



Five Things about Chemical Security That Nobody Is Discussing

#5: Government-Mandated “Inherent Safety” Will Have Damaging Impact on Pharmaceuticals and Microelectronics

Imagine life without a ready supply of ibuprofen or Tylenol on pharmacy or grocery store shelves. As established by H.R. 2868, which is now before Congress, Section 2111 of the federal Chemical Facility Anti-terrorism Standards (CFATS) statute would require Tier 1 and 2 “high risk” facilities to implement “methods to reduce the consequences of a terrorist attack” – i.e., Inherently Safer Technology, or IST – whenever DHS made specified findings about risk reduction and technical and economic feasibility. However commonsense such a mandate might appear on the surface, it is fundamentally a bad idea in the security context. Inherent safety is a superficially simple but truthfully very complex concept, and one which is inherently unsuited to regulation. Any IST mandate is bound to create situations that will *actually increase or transfer overall risks*. It would also wreak economic havoc on regulated facilities, notwithstanding the findings DHS would have to make. Makers of active pharmaceutical ingredients, common fuels and other federally-regulated substances would be most at risk of such economic damage.

One of SOCMA’s greatest concerns with Section 2111 is the real possibility that it will negatively restrict the production of active pharmaceutical ingredients (APIs), many of the key raw materials of which are included on DHS’s Appendix A of covered chemicals. APIs are used in prescription and generic drugs, life saving vaccines and over-the-counter medicines. They are thoroughly regulated by the FDA and must meet demanding quality and purity requirements. Substituting chemicals or processes used for the production of APIs would likely violate the conditions of their FDA approvals. Requiring IST could delay clinical trials while new replacement chemicals are identified or invented, and would force API manufacturers and their customer drug manufacturers to reapply for FDA approval of their products because of the significant change in the manufacturing.¹ The lengthy 1 - 4 year approval timeline for a new or equivalent replacement chemical would be a high price to pay for American consumers, many of whom rely on ready access to pharmaceuticals. To meet continuing consumer demand, API

¹ See 21 U.S.C. § 351(a)(2)(B).

production would likely shift to foreign countries, where the FDA is less able to monitor conformance to quality standards.

Many SOCMA members' products are also vital to the manufacture of microelectronics. Below, we offer several examples, provided by SOCMA members, of how IST could cripple the pharmaceutical and microelectronics industries.

Lifesaving Antibiotics: Company A

Company A is a minority-owned small business located in Pennsylvania regulated by DHS under CFATS. It produces an active pharmaceutical ingredient critical to specific antibiotics used in the treatment of a life-threatening bacterial infection. For this purpose, the company is also regulated by the Food and Drug Administration (FDA). Since the product's specifications are likely not to be attainable via any chemical substitution or altered process, if a "safer" manufacturing process alternative was mandated, the company would likely be forced to discontinue production, lay off workers and increase our nation's vulnerability to bacteriological threats. The impact of a mandatory alternative would thus be swift and direct.

Common Pain Reliever: Company B

Company B manufactures the active pharmaceutical ingredient Ibuprofen. Ibuprofen is a non-steroidal anti-inflammatory drug (NSAID) used to treat pain and relieves symptoms of arthritis such as inflammation, swelling, stiffness, and joint pain. It is one of the world's most successful and widely-used pain relievers, and is listed on the World Health Organization's model list of medicines.² Changing the raw materials, and consequently the process, used to manufacture it presents a risk to public health and a substantial cost for re-qualification from a technical, regulatory, and potentially clinical perspective. Company B's 31-year old process to manufacture Ibuprofen bulk active is well characterized and controlled, and consistently makes a safe and efficacious product. The process-characteristic impurity profile, specified under the prevailing USP and European Pharmacopoeia compendia, is proven to have no impact to public health by its use by millions of people worldwide. The costs derived from IST, if it impaired production quantities or product quality, would ultimately be felt by consumers.

Microelectronics: Company C

Company C manufactures two Appendix A chemicals of interest targeted by industry critics. First, Company C uses small amounts of hydrochloric acid (HCl) in a very high purity, aqueous form (37%) to manufacture a product that represents almost half of the company's revenue worldwide (~\$30 million/yr). The product is used in the microelectronics industry to manufacture integrated circuits and LCD displays. If HCl were not available, Company C would be unable to make its largest product, resulting in at least a 50% reduction in workforce, which would equate to losing 60 jobs. If the company chose to continue the business, alternatives would have to be developed and implemented to continue manufacture of those products, which could easily require billions of dollars of research, development and implementation, resources

² World Health Organization, *WHO Model List of Essential Medicines* (March 2005).

that small companies like Company C, which include many of SOCMA's members, do not have. Additionally, Company C uses HCl to protect the environment: its use brings the pH of the company's wastewater into the range dictated by its wastewater permit.

The company also uses small volume products using aqueous (49%) hydrofluoric acid (HF) that are sold into the microelectronics industry. Customers of Company C that need HF for their products require Company C to undergo specific certification standards as a product supplier. If Company C was forced to use a substitute, it would immediately be out of compliance with its customers' product standards, which (obviously) would negatively impact Company C's business. Additionally, in some cases, the HF is being used as a safer alternative to replace hydroxylamine (HA), the use of which has been reduced due to the multiple explosions at HA manufacturing facilities. In some cases, anhydrous HF may be necessary as water may be incompatible with the manufacturing process. If manufacturers of microelectronics were denied a supply of HF, there would be a negative consequence to the domestic manufacture of integrated circuits and LCD displays.

What member of Congress wants to stand before his or her constituents and admit that their vote contributed to the unavailability of common pain relievers or, worse, effectiveness of vaccines?

#4: Experts Agree IST Should Not Be Mandated

As these examples show, a "simple" reduction in hazard may not necessarily result in a reduction of overall risk, and a poorly thought out or incomplete analysis could result in a "safer" alternative producing more harm than good. That is why government agencies and experts who really understand inherent safety have consistently opposed giving government the power to mandate it. This includes:

- Neal Langerman, representing the American Chemical Society – the majority's own technical witness at the Homeland Security Committee hearing in June.³
- Sam Mannan, Director of the Mary Kay O'Connor Process Safety Center at Texas A&M University, in testimony before the Homeland Security Committee on December 12, 2007.⁴

³ See <http://homeland.house.gov/SiteDocuments/20090616103505-95857.pdf>, page 7:

In conclusion, the existing regulatory structure, under the U.S. EPA Risk Management program and the U.S. OSHA Process Safety Management standard, provide strong incentives to examine and implement IST. These programs work in natural conjunction with Homeland Security's mandate to enhance infrastructure security. The provisions of the Chemical Facility Antiterrorism Act of 2006 provide a sufficient legislative framework for this purpose. The most effective steps to further infrastructure protections will likely include incentives, rather than new regulations.

⁴ Go to <http://homeland.house.gov/Hearings/index.asp?ID=108>, click on "Dr. Mannan's testimony," pp. 6-7:

[I]n developing inherently safer technologies, there are significant technical challenges that require research and development efforts. These challenges make regulation of inherent safety

- Dennis Hendershot, testifying on behalf of the Center for Chemical Process Safety before the Senate Environment & Public Works Committee Administration on June 21, 2006.⁵

It is instructive that New Jersey, whose chemical facility security program is regularly contrasted with the CFATS program, only requires consideration of IST – *it does not require facilities to implement it*. It is even more telling that the companion bill the Subcommittee is now considering ducks the politically sensitive question of whether to require public drinking water systems to implement IST by deferring the decision to EPA and the states.⁶ Congress should not require DHS to do what all these experts have concluded is unwise, and what it is unwilling to do directly when the public is picking up the tab.

#3: DHS Cannot Mandate Inherent Safety without the Ability to Measure It

The Obama administration recently yielded to political pressure from special interests like Greenpeace and now supports mandating environmentally-based (not security- or risk-based) IST for Tier 1 and 2 facilities when unspecified “key criteria” are met. But that approach does not address a fundamental objection to the concept, which is that it would take IST decisions away from the process safety experts who know their own processes the best and would allow their judgments to be second-guessed by busy government officials sitting miles away reviewing documents. While these officials may be sincerely trying to do their best, we simply do not trust that their judgments will be better than ours. We also fear the prospect of liability if a “safer” process or chemical that one of our member companies is compelled to use ends up causing an accident or some other harm. Will the federal government indemnify facilities in the cases where it overrules their judgments regarding inherent safety? And even if a facility ultimately

very difficult. . . . Instead of prescriptive requirements for inherently safer technology and approaches, facilities should be allowed the flexibility of achieving a manageable level of risk using a combination of safety and security options. . . . Over the past 10-15 years, and more so after 9/11, consideration of Inherently Safer Technology (IST) options and approaches has effectively become part of industry standards, with the experts and persons with know-how assessing and implementing inherently safer options, without prescriptive regulations that carry risks (both as trumping other tools or potentially shifting risk). A better approach for applying IST in security is by allowing the companies to assess IST as part of their overall safety, security and environmental operations and therefore, cannot be prescriptive.

⁵ See http://epw.senate.gov/109th/Hendershot_Testimony.pdf, at 4-8, esp. 5-6:

There are tens of thousands of chemical products manufactured, most of them by unique and specialized processes. The real experts on these technologies, and on the hazards associated with the technology, are the people who invent the processes and run the plants. In many cases they have spent entire careers understanding the chemistry, hazards, and processes. They are in the best position to understand the best choices, rather than a regulator or bureaucrat with, at best, a passing knowledge of the technology.

⁶ See 42 U.S.C. § 300i-2(g)(3), (5), as modified by H.R. 3258, § 2(a).

succeeds in persuading DHS to allow it to retain its proposed approach, that process will inevitably have costs in time and resources.

Preceding all these concerns, moreover, is an even more basic one: no one knows how to compare the “inherent safety” of two processes. Here is what the experts have told Congress:

- I do not believe that the science currently exists to quantify inherent safety. . . . The first challenge is simply to measure the degree of inherent safety in a way that allows comparisons of alternative designs⁷
- Inherently safer design is not a specific technology or set of tools and activities at this point in its development. . . . Current books and other literature on inherently safer design . . . describe a design philosophy and give examples of implementation, but do not describe a methodology.⁸
- While scientists and engineers have made great strides in understanding the impacts of industrial processes and products over the past several decades, there is still no guaranteed formula for developing inherently safer production processes.⁹

The experts at the National Research Council concluded recently: “Inherently safer chemistry . . . offers the potential for improved safety at chemical facilities. While applications show promise and have found use within the chemical industry, these applications at present are still quite limited in scope.”¹⁰

While it may be feasible to develop a technical consensus methodology for measuring and comparing inherent safety, none exists at present.

#2: Citizen Oversight of Enforcement of Security Laws Would Actually Be Counterproductive

Another controversial provision stuck in H.R. 2868 is a citizen suit provision. As revised by H.R. 2868, Section 2116 of the CFATS legislation would authorize literally “any person” to file suit against either

- anyone who the plaintiff believed was violating some requirement of the new law; or

⁷ Testimony of Sam Mannan, *supra* note 4, at 6.

⁸ Testimony of Dennis Hendershot, *supra* note 5, at 1-2.

⁹ Testimony of Neal Langerman, *supra* note 3, at 6-7.

¹⁰ National Research Council, Board on Chemical Sciences & Technology, *Terrorism and the Chemical Infrastructure: Protecting People and Reducing Vulnerabilities* (2006), at 106.

- DHS, if the plaintiff believed that DHS had failed to take some nondiscretionary action the law required it to take.

Both of these prospects would be bad security policy.

Section 2116 is very closely modeled on the citizen suit provisions of environmental and natural resource statutes. One of the main reasons that citizen suit provisions are found in some such laws is because the obligations – and the compliance status – of regulated entities under them is a matter of public record. It is relatively easy to get access to facilities’ permits, and their compliance data is normally also made public as a matter of law – in many cases, on the Internet. Also, citizen enforcement is generally thought to promote the purposes of these laws. By adding citizen oversight to EPA and state enforcement, Congress believes it can help eliminate or reduce emissions, discharges, etc. of pollution.

Citizen oversight of enforcement of security laws, by contrast, would actually be counterproductive to the purposes of those laws. Currently – and under H.R. 2868 – the only fact about a facility’s regulation under the CFATS program that a citizen might be able to obtain legally is that fact that the facility *is* regulated. Every other item of information that the facility or DHS has developed under the law – the facility’s tier level, vulnerability assessment, security plan, list of security measures, etc. – is prohibited from being released to the general public (for example, under the Freedom of Information Act), both under current law and under H.R. 2868. And for good reason: if this information were publicly available, terrorists could use that information to target the facility and its surrounding community. Because this information is protected (currently as “Chemical-terrorism Vulnerability Information” or “CVI”), there is no way that “any person” could evaluate the compliance status of a facility. Indeed, it is questionable whether such a person, relying on publicly-available information, could even form the reasonable belief regarding noncompliance that would be required to file a lawsuit in federal court under Rule 11(b) of the Federal Rules of Civil Procedure.

SOCMA disputes the view, regularly asserted by proponents of a citizen suit provision, that such provisions are normal features of any federal regulatory statute. Such provisions are in fact not common: they are not contained in statutes regulating food and drugs, aviation safety, consumer product safety, bank safety & soundness, transportation safety, or any of the myriad substantive areas that the federal government regulates. Nor has the Supreme Court inferred a private right of action in ages.¹¹ Most important, citizen suit provisions are absent from federal statutes regulating the security of ports, port facilities, vessels, aircraft, railroads, or motor vehicles. As the listing on page 49 of the Homeland Security Committee’s report on H.R. 2868 (the “Report”) makes clear, citizen suit provisions are exclusively an environmental/natural resources phenomenon. And chemical facility security is a security matter, not an environmental matter.

¹¹ Thus SOCMA is troubled by the Report’s curious description of the citizen suit provision as “remov[ing] the current restrictions on citizen suits” from a statute that is silent on the topic. Report at 21.

#1: There is No Denying the Fact that Congress Can Pass a Comprehensive Chemical Security Bill Today

Many within DHS, Congress, and industry regard the existing chemical security law, while temporary, a success thus far. Almost 40,000 facilities have submitted Top-Screens, close to 7,000 have completed SVAs, and DHS has now requested SSPs from three of the four tiers of facilities under the program. Tier 1 SSPs are being actively reviewed and inspections will follow soon. We are already hearing of disputes between DHS and facilities, proof that the CFATS program has teeth. Of perhaps greatest interest to skeptical members of Congress, we understand that some 600 facilities – roughly 10 percent of the initial Top-Screen population- have changed processes or inventories in ways that have enabled them to screen out of the program. Thus, as predicted, CFATS is driving facilities to reduce inherent hazards, where doing so is in fact safer and does not transfer risk to some other point in the supply chain, and makes economic sense. Unfortunately, Congress is deciding to risk having the temporary program sunset because of inaction rather than simply extending it, leaving thousands of covered facilities in limbo. Such disregard of the investments by both the government and industry to comply with comprehensive site security laws undermines the fervor voiced by industry opponents in Congress to pass stricter laws, to say nothing of the need to continue protecting chemical facilities – a critical infrastructure – against terrorism.

Congress needs to either pass a bill extending the current CFATS law for another year or permanently approve the existing law.

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