Biotechnology Innovation Organization

25 YEARS OF INNOVATION

January 11, 2018

Nancy B. Beck
Deputy Assistant Administrator, Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, DC 20460

Re: Docket ID No. EPA-HQ-OPPT-2017-0585

Dear Deputy Assistant Administrator Beck:

The Biotechnology Innovation Organization (BIO)'s Industrial and Environmental Section (IES) respectfully requests a 30-day extension to the comment period for the U.S. Environmental Protection Agency (EPA or the Agency)'s New Chemicals Review Program Implementation under the Toxic Substances Control Act as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (TSCA), currently ending on January 20, 2018. An extension until February 19, 2018, is needed to allow stakeholders sufficient time to consider the new material provided by the Agency on December 6, and to organize meaningful comments and feedback.

BIO IES represents the companies which manufacture biobased or 'renewable' chemicals using biotechnology. Many are small to medium sized and the New Chemicals Program is the route by which their products are regulated prior to their release onto the market. Any changes to the current system of reviewing new chemicals will, therefore, have a significant impact on the decision making and resource requirements of our members. Because of this, the documents and presentation provided by the Agency on December 6, 2017, are of great importance to BIO members and they would like to ensure they have ample opportunity to provide an adequate and helpful response to the Agency. A 30-day extension would provide the necessary time to process, review, and comment on these technically complex documents, particularly as this is one of three comment deadlines for separate and distinct TSCA implementation initiatives, all of which are in the formative stage. Namely, comments on EPA's Strategic Plan for Alternative Test Methods were due January 10, these comments are due by January 20, and comments on EPA's proposed Approaches for Prioritization are due by January 25. In the case of the Alternative Testing comment submission deadline, EPA did allow an extension of time which was helpful albeit rather short.

Furthermore, it is unclear whether there will be a future opportunity to comment on the new material or the proposed changes to the program before they are finalized. If this is stakeholders' opportunity to engage the Agency, it is important that the Agency ensure this opportunity to comment is sufficient to gain meaningful feedback from the regulated community.

1201 Maryland Avenue SW
Suite 900
Washington DC 20024

202.962.9200 »
202.488.6301 »
bio.org

Importance of New Information and Need for an Extension:

On December 6, 2017, EPA held a public stakeholder meeting to update and engage with the public on the Agency's progress in implementing changes to the New Chemicals Review Program as a result of the 2016 amendments to TSCA, including discussion of EPA's draft New Chemicals Decision-Making Framework. At this meeting, EPA described its review process for new chemical substances under the amended statute and allowed interested parties to provide input and to ask questions. The Agency plans to utilize the feedback it receives from the public meeting and comments received to improve policy and processes relating to the review of new chemicals under TSCA.

During the stakeholder meeting EPA provided two new documents to stakeholders for review and comment. It should be noted that this was the first time these documents had been provided to the public with explanation and for comment. They are:

1. Draft Points to Consider when preparing new chemical notifications

2. New chemicals decisions manual

Upon conclusion of its presentation of these materials, EPA requested input from stakeholders on a number of important items. The following is a nonexclusive list of items that that the Agency raised, that are of importance to BIO members and for which additional time is needed to adequately address.

- The use of Significant New Use Rules, particularly as this can extend the review period by up to 180 days;
- Whether EPA should consider exposure in its determinations of "not likely to represent a risk" – currently the only chemicals which have obtained this determination are of low hazard (EPA followed up on this request and the response was posted on January 8, 2018);
- How far into the future is "reasonably foreseeable", and how will the Agency define this term, plus the uncertainty the further into the future one projects;
- Implementation of a pre-notice consultation process, which encourages companies to consult with EPA prior to submitting a Premanufacture Notice so that companies know what information they will be required to provide;
- Whether low solubility Class 2 chemicals need appropriate test methodologies;
- EPA stated that companies need to pay attention to the default assumptions that will be made in the absence of information. They are very conservative. For example, in the absence of data on particle size distribution, EPA will assume the particles are respirable. During the public meeting, interest was expressed by the regulated community in receiving more information on how the scores for EFATE are determined and how ECOSAR data are used.

- The current status of the Sustainable Futures program – whether it is still relevant, should it be updated, do they need to increase or decrease the number of training workshops, should they update the framework manual to reflect TSCA as amended.

Providing responses to these more specific requests is important and necessary, but will require time for industry associations to consult with their members.

We thank the Agency for providing this opportunity to engage with it, for developing comprehensive written material and for providing the forum at which this material was presented. BIO members recognize the significant time and resources the Agency has invested in doing so. To provide meaningful feedback to the Agency, we request that the timeline for receiving comment be extended by a minimum of 30 days to ensure members have the time needed to provide a substantive response to this significant endeavor by the EPA, one which impacts our members considerably, both now and into the future.

Sincerely,

Clare Thorp, PhD
Managing Director, Industrial and Environmental Section
Biotechnology Innovation Organization