October 31, 2022

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Office of Emergency Management (5104A)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460
Docket No. EPA-HQ-OLEM-2022-0174

Submitted via Regulations.gov

Re: Accidental Release Prevention Requirements: Risk Management Programs Under the Clean Air Act; Safer Communities by Chemical Accident Prevention

Dear Ms. Grant:

The Society of Chemical Manufacturers & Affiliates (SOCMA) appreciates the opportunity to submit comments regarding EPA's proposed rule to update its Risk Management Program (RMP) rule.[1] SOCMA strongly urges EPA to focus its time and resources on enforcement of the existing RMP rule, for two reasons: (i) the current rule has successfully decreased RMP incidents year over year, and (ii) the majority of RMP violations are by a small percentage of RMP facilities. Hence, focusing on enforcement, instead of broadening the rule, will more reliably lead to greater decreases in RMP incidents. If EPA insists on pursuing a new rule, it should provide an exemption for batch manufacturing processes from provisions of the rule, as discussed further in these comments, regarding safer technology and alternatives analysis (STAA), third-party audits and fenceline monitoring. These provisions will not have a positive impact on release prevention and instead will require these facilities to spend resources that would better be focused on internally identified issues.

[1] 87 Fed. Reg. 53556 (Aug. 31, 2022).

SOCMA is the national trade association dedicated to the specialty and fine chemical industry. Founded in 1921, SOCMA represents a diverse membership of chemical companies who batch manufacture new and innovative chemistries used in a wide range of commercial, industrial, and consumer products. SOCMA maintains a strong record of member service through programs that maximize commercial opportunities, enhance regulatory and legal compliance, and promote industry stewardship. SOCMA's members also implement ChemStewards®, an EHS&S performance improvement program that is a mandatory component of membership.

Many manufacturing facilities operated by SOCMA members are subject to the current RMP rule. The changes that EPA is proposing, if adopted, will have a significant economic impact on those companies, with adverse repercussions for their processes, productivity, and growth. SOCMA has a vital interest in ensuring that, as Congress required, the RMP rule remains "reasonable," "practicable," and "recognizes differences in size, operations, processes, class and categories of sources and the voluntary actions of such sources. . . ."[2] At least as many SOCMA member facilities are subject to OSHA's Process Safety Management (PSM) Rule. Changes that EPA makes to the RMP rule may effectively dictate the changes that OSHA will make in its upcoming rewrite of the PSM rule. For both of these reasons, SOCMA has a significant interest in the outcome of this rulemaking.

Summary of Key Issues

As EPA has requested, these comments are organized along the list of issue headings set out in the proposed rule. For EPA's convenience, however, the highlighted issues immediately below represent the most important issues from SOCMA's perspective:

Inadequate basis for the rule. The Agency's own data undermine, rather than make, the case for this rulemaking. This rulemaking is even less justifiable than the 2017 rule, as reportable accidents have continued to decline. A compliance-driven approach would accomplish EPA's regulatory objectives without burdening the 97% of RMP facilities that have not had a reportable accident.

Safer Technology and Alternatives Analysis (STAA). SOCMA members regularly conduct STAA analyses, particularly during process design, but EPA should leave manufacturers (particularly batch manufacturers) free to determine exactly when and how to complete analyses and implement changes. If EPA proceeds with its proposed requirement, it should confirm that facilities are not required to conduct STAA analyses of aspects of processes that are governed by specifications established by a government agency or a customer. Such an exclusion is crucial to the continuing vitality of many SOCMA members' businesses.

[2] 42 U.S.C. § 112(r)(7)(B)(i).

Third-party audits. The ability of an implementing agency to require a third-party audit "due to conditions at the stationary source that could lead to an accidental release of a regulated substance" is hopelessly vague. SOCMA highly doubts that its member facilities will be able to locate and retain independent consultants who understand the particular process at issue in any given investigation sufficiently well to make better compliance judgments than the facility. Further, manufacturers and local communities would be better served by reinvesting the resources that would be required for third-party audits in the company to improve process safety and operations, as well as growing the business and creating new jobs in the local community.

Fenceline monitoring. SOCMA agrees with the Agency's enumeration of reasons in the Technical Background Document why fenceline monitoring is both inappropriate for the RMP program and not remotely ready for implementation. As batch manufacturing facilities, SOCMA members use a myriad of chemicals that may change frequently or on short notice. This completely undermines the ability of a facility to employ a release monitoring strategy dependent upon a particular chemical identity.

Information disclosure. Now that EPA is proposing to reinstate many of the information elements that it included in the 2017 rule, it needs to reinstate previous language that enabled facilities to assert a claim of business confidentiality regarding any information they are required to make public under the RMP rule, as mandated by Section 114(c) of the Clean Air Act. EPA must also protect facilities from harassment from information disclosure requests.

Discussion

1. Natural Hazards

In principle, SOCMA does not oppose requiring hazard reviews and process hazard analyses (PHAs) to address natural hazards. SOCMA members already take natural hazards into account when they conduct these activities. While climate change can cause or contribute to the frequency and intensity of hurricanes, extreme precipitation events and similar phenomena, it is not climate change that directly causes the risk, but the event itself. The final rule should thus refer to those sorts of events (e.g., high winds, storm surge, flooding, etc.).

Further, facilities in different locations in the United States assume different potential natural hazards. It is not reasonable to expect a facility in Florida to prepare for a blizzard nor facility in Ohio to prepare for a tsunami. If a final rule retains this requirement, it should refer to "reasonably foreseeable" or "applicable natural hazards."

2. Power Loss

In theory, SOCMA does not oppose requiring hazard reviews and PHAs to address power loss. Again, SOCMA members already take power failures into account when they conduct these activities. In many cases, a company's RMP plan considers both natural hazard and power loss and will dictate what processes should not be run or shut down when a specific type of inclement weather is anticipated.

SOCMA members also provide for backup power supplies to the extent necessary to prevent power loss from triggering runaway reactions, etc. SOCMA would not support an across-the-board requirement that RMP facilities maintain backup power capability, however, because the need for such capability depends entirely on the nature of the processes being run at a facility.

SOCMA is perplexed by the statement in the preamble that "EPA is proposing to require air pollution control or monitoring equipment associated with prevention and detection of accidental releases from RMP-regulated processes to have standby or backup power to ensure compliance with the intent of the rule."[3] This requirement does not seem to be expressed anywhere in the proposed regulatory text. SOCMA vehemently opposes this requirement. A PHA may well conclude that backup power is appropriate for monitoring equipment, particularly if the process is one that requires refrigeration or other electricity-dependent activity to maintain the process within safe operating parameters. But in many other processes, the relevant reaction may simply cease if electric power is no longer available. There would be no reason to continue powering air pollution control devices or monitors in such a case.

3. Stationary Source Siting

SOCMA does not oppose requiring hazard reviews and PHAs to address placement of processes, equipment, and buildings within the facility, hazards posed by proximate facilities, and potential accidental release consequences to nearby public and environmental receptors." Again, SOCMA members already do this when they conduct these activities.

4. Hazard Evaluation Recommendation Information Availability

SOCMA thinks it will be unusual for a site to decline to implement a hazard review or PHA recommendation involving natural hazards, power loss or siting. SOCMA is concerned that, in the rare event where that occurred, being required to describe it in a risk management plan would only be drawing attention to an idea that was not well-founded.

5. Safer Technologies and Alternatives Analysis

A. EPA Should Not Require Consideration of STAAs

[3] 87 Fed. Reg. 53571.

SOCMA has consistently opposed any regulatory requirements to conduct STAA analyses. SOCMA members regularly conduct such analyses, particularly during process design, but SOCMA believes EPA should leave manufacturers to determine exactly when and how. If EPA proceeds with its proposed requirement, it should reiterate that facilities are not required to conduct STAA analyses of aspects of processes that are governed by specifications established by a government agency or a customer. Such an exclusion is crucial to the continuing vitality of many SOCMA members' businesses.

SOCMA appreciates that, as in the 2017 rule, EPA has not proposed that facilities be required to implement the results of safer alternatives analyses. EPA was correct when it stated, in 2016, that "facility owners or operators are in the best position to identify which changes are feasible to implement for their particular process."[4] Additionally, EPA is unlikely to have the resources or expertise to second-guess these decisions.

SOCMA also recognizes, and appreciates, that EPA has restricted the applicability of its STAA proposal to facilities in NAICS codes 324 and 325 that are located within a mile of other 324 or 325 facilities. Still—

- SOCMA believes that many of its members' Program 3 facilities are located within a mile of another 325 facility.

- The proposed rule would still require Program 3 facilities to—
    - Identify and consider safer technology and alternative risk management measures, ranked in a hierarchy;
    - Document that consideration; and
    - Determine and document the practicability of each measure, including documenting any methods used to determine practicability.

The foregoing is not a casual or low-cost undertaking – it is a demanding and costly one that will divert resources into the creation of massive documents akin to Response to Comments documents. SOCMA members can ill-afford to spend large amounts of staff time to document the conclusions that they would have reached in any event. Indeed, the amount of time and resources required to document the many consideration requirements may actually increase risks by distracting process engineers and safety professionals from other potential hazards. As EPA has frankly noted, it estimates the STAA requirement would account for 69% of the rule's total costs ($518.2 million out of $751.8 million, undiscounted). Even annualized and discounted, this requirement would cost $52 million a year. SOCMA sincerely doubts that these reviews will produce benefits justifying these costs.

[4] 81 Fed. Reg. 13638, at 13663-13664 (March 14, 2016).

SOCMA is also concerned about the prospect for EPA's proposal to increase civil liability risks. Even though EPA would not require a facility to implement an identified safer alternative, courts and juries would be sorely tempted to hold a company liable if there were an accident and some identified alternative had not been implemented, no matter how tenuous the case that implementing it would have averted the accident. Or they might simply argue that the earlier decision was evidence that the facility had a history of not making changes to increase safety. Juries and potentially judges would be evaluating the earlier decision with luxury of 20/20 hindsight. They would feel a strong temptation to conclude that such decisions were evidence of negligence. As a result, facilities would feel compelled to make identified changes even if they felt that those changes were infeasible. The preamble to the 2016 final rule summarized these concerns but did not attempt to explain why they are invalid.[5]

The Agency in 1996 explained why it need not require even consideration of safer alternatives:

> EPA has decided not to mandate inherently safer technology analyses. EPA does not believe that a requirement that sources conduct searches or analyses of alternative processing technologies for new or existing processes will produce additional benefits beyond those accruing to the rule already. As many commenters, including those that support such analyses, pointed out, an assessment of inherently safer design alternatives has the most benefit in the development of new processes. Industry generally examines new process alternatives to avoid the addition of more costly administrative or engineering controls to mitigate a design that may be more hazardous in nature. Although some existing processes may be superficially judged to be inherently less safe than other processes, EPA believes these processes can be safely operated through management and control of the hazards without spending resources searching for unavailable or unaffordable new process technologies. Good PHA techniques often reveal opportunities for continuous improvement of existing processes and operations. EPA encourages sources to continue to examine and adopt viable alternative processing technologies, system safeguards, or process modifications to make new and existing processes and operations inherently safer. EPA included questions related to process modifications in the RMP so that sources can demonstrate, and users of the RMP information can observe, progress toward safer processes and operations.[6]

Those conclusions remain true today. As EPA notes in the preamble to the current proposal, "EPA believes facility owners and operators will adopt IST and other safer technology alternatives when it is practicable technically and economically and when the risk reduction is

[5] See 81 Fed. Reg. at 4630-4631.
[6] 61 Fed. Reg. 31699-31700 (June 20, 1996).

significant even in the absence of a mandate."[7] EPA should implement this belief and omit any STAA requirements from the final rule.

B. Any STAA Mandate Should Be Limited to Process Design at NAICS Code 324 and 325 Facilities That Have Had a Reportable Accident in the Past Five Years

If EPA decides, against the recommendation of SOCMA, to proceed with the STAA requirement:

- It should only be required at the design stage of new processes. As the National Research Council has explained:

> It is clear that the best opportunity for implementing ISP [inherently safer processes] into a facility is early in the life cycle of a product or process. At that early stage, process technologies have not been chosen, facilities have not been built, and customers have not yet evaluated product samples or made commitments based on products with particular characteristics. As a product moves through its life cycle, these and other factors may limit options, make changes more difficult, or involve more people and organizations in the change. Development of an ISP, as with the development of any new process, requires extensive resources, including for example, expert personnel, laboratory facilities, pilot plant facilities, and significant financial expenditures, and modifications can become more costly when the process involves modification of an existing facility.[8]

- EPA should adopt the alternative proposal to apply STAA only to NAICS code 324 and 325 facilities that have had a reportable accident in the past five years.[9] That would at least focus the requirement on facilities that have demonstrated the need for closer attention to process safety.
- EPA should exclude from the requirement aspects of processes governed by external specifications, as discussed in the next section of these comments.

C. EPA Should Confirm That any STAA Requirements Do Not Apply to Aspects of Processes Governed by External Specifications

SOCMA members primarily manufacture products in discrete batches, usually in campaigns lasting a short period of time, using equipment that can be configured or reconfigured to make a multiplicity of products. And – of particular relevance to this rulemaking – the details of those manufacturing processes are often specified externally and are beyond the ability of the

[7] 87 Fed. Reg. 53580.
[8] NRC, THE USE AND STORAGE OF METHYL ISOCYANATE (MIC) AT BAYER CROPSCIENCE (2012), at 4-59.
[9] 87 Fed. Reg. 53579-53780.

manufacturer to alter at will. This happens in two principal types of cases: (i) manufacture of government-regulated products and (ii) contract manufacturing. If EPA finalizes an STAA requirement, it should exclude from coverage aspects of processes governed by government or contractual approvals or requirements. A requirement that the manufacturer assess the feasibility of safer alternatives in these cases does not make sense – and could destroy the underlying business model.

1. Government-regulated products

Many of the pharmaceuticals in use today start with chemical synthesis of the active pharmaceutical ingredients (APIs) – the molecules that actually provide the bioactive effect (as opposed to binders, coatings, colorants, etc.). Basic chemicals are used and reacted to form intermediates and ultimately the final API. The final APIs often have a highly complicated chemical structure and require specialized chemistries to make. The process or recipe involves many steps and many pieces of equipment much of which needs to be portable and capable of being rearranged. Small quantities are often required over years for validation and approval of the drug prior to commercial manufacturing. Manufacturing campaigns therefore vary in both size and duration.

APIs also must be manufactured under extremely precise and controlled processes so as to assure the purity and consistency of the resulting product. As a result, the API manufacturing sequence is specified, and regulated, under Food and Drug Administration (FDA) Good Manufacturing Practice (GMP) regulations[10] These regulations are clear that "failure to comply with any regulation set forth in [these rules] in the manufacture, processing, packing, or holding of a drug shall render such drug to be adulterated under section 501(a)(2)(B) of the act and such drug, as well as the person who is responsible for the failure to comply, shall be subject to regulatory action."[11] Many API manufacturing processes are additionally specified in "Drug Master Files"(DMFs), which allow an entity (the "holder") to (i) incorporate information by reference when it submits an application, amendment or supplement to the FDA, and (ii) authorize other persons to rely on the information to support a submission to FDA without the holder having to disclose the information to the person.[12] While DMFs are not legally enforceable, they are contractually applicable when a company manufactures an API for the holder of the DMF.

EPA imposes a similar regulatory regime on the manufacture of pesticide products. EPA's rules under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) require pesticide registrants to supply EPA with detailed information on the production process for each

[10] These are primarily set out at 21 C.F.R. Parts 210 & 211.
[11] *Id*. § 210.1(b).
[12] *See id.* § 314.420.

pesticide active ingredient and each establishment that will conduct the process.[13] Much of this same detail is also required for the process of formulating a pesticide.[14] Following registration of the pesticide, registrants are required to follow these specifications in manufacturing pesticide active ingredients and formulating pesticides – and to contractually ensure that any companies conducting these activities on behalf of the registrant do the same.

Conducting a safer alternatives analysis for any of these pharmaceutical or pesticide activities is a waste of time because the manufacturing process for these chemicals is already specified in the GMPs, DMFs, and registrations.

2. Toll and other contract manufacturing

Tollers and other contract manufacturers make up the majority of SOCMA's manufacturing members. In the typical case, a SOCMA member manufactures the customer's chemical according to a process that is specified in the contract. The overall practice is referred to as contract manufacture. Toll manufacturing is the subset of contract manufacturing in which the customer owns the raw materials or intermediates, or designates a specific supplier, that the member uses to manufacture the product. The key element in all these cases, to reiterate, is that the customer is the one who specifies the manufacturing process. In many cases, these customers are FDA or EPA regulated, as discussed in previous sections. And while *their* suppliers may not be government-regulated, the processes used by those suppliers are often still specified by their regulated customers, who oversee and often inspect those production processes. Any change to those processes, materials, suppliers, etc. would violate the contract.

SOCMA understands and agrees that the basic obligations of process safety management apply to contract manufacturers just like any other manufacturer. Contract manufacturers must understand and assess the hazards of their processes. Accordingly, they review the process safety information provided by the customer, and still conduct process hazard analyses themselves, particularly regarding the precise equipment they might use to implement the process. A contract manufacturer might well conclude that what its customer wants it to do is not in the company's best interest, due to hazard, safety, facility limitations, etc. and decline a job.

It is not consistent with commercial reality to extend current process safety requirements to require manufacturers not only to have to understand the hazards of the processes they are being contracted to use, but also to assess whether there are inherently safer ways to make the product, and to engage with the customer and try to persuade it to agree to some safer process. For one thing, most customers in such a case would simply seek another manufacturer that does not interpret STAA similarly. And due to the subjectivity of STAA, the potential

[13] 40 C.F.R. § 158.330.
[14] *Id*. § 158.335.

customer is likely to find another company. That could well include finding a manufacturer located in another country that does not impose an STAA requirement. A further problem is that, typically, customers want a manufacturer to start work in a matter of months and in some cases weeks. In such circumstances, there may not be enough lead time to allow the sort of analysis that EPA envisions. Finally, many contract manufacturing campaigns are quite short -- a month or so. It would not be cost-effective to manufacture on such a basis if you first had to do a safer alternatives analysis.

3. Recommended language for excluding aspects of processes governed by external specifications

The preamble to the 2017 final rule implicitly exempted facilities from having to conduct STAA reviews with respect to aspects of processes that are specified by a government regulation or contractual provisions:

> Safer technology alternatives include many options beyond chemical substitution. For example, IST could involve minimization of stored raw material chemicals, making process changes that make it less likely to release the chemical (moderation), or reducing complexity in the process in order to make accidents less likely (simplification). Therefore, even where a contractual relationship or regulation requires a regulated batch toll manufacturing facility to use a particular regulated substance in specified quantities, owners and operators of batch toll manufacturing facilities should still consider other potential IST measures besides chemical substitution. The facility must also consider potential safer alternatives beyond IST, such as passive measures instead of or in combination with active measures, or active measures instead of procedural measures. Toll manufacturers may use RMP chemicals for purposes in addition to making a formulated product, such as for cleaning equipment, wastewater treatment or refrigeration, for which chemical substitution may not be prohibited by regulation or contractual relationship. Also, the final rule does not require regulated sources to implement IST or ISD considered, so there is no conflict between this final rule and other regulations that may apply to RMP-regulated facilities subject to STAA requirements. For example, an owner or operator would be in compliance with the STAA requirement to consider potential chemical substitution as part of the analysis if he or she determines that a chemical substitution is not practicable because the substitution is prohibited by another regulation. The owner or operator would still need to consider other types of IST (minimization, moderation, or simplification), and passive, active, and procedural measures in the analysis.[15]

[15] *See* 82 Fed. Reg. at 4634-4635.

If EPA retains an STAA requirement, the Agency should incorporate this exemption into the regulatory text. For example, in proposed 40 C.F.R. § 68.67(c)(9), the Agency could renumber proposed subparagraph (iii) as (iv) and insert the following new subparagraph:

> (iii) The owner or operator need not consider, or determine the practicability of, safer technology and alternative risk management measures to the extent that the aspect of the process they address is specified in a governmental or contractual approval or requirement.

6. Root Cause Analysis

SOCMA members do not believe that the RMP rule needs to include a root cause requirement. SOCMA members regularly perform root cause analyses as part of their incident investigations and should be left free – as they are now – to determine when and how. If EPA proceeds with such a requirement, SOCMA supports EPA's proposal to limit it to Program 2 and Program 3 processes that have experienced a reportable accident. SOCMA also supports the proposal to allow root cause investigations to be conducted using "a recognized method."

SOCMA strongly supports the Agency's decision not to propose a definition of "near miss." As EPA notes, facilities have been required since 1996 to "investigate each incident which resulted in, *or could reasonably have resulted in* a catastrophic release."[16] As a practical matter, this language does all that is necessary to require facilities to investigate near misses – a point the Agency recognizes in the preamble.[17] Anything more elaborate that EPA might prescribe can only cause confusion, as EPA recognized in 2017, when EPA chose not to adopt a definition of "near miss."[18] Indeed, the more detail the Agency adds to the concept, the more issues EPA, facilities and stakeholders would need to debate (e.g., how different a circumstance needs to be to be "slightly different" than what occurred). SOCMA particularly opposes the NJDEP language ("an unplanned, unforeseen, or unintended incident, situation, condition, or set of circumstances which does not directly or indirectly result in a regulated substance release)." This language is almost comically overbroad, as it would literally apply to every event at an RMP facility, however trivial, that does not directly or indirectly cause a release. By the same token, it could be underinclusive, as anything that could indirectly cause an accidental release would be *excluded* from the definition of "near miss." The Agency took the correct approach in 2017, and it should stick with that conclusion.

If EPA finalizes a root cause requirement, it would also be useful for EPA to develop guidance to address issues such as what to do if the root cause cannot be determined because the relevant evidence was destroyed. SOCMA hopes that EPA also recognizes the need to develop this

[16] 40 C.F.R. § 68.60(a) and § 68.81(a).
[17] *See* 87 Fed. Reg. at 53584.
[18] *Id.*

guidance contemporaneously with the rule or, at a minimum, to issue it before the effective date of the rule.

7. Third-Party Compliance Audits

SOCMA remains resolutely opposed to any requirement that facilities hire third-party auditors to conduct incident investigations – the second-most costly feature of this proposal. (EPA estimates the total costs of the third-party audit requirement as $102.7M, or 14% of the total costs for this rulemaking ($751.8M).)[19] SOCMA recognizes, and appreciates, that the Agency has scaled back what it finalized in 2017, as regards both (i) the circumstances under which this requirement would be triggered and (ii) the most limiting aspects of the independence criteria. SOCMA continues its opposition for two reasons:

- The first is the language retained from 2017 that would trigger a third-party audit whenever "[a]n implementing agency requires a third-party audit due to conditions at the stationary source that could lead to an accidental release of a regulated substance." The standard set by this language is so vague that it would allow EPA or authorized states to require a third-party audit whenever they wanted, without any administrable or justiciable limit to that discretion. Given this language, it makes little difference what other triggers EPA establishes.
- Second, and ultimately more important, SOCMA fundamentally doubts that its member facilities will be able to locate and retain independent consultants that understand the particular process at issue in any given investigation sufficiently well to offer expertise or insight superior to that possessed by a facility owner. As noted at the outset, SOCMA members typically manufacture products through batch processes rather than continuous processes. The two types of processes are fundamentally different, and a consultant who lacks deep experience with batch processes is unlikely to be able to add any value to the facility's own investigation of an incident. But even familiarity with batch manufacturing is only a threshold qualification; the consultant would also need to be expert in the particular sort of chemistry used in a given process. SOCMA members typically specialize in types of molecules, processes, or applications, and it is rare to find consultants with similarly deep expertise. Finally, SOCMA members are usually being asked to invent new molecules, or to make substances with purities or properties not readily commercially available. The processes they assemble to manufacture these chemicals are accordingly not commercial, off-the-shelf processes that a consultant may be familiar with.

Again, the statute requires EPA to "recognize[] differences in size, operations, processes, class and categories of sources and the voluntary actions of such sources. . . ."[20] SOCMA members believe that a third-party audit requirement would contravene this requirement. If EPA proceeds with this requirement, it should exempt batch manufacturers.

[19] *Id*. at 53560-61.
[20] 42 U.S.C. § 112(r)(7)(B)(i).

These considerations also motivate SOCMA members' opposition to the requirement that they publicly release audit findings not adopted. The reason that facilities will not be adopting findings in many cases is likely to be that the "finding" was actually unfounded, for the reasons noted above. SOCMA is concerned that having to release these findings will trigger difficult technical debates about why the findings were mistaken or otherwise unwise.

Finally, SOCMA urges EPA to revise the proposed compliance certification language that "deficiencies were corrected, or are being corrected."[21] This certification language needs to leave room for cases where the facility disagrees that an identified issue was in fact a "deficiency."

8. Employee Participation

SOCMA member companies already include employee participation in PHAs and the development of RMP plans. Nonetheless, SOCMA opposes a mandate from EPA requiring employee participation, as there is inevitable subjectivity as to specific employee expertise, knowledge, and ability to contribute. Establishing employee qualifications and appropriate participation in the development of an RMP plan is best left to the company itself, as it has the best working knowledge of the facility and role that employees play in the company. Any third party, including EPA, is not likely to have a deep enough understanding of the facility or processes in the facility to assess the appropriate level of employee participation.

9. Proposed Modifications and Amplifications to Emergency Response Requirements –

a. General

SOCMA does not oppose a requirement that nonresponding facilities work with local, state, and federal officials to ensure that a community notification system is in place. As EPA notes, this should be feasible so long as the FEMA Integrated Public Alert and Warning System (IPAWS) is operational in the area where the facility is located. Based on input during the SBA Environmental Roundtable meeting on October 7, however, SOCMA is concerned that IPAWS may not in fact be available in all locations. Also, SOCMA's understanding is that IPAWS will only accept information from governmental entities, not from private entities. Facilities cannot be expected to unilaterally create and operate community notification systems.

SOCMA also does not oppose a requirement that, in the event of a release, facilities provide local responders with current information or best estimates regarding the release.

[21] Proposed 40 C.F.R. § 68.59(f)(1)(iv) & § 68.80(f)(1)(iv).

SOCMA is concerned, however, about the proposed revisions to § 68.90(b) regarding community emergency response plans. It is one thing to require nonresponding facilities to be included in such a plan – the current RMP rule requires as much, and LEPCs are required by EPCRA to include facilities that notify them in these plans.[22] But it is not reasonable to expect facilities to *ensure* that such plans will include the multitude of features enumerated in proposed § 68.90(b) (e.g., "evacuation plans, including provisions for a precautionary evacuation and alternative traffic routes"). It is neither reasonable nor fair for facilities to lose their non-responding status in the event that a plan omits one of these features. SOCMA appreciates that EPA uses the word "should" regarding these aspects, rather than "must," but urges EPA to clarify that these features are desired, and that non-responding facilities will have discharged their responsibilities when they have worked in good faith with their LEPCs, including responding timely to requests for information.

With this caveat, SOCMA does not oppose a requirement that such facilities advise their local emergency planners regarding the "methods for determining the occurrence of a release" used by the facility.[23] SOCMA would also not oppose facilities being required to advise local emergency planners of "monitoring and detection systems in use," a phrase used in the preamble but not in the proposed regulatory text.[24] In either case, SOCMA interprets such language as requiring facilities to describe such monitoring and detection systems or other methods as the facilities employ.

The preamble is less clear when it discusses "process area detectors and perimeter monitors." The preamble states, apparently referring to RMP*eSubmit:

> When process area detectors or perimeter monitors are selected, no further information is collected. To better understand electronic detection methodologies available and in use among RMP facilities, EPA is proposing to require owners and operators to input, in an open text field in the risk management plan, specific information on their process area detectors and perimeter monitor technologies and models in use to detect RMP-regulated substances.[25]

If this simply requires facilities to report on such capabilities *when they exist*, SOCMA has no objection. SOCMA would oppose, however, a requirement that facilities install and operate process area or perimeter monitoring equipment, since in the case of many processes, any reportable release could be detected by other means (e.g., sight, sound, smell, or process parameter indicators such as temperature, pressure, etc.).

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[22] See 42 U.S.C. § 11003(c)(1).
[23] Proposed § 68.90(b)(1).
[24] *See* 87 Fed. Reg. 53595.
[25] Id.

b. Fenceline monitoring

The preamble requests comments on "fenceline monitoring,"[26] and the Technical Background Document (TBD) discusses it extensively.[27] SOCMA agrees with the Agency's enumeration of reasons in the TBD why fenceline monitoring is both inappropriate for the RMP program and not remotely ready for implementation:

i. Size and scale issues

Fenceline monitoring is currently in use only at large, outdoor petroleum refining, petrochemical and commodity chemical operations, where large quantities of familiar chemicals are manufactured, stored and processed. Only in such circumstances are there likely to be releases of the scale that fenceline monitors could reliably detect them. And only in such circumstances is it likely that such large releases can occur without facility personnel becoming aware of them.

SOCMA member facilities, by contrast, are largely indoor operations in which much smaller quantities of less familiar chemicals are used. In such cases, a release that could ultimately become reportable if not corrected is likely to be immediately apparent to process operators or other facility personnel, either because it can be seen, heard or smelled, or because changes in process parameters (temperature, pressure, etc.) would trigger an alarm or otherwise be detected by process personnel.

Also, as batch manufacturing facilities, SOCMA members use a myriad of chemicals that may change frequently and unpredictably. In many cases, SOCMA members do not know at the beginning of the year what chemicals the facility will use in the course of that year. This completely undermines the ability of a facility to employ a release monitoring strategy dependent upon a particular chemical identity. In some cases, a process might use a common solvent or other commodity chemical that is capable of being detected mechanically. In such cases, as EPA notes, a process area detector would be quicker, more reliable and more cost-effective than a fenceline monitor.

ii. Feasibility issues

The TBD does a good job of describing how few real-time monitoring systems exist, particularly systems capable of detecting chemicals at the low ambient concentrations that are frequently of concern from a chronic health perspective. As EPA notes, there are 140 RMP chemicals, and SOCMA is not aware of devices that are designed to monitor for such chemicals individually. Monitors that screen more broadly – e.g., for volatile organic chemicals – are likely to be set off

[26] *See id.* at 53597 n.287, 53607.
[27] *See* TBD at 22-33.

routinely by non-facility-related releases, from motor vehicles or other sources. At bottom, the current calls for fenceline monitoring are more a naive aspiration than a serious possibility.

iii. Statutory standards

Clean Air Act Section 112(r)(7)(B)(i) requires the RMP program rules to be "reasonable" and "practicable."[28] This requirement precludes any sort of technology-forcing approach to monitoring, especially where equally or more effective approaches are cheaper or less technically demanding. That is particularly the case given that monitors for one of the most commonly-monitored chemicals, benzene, can cost a refinery half a million dollars just to install four monitors.[29]

The statute adds that RMP requirements "shall, as appropriate, recognize differences in size, operations, processes, class and categories of sources . . . ."[30] This language mandates that EPA recognize the vast differences between large, outdoor, commodity chemical operations and small, indoor, specialized batch chemical operations. In the TBD, EPA asks whether "such a program may be better suited to some types of facilities."[31] SOCMA submits that, for the reasons discussed above, batch manufacturing processes should be exempted from any fenceline monitoring requirement.

10. Emergency Response Exercises

SOCMA has no objection to the proposed emergency response exercise requirements (exercises must be at least every 10 years; exercise reports mandatory).

11. Information Availability

The 2017 version of § 68.210 ("Availability of information to the public") included § 68.210(g), which enabled facilities to assert a claim of business confidentiality regarding any information they were required to make public under that section.[32] This is mandated by Section 114(c) of

[28] 42 U.S.C. § 7412(r)(7)(B)(i).
[29] TBD at 32.
[30] 42 U.S.C. § 7412(r)(7)(B)(i).
[31] TBD at 28-29.
[32] That provision read as follows:

> (g) CBI. An owner or operator asserting CBI for information required under this section shall provide a sanitized version to the public. Assertion of claims of CBI and substantiation of CBI claims shall be in the same manner as required in §§ 68.151 and 68.152 for information contained in the RMP required under subpart G of this part. As provided under § 68.151(b)(3), an owner or operator of a stationary source may not claim five-year accident history information as CBI. As provided in § 68.151(c)(2), an owner or operator of a stationary source asserting that a chemical name is CBI shall provide a generic category or class name as a substitute.

the Clean Air Act, which declares that the public availability of information that EPA requires a person to report publicly is subject to protection under the Trade Secrets Act.[33] As SOCMA's comments noted, to completely implement Section 114(c), that provision should have referred to "this part," rather than "this section," since other provisions of Part 68 also require facilities to make information publicly available (e.g., § 68.95(c)). EPA removed Subsection (g) in 2019 because it was also eliminating most of the information disclosure requirements of that section.[34] Now that EPA is proposing to reinstate in § 68.210 many of the information elements that it included in the 2017 rule, it needs to reinstate § 68.210(g), with the corrected reference to "this part" – or else rescind its proposals regarding § 68.210.

Further, the disclosure requirements related to safety data sheets for RMP chemicals should be limited not only to RMP chemicals, but to those chemicals present onsite above their threshold quantities.

Finally, EPA must provide a protection from harassment. Unfettered disclosure requests could be used to harm the operations of a facility by bombarding it with information disclosure requests, akin to what is happening with many local election offices.[35] This is something that batch manufacturers would be particularly susceptible to as they have a larger variety of chemicals in and out of their facilities than continuous process facilities.

12. Other Areas of Technical Clarification

SOCMA has no comments on these topics.

13. Regulatory Impact Analysis

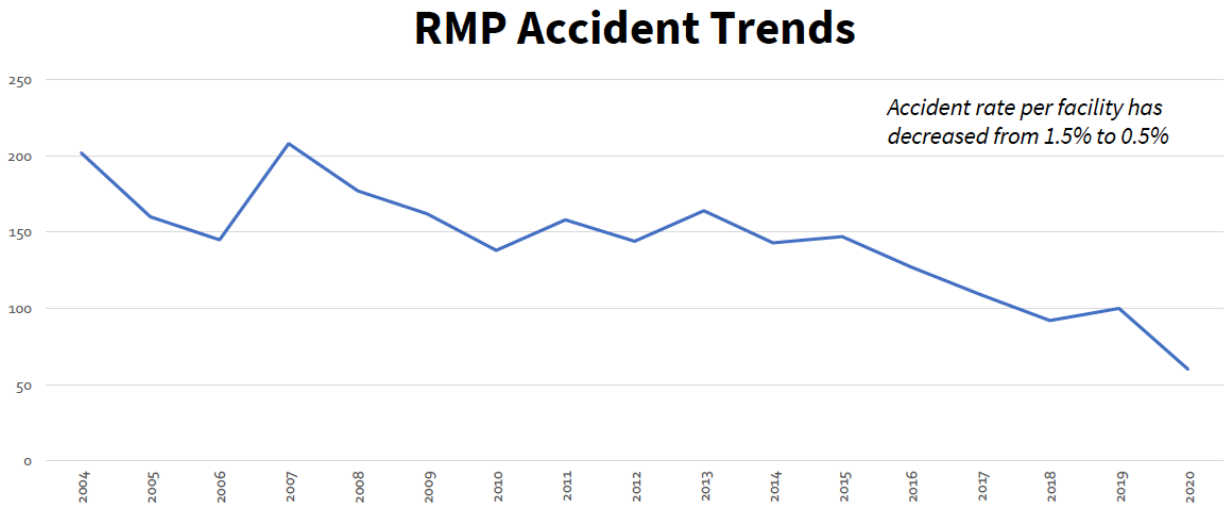
Executive Order 12866 directs each federal agency to (i) "promulgate only such regulations as are . . . made necessary by compelling public need, such as material failures of private markets to protect or improve the health and safety of the public, the environment, or the well-being of the American people,"[36] and to (ii) "tailor its regulations to impose the least burden on society, including individuals, businesses of differing sizes, and other entities (including small communities and governmental entities), consistent with obtaining the regulatory objectives."[37] As SOCMA documents below, however:

See 82 Fed. Reg. 4705.
[33] *See* 42 U.S.C. § 7414(c).
[34] *See* 84 Fed. Reg. 69837.
[35] *See, e.g.*, "Election officials confront waves of public records requests from Trump supporters," CNN (Sept. 21, 2022), available at https://www.cnn.com/2022/09/21/politics/public-records-requests-trump-supporters.
[36] E.O. 12866, § 1(a).
[37] *Id*. § 1(b)(11).

- EPA's proposed updates to the RMP rule are not made necessary by any public need – indeed, they are less justifiable now than they were when EPA first proposed them in 2016.
- EPA could accomplish its regulatory objectives with vastly lower burdens on regulated facilities by simply enforcing its existing regulations against the small subset of RMP facilities that are, or are likely to, account for all reportable accidents.

A. This Rulemaking Is Even Less Justifiable than the 2017 Rule, as Reportable Accidents Have Continued to Decline

As EPA has explained, the current proposal is largely an effort to reinstate the requirements that EPA added to the RMP rules in 2017. SOCMA demonstrated at length in its 2016 comments that EPA's proposed expansion of the RMP rules was unnecessary, as reportable accidents were rare and declining. EPA's newer data show that this decline has continued through 2020, thus making the economically significant costs of this rule even less justifiable than they were six years ago. The graph below – slide 4 from EPA's October 17, 2022 presentation to the Small Business Administration's Environmental Roundtable – illustrates how the number of RMP reportable accidents has dropped by two-thirds over 17 years – from 2004 to 2020:



- **97% of all RMP facilities had no RMP reportable accidents.**
- **Most RMP reportable accidents occurred at facilities with complex processes**.

EPA has also documented this downward trend in tabular fashion in the Regulatory Impact Analyses it prepared in support of the 2019 final rule and this rulemaking:[38]

[38] Source: 2019 RIA (at 33) and 2022 RIA (at 52). The asterisks represent years for which not all 5-year accident histories had yet been reported to EPA, and the values for those years may ultimately have been higher.

Year	Impact Accidents
2004	197
2005	152
2006	140
2007	204
2008	168
2009	149
2010	128
2011	138
2012	118
2013	123
2014	128*
2015	113*
2016	127
2017	109
2018	92
2019	100
2020	60

Imposing greater requirements in the face of a declining problem is the essence of diminishing returns. Yet EPA is proposing to greatly increase the current cost of RMP compliance.[39] EPA estimates the total cost of onsite and offsite consequences from reportable accidents as $4.89M/accident.[40] EPA also estimates the average annualized costs of compliance with the rule as $75.8M (at a 3% discount rate).[41] If the new rule averted 10 accidents a year, the cost of the rule per accident averted would be $7.6M. On a breakeven analysis, the rule would have to avert 15.5 accidents per year ($75.8/$4.89M) before the benefits would justify the costs. The average number of reportable accidents per year, from 2016-2020, is 97.6,[42] so the rule would have to reduce reportable accidents by 16%. SOCMA is deeply skeptical that the rule would be so successful.

Unfortunately, EPA does not appear to have published final values for these years – but EPA obviously possesses the data.

[39] The RIA for this rulemaking inexplicably says it "does not estimate the baseline costs incurred to comply with the current RMP regulations." RIA at 27.

[40] 87 Fed. Reg. 53561.

[41] *Id*.

[42] RIA at 52.

Finally, much of the benefit of the RMP rule actually results from the PSM rule that it incorporates by reference, especially the requirement for a PHA. And 91% of the costs of accidents are experienced *onsite,* which is the purview, and purpose, of the PSM rule.[43] So facilities would be incurring the costs of the proposed RMP rule changes, which are completely additive to those of the PSM rule, to produce only 9% of the benefits that EPA claims for the current rulemaking.

B. A "Compliance-Driven" Approach Would Accomplish EPA's Regulatory Objectives Without Burdening Regulated Facilities.

In their comments on the 2018 proposal, SOCMA and others argued that, since only a handful of regulated facilities are responsible for all reportable accidents, EPA's most effective action would be to focus its enforcement resources on those facilities, rather than imposing another regulation on all facilities:

> From 2003 to 2013, only 8% of total RMP facilities were responsible for 100% of the reportable accidents. That 92% of RMP facilities have never had a reportable accident indicates that the cause and frequency of reported accidents is not related to any inadequacy of existing regulatory requirements but rather to a specific subset of facilities that ought to be the subject of enhanced compliance attention. . . . [E]ven if all RMP facilities were required to comply with additional layers of accident prevention requirements, it does not necessarily mean that improved results will be generated at those small number of facilities where management is already willing to ignore identified process safety issues or where releases are caused by intentional acts. For this reason, SOCMA has long supported a focused approach that emphasizes more active EPA enforcement of existing RMP requirements. Doing so would address program areas that need better regulatory oversight while supporting the goals EPA was trying to achieve through the 2017 RMP Amendments.

The Agency endorsed this "compliance-driven" approach in the 2019 rule.[44]

Over and over, the preamble to the current proposal confirms the continued truth that, as "EPA realizes, . . . only a small number of facilities are responsible for a significant percentage of RMP accidents":[45]

> This holds true for the updated analysis, with only 3 percent (n = 382) of facilities between 2016 and 2020 reporting one RMP-reportable accident and 0.5 percent (n =70) of all RMP facilities reporting two or more RMP-reportable accidents during that period.

[43] 87 Fed. Reg. 53561 ($434M/$477M).
[44] *See* 84 Fed. Reg. 69843.
[45] 87 Fed. Reg. 53575.

> Among facilities reporting accidents, facilities who reported one often have multiple accidents, indicating a failure to properly address circumstances leading to subsequent accidents. For example, between 2016 and 2020, these facilities accounted for 36 percent (n = 176) of all accidents reported (n = 488). Additionally, of these 70 facilities, 61 percent (n = 43) had experienced another accident prior to 2016. Between 2004 and 2020, 18 facilities had more than 10 accidents each, with two facilities reporting over 20 incidents each to EPA.[46]

Again:

> RMP accident history data show that while 97 percent of all RMP facilities had no RMP-reportable accidents from 2016–2020, 3 percent of all RMP facilities had at least one RMP-reportable accident and 0.5 percent of all RMP facilities had two or more RMP-reportable accidents.[47]

In attempting to dismiss the obvious conclusion that flows from these facts, the Agency misrepresents the "compliance-driven" approach. That approach is not just about when and how severely EPA punishes facilities after they have the biggest releases, but how effectively EPA targets its enforcement efforts at facilities *before* they have a really consequential release. SOCMA submits that the most economically efficient approach to accomplishing the goals of Section 112(r)(7) is to identify the facilities who are most likely to have releases, based on their past history of accidents or related noncompliance, and focusing compliance attention on them. It is just as "prevention-focused" as the "rule-based approach."[48] Moreover, it is not as though EPA in 2017, and again now, is imposing a rule where none exists. There already *is* an RMP rule and has been since 1996. The question before EPA is how to enhance its effectiveness: by better, more focused compliance and enforcement, or by imposing an additional layer of regulation on all regulated entities?

EPA insists that the "low probability, high consequence nature of accidental releases" means that trends over time are an "improper" basis for determining what the Agency should do, citing the TPC Group explosion in 2019.[49] But the TPC Group event was just *one* accidental release, and was incapable of skewing the declining trend of accidents. EPA highlights the unusually sizeable consequences of that accident (e.g., number of offsite individuals evacuated; value of property damage), but that just confuses what is at bottom a simple issue: are total reportable accidents increasing, fluctuating randomly, or declining? The answer is the latter.

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[46] *Id*. at 53581-82.
[47] *Id*. at 53584.
[48] *Id*. at 53565-66.
[49] *Id*. at 53565.

The TPC Group example is actually a good case study for why a compliance-driven approach is likely to be successful. That facility had an extraordinarily long history of air-related noncompliance. As was reported in 2019, TPC "has been fined by the Texas Commission on Environmental Quality (TCEQ) and U.S. Environmental Protection Agency (EPA) more than half a dozen times in the past five years after the agencies found some of the facility's air pollution emissions avoidable."[50] EPA's ECHO database contains a lengthy list of enforcement/compliance activity at the facility for air issues, including a Section 112(r)(1) general duty clause investigation by EPA in 2015 for a chlorine release that resulted in an administrative order on consent in 2017.[51] As recounted in a judicial complaint filed by neighbors:

> **14.** But TPC's Port Neches, Texas chemical plant has a years-long history of state and federal environmental violations. It has been considered a high priority violator by the U.S. Environmental Protection Agency for more than two years, and been out of compliance with federal clean air laws since the agency's last inspection in August 2017. State data shows the facility has reported spewing more air pollution than allowed by its government-issued permits five times this year, including hundreds of pounds of butadiene.
>
> **15.** Together, the EPA and the Texas Commission on Environmental Quality, the state's environmental regulatory agency, have fined TPC for air emissions violations more than half a dozen times in the past five years after finding many of the missteps preventable. The last federal censure TPC faced was in 2017 when it was ordered under a consent decree to pay a civil penalty of $72,187, make various equipment upgrades, and spend no less than $275,000 on fence line monitoring for butadiene.[52]

It is hard to imagine that a requirement to do an STAA assessment would have led TPC to actions that would have prevented the 2019 release. It seems more plausible that more aggressive enforcement would have.

14. Regulatory Flexibility Analysis

Due to the disproportionately costly impacts of the following proposed provisions of the rule on batch manufacturers, many if not most of which are small businesses, SOCMA has recommended the following exemptions from or limitations on any final rule:

STAA (see § 5 above):

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[50] https://www.texastribune.org/2019/11/27/texas-plant-rocked-explosions-mandatory-evacuations-ordered/.
[51] https://www.epa.gov/tx/enforcement-compliance-assurance-documents-texas; https://echo.epa.gov/detailed-facility-report?fid=110000504801.
[52] https://www.courthousenews.com/wp-content/uploads/2019/12/tpc-federal-lawsuit.pdf.

- STAA should only be required at the design stage of new processes.
- EPA should adopt the alternative proposal to apply STAA only to NAICS code 324 and 325 facilities that have had a reportable accident in the past five years.
- EPA should exclude from the requirement aspects of processes governed by external specifications.

Third-Party Audits (see § 7 above):

- EPA should exempt batch manufacturing processes.

Fenceline Monitoring (see § 9 above):

- Batch manufacturing processes should be exempted from any fenceline monitoring requirement.

Conclusion

SOCMA appreciates the opportunity to comment on EPA's proposed RMP rule revisions. We look forward to continued involvement and collaboration with EPA on this topic. If you have any questions about these comments, please feel free to contact me at rhelminiak@socma.org or 571-348-5107.

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