

VIA ELECTRONIC SUBMISSION

October 12, 2010

Document Control Office (7407M)
Office of Pollution Prevention and Toxics (OPPT)
Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington DC 20460-0001

RE: TSCA Inventory Update Reporting Modifications; Proposed Rule;
EPA-HQ-OPPT-2009-0187; 75 Fed. Reg. 49656 (August 13, 2010)

Dear Sir or Madam:

The Society of Chemical Manufacturers and Affiliates (SOCMA) appreciates the opportunity to comment on the Environmental Protection Agency's (EPA) proposed modifications to the Inventory Update Reporting (IUR) regulations.

SOCMA is the leading trade association representing the batch and custom chemical manufacturing industry. SOCMA's nearly 250 member companies make the products and refine the raw materials that make our standard of living possible. From pharmaceuticals to cosmetics, soaps to plastics and all manner of industrial and construction products, SOCMA members make materials that save lives, make our food supply safe and abundant, and enable the manufacture of literally thousands of other products. Over 70% of SOCMA's active members are small businesses.

SOCMA appreciates EPA's efforts to enhance the IUR. Our organization believes that the IUR has been an effective information gathering tool and can be improved. SOCMA shares the primary goals that the agency has outlined, but we have some concerns about the type of information EPA is seeking and the approach proposed for gathering it. Equally important is whether the information can be utilized by the agency within a reasonable time. The following comments identify the issues that SOCMA believes are most important and offer some recommendations to address them.

Timing for Transitioning to New Requirements

Given the broad changes being proposed, our biggest concern is the timing of new reporting requirements and, in particular, their retroactive effect. Since this calendar year is the principal reporting year for the 2011 submission period, companies are already in the 3rd quarter of information gathering. Understandably, companies have been geared up to report information based on the last IUR. We sought advice from EPA as recently as the GlobalChem chemicals

regulation conference this past March on any likely changes that EPA might make for this year, but have received little guidance. It would be unfairly burdensome now to require companies to reassess their 2010 data in light of new reporting requirements. This unfairness is compounded by the fact that the rule is projected to go into effect next spring and shortly thereafter, beginning in June 2011, to require companies to start reporting information from 2010. The information would mandatorily have to be sent electronically, using unfamiliar software. We believe that this is insufficient time to transition to the proposed changes.

This problem would be further compounded if the proposed changes in the reporting volume trigger were retroactive to 2006. The proposal is inconsistent on this point; the text of the proposed rule itself (§ 711.8(a), and part of the preamble (page 49663) indicate that they are not, but elsewhere the preamble (page 49657) and the Fact Sheet indicate that they are retroactive. We trust that the latter is an error, and ask that EPA make clear that the rule will not be retroactive to 2006.

In order to facilitate transitioning to the modifications, we urge EPA to move the principal reporting year forward to 2011, with the submission period occurring in 2012. EPA could retain the proposed reporting schedule for future years – thus, assuming that reporting frequency becomes every 4 years, the following principal reporting year could be 2014 with a submission period sometime in 2015.

A less satisfactory approach – but still better than the proposal – would be simply to push the next submission period forward a matter of months from June 2011 to later in 2011. The extra months would give companies more time to digest the many changes reflected in the final rule and the agency more time to provide guidance and outreach. The added time lapse between the end of the information collection period and the submission period would not contribute to any significant impact on the timeliness of the data reported. Both suggestions we believe would only have a positive impact on the information quality and utility.

Lowering the Production Volume Threshold for Reporting Processing and Use Data

Although industry certainly supports EPA's need to obtain useful data in order to make the most appropriate worker and environmental exposure assessments, lowering the threshold for such reporting to 25,000 lbs. will have a substantial adverse impact on many SOCMA member companies.

To shed some light into why, oftentimes mixtures of 2 or more discrete chemicals are used to make a variety of products. All of these products would require thorough analysis to determine the reportability of the individual chemicals used to make them. The concentrations of these individual chemicals would need to be determined and pounds calculated and aggregated across products.

A company may, for example, have a series of imported products containing methanol at 2% in complex formulations. Assuming 20 products sold to 20 customers in 10 different markets, the individual(s) reporting for the IUR would have to manage, in essence, approximately 20 X 20 X 10 possible combinations. One company estimated, based on data generated for the last IUR, that reducing the threshold from 300,000 lbs. to 25,000 lbs. would more than triple their reporting burden. Dropping the threshold to any lower number (e.g., 10,000) would geometrically exacerbate this burden.

The reporting challenge becomes even more complex and burdensome when the supply chain includes distributors, as it is often difficult (if not impossible) to determine end uses.

Individual chemicals may be present in very small quantities in final products, so that the exposure assessments for these small volumes do not significantly contribute to the overall consumer exposure for the individual chemicals, even if the volumes are aggregated over 25,000 lbs.

Lowering the reporting threshold to 25,000 lbs will not enhance the quality or integrity of the resulting IUR data – to the contrary, it will reduce it. The uncertainties inherent in making estimates of such low concentrations of chemicals in so many products will result in much more speculative and unreliable data than EPA now receives.

Nor should EPA base its decision on the fact that the EU's REACH program employs a 10-metric ton (i.e., 22,000 lb) threshold. The REACH program is phased in over multiple years and employs tiered reporting, and companies have had four years to prepare for it. None of these is true of the IUR.

SOCMA supports maintaining the threshold at 300,000 lbs. If EPA feels compelled to lower this amount, SOCMA recommends that EPA use 100,000 lbs, which is consistent with one of the triggers for the small business exemption.

Reporting Standard for Processing and Use Data

SOCMA supports maintaining the “readily obtainable” standard in lieu of the proposed “known to or reasonably ascertainable by” standard. While EPA's intent may be only to encourage further examination of internal files, we are concerned that the proposed standard could be interpreted as an expectation for manufacturers to poll their customers for exposure data, which is unrealistic given the inherent complexities of a supply chain.

The fact that the PMN program uses the proposed standard is no basis for applying it to the IUR. As EPA well knows, it is far easier for a manufacturer to gauge projected uses when it is planning to manufacture a new chemical. It is orders of magnitude more complicated for a manufacturer to estimate actual uses of a chemical that sells through a complex distribution

network. Also, any further precision is speculative for a chemical that has not yet been manufactured. Further precision is theoretically feasible where a chemical is in fact used – but the demands of doing so could be immense and commercially problematic. Companies have been compelled under the REACH program to seek use and exposure information from their downstream customers, but in many cases are only beginning to get responses after years of inquiries.

Similarly, the fact that the proposed standard was used for IURs before 2006 is also misleading, since IURs prior to 2006 sought only production volume data. Use and exposure data is far more complicated to obtain.

Every-year Data Analysis to Determine Reportability

As previously mentioned, many companies are preparing for the 2011 submission period by collecting 2010 data. EPA's proposal to have industry review production data for each year going back to the previous report could increase that burden by at least a factor of approximately 3. Even assuming that exposure data would not have to be gathered and that a final formal report would not have to be developed, a significant amount of time for the IUR report is spent in gathering and organizing manufacturing and import volumes.

Although we understand that manufacture may vary from year to year, the core, large-volume chemicals produced tend to remain at fairly constant levels, barring significant changes (purchase or divestiture or business lines etc). Thus, the proposed 4-year interval for triggering applicability, especially when aggregated across all US manufacturers and importers, provides a realistic estimate of volumes. It is unclear what utility a multi-year approach would have.

Inclusion of Processors

SOCMA strongly believes that processors should be held to the same requirements as manufacturers for IUR reporting. A dominant theme in debates on improving chemicals management is who should have the burden for reporting certain information. We believe this burden can and should be shared. The current approach of making manufacturers collect data fails to recognize the inherent challenges in collecting useful information throughout a complex supply chain where protection of trade secrets can mean the difference between a business' success or failure. Processors have much more accurate knowledge about the chemicals they process, and will be much more comfortable reporting this information directly to EPA than they are reporting it to businesses who may also be their competitors.¹

¹ SOCMA also supports the proposal to allow suppliers to file reports directly with EPA as part of a joint submission with manufacturers.

Electronic Reporting

We support EPA's effort to streamline reporting through the use of information technology. Again, our main concerns are with timing and whether software adjustments can be made within the narrow window between the final rule and the reporting time frame projected.

It is also unclear how much time will be provided to company representatives to familiarize themselves with the software. A phased-in approach consistent with what EPA has done with e-PMNs should be considered, as it provides companies with options and more time to transition.

SOCMA supports giving companies the option to have more than one individual complete an Electronic Signature Agreement (ESA) on a site-by-site basis. We would also support the ability to have the technical contact involved in PMNs also to have access to the IUR. In smaller companies, one person is more likely to be involved in multiple aspects of regulatory affairs. A CDX applicable to all TSCA programs has some merit. The software will ultimately need to have this flexibility.

We ask that EPA provide webinars to the public as it did with the e-PMN software. It would be helpful if EPA could demonstrate how the software will work and how it may tie in with other TSCA programs. The GlobalChem conference being held next March in Baltimore, MD would be another good venue to hold an IUR Workshop and training on electronic reporting.

Conclusion

As EPA considers changes to the next IUR, we believe that the information of greatest utility will be that which promotes a risk-based approach to chemicals management. EPA will also need to be able to process the information it collects and make it available to the public in a reasonable time. To alleviate the burden associated with the IUR and improve the quality of the resulting data, companies will need adequate time and guidance to adjust to the modifications. We appreciate EPA's efforts to enhance the IUR and consideration of our comments.

Sincerely,



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