

**ASSESSMENT OF BISPHEENOL A FOR USE IN
FOOD CONTACT APPLICATIONS**

Instruction to Reviewers

Thank you for agreeing to review the document entitled “Draft Assessment of Bisphenol A for Use in Food Contact Applications.” We ask that you address the following questions:

1. Does the assessment report objectively and transparently identify the data and methodology used, explain how data were selected, and identify what criteria were used to determine the suitability of the data? Does the report identify the scientific support for these criteria and methods?
2. Are uncertainties in the assessment objectively and transparently identified and characterized?
3. Are there additional scientific/ technical studies relevant to the endpoints examined and the route of exposure that should have been considered?
4. Is the no observed adverse effect level (NOAEL) used in this assessment the appropriate point of departure for calculating the margins of safety (MOS), for purposes of this safety assessment or do data support the use of an alternative endpoint? In selecting the NOAEL, did FDA make the best scientific choice based on the available data and information?
5. Were scientific assumptions that are not strictly linked to the data explained and appropriate for the purposes of this safety assessment?
6. Are the scenarios addressed representative, comprehensive, and scientifically sound, considering the public health risk evaluated?
7. Are the recommended studies in the tiered testing strategy presented appropriate in relation to bisphenol A exposure through the use of food contact applications, and will those studies reduce the uncertainties associated with the assessment? Please suggest any other recommended studies and/or endpoints that you think would be useful for future assessments.
8. Do the assessment results objectively and transparently support the conclusions? Are they supported by the available data and science?
9. Do you have any additional comments that would assist FDA in refining the assessment?
10. Does the information and data in Appendices 1 and 2 support the underlying assumptions used in the interim assessment?

FDA is required to prepare a report that described the nature of your review and your findings and conclusions. The report may either (a) include a verbatim copy of each

reviewer's comments (and will attribute the comments to individual panel members); or (b) represent the views of the group as a whole including any disparate and dissenting views. To assist us in developing this report, we will be preparing a written transcript of the public meeting of the Science Board Subcommittee. The report will disclose the names of the members of the Subcommittee and their organizational affiliations. It will be publicly disseminated on FDA's website.