Message

From: Lynn L. Bergeson [lbergeson@lawbc.com]
Sent: 3/26/2019 12:55:15 PM
To: Baptist, Erik [Baptist.Erik@epa.gov]
Subject: FW: Follow Up
Attachments: 00264051.doc

Hi Erik,

Trust you saw this.

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From: Lynn L. Bergeson
Sent: Friday, March 22, 2019 3:50 PM
To: Erik Baptist, Esquire
Cc: Richard E. Engler, Ph.D.
Subject: Follow Up

Hello Erik,

Rich and I spoke with you back in February (see below). When we spoke, we offered to suggest consent Order language to address the commercial reality of our client's (as well as other clients) need to distribute a PMN substance that has a invited a SNUR (but none has been issued in final) to its customer and its customer's need to distribute further the PMN substance, and the limitations in the Consent Order disallowing such further distribution. The appended suggests language to address this situation, while still providing EPA with the information it seeks to track the distribution of the substance. T

Ex. 4 CBI

We would be pleased to discuss.

Thanks

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From: Lynn L. Bergeson
Sent: Tuesday, February 12, 2019 8:55 AM
To: Erik Baptist, Esquire
Cc: Richard E. Engler, Ph.D.
Subject: Follow Up

Good Morning Erik,

We suspect EPA OPPT has received similar requests from others, but we wanted to run this scenario by you. We have a number of clients who have signed consent orders and are finding that the delay in promulgating final SNURs is a formidable barrier to the commercialization of the new chemical substances.

As you know, EPA consent orders allow distribution of a PMN substance to the submitter's direct customer provided the end-user agrees in writing to abide by the restrictions of the consent order and to not further distribute the PMN substance. The prohibition against further distribution automatically sunsets 75 days after the promulgation of a SNUR for the substance. The problem arises between the time when the consent order is signed and when the SNUR is published in final. An OPPT attorney-advisor has suggested that a submitter's customer's customer may submit a SNUN under 40 CFR Section 721.45(h) to allow the submitter's customer to distribute further a PMN substance once the SNUR is proposed but before it is published in final.

40 CFR §721.45 provides:

The persons identified in §721.5 are not subject to the notification requirements of §721.25 [SNUN requirements] for a chemical substance identified in subpart E [a specific SNUR] of this part, unless otherwise specified in a specific section in subpart E, if:

(h) The person submits a significant new use notice for the substance prior to the promulgation date of the section in subpart E of this part which identifies the substance, and the person receives written notification of compliance from EPA prior to the effective date of such section. The notice submitter must comply with any applicable requirement of section 5(b) of the Act. The notice must include the information and test data specified in section 5(d)(1) of the Act and must be submitted on the notice form in Appendix A to part 720 of this chapter. For purposes of this exemption, the specific section in subpart E of this part which identifies the substance and §§721.1, 721.3, 721.11, 721.35, and 721.40 apply; after the effective date of the section in subpart E of this part which identifies the substance, §721.5 applies and §721.20 continues to apply. EPA will provide the notice submitter with written notification of compliance only if one of the following occurs:

1. EPA is unable to make the finding that the activities described in the significant new use notice will or may present an unreasonable risk of injury to health or the environment under reasonably foreseeable circumstances.
2. EPA and the person negotiate a consent order under section 5(e) of the Act, such order to take effect on the effective date of the section in subpart E of this part which identifies the substance.

We would expect EPA to push back with a concern that the submitter (of the significant new use notice in this fact pattern) many not actually be engaging in a significant new use as envisioned in 721.45 (h), because the SNUN describes operating under the conditions specified in the consent order, and conclude this interpretation of 721.45(h) and the SNUN are invalid. In addition, EPA's approval of a SNUN submitted by the customer's customer would not change the prohibition in the consent order against further distribution. The customer's customer may be permitted to receive the substance as a result of EPA's action under 721.45(h), but the submitter's customer is still bound by the prohibition against further distribution. Conversely, if the submitter's customer submits a SNUN under 721.45(h), it is not clear how such a submission would bind the customer's customer.

We question whether 721. 45(h) allows the further distribution of a PMN substance as outlined above as suggested by the attorney-advisor. We recognize that even if this interpretation were deemed colorable, we would likely need OGC sign off.

Are we missing anything? Are there other options to permit distribution in supply chains that are more complex than just a manufacturer and direct customer, such as modifying consent orders to permit further distribution as long as written agreements are in place throughout the supply chain?

We would be happy to discuss. We suspect we are not alone in seeking guidance on this issue as supply chains today are more complicated than the "single distribution" language contemplates.

Thanks

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