Message

From: Culleen, Lawrence E. [Lawrence.Culleen@arnoldporter.com]
Sent: 10/31/2019 11:46:53 PM
To: Dekleva, Lynn [dekleva.lynn@epa.gov]
Subject: Proposed Revisions to Draft Consent Order
Attachments: PAG Consent Order Compare EPA Draft to Consortium Draft October 2019.docx; PAG Conortium Edits to Proposed Draft Consent Order Updated 10_31_19 w_PAG Consortium Comments Accepted.DOCX

Lynn --

As discussed, the PAG Consortium members have reviewed and have made proposed edits to the draft model Consent Order that was shared with us just prior to our meeting with you and others at the Agency. The Consortium has been diligent in its efforts to timely review and digest the Agency's draft and to identify (and constructively address) only those items of greatest concern to the Consortium members, and to the PMN submitters among them in particular. Our good-faith efforts are reflected in the revised version of the draft Consent Order we have prepared.

Attached are two versions of the same document: one version reflecting the edits the Consortium members have proposed to the Agency's draft model Consent Order which are reflected in "red-lined" mode (and with explanatory comments in the margins); a second edition, in which the various track-changes portions have been "accepted" but with the Consortium's explanatory comments retained in the margins. This second edition might be easier to read, however the first attachment enables you to focus attention on the passages in which changes have been made. Depending on the layout of your computer, you might need to expand some of the comment "bubbles" to review the entirety of the text within.

In the edition attached, we have proposed changes to address and accommodate the certain concerns the members have about several areas I summarized for you during our phone calls. Following highlights some of the areas of concern and the manner in which the attached draft addresses them:

1. Concerns arising due to passages in the model Consent Order the members had not seen previously. As I have mentioned, the versions of the draft Consent Order previously shared with the Consortium members have not included language other than the testing section. Thus, since many members have never submitted PMNs before, nor been subject to Consent Orders, they were very unfamiliar with (and taken aback by) certain terms -- such as those included in the Hazard Communications section, record keeping provisions, and distributions limitations (among others). Those passages include volume limitations, requirements concerning the physical state of the PMN substances ("in solution" only), hazard warnings and labeling requirements, and specifications for the use of certain PPE that here-to-fore were not discussed. To address this, we have added comments in the margins requesting EPA to confirm that the Consent Orders to be presented to the PMN submitters who are Consortium members will incorporate the practices and use conditions set forth in the PMNs submitted. Thus, by way of example, if a PMN substance is expected to be manufactured or imported in a solid form, and this was described clearly in the submitted PMN, the draft Consent Order prepared for that PMN submitter should not be expected to include an "in solution only" limitation. We think this should be easy to confirm; my recollection is that you had been planning to look into this and get back to me, and I look forward to your confirmation on this.

2. Timing intervals between testing "due" dates. The intervals in the draft Consent Order for the due dates for submitting studies were very brief, especially given the number of substances included, and the need to potentially modify and adapt certain methods. We have proposed that the "clock" on the interval of time by which a triggered study grouping (or Step) must be completed within a given Tier should only commence running when the Agency has reviewed and approved the pertinent protocol for the triggered study. This avoids difficulties that can frequently arise if the Agency is behind schedule on protocol review, and/or when there might be a need for the Agency technicians to confer with the study director/investigator concerning specific test methods. We also have edited the document to clarify when the "meet and confer" sessions between Steps and Tiers are to begin, and we have built-in terms to ensure those sessions are not only convened promptly after a required study is submitted, but that the sessions also conclude

within a set period of time. This addresses the concerns you have raised about open ended consultations on such matters.

3. Focusing attention on a limited number of substances to test within each Step or Tier. As you and I have discussed, the cost of the testing set forth in the Steps and Tiers is considerable. Such costs can be contained (and potentially managed) if there are controls in place to avoid the potential expansion of the number of substances to be tested in any given Step or Tier. Accordingly, we have included language that should help achieve this end by proposing that the number of substances to be tested in any Step or Tier not exceed the original number of representative substances on which testing will initially occur. This will encourage the conferring parties to identify and focus testing solely on the substances that may present the greatest concerns under the conditions of use. We also have added a volume-based trigger that must be met before the studies in Tiers 2(a) or (b) would be undertaken. We think such a trigger can be effective and reflects a risk-based relationship to requiring the more costly and time-consuming studies (i.e., if the volume limit is exceeded, it follows that exposures or releases also might increase; making it more reasonable to require testing on aquatic species and mammals). The quantity-based trigger we have proposed would not pertain to the 3 clusters of studies imposed in Steps 1 - 3 of Tier 1 testing to ensure the Agency is certain to receive the data needed to fill certain data gaps and better estimate exposures and releases and assess potential risk.

We recognize there may be a number of ways to successfully address the various concerns the Consortium has identified with the draft Consent Order terms. I would be pleased to meet with you in your offices to walk through and explain in greater detail the various changes we have proposed and to learn about any suggestions that you may have considered that also address these issues while likewise meeting the Agency's information needs and regulatory objectives.

In closing, the Consortium has asked that the Agency provide a responsive draft and any feedback concerning the attached version in advance of submitting draft Consent Orders directly to the Consortium's PMN submitter/members. This will help reduce review time and allow us to more swiftly respond and seek resolution on issues that could affect all members, including not only the producers but also the formulation users in the semiconductor sector who also are cooperating with this effort.

Thank you. I look forward to speaking with you soon.

Larry

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