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TSCA Inventory Notification (Active/Inactive) Requirements– The Final Rule

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Herb Estreicher

Herb Estreicher has an interdisciplinary approach combining law and science. He represents leading manufacturers of chemicals, pesticides, insect repellents, food additives, and consumer products before Federal and State regulatory agencies. Dr. Estreicher provides advice on product liability risk control and assists clients with crisis management for embattled products, including chlorinated pesticides, wood preservatives, dioxins, and persistent, bioaccumulative, and toxic (PBT) chemicals.

He helps clients secure and maintain chemical approvals and pesticide registrations in Canada and Europe, advises clients on responding to the CEPA challenge program, and provides advice on European chemical directives and initiatives, such as the EU Biocidal Products Directive, and the EU Registration, Evaluation and Authorization of Chemicals (REACH) regulation. Dr. Estreicher also represents clients in the negotiation and development of various international environmental instruments governing persistent organic pollutants (POPs), has been actively involved in the Great Lakes Binational Toxics Strategy, and has participated in the Canadian Strategic Options Process (SOP). He is actively engaged in the areas of TSCA Reform, Korea REACH and the California Green Chemistry Initiative.

Tom Berger

Tom Berger has a chemical engineering background, and is a partner in Keller and Heckman's Washington DC office and heads Keller and Heckman's Indianapolis satellite office. Mr. Berger has extensive experience in representing foreign and domestic companies in a broad range of areas, including counseling, advocacy, and rulemaking in environmental law, occupational safety and health law, contracts, EPA enforcement proceedings, and chemical and product liability management.

Mr. Berger assists clients in bringing new products to market in an expedient, cost-effective manner using an interdisciplinary approach that combines law and science with an emphasis on emerging technologies in the industrial chemicals area.

Mr. Berger's practice focuses on the regulation and approval of new and existing chemicals under the U.S. Toxic Substances Control Act (TSCA) and its international counterparts in Australia, Canada, China, the European Union, Japan, Malaysia, New Zealand, the Philippines, South Korea, and Taiwan. Mr. Berger also counsels trade association clients on various issues, including environmental, product disparagement, and defense matters.

8(b)(4) – (5) Inventory Status Notification

- Under Lautenberg Chemical Safety Act, by June 22, 2017 EPA to issue rule requiring manufacturers and importers ("M/Is") ("may" require processors) to notify EPA within 180 days of each Inventory-listed non-exempt substance produced within 10 years prior to June 21, 2016 ("Lookback Period")
  - Reported substances = "active"
  - Non-reported substances = "inactive"
    - EPA cannot delist, or require PMNs for inactive substances upon change to active status
- The Final Rule signed on June 22, 2017.

Proposed Rule

- On January 13, 2017, EPA issues proposed Inventory Status rule
  - 82 Fed Reg. 4,255
- Comments were due March 14, 2017
- 55 Comments Filed by Trade Associations and *Ad Hoc* Coalitions and ENGOs
- Final rule reflects Major Improvements to the EPA Proposal

Major Changes to the Proposed Rule

The Good

- EPA Eliminated the Proposal to Require Notifiers to Indicate the 1st and Last Day of Manufacture/ Import During the 10-Year Lookback Period.
- EPA has agreed that 2016 CDR Chemicals can be Exempt:
  - ✓ No Notification for Non-CBI 2012 or 2016 CDR Chemicals
  - ✓ No Notification for CBI 2012 or 2016 CDR Chemicals if M/I no longer claims identity confidential

Major Changes to the Proposed Rule

The Good (continued)

- Chemicals added to the Inventory during the 10-year lookback period are automatically on the Interim List of Active Substances but CBI claims must be dropped to take advantage for confidential substances.
- M/Is need Not Notify if they have a CDX receipt from someone else that has notified but risk if submitter withdraws notice.
- Processors are allowed to report to EPA not later than 420 days after the final rule is published in the FR (up from 365 days).

Major Changes to the Proposed Rule

<u>The Good</u> (continued)

- M/I and processors to notify intent to reactivate an inactive substance not more than 90 days (up from 30 days) before the anticipated date of manufacturing or processing.
- A substance is not designated as "inactive" until 90 days after EPA has identified the substance for inactive designation. Eliminates the GAP problem.
  - Obligation to submit an NOA Form B does not arise until 90 days after EPA has identified chemical substances for the inactive designation.
  - M/Is and processors can submit an NOA Form B for a substance that EPA has identified for inactive designation even before the effective date of such designation.
  - Validity of the notice does not depend on whether the intended manufacturing or processing actually occurs by the anticipated date.

Major Changes to the Proposed Rule

The Good (continued)

- EPA Eliminated the Need to Report Activity Type.
- EPA clarified the due diligence needed for retrospective reporting.
- Drop down list of substances on the Interim List of Active Substances includes Accession Numbers for confidential chemicals to alleviate some joint reporting.

Major Changes to the Proposed Rule

The Bad or Neutral

- EPA declined to establish a formal corrections process.
  - However an M/I or processor can withdraw an NOA Form A if done before 420 days after the final rule is published in the FR.
  - M/I may correct an NOA Form A by filing a new NOA Form A following withdrawal, so long as the new Form A is filed no later than 180 days after the final rule is published in the FR.
  - Can correct NOA Form A before EPA acts.
- EPA declined to update the interim list in real time

Major Changes to the Proposed Rule

The Ugly

- M/Is of substances under a LVE/ LOREX/ Polymer Exemption Will need to Notify the Substance (unless otherwise exempt) if:
  - It is on the Public Version of the TSCA Inventory (or known to or reasonably ascertainable by the M/I to be on the Confidential Inventory); and
  - Not on the Interim List of Active Substances (only for non-CBI substances) or the M/I has proof (CDX receipt) that someone else has notified.
- Fortunately a company manufacturing a substance solely for export or test marketing is Not subject to the Notification requirement.

Major Changes to the Proposed Rule

The Ugly (continued)

- EPA declined to add Y-designated polymers to the Interim List of Active Substances.

“Details”
Who, What, When, *etc*…

Important Definitions

- ***Active substance***
  - Interim active substance
  - "Naturally occurring" substance
  - Substance added to Inventory on/after 6/21/06 by NOC received on or after that date
  - Substance subject to commercial activity designation that EPA designates as active based on receipt of reset notice
- ***Inactive substance***
  - Substance subject to commercial activity designation that EPA designates as inactive based on lack of receipt of reset notice, effective 90 days after EPA identifies substance for such designation
- ***Lookback period***
  - Period beginning 6/21/2006 and ending 6/21/2016

Important Definitions

- ***Interim active substance***
  - Reported for CDR as being produced in 2010, 2011, 2012, 2013, 2014, or 2015
    - Even if on confidential Inventory (NEW)
      - But must report to maintain chemical identity as CBI
- ***Chemical substance subject to commercial activity designation (SCAD)***
  - Added to Inventory before 6/21/06
  - Not interim active
  - Not naturally occurring, and
  - Not yet designated by EPA as active or inactive

Important Definitions

- ***Reportable chemical substance***
  - Substance listed on Inventory, and either:
    - subject to SCAD for which notification with Form A is required or allowed;
    - added to confidential portion of Inventory before 6/22/2016; or
    - inactive substance for which notification is required using Form B
- ***Notice of Activity (NOA) Form A***
  - Form for supplying retrospective notification under 40 CFR 710.25(a)
- ***Notice of Activity (NOA) Form B***
  - Form for supplying forward-looking reporting under 40 CFR 710.25(c)

Who Must Report (Form A)

- Manufacturers and importers who produced SCAD substance for non-exempt purpose at any time during lookback period
- Except:
  - Have CDX receipt documenting EPA receipt of Form A from another person for same substance
    - But must submit Form B if inactive due to withdrawal of Form A, or
  - Prior manufacture of substance is not known to or reasonably ascertainable
    - "All information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know…"

Who May Report (Form A)

- Any person not required to submit Form A, but who manufactured, imported, or processed reportable substance during lookback period
  - Processors
  - Persons who choose not to avail themselves of exemptions, as must report to assert and substantiate CBI

Who Must Report (Form B)

- Any person who intends to manufacture, import, or process an inactive substance, for non-exempt purpose after effective date of EPA designation of substance as inactive
- Unless:
  - Listing of inactive substance on confidential portion of Inventory not known to or reasonably ascertainable by the person

Exemptions

- Non-"chemical substances"
- R&D and test marketing substances (NEW)
- Substances in "articles" that are processed or imported
- 720.30(g) and (h) substances
  - Byproducts, impurities, end-use, non-isolated intermediates, *etc*.
- Export-only substances (unless 12(a)(2) finding made) (NEW)
- Naturally occurring substances
  - Unless produced "synthetically"
- NOT LVE, LoREX, "polymer exempt" substances
  - But "EPA anticipates that the presence of a substance on the confidential portion of the Inventory may be information that is not 'known to or reasonably ascertainable by' a person who is operating under a PMN exemption and who did not submit the confidentiality claim for the specific chemical identity of that substance."

When is Form A Due?

- **Manufacturers/importers:**
  - 180 days after FR published (~end of CY2017)
    - Can withdraw 420 days after FR published (~late August 2018)
- **Processors:**
  - 420 days after FR published (~late August 2018)

When is Form B Due?

- Before actual but not more than 90 days prior to anticipated date of manufacturing or processing
  - Also may be submitted during 90-day period between identification and effective date for inactive designation, by person currently manufacturing or processing or who anticipates doing so within 90 days following submission
  - If EPA receives submitter request to withdraw Form B and EPA has not moved substance to active or public Inventory EPA can grant request

What Must Form A Contain?

- Company, official, technical contact
- CASRN, CA Index name, Accession No.
  - "pick list"
  - Accession No. / generic name can be used to avoid joint submission procedure (*below*)
  - Importers of proprietary substances or substances made from proprietary reactants
    - Importer must ask foreign supplier to provide chemical identity information directly to EPA in joint submission
    - Must include supplier contact information, trade or other name, and copy of request to supplier
- Certification statements

What Must Form B Contain?

- Same information as Form A, and
- "Anticipated" date by which substance is to be manufactured or processed in U.S.
  - If Form B filed prior to "effective date" of inactive designation, most recent date of manufacturing or processing may be provided

"Co-Manufacturing"

- ***Manufacture*** definition:
  - "…When a chemical substance, manufactured other than by import, is: (1) Produced exclusively for another person who contracts for such production, and (2) that other person specifies the identity of the chemical substance and controls the total amount produced and the basic technology for the plant process, then that chemical substance is co-manufactured by the producing manufacturer and the person contracting for such production…"
- **Form A:** In "single instance" of manufacturing or importing a particular volume during the lookback period, if two or more persons qualify as manufacturer or importer, may determine among themselves who should submit Form A
  - If no notice submitted EPA will hold each person liable
- **Form B:** If multiple persons would qualify as manufacturer, importer, or processor, may determine among themselves who will submit Form B
  - If no notice submitted, all persons remain subject to reporting requirements and EPA will hold each person liable for failure to submit notice

Confidential Business Information (CBI)

- Chemical identity information
  - Can claim CBI but only if substance listed on confidential portion of Inventory when notice submitted
    - CBI claim must be made at the time the information is submitted
      - Claim can be made even if not original claimant
    - If no person requests that claim be maintained, EPA will treat specific chemical identity as not subject to confidentiality claim and will move substance to public Inventory
  - May substantiate by providing responses to CBI questions with notice
    - Otherwise fall within separate EPA CBI plan
- Form B – must substantiate w/i 30 days of notice
- Other than chemical identity information
  - Must make and substantiate when information submitted

THANK YOU

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