Kamdem earned a PhD in Wood Science from University Laval in Quebec, Canada.

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Dr. Michael Skinner is Professor in the School of Biological Sciences at Washington State University. He has been on the faculty of Vanderbilt University and the University of California at San Francisco. Dr. Skinner's research focuses on the investigation of gonadal growth and differentiation, with emphasis in reproductive biology. His current research has demonstrated the ability of environmental toxicants to promote the epigenetic transgenerational inheritance of disease phenotypes due to abnormal germ line epigenetic programming in gonadal development. Dr. Skinner established and was the Director of the Washington State University and University of Idaho Center for Reproductive Biology and established and was the Director of the Center for Integrated Biotechnology. He received the 2013 American Ingenuity Award from the Smithsonian. Dr. Skinner earned a PhD in Biochemistry from Washington State University.

Huqiu Zhang

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Dr. Huqiu Zhang is Senior Scientist at Sevee & Maher Engineers. Dr. Zhang specializes in optimizing chemical testing programs, applying analytical methods, and implementing chemical controls in the manufacturing process, covering the entire supply chain of food packaging. She has international experience in regulatory compliance for consumer product chemical safety, food contact, and food packaging. Dr. Zhang's expertise includes chemical and material industry product supply chains and chemical management, particularly in paper, paperboard, and plastic products, as well as chemical hazard identification, exposure evaluation, and risk assessment. Dr. Zhang's early research was in perfluorine chemistry. Dr. Zhang earned a PhD in Organic Chemistry from the University of Tennessee, Knoxville.

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Cover Letter - Transmission of Peer Review

October 5, 2020

Ken Zarker
Pollution Prevention Regulatory Assistance Section Manager
Washington State Department of Ecology
ken.zarker@ecy.wa.gov

Dear Ken,

Enclosed you will find an independent peer review of the draft report prepared by Ecology related to the identification of safer alternatives to per- and poly-fluoroalkyl substances in plant fiber-based food packaging. This peer review was prepared per the terms of the Washington State Academy of Sciences (WSAS) Scope of Work with Ecology (Contract No. C2000115) and the directive of RCW 70A.222.070 (formerly RCW 70.95G.070).

The WSAS Committee realizes that Washington State is a leader – if not *the* leader – in using the alternative assessment guide to identify alternatives for PFAS in food packaging, and that Ecology's assessment might be the first of its kind in the nation.

We hope you find this independent peer review to be useful, and would be pleased to talk with you about engaging in other such reviews as appropriate and as funding allows.

Sincerely,

Donna Gerardi Riordan

Donna Gerardi Riordan
Executive Director

Cc: Elaine Faustman, Committee Chair
Yasmeen Hussain, Program Officer
Roger Myers, WSAS President

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Review of PFAS in Food Packaging Alternatives Assessment

Prepared for the Washington State Department of Ecology
By WSAS PFAS in Food Packaging Committee

October 2020

Contents

Committee Charge

The Washington State Department of Ecology (Ecology) requested that the Washington State Academy of Sciences (WSAS) conduct an independent peer review of a report prepared by Ecology related to the identification of safer alternatives to per- and polyfluoroalkyl substances (PFAS) in plant fiber-based food packaging. Ecology's alternative assessment was conducted per RCW 70A.222.070 (formerly RCW 70.95G.070), which refers to PFAS as PFAS chemicals.

In response to Ecology's request, the WSAS convened a seven-member committee of disciplinary experts (referred to in this document as "the committee" or "we") with the charge to conduct an independent peer review. The Committee performed its review between August 18 and October 5, 2020. Committee members are listed below and their full bios are in Appendix A.

The committee reviewed Ecology's use of the assessment modules delineated in the Interstate Chemicals Clearinghouse Alternatives Assessment Guide (IC2 AA Guide) (Version 1.1, January 2017, as required for Ecology's assessment), whether suitable alternatives were considered, and the draft report's conclusions regarding alternatives for food packaging containing PFAS. The committee interpreted its charge as commenting on both the process used and the science documented in the draft report. The goal of the committee's comments is to strengthen the report.

The draft report includes a detailed description of the stakeholder outreach and engagement process used during the alternative assessment. As noted in the IC2 AA Guide, stakeholder engagement is an important element in the overall process (see Stakeholder Involvement Module). However, inasmuch as stakeholder engagement does not directly involve scientific or technical questions, the committee concluded that with the exception of minor comments at the end of this review, detailed review of that process was outside the scope of this review.

This document is organized as a summary of the committee's review, followed by comments on the report as a whole and specific comments on report sections. Page numbers correspond to the PDF versions of Ecology's draft report and Appendixes A-N, and the Word document of Appendix O.

Committee Members

Dr. Elaine Faustman *(chair),* Professor & Director, Department of Environmental & Occupational Health Sciences, Adjunct Professor, Evans School of Public Policy and Governance, University of Washington
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Dr. Michael Skinner, Professor, School of Biological Sciences, Washington State University
Dr. Huqiu Zhang, Senior Scientist, Sevee & Maher Engineers

Summary of Review

The committee recognizes the complexity and lack of complete information inherent in the process of conducting alternatives assessments. However, the report's conclusions would be stronger if the report included clearer and more transparent descriptions of the kinds of information and science (or data or analysis) that support them.

The committee has several comments and suggestions about the alternatives assessment process as applied in this report. The key points include:

1. **Justify more clearly the choice of the chemical of concern.** The report mentions that stakeholder opinions were conflicted about whether to use a single representative chemical of concern, but does not fully explain why Ecology nevertheless decided to take this approach. The only explanation provided is that the "C6-based fluorinated polymers are the predominant PFAS used in U.S. food packaging materials"; however, the FDA announced on July 31, 2020 that all C6-based fluorinated polymers, including the selected chemical of concern, will begin a voluntary three-year phaseout in January 2021. Some of the remaining PFASs that will not be phased out are perfluoropolyethers (PFPEs). The report would benefit from a clear statement of why PFPEs are expected to have a similar hazard and exposure potential as the C6-based compound selected as the chemical of concern.

2. **Review alternative compounds more thoroughly**. To document that alternatives are not potentially as harmful as the banned products, the committee suggests including substantive evidence from the peer-reviewed literature (examples are provided below). In particular, the report relies heavily on concluding that there is "insufficient information" despite a body of evidence on the alternatives. For example, PE and PET could be evaluated as generic substances using information in the peer reviewed literature about typical chemical constituents without having to obtain full ingredient disclosure from a manufacturer. The report would also be strengthened by providing an explanation of why Ecology chose those specific alternatives to be assessed, and how it reached the conclusions of the assessment. In addition, the report's analysis would benefit from a more thorough assessment to strengthen the conclusion that the safe alternatives are available in sufficient quantities, as per the legislation.

3. **Provide the full rationale for the chosen assessment levels for each module.** In particular, there are items out of scope for a Level 1 Exposure assessment that could be valuable for this report. The report would also benefit from providing the rationale for the Cost and Availability Assessment level and how the analysis supports the assessment.

4. **Clearly present a rationale for the choice of the decision framework used in the assessment.** Figure 1 of Ecology's draft report shows one version of a decision framework presented in the IC2 AA Guide; others are also mentioned in the guide. The committee suggests including a) a section at the beginning of the report with an explanation of the rationale for choosing the simultaneous decision framework to evaluate data from the four modules; and b) a section at the end of the

report presenting the results of applying the decision framework and then integrating the data gathered in each module into the framework to make recommendations.

5. **Structure the report to show more clearly the logical flow of evidence and decision-making.** In order to do so, the report should follow the structure of the IC2 AA Guide, starting with scoping, including descriptions of the stakeholder involvement module and decision framework, then working sequentially through the other four modules, and ending with a summary of results from applying the decision framework to the data gathered in each module, followed by one consolidated reference section. In addition to restructuring, the report would benefit from removing redundancies and improving readability.

Scope of the Assessment Process

Ecology's draft report included four assessments: Exposure, Performance, Cost and Availability, and Hazard. We suggest that Ecology provide the rationale for the levels of assessment chosen. As outlined in this report, Ecology used a Level 1 assessment for the Exposure, Performance, and Cost and Availability assessment modules, and a Level 2 assessment for Hazard and Stakeholder Engagement. Ecology referred to its Washington State Alternatives Assessment Guide to justify the use of these levels, and that guide recommends "The alternatives with the lowest hazard are evaluated further using the three remaining modules, i.e., Performance, Cost and Availability, and Exposure. As a minimum, Level 1 is recommended for these three modules. Assessors may use higher levels if they have the resources or expertise." (page 4, Washington State Alternatives Assessment Guide 2015).

A Level 1 Exposure assessment is a basic exposure evaluation that identifies potential exposure concerns and includes a qualitative assessment using readily available data. Items out of scope for a Level 1 assessment that could be valuable for this report include accounting for cumulative exposure from other PFAS sources and of life-cycle components such as breakthrough and compounds used for coating. Given the complexity of information available on PFAS, and realizing that Ecology has limited time and budget for the assessment of safer alternatives to per- and polyfluoroalkyl substances in plant fiber-based food packaging, the committee understands that there may be a rationale for a Level 1 Exposure assessment; this rationale would simply need to be written in the report.

Regarding the Cost and Availability assessment, Question 2 of the analysis, "Is the alternative currently offered for sale for the application of interest?" (Appendix O, page 1) may address the requirement in RCW 70A.222.070 for "readily available" but does not appear to address the requirement of "sufficient quantity" (also referenced in Appendix O, Table 9 on page 20), thus raising the question of whether applying Level 1 of the "cost and availability" module is adequate. The report would also benefit from providing the rationale for the choice of a Level 1 Cost and Availability Assessment, and how the questions in the analysis support the assessment.

The Executive Summary outlines the scope of the assessment, but is unclear about some specific points, such as: 1) Is all plant fiber-based packaging included? and 2) Are mold release agents not considered intentional PFAS additions? Page 57 states that "Third-party verification has demonstrated that most molded fiber products on the market contain PFAS"; the PFAS in these molded fiber products might also

originate from mold release agents (California Safer Consumer Products, Public Workshop on Food Packaging with PFASs, January 14 2020 [transcript]; Work Plan Implementation, October 2019). Even if non-PFAS alternatives are used for oil and grease resistance (OGR) and leak resistance, some molded fiber products may continue to contain PFAS unless the mold release agents are also substituted.

More Thorough Assessment of Alternative Compounds

Inclusion of Peer-Reviewed Literature

More references to peer-reviewed scientific literature about the hazards, toxicity and general safety of suggested alternative compounds are needed to support the more general information provided from EPA Safer Chemicals lists. In addition, a more thorough review of the scientific literature about the compounds and compound classes listed as alternatives, the potential toxicity of the alternatives, their breakdown products (including microplastics, where applicable), and their precursors is also needed. Furthermore, the literature review should distinguish peer-reviewed technical reports and papers from materials with a lower standard of evidence.

The following are examples from the committee of a brief review of PubMed literature on some of the safety and toxicity information of proposed alternatives. The committee suggests that this kind of information be included in the Report:

Alternative PLA -- This is poly(lactide) which is often used with poly(ethylene glycol) PEG. These are safe compounds that have been used for drug delivery and nanoparticle in therapeutics (Part Part Syst Charact. 2013 Apr;30(4):365-373. doi: 10.1002/ppsc.201200145. Epub 2013 Feb 28. PMID: 27642231). No literature on toxicity or hazards of this class of compounds was found.

Alternative PVOH -- This is polyvinyl alcohol PVA or PVOH with polyethylene glycol PEG or other compounds to generate microparticles and coatings. These are generally safe, but some toxicity has been observed (Food Chem Toxicol. 2013 Jul;51 Suppl 1:S7-S13. doi: 10.1016/j.fct.2012.12.033. Epub 2013 Jan 7. PMID: 23306789). Although there are many types of these compounds for coating and particles, a more thorough description of what they are and potential toxicity was not presented.

Alternative PET -- This is polyethylene terephthalate (PET) that is used with other compounds for coating food containers. This is generally safe (Food Addit Contam Part A Chem Anal Control Expo Risk Assess. 2017 Jul;34(7):1239-1250. doi: 10.1080/19440049.2017.1322221.), but some toxicity has been observed in various applications (Biomaterials. 2010 Apr;31(11):2999-3007. doi: 10.1016/j.biomaterials.2009.12.055. Epub 2010 Jan 15. PMID: 20074795).

The report also needs to include basic compound name, chemical composition, past use, and safety information for alternatives proposed. It is essential that alternatives not be suggested that are potentially as harmful or more harmful than the PFASs banned (an industry example of this is the selection of BPS as the alternative for the plastic compound BPA, as BPS is potentially more toxic). Any hazards previously observed should be highlighted to allow the reader to conclude that the report is thorough in its assessments of alternatives.

Furthermore, a lack of information is often indicated in tables as "insufficient data," but this phrase is not defined in the report. Relying solely on precursors and breakdown products for toxicity analysis is inappropriate. It is important to note that lack of information is not evidence of lack of toxicity.

Gaps in Hazard Assessment of Particular Materials

The report also has gaps in its assessment of particular materials. For example, there is a gap in the draft report in assessing PE- and PET-coated materials as potential safe alternatives. In the Hazard module, the report simply concluded that there is "insufficient information" around PE and PET (page 38: "insufficient public data were available at the time of this assessment to evaluate PE, PET, and EVOH copolymers"), but this statement is questionable. PE and PET have long been used in food packaging, before PLA, and there should be plenty of publicly available research literature and information about the precursors, degradation, residue by-products, monomers or oligomers for PE and PET, as well as microplastics.

Although precursors and degradation products are not a substitute for a toxicity analysis of the substance itself, and PLA also contributes to microplastic contamination, which is a hazard that should be considered in the discussion of this material, it is not clear why the same method applied to PLA could not also be applied to PE, PET, and EVOH in this report (page 37: "Due to a lack of information about specific proprietary versions of the candidate chemicals, both the PFAS COC and PLA were evaluated using precursors and degradation products, and siloxanes were evaluated using a representative substance."; page 39: "In the absence of polymer information, both the PFAS COC and PLA were evaluated using precursors and degradation products"). These gaps throw into question the final Safe Alternative conclusions; the committee recommends that the authors conduct additional research literature review and analysis to close these gaps.

Gaps in Cost and Availability Assessment of Particular Materials

The Cost and Availability Assessment includes the statement "The prevalence of non-PFAS-containing products in each food packaging application…indicates that PFAS-free alternatives are readily available" (Appendix O, page 8). This statement references Table 5 of Appendix O, which shows the PFAS testing results of products that are already on the market. However, the test results in Table 5 do not show which materials are present in these PFAS-free products. Specifically, the data in Table 5 of Appendix O does not indicate that PVOH and PLA-coated are the predominant PFAS-Free products tested; it is possible that some other material, including PE- or PET-coated may be the predominant materials in the PFAS-Free products listed in Table 5 of Appendix O.

Therefore, the conclusion of "sufficient supply" in the Cost and Availability Assessment module, which leads to the conclusion of Safe Alternative for the materials listed in Tables 7-16 of the draft report (summarized by this committee in Table 1 below) and also suggests that the predominant PFAS-Free Safer Alternatives will be PVOH and PLA-based materials, while appearing to exclude PE and PET, becomes questionable.

Table 1: Summary of safer alternatives conclusions from Tables 7-16 of the draft report. The numbers indicate the number of alternatives identified in the report

Use of Material	Wrap/ Liner	Bags/ Sleeves	Plates	Bowls	Trays	Boats	Pizza Box	Open Carton	Clamshells	Containers	Total
Uncoated	1		1				1				3
Wax	1										1
PVOH		1	1	1	1	1	1	1	1	1	9
Clay			1	1		1				1	4
PLA			1		2		1	1	1	1	7

PE and PET plastics have a long history of safe use in food contact applications. They both were cleared by FDA for food contact uses in 1977, PET in 21CFR177.1630 and PE in 21CFR177.1520. The first FDA clearance for food contact uses of PLA was in 2002, Food Contact Notification 178. As such, PE and PET should be thoroughly assessed in the Cost and Availability Assessment module.

Report Structure and Presentation of Evidence

Decision Framework

It is unclear in this report which of the three decision analysis frameworks from the IC2 AA Guide was applied, and the justification for why this particular framework was chosen. This is a critical oversight. Figure 1 (page 3 of Ecology's draft report) shows one version of a decision framework presented in the IC2 AA Guide; others are also mentioned in the guide. The committee suggests fully explaining this figure.

In the IC2 AA Guide, there is some emphasis on decision analysis in the beginning of the process, as part of scoping, to clarify the decision framework that is used. Primarily, the IC2 AA Guide relegates decision analysis to the end of the process and makes use of the data and the analysis associated with each module.

The committee suggests including a) a section at the beginning of the report with an explanation of the rationale for choosing the simultaneous decision framework to evaluate data from the four modules; and b) a section at the end of the report that clearly describes the decision framework, how the data from each module were integrated into the decision framework, and the results of applying the decision framework to make recommendations.

Report Structure

The report's readability would benefit from a structure that shows more clearly the logical flow of evidence and decision-making and from eliminating the redundancy of multiple overview sections and reference sections.

The IC2 AA Guide provides an example of such a structure, starting with scoping, including descriptions of the stakeholder involvement module and decision framework, then working sequentially through the other

four modules, and ending with a summary of results from applying the decision framework to the data gathered in each module, followed by one consolidated reference section.

The committee suggests changing the report structure to follow more closely the approach in the IC2 AA Guide (page 6 of Interstate Chemicals Clearinghouse Alternatives Assessment Guide Version 1.1), with items from the IC2 guide in **bold**:

1. Scoping
    a. **Stakeholder module:** It is not clear if the stakeholder module presented is as part of the IC2 AA Guide, or if stakeholder engagement was part of the general approach, separate from the IC2 AA Guide. In the guide, stakeholder involvement is a module and should be presented accordingly. This would indicate that Ecology's Alternatives Assessment used 5 modules rather than 4.
    b. **Decision framework decision:** As noted in Decision Framework above, this section needs more explanation about which of the three approaches is used, and why.
2. **Framework modules** (Hazard, Exposure, Cost and availability, Performance)
3. **Summary of results from application of decision framework:** This report needs to be clear about which decision framework was used and how that relates to the findings from each module.
4. **References**: The committee suggests putting references in a single reference section at the end of the document rather than at the end of each section. The current presentation of references with a reference list in each section makes it challenging to find citations, difficult to see which resources were considered in the entire report, and invites redundancy and unnecessary verbosity.

In addition, the conclusions of the Summary of Assessment Modules Outcomes (Section 7) would be greatly clarified by consolidating Tables 7-16 (similar to Table 1 in this committee's review).

The report would also benefit from ensuring that the brief introduction addresses the project as a whole rather than repeating material, and that each chapter on the four (or five) modules includes an overview of the module's content and provides any needed scope of background information. The report could then be much shorter and more clearly state the evidence and conclusions.

Choice of Chemical of Concern

Chosen Chemical of Concern

The choice of the copolymer of perfluorohexylethyl methacrylate, 2-N,N-diethylaminoethyl methacrylate, 2-hydroxyethyl methacrylate, and 2,2'-ethylenedioxydiethyl dimethacrylate, acetic acid salt (Chemical Abstracts Service Registry Number 863408-20-2) as the chemical of concern, and the decision to use a single representative compound for this alternative assessment, requires clearer justification.

The report states that "Stakeholder opinions were conflicted about whether to use a single, representative PFAS compound for this AA." (page 7). Given the differences in opinion of stakeholder input, the report

would be strengthened by more complete description and justification of the decision to use a single representative compound for this alternative assessment.

The only explanation provided is that "C6-based fluorinated polymers are the predominant PFAS used in U.S. food packaging materials." (page 6). However, FDA announced on July 31, 2020 that all C6-based side-chain fluorinated polymers that contain 6:2 FTOH as an impurity (including the one selected by Ecology as the chemical of concern) will begin a voluntary three-year phaseout in January 2021 (FDA announcement). The phaseout is a result of FDA research finding that 6:2 FTOH has a biopersistent and toxic intermediate degradation product. The chemical of concern used as a benchmark for comparison to the alternatives, per the IC2 guide, is one of the compounds that is being phased out.

The committee believes it is important for the report to emphasize that the PFASs that are not being phased out, some of which have a different chemical structure than the selected chemical of concern, are of similar concern. Four of the remaining PFASs that will not be phased out are perfluoropolyethers (PFPEs).

The hazard traits of PFPEs may be to some extent different from those of 6:2 fluorotelomer compounds, but they include extreme persistence, multiple data gaps, and potentially toxic impurities, degradation, and combustion products. See for instance:

- Carol F. Kwiatkowski, David Q. Andrews, Linda S. Birnbaum, Thomas A. Bruton, Jamie C. DeWitt, Detlef R. U. Knappe, Maricel V. Maffini, Mark F. Miller, Katherine E. Pelch, Anna Reade, Anna Soehl, Xenia Trier, Marta Venier, Charlotte C. Wagner, Zhanyun Wang, and Arlene Blum. Scientific Basis for Managing PFAS as a Chemical Class. Environmental Science & Technology Letters 2020 *7*(8), 532-543. DOI: 10.1021/acs.estlett.0c00255
- Wang, D. Z., Goldenman, G., Tugran, T., McNeil, A., & Jones, M. (2020). Per- and polyfluoroalkylether substances: identity, production and use (Nordiske Arbejdspapirer). Copenhagen: Nordisk Ministerråd. https://doi.org/10.6027/NA2020-901

The committee recognizes that some stakeholders recommended the use of this particular chemical of concern, supports Ecology's approach of selecting the PFAS with most available data as the chemical of concern, and understands that the assessment of alternatives is the most critical item in the committee's review of the report. Nevertheless, the committee believes that the report would be strengthened by a more complete description and justification of the choice of the chemical of concern and the decision to use a single representative compound for this alternative assessment.

Survey of PFAS Currently Used in Food Packaging

The draft report contains inaccuracies and incomplete information about the chemicals considered in the survey of PFAS currently used in food packaging.

The committee recommends revising the last paragraph of page 7 and the first paragraph of page 8 to make the statements and numbers more accurate, and referencing the July 31, 2020 FDA announcement mentioned above. For example, the last sentence of the first paragraph on page 8, "leaving 16 FCNs" does not seem accurate. In addition, the statement on page 7 regarding "an initial list of 35 FCNs for 25 PFAS

compounds" should be changed to "28 FCNs and 7 CFRs."

In addition, the logic is not clear about why PFPEs were removed from consideration (page 8: "perfluoropolyethers were also removed from consideration, leaving 16 FCNs") and requires additional explanation. *(More in Chosen Chemical of Concern, above.)*

Finally, there were inaccuracies in referencing a study (page 8: "This claim is also supported by published food packaging monitoring studies, which have detected 6:2 FTOH, a degradation product of concern for C6 PFAS polymers (Schaider et al., 2017b;"). This study does not confirm this claim. The study did not measure 6:2 FTOH. Four of the 20 samples tested contained polyfluorinated ethers, and most contained a large percentage of unknown PFASs (Schaider et al 2017).

Note about Chemical Naming

The committee understands that the legislation governing this report indicates that the terminology that "Perfluoroalkyl and polyfluoroalkyl substances" or "PFAS chemicals" means, for the purposes of food packaging, a class of fluorinated organic chemicals containing at least one fully fluorinated carbon atom. Thus, the report's terminology is consistent with the terminology used in the law. The committee notes, however, that there are multiple definitions of the PFAS class, and it would be helpful for this report to define up front what exactly is meant by "PFAS" in the scope of the assessment.

The siloxane selected from a group of silicone material is CAS# 68083-19-2. It is a dimethylsiloxane which is vinyl terminated; the vinyl group is a small portion of the polymer backbone. The draft report calls this compound "vinyl silicone polymer," which may not be an adequate description.

Choice of Alternatives to Assess

The Introduction lists the other states that are regulating PFAS in food packaging and are looking for alternatives, although it appears Washington State is leading on alternatives assessment. We suggest that this section be supplemented with some material and lists of alternatives to consider that have been developed elsewhere, including from a new report by the Organization for Economic Cooperation and Development (OECD (2020), PFASs and Alternatives in Food Packaging (Paper and Paperboard) Report on the Commercial Availability and Current Uses, OECD Series on Risk Management, No. 58, Environment, Health and Safety, Environment Directorate, OECD.) None of this information is in the report, and it needs to be listed and expanded on to help validate the recommendations in Ecology's report.

For example, the California Safer Consumer Products program identified the following alternatives in their research (Safer Consumer Products. Chemical Profile for Food Packaging Containing Perfluoroalkyl or Polyfluoroalkyl Substances. July 2020. California Environmental Protection Agency & Department of Toxic Substances Control):

1. Physical barriers, which can be made of plastic such as polyethylene, polyethylene terephthalate (PET), polyvinyl alcohol, or polylactic acid (PLA), as well as of silicone, aluminum, clay, wax, or biowax such as Clondalkin ECOWAX.

2. Alternative processing, such as machine-finished paper (e.g., natural greaseproof paper and vegetable parchment), mechanical densification, or mechanical glazing.
3. Alternative chemical barriers, such as starch, carboxymethyl cellulose, aqueous dispersions of copolymers such as styrene and butadiene, aqueous dispersions of waxes, water-soluble hydroxyethylcellulose, chitosan, alkyl ketene dimer, alkenyl succinic anhydride, silicone, and several proprietary coatings of unknown composition.
4. Alternative materials, such as palm leaf, bamboo, and various plastics.

It is important to note that the relative safety of these alternatives has not been assessed in California's process. If one or more plant fiber-based food packaging products containing PFASs are listed as Priority Products in the California Code of Regulations, those entities who wish to continue selling the product in California will have to submit an Alternatives Analysis (AA) to the California Department of Toxic Substances Control (DTSC).

Ecology's report provides a list of alternatives, but more information on why they were selected and how the conclusions were made need to be provided. Each alternative needs a review summarizing its known toxicity and biological impacts, and whether it is available in sufficient quantities.

Stakeholder Engagement

The stakeholder engagement section of the report was very thorough. It should probably be placed before the other modules in this report, as this is the order presented in the IC2 AA Guide. While the process of engaging stakeholders was clear, it was not clear what specific input they provided for the report and thus for Ecology's assessment.

Including the full list of stakeholders that commented in this report is important for transparency. Additionally, a plot showing growth in stakeholder participation with each call/webinar would be helpful for visualization.

Additional Comments on Report Content

Hazard Assessment

ListTranslator scores were incorrectly interpreted in the Hazard assessment. For example, the statement "LT-UNK, meaning these substances were present on some lists, but a ListTranslator score could not be calculated" (page 40) is an incorrect interpretation. LT-UNK indicates that the chemical is not on any high hazard lists that would score it as LT-1 or even LT-P1. Chemicals rated as LT-UNK may be of low hazard (thus why they are not on any high hazard lists) or this score may mean that there is very little information on the chemical and that it is not well tested.

Performance Assessment

The performance assessment results tables indicate products that are "favorable." The definition and metrics for favorability need to be defined up front in this assessment. In one example, page 56 states that "For each prioritized alternative, promotional data was found that identified that alternative as have OGR and/or leak resistance." From this statement it seems that only one of these criteria is sufficient for an alternative to be identified as favorable.

The statement on page 58 that "PFAS has likely led to a standard of over-engineered performance expectations in the food packaging industry" is an important consideration.

Cost & Availability

The databases from the Biodegradable Packaging Institute or the Compost Manufacturer's Alliance are key references in the Cost and Availability Assessment (page 11 of Appendix O). The draft report also added some focus on reusable products in Appendix O. The draft report appears to make some effort to consider sustainability; however, the concept of recycling is ignored. It is not clear to the committee how Ecology weighted considerations on biodegradability, compostability, and recyclability; there needs to be more description to justify the decision.

The report does not effectively distinguish PFAS added on the wet end of the production process from coatings that are added later on in the production process. The technology needed for both types of coating strategies is very different and will lead to differences in production cost.

The report also states conclusions that may not be explained by the evidence presented. For example:

- The statement on page 71 that "This difference may be due to differences in PFAS levels between wrappers and liners versus bags" does not indicate how variances between products explains the difference. Another factor to consider is how many different food establishments use these products. For instance, if 100% of 10 bags collected from different locations of the same fast food chain contain PFAS, that only tells you that this one fast food chain uses PFAS-treated packaging, but doesn't tell you how widespread the use of PFAS-treated packaging is across fast food chains.
- The statement on page 73 that "Conventional sandwich bags, which were not tested for PFAS and therefore not available in the Center for Environmental Health database, had an average unit price of 2 cents. This difference indicates that wax-coated bags are not cost comparable" does not explain that conclusion, given that it's unclear whether the 2 cent bags contain PFAS.
- The statement on page 78 that "Particularly because the cost of labor and cleaning are minimized, reusable boats are likely a cost-comparable alternative" is unclear on how the cost of labor and cleaning is minimized for reusable boats compared to single-use products.
- The statement in Appendix O page 5 that "Schaider et al (2017) found PFAS in approximately half of 42 dessert/bread food contact papers tested, but only in approximately one-third of…sandwich/burger contact paper products tested. This difference may be due to differences in PFAS levels between wrappers and liners versus bags" seems to indicate that more than one-third of wrappers tested in this study may contain PFAS. This would contradict the statement in

Appendix O page 7 that "The results of these studies can be found in Table 5 above and highlight a significant percentage of the market is already using PFAS-free products." If Ecology believes these results may be inaccurate, how can it conclude based on these data that a significant percentage of the market is already PFAS-free? Additionally, it is our understanding that if PFASs are intentionally added to food packaging, they are added at levels high enough to be detected by PIGE, the test method used in Schaider et al. (2017). Smaller amounts would be impurities, thus not covered by the Washington food packaging law.

- The statement in Appendix O page 11: "As such, it was difficult to identify any PFAS-containing items" is difficult to accept, given that PFAS were found in 22% of the wrappers tested by Toxic-Free Future in 2020.
- The statement in Appendix O page 12 that "PFAS-containing bags are in regular use (Table 5)" needs clarification about what is being referred to. What is the difference between sandwich bags, sandwich/burger food contact paper, and sandwich wrappers? Do sandwich food contact paper and wrappers fall under Product Category 1, because they are sheets of paper wrapped around the sandwich, rather than bags? Which entry in Table 5 is being referenced?
- The statement in Appendix O page 12 that "Therefore, this difference indicates that wax-coated bags are not cost comparable" is a major conclusion made without any solid data. Was it not possible to test a sample of the conventional sandwich bags for total F?
- The statement in Appendix O page 11 that "Of note, paper products coated with non-PET polymers (which includes PVOH, EVOH, PE, and polypropylene coatings) appear to be cost comparable with PFAS-containing paper products" does not have a clear explanation of how this conclusion is reached. Is PET-coated excluded because PET-coated is more expensive, or because no information about PET-coated is available?
- It is not clear in Appendix O Table 7 (page 11) which product categories are referenced in the "Difference in price" column.

Inconsistencies between Appendix O and Cost and Availability Conclusions in Report

The data in Appendix O appear to be inconsistent with the conclusions in the Cost and Availability section of the report. For example:

- Appendix O page 12: "EVOH-coated sheets were identified as cost comparable"
  - In table 7 on page 27 of the draft report, EVOH is listed as "Insufficient data" for this module. This is inconsistent with the conclusion here.
- Appendix O page 12: "EVOH-coated bags should qualify as a cost-comparable alternative."
  - This is inconsistent with the conclusion in Table 8 on page 28 of the draft report.
- Appendix O page 12: "EVOH-, and PE-coated plates were also identified as cost comparable"
  - This is inconsistent with table 9 on page 29 of the draft report.
- Appendix O page 14: "EVOH-, and PE-coated bowls were identified as cost comparable."
  - This is inconsistent with table 10 on page 30 of the draft report.
- Appendix O page 15: "EVOH-, and PE-coated trays were also identified as cost comparable."
  - This is inconsistent with table 11 on page 31 of the draft report.
- Appendix O page 15: "PVOH-, EVOH-, and PE-coated boats were cost comparable"
  - In table 12 on page 32 of the draft report, "PET coated" is listed, but it is not listed here.

- Appendix O page 16: “EVOH-, and PE-coated paper clamshells were also identified as cost comparable”
    - This is inconsistent with table 15 on page 35 of the draft report.
- Appendix O page 17: “EVOH-, and PE-coated food containers were also identified as a cost-comparable alternative”
    - This is inconsistent with table 16 on page 36 of the draft report.
- Appendix O page 20-22: Tables 9-11
    - The committee recommends verifying information consistency between these tables and tables 7-16 in the draft report.

Addendum: Copy-Editing & Minor Comments

The report should aim to be well documented, clear, and concise.

The report could use a close eye to proofreading – the use of extraneous punctuation and capitalization, inconsistent use of plural vs singular “data,” and other grammatical errors, were distracting to the reviewers. We recommend ensuring that:

- All figures, tables, and appendices have citations in the body of the report.
- All acronyms are defined at first use.
- All hyperlinks in the report work.

It would also be helpful to have a continuous page numbering system through the entire document for ease of providing review.

A visual timeline for the project to illustrate both the regulatory requirements and the different elements of the alternative assessment would be helpful to clearly show the process and save a lot of words.

Throughout the report, the products evaluated (for example, listed in tables) remain unnamed and “anonymous.” It’s not clear why this is the case, as publicly available promotional materials were used to evaluate the products.

Comments corresponding to specific pages

- Executive Summary page viii: “a single PFAS chemical and the products of its breakdown were identified” is unclear.
- Page 1: Regarding the list of other states and countries that are regulating PFAS in food packaging and are looking for alternatives, "regulate" would be more correct than “restrict.” The California DTSC action might not necessarily restrict the use of PFAS in food packaging.
- Page 1: “degrade into products such at 6:2 fluorotelomer alcohol (FTOH)” - The phrasing in this report is inconsistent about whether these polymers can degrade into 6:2 FTOH, or whether 6:2 FTOH is a manufacturing impurity. Using the language in the FDA July 31, 2020 announcement would make the language of this report more consistent and accurate.

- Page 1: "all 6:2 fluorotelomer alcohols (FTOH) in food packaging, both the chemical and all polymer compounds" is confusing. Are alcohols plural? Was 6:2 FTOH intentionally used in food packaging?
- Page 2: "the selection of a regrettable substitute is further reduced." This language is unclear.
- Page 3: Could use a separate subtitle starting at "The following recurring issues and confounding factors should be considered when reviewing this AA."
- Page 6: "RCW 70.95G.070 prohibits the sale of all PFAS in food packaging" or the sale of all food packaging with PFAS?
- Page 7: second to last paragraph, "(FDA, 2015)" should be "(FDA, 2016)." FDA removed these 5 substances from CFR, as noted in the table, and should not be cited here.
- Page 10: Since Stakeholder Involvement is a module of IC2 Guide, should we call the current "Section 2. Stakeholder Outreach and Engagement" an IC2 module?
- Page 11: "identify the alternative as unfavorable" -> characterize.
- Page 15: "PFAS and PFAS-free" -> PFAS-treated and PFAS-free.
- Page 20: "Product producers appeared apprehensive" Use food packaging producers or chemical producers instead?
- Page 24: Is there test data for foodservice containers to show the % of this category product containing PFAS?
- Page 27-36: It would make more sense for Tables 7-14 and associated text to be part of the summary and conclusions. These tables fall in the middle of the report; out of alignment with the IC2 guidance approach.
- Page 41: "(Fengler et al., 2011; Müller et al., 2012; Tier et al., 2017)."
    - Many of the studies summarized in Trier et al. (2017) are from older formulations containing diPAPs, which would suggest that the 2011 and 2012 studies were, too. When were diPAPs officially phased out?
    - Trier et al is also not in this section's list of references.
- Page 42: table 9, recommend to define "DG."
- Page 48: "(Trier, Taxvig, Rosenmai, & Pedersen, 2017)." Is this different from Trier et al 2017?
- Page 48: "the PFAA load in streams" -> waste streams.
- Page 48: "The PFAA was leachable to pore water (25–49%) and was strongly correlated with the PFAA load (Choi et al., 2019)."
    - The PFAA was strongly correlated with the PFAA load? This is unclear.
- Page 48: "In addition, 6:2 FTOH is often used as a precursor to PFAS polymers used in food packaging products and can be present as a residual (Boucher, 2020)."
    - This seems to contradict earlier statements about the reason for the presence of 6:2 FTOH in food packaging.
- Page 48: "Although the magnitude cannot be predicted, a decrease in exposure to certain PFAS via food packaging is expected with increased use of safer alternatives; however, there are many routes of exposure to PFAS, so exposure to these chemicals would not be completely eliminated."
    - This statement is unclear.
- Page 54: "Leak resistance: Ability of a product to resist grease or other fluid by either the ability to reduce permeation AND transfer through the substrate, or the ability to resist leaks through folds or seals (e.g., folded paperboard products)." -> delete "the ability to" and add "ing" to both parts.
- Page 54: "products that are certified compostable by Biodegradable Products Institute."

    - Specify when BPI started certifying products that are PFAS-free. Products certified before that date may not be PFAS-free. Give details of the specification; e.g. is there a threshold for F that is tested?
- Page 56: “For each prioritized alternatives, promotional data was found that identified that alternative as have OGR and/or leak resistance” alternatives -> alternative, have -> having.
- Page 56: “and this treated paper can easily be developed into bag or sleeve products” Reference for this statement?
- Page 69: “Eleven manufacturers comprise half of the single-use foodservice market.” How many manufacturers are there in total? And how about for single-use packaging?
- Appendices Page 49: “Highly persistent and/or highly bioaccumulative and/or toxic alternatives” This says and/or, but there's no vP or vB or T option listed in the brackets.
- Appendix O Page 4: “across three different organizations” The Schraider et al 2017 study is from 9 different organizations.
- Appendix O Page 9: “noted that their product uses a new technology that is starch and cellulose based” Specify what type of product: food contact paper, dinnerware, or takeout container.
- Appendix O Page 10: Paragraph beginning with “Using a conservative 5-10% cost increase as a benchmark, …” Rephrase the first sentence, as it is unclear how the two halves of the sentence are connected. It is not clear why the last sentence starts with “Instead.”
- Appendix O Page 18: “In several of these case studies, expected investments from companies.” Why "expected?" Looks like those were actual investments made in some case studies.
- Appendix O Page 23: “ReThink Disposable. 2018. Business Cost Impacts from disposable food service items. Clean Water Action Fact Sheet.” Is there a link to this resource?

WASHINGTON STATE
Academy of Sciences
Science in the Service of Washington State

Cover Letter - Transmission of Addendum to Peer Review

October 23, 2020

Ken Zarker
Pollution Prevention Regulatory Assistance Section Manager
Washington State Department of Ecology
ken.zarker@ecy.wa.gov

Dear Ken,

Enclosed you will find a clarification of the independent peer review of the draft report prepared by Ecology related to the identification of safer alternatives to per- and poly-fluoroalkyl substances in plant fiber-based food packaging. This document was prepared in response to your letter on October 15, 2020 requesting clarification to the peer review, per the terms of the Washington State Academy of Sciences (WSAS) Scope of Work with Ecology (Contract No. C2000115) Task 3, and the directive of RCW 70A.222.070 (formerly RCW 70.95G.070).

We thank Ecology for reaching out to us with questions regarding the peer review – our intent is to provide useful, constructive feedback that you can use to further improve your report on PFAS alternatives. The WSAS committee would welcome the opportunity to address any further questions you have and discuss these considerations further with the Department of Ecology if desired.

We hope you find this clarification to be useful, and would be pleased to talk with you about engaging in other such reviews as appropriate and as funding allows.

Sincerely,

Donna Gerardi Riordan
Executive Director

Yasmeen Hussain
Program Officer

Cc: WSAS Committee on PFAS in Food Packaging – Elaine Faustman (Chair), Simona Balan, Lauren Heine, Pat Hunt, Donatien Pascal Kamdem, Michael Skinner, Huqiu Zhang
Roger Myers, WSAS President

Attachment: Addendum to Peer Review by PFAS in Food Packaging Committee

ADDENDUM TO PEER REVIEW
Underwater Acoustics and Disturbance Committee

Thank you for your questions and request to clarify our review transmitted on October 5, 2020. The committee's intent in the peer review process is to provide constructive feedback for Ecology's Alternatives Assessment report. The committee agrees with the report's overall conclusions; our comments in our original review and in this clarification are intended to strengthen the evidence supporting the report's conclusions to ensure that the methods used and the information on which they are based are thoroughly described, transparent, and well-documented.

Peer Review Process

The committee's peer review in its entirety reflects a consensus view. No portion of it should be construed as an individual committee member's suggestion.

Generally speaking, the WSAS Committee peer review process aims to make comments and suggestions on a work product as presented, rather than recommendations derived from a study committee, which is a different kind of project, and thus a different process. The latter requires a longer, more in-depth project with iterative deliberations that are beyond the scope and timeline of this independent peer review.

Precursors and Breakdown Products

To clarify the statement "Relying solely on precursors and breakdown products for toxicity analysis is inappropriate," the committee intended to communicate that it is insufficient to rely solely on precursors and breakdown products for toxicity analysis when publicly available data exist about the polymer (either the specific polymer as defined by trade name or a generic example of the compound). Thus, Ecology's process of conducting a hazard evaluation on only the impurities/residuals of certain alternatives does not fully assess the hazard of those alternatives.

Standard practice would have Ecology use the following procedure to do due diligence in assessing all viable alternatives:

1. Attempt to evaluate the polymer in question
    a. The first priority is to assess the specific compound sold as a trade-named substance.
    b. If specific compound information is unobtainable due to confidential business information or other considerations, assessments could be performed on generic compounds that serve as proxies for commodity polymers such as PE, PET, and EVOH, to assess the polymer.
    c. The consideration of relatively small molecular weight species of the polymer (e.g. oligomers) or functional groups to inform the assessment.

2. Evaluate relevant precursors and breakdown products (for example, using publicly available generic information about precursors and degradation products for commodity polymers like PE and PET)

The report would benefit from greater transparency on how hazard analysis was or was not performed on the polymer. For example, the report could state that a compound was evaluated but not enough data was found to form a conclusion, or that literature suggests that a polymer does not pose a hazard.

Use of GreenScreen® Methodology

Explanation in report

The committee appreciates Ecology's detailed and coherent explanation in its letter on October 14, 2020 of why and how GreenScreen® assessments were used in the hazard evaluation module. This explanation could also be included in the Report or Appendices. The committee also recognizes that there are structural and resource limitations in conducting the alternatives assessment, and suggests including a detailed explanation of the overall decision process, and especially related to addressing these limitations.

The committee also concludes that Ecology's report would benefit from a clearer explanation of the use of the term "insufficient data" to specify that this means that an existing GreenScreen® is not available, rather than stating that there is no publicly available data on the chemical for which a GreenScreen could be developed. While the report currently includes a link to the GreenScreen® website containing the relevant hazard evaluation, the report could also (1) more clearly list the peer-reviewed literature referenced in the GreenScreen®; (2) more clearly note the dates of existing GreenScreen® evaluations that were cited, and (3) if the screens are not current (more than 3 or 4 years old) also show the results of a literature search for any relevant studies published since the GreenScreen® report was produced. The committee also suggests that the report include clarifying statements that existing GreenScreen® assessments were the sole hazard evaluation tool used for the alternatives assessment, and that Ecology continues to seek information to perform GreenScreen® or other hazard evaluations for these alternatives.

The abovementioned clarifications would partially address the committee's comments. Changes in the assessment process, as noted below, would address the committee's other comments.

Changes in assessment process

The committee recognizes that the IC2 AA guide for a Level 2 Hazard Assessment indicates use of the GreenScreen® methodology for evaluation, and the committee supports its use to evaluate alternatives. The committee did not find, however, that the GreenScreen® methodology was used to conduct a new hazard assessment. Its use seems to have been limited to examining existing GreenScreens®.

A Level 2 Hazard Evaluation would use the GreenScreen® method to evaluate hazard information, not only rely on existing publicly available GreenScreen® evaluations. If information pertaining to a trade-name compound is unavailable, Ecology can acknowledge the unavailability of confidential business information and instead use generic chemical information and publicly available literature about typical formulations to

conduct an assessment with the GreenScreen® tool. For transparency and to strengthen its conclusions, Ecology could document how far they were able to get in the GreenScreen® assessment and outline what data is and is not available.

By stating "These gaps throw into question the final Safer Alternative conclusions," the committee intended to call attention to the need to support Ecology's conclusion that there is insufficient information to readily assess PE, PET, and EVOH. It is not accurate to report "insufficient data" and end the assessment at that point when publicly available data exist that can be used to evaluate a compound; it is important for the alternatives assessment to convey accurate information.

At the very least, the committee suggests that Ecology do due diligence by conducting a brief literature review to *supplement* the existing GreenScreen® evaluations and more completely assess potential hazards of the alternative suggested. When existing GreenScreen® reports are not available, a review of the published peer-reviewed literature search should be done to confirm the alternatives suggested have limited hazard. All chemical alternatives should undergo a consistent hazard assessment, whether or not there is an existing GreenScreen®.

A literature review would strengthen the report by being a proactive approach to carefully determine the safety of the proposed alternatives. Related methods of hazard assessment such as the Globally Harmonized System of Classification and Labelling of Chemicals and governmental hazard information databases could be used to fill in gaps in information and fit within the GreenScreen® framework without adding an excessive burden.