



SOCMA's Position on A Sector-Based Conditional Exemption From the RCRA Definition of Solid Waste for Toll Manufacturing

SOCMA is the leading trade association representing the batch and custom chemical manufacturing sector, with over 260 members, of which more than 85% are small businesses.

Toll manufacturing arrangements play an important role in the economic viability and competitiveness of the batch specialty chemical manufacturing sector in the United States. SOCMA is particularly focused on these opportunities to increase recycling and recovery of secondary materials as many of its members participate in toll manufacturing of specialty chemicals.

The following discussion provides background information on how toll manufacturing arrangements within the specialty batch chemical manufacturing sector provide unique opportunities for reuse and recycling of valuable secondary materials. Establishing a conditional exemption from the RCRA definition of solid waste will remove unnecessarily regulatory barriers that currently limit reuse and recycling of valuable secondary materials produced by toll manufacturing operations in the specialty chemical sector.

Specialty Batch Chemical Toll Manufacturing Operations.

In a batch toll manufacturing arrangement, one party contracts with another to have a particular specialty chemical product batch manufactured for it at the other's facility. The arrangement identifies the specialty chemical to be made, the materials to be used, the manufacturing process to be employed, and the quantity to be made. Essentially, the "toll contractor" is specifying the terms for production of a particular specialty chemical at the "toll manufacturer's" facility.



A company may use a toll manufacturer for specialty batch production of a particular specialty chemical for any of a number of reasons, such as a need for special production techniques or equipment, research and development, special expertise of the toll manufacturer, the relatively small volume to be produced, or variable or sporadic demand for the material to be produced. Regardless of the reason for the toll manufacturing, both parties agree in advance on certain critical details of the production run, such as the product specifications to be met, the materials to be used, and the manufacturing process to be employed.

Due to the highly prescriptive and defined terms governing the manufacturing process, the toll contractor can predict ahead of time the content and value of the secondary material that will be produced at the toll manufacturing site. These secondary materials can contain constituents that are of value for further production operations. In many instances, these secondary materials could be recycled or reclaimed, **if** regulatory action were taken to establish a conditional exemption from the regulatory definition of solid waste under the RCRA program.

Need for a Focused Exemption from the Definition of Solid Waste.

SOCMA and its members have consistently sought revision of the definition of solid waste regulations with one goal in mind – to enable members to recycle valuable secondary materials. SOCMA believes that the defined nature of these toll manufacturing arrangements can be used to establish a focused exemption to reuse and recycle secondary materials from toll manufacturing operations in a manner that preserves resources and protects the environment, while also providing significant cost saving to this competitive sector of the U.S. economy.

In prior submissions, SOCMA has detailed specific opportunities for its members to reuse and recycle secondary materials and provided the results of a survey identifying the customer base that would be able to reuse and recycle these materials. See SOCMA's prior comments on the Proposed Rule for Revisions to the Definition of Solid Waste (the "Proposed Rule") (68 Fed. Reg. 61557 (Oct. 28, 2003)). As explained in prior submissions, secondary materials generated at these facilities often have tremendous value and potential for reuse. Yet, these opportunities are presently lost due to the regulatory constraints (and complexity) established by the EPA regulations known as the "definition of solid waste."

The defined nature of the activities at specialty batch toll manufacturing facilities, however, offers a basis for a focused exemption for instances where secondary materials have value and could be reused or recycled. A well-defined sector-based exemption is an effective way to move this issue forward, and EPA has successfully developed tailored conditional exemptions to promote resource conservation and recycling for a variety of industries sectors.

SOCMA has been tracking industry practices in this area for some time. A number of years ago, SOCMA surveyed its members to identify the key attributes of toll manufacturing arrangements in the specialty batch chemical sector and evaluate regulatory impacts. Based on this survey, SOCMA confirmed that there was no single standard or typical toll manufacturing arrangement but determined that a majority of toll contractors:

- Use contracts, agreements, purchase orders, audits, and other





environmental and safety management systems to provide oversight of toll manufacturing operations.

- Cannot receive secondary materials from their toll manufacturers because the toll contractors do not have RCRA Part B permits or because their permits prohibit receipt of wastes not identified in advance in the Part B permit.
- Want to recover valuable constituents from RCRA spent materials and by-products generated by their toll manufacturers, but cannot do so because of the regulatory consequences of the RCRA definition of “solid waste.”
- Said the existing RCRA regulation of “hazardous waste” is impeding toll manufacturing and therefore constraining production and growth because disposal costs are too high.
- Said the existing RCRA regulation of “hazardous waste” is wasting natural resources.

These member responses helped SOCMA identify the need for and potential benefits of a focused exemption from the definition of solid waste for facilities engaged in specialty batch chemical toll manufacturing operations.

Further Background on Specialty Batch Chemical Toll Manufacturing Operations

SOCMA’s review of toll manufacturing operations indicates there is a high degree of oversight by the toll contractor over the production run of the toll manufacturer. The detailed terms of the manufacturing agreements and mutual understanding of the processes to be used allow the parties to predict not only the particular product but also the resulting intermediates, secondary materials and wastes. Accordingly, SOCMA has worked with members to identify the various practices by which toll contractors exercise and provide this degree of oversight.

SOCMA has determined that the toll contractor’s oversight can be accomplished through a range and mix of practices. SOCMA members typically use different types of management control systems to ensure continuing product quality, personnel and process safety, and environmental protection, including proper waste disposal. The approaches can vary significantly in content and scope but often involve some of the following elements:

- A review of environmental, health and safety practices is conducted in selecting new toll manufacturers.
- Quality audits are conducted to monitor the performance of existing toll manufacturing.
- Confidentiality and non-use agreements are executed before the toll



contractor reveals its technology and know-how.

- Custom manufacturing agreements are used to establish specific terms and conditions for the toll manufacturing operations.
- Purchase orders can also be used to establish and document specific obligations of the toll manufacturing site.
- The toll manufacturer may develop a specific technical and operating manual or written manufacturing operating procedures, which are reviewed and agreed to by both parties before manufacturing starts.
- Information on the manufacturing and operating procedures may be reviewed directly with the toll manufacturer's supervisors and operators prior to the start of manufacturing.

Any particular toll contractor may use a mix of these approaches, supplemented with different types of oversight practices and specifications. The specific contract terms, details for manufacturing processes and specifications, and other aspects of these arrangements often involve highly sensitive and confidential information, consistent with the highly competitive nature of this industry sector.

The toll contractor generally uses these and other practices to establish parameters of the manufacturing process itself and the incidental operations of the toll manufacturer. A toll contractor can do so by specifying:

- The technology to be used by the toll manufacturer;
- Performance and product quality criteria to be met;
- Use of the toll contractor's own labeling and packaging criteria;
- Process and operating information;
- Obligations regarding management of and responsibility for the resulting products, secondary materials and wastes; and
- Confidentiality and agreements of non-use.

Through these and other steps, a toll manufacturing relationship is established that assures that the each party has a common understanding and expectations for the processes to be used, the materials to be used, the product quality and specifications, and the secondary materials resulting from the process.



Appropriateness of a Conditional Exemption for Specialty Chemical Toll Manufacturing

Use of a focused conditional exemption for secondary materials from toll manufacturing in the specialty chemical sector would be consistent with prior regulatory exemptions established by EPA, would build upon EPA recognition of the specialty chemical sector under other programs, and would be supported by the record and issues addressed by EPA during its rulemaking activities:

- 1) EPA has successfully established and implemented similar conditional exemptions that address the practices and processes unique to management of secondary materials on a sector-specific basis;
- 2) Specialty batch chemical manufacturing has already been identified and addressed on a sector basis by EPA in air regulations and the Sector Strategies Division in EPA's Office of Policy;
- 3) A conditional exemption could be readily implemented as a practical matter, as the business records, contracts and shipping papers already used to document toll manufacturing operations establish a sound basis for reliance on basic notification requirements and business records as key elements for a toll manufacturing exemption;
- 4) As part of the October 2003 Proposed Rule, EPA has already sought and received public comment on the ways in which specialty batch chemical manufacturing operations may warrant different regulatory treatment under this rulemaking; and
- 5) Information documenting the need for and appropriateness of such a conditional exemption has been provided in comments on the Proposed Rule.

Accordingly, SOCMA believes that a sound basis has been established, from a both legal and a practical perspective, for issuance of a specialty batch chemical toll manufacturing conditional exemption as a final rule:

The Benefits of a Conditional Exemption for Specialty Batch Toll Manufacturing

A conditional exemption for secondary materials from specialty batch chemical toll manufacturing operations could yield significant benefits:

- Smaller chemical companies would have an opportunity to recycle materials with customers in the specialty chemical sector, broadening their recycling and business opportunities;
- Previously unused industrial resources could be recovered, and the energy costs and emissions caused by having to dispose of these materials as wastes could be avoided; and



- Increased resource recovery through recycling could decrease the regulatory burden on this sector and enhance economic competitiveness for an important sector of the U.S. chemical industry, including many small businesses that are substantially challenged by overseas competition.

If you have any questions or you need further information please do not hesitate to contact either Rob McArver at mcarver@socma.com or 202-721-4122 or Jeff Gunnulfsen at gunnulfjen@socma.com or 202-721-4198.

SOCMA DSW Examples---

I.

If there were RCRA relief and possible to do so, would most likely be sending solvents back to our customers. However, our customers may not necessarily be in the same SIC code as we are. If EPA doesn't include a provision specific to contract work, regardless of NAIC, the relief will be minimal.

For example, what if we are making a pharmaceutical active ingredient for a customer. Their primary NAIC code is 2834 (pharm preparations), and our primary NAIC code is 2821(plastics materials, synthetic resins, and elastomers). Does this mean we could not be able to return material to our client because they don't have the same NAIC code?

II.

Why does it have to be the same industry? Lets say that I have a solvent that could be used by a a paint & coatings manufacturer. Can't because it meets the definition of a hazardous waste. That is the only reason that they are not allowed to use it. What's the difference if it goes to a paint & coatings plant or a custom chemical batch producer? End use is the only issue not SIC code. (Note same could apply if it went to a reclaimer)

What would be wrong with sending a solvent back to the manufacturer for reclamation? This would be a viable alternative also, if it did not fit into the waste regulations, many manufacturers would most likely be interested in reclaiming as opposed to the cost of manufacturing new material. This would be a tremendous sustainable development opportunity. Minimize the use of valuable raw materials--reuse existing feedstocks. This would be particularly important for small customer chemical manufacturers who may not have the resources to install expensive distillation equipment for reclaiming.

III.

We used to generate an aqueous aluminum chloride solution as a by product of a process to produce a pharmaceutical intermediate. The solution could be a hazardous waste since it is corrosive. We accumulated it and sent it back to the supplier of the anhydrous aluminum chloride who used it as feedstock to an aqueous chloride solution blend that they sold to water treatment plants. Our by-product went from pharmaceutical manufacturing (2833) to inorganic chemical manufacturing.

IV.

Many SOCMA members manufacture chemicals for industries that are regulated under the Food and Drug Administrations such a Pharmaceuticals (NAIC code 3254). Process Quality Control is very strict and current Good Manufacturing Practice (cGMP) apply (see 21 CFR Parts 210 and 211). Under these standards, facilities are generally

prohibited from recycling solvents and other raw materials due to potential cross-contamination. However, these recovered solvents and other raw materials would be acceptable for use in other industries. In one example, valuable excess raw material in a pharmaceutical process (NAICS 3254) could potentially be recycled into a product in Adhesives and Sealants (3255) if it could first be reclaimed from a solvent byproduct at another plant. In this case the adhesive would be used to cement plastic sewer pipe. However, the byproduct had to be burned as ignitable waste, since the second plant was not permitted to accept and treat hazardous waste. Pharmaceutical processes, like other specialty processes, use solvents as a reaction media. These solvents could be distilled and reused to make other products. However, cGMP generally prohibit such recycling.

FROM THE ORIGINAL COMMENTS:

Example from Member A. As noted above, many SOCMA members manufacture chemicals for industries that are regulated under the Food and Drug Administration, such as Pharmaceuticals (NAICS code 3254). Process Quality Control is very strict and current Good Manufacturing Practice (cGMP) apply.¹ Under these standards, facilities are generally prohibited from recycling solvents and other raw materials due to FDA regulations that impose costly and burdensome requirements for safety, purity and efficacy of the drug product. However, these recovered solvents and other raw materials would be acceptable for use in other industries. By way of example, SOCMA Member A has valuable excess raw material in a pharmaceutical process (NAICS 3254) that could potentially be recycled into a product in Adhesives and Sealants (3255) if it could first be reclaimed from a solvent byproduct at another plant that is owned and operated by Member A and has a NAICS code of 3251. In this case, the adhesive would be used to cement plastic sewer pipe. However, the byproduct instead has had to be burned as ignitable waste, since the second plant was not permitted to accept and treat hazardous waste. Pharmaceutical processes, like other specialty processes, use solvents as a reaction media. These solvents could be distilled and reused to make other products. However, cGMP generally prohibit such recycling within the pharmaceuticals industry.

Example from Member B. In another instance, Member B has generated methanol in a cGMP process that similarly could not be reused in the generating process due to FDA and customer quality requirements. However, the recovered methanol was appropriate for and could have been used in another organic chemical based process after reclamation. Yet, the existing regulations precluded Member B from on-site reclamation to itself produce a usable solvent. Nor was Member B able to locate a permitted facility to conduct the reclamation. However, if a three-digit NAICS approach is implemented, this methanol stream could be sent for recovery to another "325" customer that can use the methanol. This option would not be available at the four-digit level due to FDA restrictions on pharmaceuticals operations.

Examples from Member C. A third SOCMA member provided broader perspective on the potential impact on its operations. Member C's primary four-digit

¹ See 21 C.F.R. Parts 210 and 211.

NAICS code is 3252. However, Member C is a custom chemical toll manufacturer that makes a variety of products using batch operations in four plants. On any given day, Member C may be making products in the following NAICS codes: 3251, 3252, 3253, 3254, 3256, and 3259. As a toll manufacturer, Member C can potentially be requested by existing or new customers to manufacture a wide variety of chemicals.

Member C's primary products are polymers that are used by its customers, and by their customers, to manufacture other intermediate and/or finished products. Therefore, Member C does not believe that its primary four-digit NAICS code changes as a function of its production schedule under the NAICS system. Member C currently produces secondary materials from production for customers that it believes operate under different four-digit NAICS than Member C.

The first example involves a butanol/water waste stream which Member C cannot recover on-site. Member C has never explored whether this customer could recover this material as the customer's facility does not have a Part B permit and sending this material back to the customer is not allowed under the current regulations. The proposed four-digit NAICS code matching requirement would also prevent Member C from being able to return this material to its customer to recover. In 2003, Member C disposed of over 300,000 pounds of this butanol waste stream.

Member C generates a second stream from a product which is still being developed commercially. The waste stream is a water soluble solvent and water mixture which is not suitable for distillation recovery. However, other technology, such as drying the waste solvent/water mixture using caustic could potentially work. However, because the customer operates under a different four-digit NAICS code, this option would not be available under the proposed four-digit NAICS approach. Although Member C disposed of less than 25,000 pounds of this material in 2003, the quantities generated if this product is commercially successful could exceed 250,000 pounds per year.

For each of these streams, a 3-digit NAICS code requirement could allow material to be sent back to the customer for recovery. A four-digit NAICS code requirement would preclude this from occurring.

Because Member C is a toll manufacturer, Member C notes there is always the possibility of new products and therefore new waste streams. In the case of pharmaceutical or pesticide manufacture, where waste streams are generated, and the toll manufacturer is unable to recover the solvent on site, a 4-digit NAICS code approach will exclude the possibility of sending such streams back to the customer for recovery, since such customers operate under NAICS code 3254.

Example from Member D. Member D has provided an example involving a secondary material presently handled as ignitable D001 waste. This material is generated by a toller that makes an active intermediate for a toll contractor that is a pharmaceutical company. The toller operates under NAICS Code 3254 and generates approximately 2 million pounds per year of a secondary material containing

approximately 627,000 lbs per year of Tetrahydrofuran (THF). (THF is a valuable material that is sold for about 90 cents per pound.).

In evaluating its options, the toller has evaluated the following alternatives:

1. The toller currently sends the material for off-site energy recovery at several RCRA Part B permitted cement kilns at a cost >\$758,000 per year.
2. The toller has also evaluated off-site Clean Fuels energy recovery which would cost approx. \$573,000 per year.
3. The alternative of off-site reclamation at a Part B facility is the least cost effective (e.g., costs approximately \$1.34 mm per year.)
4. The existing RCRA definition of solid waste regulations prevent the toller from implementing a fourth option that would generate a profit of approximately \$270, 000 per year. To realize this profit, the toller would have to be able to arrange for off-site reclamation at another plant owned by the same Corporation that has available distillation and tankage. The plant that has been identified as capable of performing the reclamation currently operates under NAIC Codes 3251 and 3259. The company would then sell recovered THF product in the U.S. open market to adhesive manufacturing companies; these adhesive companies operate under NAIC Code 3255.

Under the proposed four-digit NAICS approach, Member D would still be precluded from implementing the fourth option. However, this option could be implemented under the three-digit NAICS approach.

Example from Member E. Another example provided by a SOCMA member illustrates the benefits of both the three-digit NAICS approach and an on-site recycling exemption². Essentially, this scenario illustrates the difficulties faced by specialty batch chemical manufacturers due to the limitations of the 90-day on-site storage requirements in 40 C.F.R. § 262.34. In that instance, Member E has a process distillate that contains material presently identified as RCRA waste as well as components of value and is generated at a rate of 8,000 pounds per month. By reprocessing the secondary material, the facility could salvage the reusable raw materials and separate out the remaining material and manage it appropriately as a waste. However, since the minimum quantity required to make reclamation economically viable would be 40,000 pounds, the facility forgoes this opportunity due to its inability to store the material on-site for a sufficient period to accumulate an adequate quantity for reprocessing. Either the three-digit NAICS approach or the on-site recycling exemption

² As discussed in Section V, SOCMA supports the adoption of an exemption for on-site recycling.

would remove the barrier of the 90-day on-site storage rule and enable Member E to pursue this recycling opportunity.

Example from Member F. In another example, Member F is currently developing a new commercial process that uses chlorobenzene as a solvent. During pilot runs, Member F determined that the solvent usage would be much higher than originally anticipated from laboratory process. Member F's customer's product falls under the medical - device FDA regulations. For the remainder of this year, Member F will generate 225,000 lbs of this spent solvent with a projected 30 % increase next year. The material that Member F is now classifying as waste is 90 % or more the pure compound and has the potential to be used in a wide variety of arenas with some recovery work.

Member F's process is under strict change control from its customer who is regulated under the FDA. Member F cannot introduce recycled material into the approved process. In order for this material to be reused in the process, Member F would need to initiate a two step purification process, scrutinize the quality and develop a qualification plan with the customer. Typically, this takes 2 + years and in some cases cannot be done because of the customer's constraints on their product and changes in the process.

For the current year, 225,000 lbs of waste chlorobenzene will be generated, with a potential increase to 300,000 next year. The total cost of the material and waste is \$200,000 this year and does not include handling or other associated costs. This cost contributes a staggering 50 % of the variable product cost.

If this site could develop a recycle method and implement it, the purchase cost savings would be significant. However, any contribution from solvent recovery does not cover the associated fixed costs. The plant is designed to conduct highly complex tasks for high value added products. The volume, though large, does not justify installing a solvent recovery system. The process is run in sporadic campaigns throughout the year rather than all the time.

While Member F is classified as NAICS 3254, the most likely sites that could recycle the material would be under NAICS 3251. Therefore, under a four-digit NAICS approach, this material still could not be sent off-site recycling. However, if exempted under a three-digit approach, this material could be recycled and reused.

Example from Member G. At its own manufacturing site, Member G produces chemical intermediate "A," which is in extremely short supply and is used to also manufacture final product "D." Member G contracts with a toller to also manufacture final product "D" because the toller has excess capacity, while Member G is already at 100% capacity. As agreed by Member G and the toller, Member G provides chemical intermediate "A" to the toller who uses it in the process prescribed by Member G to manufacture final product "D" (e.g., reacts it with commodity chemical "B" in the presence of solvent "C" to produce final product "D"). Member G thus provides the toller with its proprietary process manufacturing specifications and requires the toller to

use the same process for manufacturing product "D" as Member G uses at its own facility.

As a result of using the same manufacturing process and the same materials, both companies generate the exact same waste stream—a RCRA spent solvent containing 90% intermediate "A". Member G is able to reclaim intermediate "A" from its waste stream in an on-site, closed-loop reclamation facility which is exempt from RCRA. Member G would like to also reclaim intermediate "A" from the toller's waste stream in the same on-site reclamation facility because this raw material is quite valuable and in short supply. However, the current RCRA regulations prevent Member G from doing so. Member G takes a double hit: it has to pay the toller to incinerate the excess intermediate stream off-site and loses the value of the raw material. The total cost to Member G exceeds \$1 million per year.

In this instance, Member G has a clear economic incentive to recover and reuse as much of raw material "A" as possible. However, the spent solvent stream which contains "A" cannot be shipped to Member G because Member G's facility does not have the RCRA Part B permit needed to receive and store the spent solvent stream. Unfortunately, the multi-year lead time, costs and related burdens associated with a Part B permit cause Member G to forgo this recycling opportunity. Further, the economics of this situation might change, due to a shift in demand for final product "D", before the lengthy Part B permit process is even finished.

The toller has a primary NAICS code of 3252 (polymers and resins), while Member G's NAICS code is 3251. Under the four-digit NAICS approach, the recycling still would be precluded. However, the three-digit NAICS code would be effective in enabling these companies to pursue this valuable recycling activity.

SOCMA-OMB Meeting on DSW Rulemaking
Wednesday, Oct. 4, 2006
3PM EST

Agenda

I. Introductions

II. SOCMA 101

**III. SOCMA Involvement with the DSW
Rulemaking**

IV. SOCMA Position on Current Rulemaking