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Flexible Packaging Association

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David Schwarz (2823)
Evi Huffer (2823)
Office of Environmental Information
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Re: Proposed Rule regarding 40 CFR Parts 3, 51, et al. Establishment of Electronic Reporting: Electronic Records, 66 Fed. Reg. 46162 (August 31, 2001).

Dear Mr. Schwarz and Ms. Huffer:

The Flexible Packaging Association (FPA) is pleased to submit comments on the proposed rule to amend 40 CFR Parts 3, 51, et al., regarding Establishment of Electronic Reporting: Electronic Records, published in the Federal Register on August 31, 2001. See, at 66 Fed. Reg. 46162. Flexible Packaging Association is the leading trade association for converters and suppliers of flexible packaging materials and allied products for consumer products, retail packaging, medical and pharmaceutical packaging, institutional packaging, and industrial applications. FPA collects, analyzes and publishes technical, manufacturing, statistical and marketing information about the industry and serves its members in a variety of ways including representation before governmental agencies. FPA has approximately 120 members and they produce more than half of the $19 billion of flexible packaging produced in the United States. The Association's membership includes small businesses as well as larger companies with multiple facilities.

FPA members are very concerned about the proposed electronic reporting/recordkeeping rule. EPA has presented and characterized the proposed rule as voluntary because facilities can continue to maintain records in paper format. However, the definition of an electronic record provided in the proposed rule is so broad that any data that passes through a computer at any point and deemed as a record would be subject to the proposed

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rule. As the proposal currently stands, if a company has converted its environmental management program to accommodate the recordkeeping and reporting requirements of existing environmental regulations at the state or federal level the rule would be mandatory.

The law, under which this rulemaking is being developed, the Government Paperwork Elimination Act of 1998, requires federal agencies to *accommodate* electronic reporting and recordkeeping for their regulatory programs by October 21, 2003. FPA does not believe, however, that the law *mandates* electronic recordkeeping, or more importantly, that it mandates a particular type of recordkeeping. The CDX system that EPA is proposing should accommodate a broad variety of different software programs in order to meet the statutory requirements of the Government Paperwork Elimination Act.

The cost impact of the proposed rule is far reaching for the Flexible Packaging Industry, affecting the smallest producer that uses a simple Excel spreadsheet to record chemical purchases to the large manufacturers with multiple LAN based and mainframe based record systems. FPA's members, like the vast majority of manufacturing companies, have implemented electronic recordkeeping and other information systems to meet environmental compliance obligations. If the current proposal was finalized, these environmental management systems would need to be adapted or replaced. EPA has estimated the cost of implementing the proposal at $40,000 per facility. FPA contends that this cost is far too low, given that EPA's rule would create sweeping new requirements that are different from those currently imposed under existing regulations and no existing systems are likely to meet the terms of the rule. After reviewing the proposed rule's recordkeeping requirements with its Information Resources department, an Association member company reported an estimated cost for existing systems modifications well in excess of $1,000,000. In addition, there will be costs of dislocation and data consistency concerns if EPA finalizes its proposed rule. FPA strongly believes that EPA should abandon its electronic recordkeeping rulemaking and rely, instead, on existing systems - many of which have been designed to meet environmental regulatory reporting and recordkeeping obligations. Alternatively, the agency should narrow the rulemaking to state only broad criteria for electronic recordkeeping that is consistent with regulatory requirements promulgated under the Clean Air Act and Clean Water Act.

The effect of the proposed rule is regressive. It will drive companies to less electronic recordkeeping, cause spending of billions of dollars changing information systems, and consume enormous amount of man-hours in responding to broad and onerous requirements of the rule. After all of this effort is completed, the environment will not be improved, pollution will not be reduced, and the air, water or soil will not be cleaner. In fact, more paper will be consumed.

We are substantially in agreement and by reference attaching it here with our comments the statement of James W. Conrad, Jr. before the House Committee on Small Business, Subcommittee on Regulatory Reform and Oversight, presented November 8, 2001.

If you have any questions about our comments or need additional information, please do not hesitate to call me at (410) 694-0823.

Sincerely,

Ram K. Singhal
Director, Technology & Regulatory Affairs

STATEMENT OF

JAMES W. CONRAD, JR.
COUNSEL

on behalf of the

AMERICAN CHEMISTRY COUNCIL

before the

HOUSE COMMITTEE ON SMALL BUSINESS
SUBCOMMITTEE ON REGULATORY REFORM AND OVERSIGHT

EPA RULEMAKING: DO BAD ANALYSES LEAD TO IRRATIONAL RULES? – EPA'S PROPOSED RULE ON ELECTRONIC REPORTING AND ELECTRONIC RECORDS

November 8, 2001

Introduction

Good morning, Mr. Chairman and members of the Subcommittee. My name is Jamie Conrad. I'm Counsel with the American Chemistry Council. The Council represents the leading companies engaged in the business of chemistry. Council members apply the science of chemistry to make innovative products and services that make our lives better, healthier and safer. The Council is committed to improved environmental, health and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and extensive health and environmental research and product testing. The business of chemistry is a $460 billion-a-year enterprise and a key element of our nation's economy. It is the nation's #1 exporting sector, accounting for 10 cents out of every dollar in U.S. exports. Chemistry companies invest more in research and development than any other industry.

While many Council members are Fortune 500 companies, many more are small businesses. In fact, we estimate that between 35-50% of our approximately 180 members meet the relevant SBA size standard for a small business. Many of these members have only a single manufacturing plant. As you might imagine, the substantial regulatory burden imposed by agencies like EPA is particularly challenging for companies of this size. At the same time, these smaller companies stand to benefit most from the efficiencies made possible by innovative information technologies.

Mr. Chairman, I am pleased to testify before you today regarding EPA's recent proposed rule on electronic reporting and electronic records, conventionally known as "CROMERRR."[1] While well intended, the rule as proposed would offer few, if any efficiency gains to businesses, small or large, that are regulated by EPA or delegated states. In fact, the regulation would have the opposite effect, imposing astronomical costs and, paradoxically, driving businesses away from electronic ways of managing information. This result seems to stem not so much from bad analysis as from ignoring the cost/benefit analysis that was done and not doing the risk analysis that OMB requires.

Summary

Everyone supports the voluntary use of electronic systems to replace paper ones where that's appropriate. Information technology enables processes to be expedited, simplified, and streamlined. This potential benefit is especially critical for small businesses, which have proportionately greater paperwork burdens and fewer resources than large businesses. That's why there was such broad support for the Government Paperwork Elimination Act of 1998.[2] CROMERRR ostensibly implements that law. But it actually conflicts with the law and will frustrate its goals.

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[1] "Establishment of Electronic Reporting; Electronic Records," 66 Fed. Reg. 46162 (Aug. 31, 2001). Until recently EPA called this the "Cross-Media Electronic Reporting and Records Rule" or "CROMERRR," a label which has stuck.

[2] Pub. L. No. 105-277, 44 U.S.C. § 3504 note.

CROMERRR addresses two topics: electronic reporting and electronic recordkeeping. At this point, the Council is reserving judgment on the reporting provisions – they may well be fine, although we are beginning to hear rumblings of inconsistencies with pilot projects that other parts of EPA have developed with states and with regulated entities. However, we have not had much time to focus on the reporting side of the proposal because we have been so alarmed by what the recordkeeping side would require of companies.

There are two fundamental problems with the recordkeeping aspect of the proposal:

- The first is its mandatory nature. While CROMERRR claims to be entirely voluntary, as a practical matter it is not. It employs an incredibly expansive definition of "electronic record," covering essentially any data that ever pass through a computer. CROMERRR further provides that *any electronic record has to meet its demanding technical requirements, or else the record will no longer satisfy the underlying recordkeeping requirement*. Since many facilities now maintain required records electronically, CROMERRR will require them to upgrade their systems or, where possible, switch to paper.
- The second problem is how enormously burdensome it would be for businesses to meet CROMERRR's technical requirements, which impose elaborate safeguards to prevent the remote prospect that data might be tampered with. No commercially-available off-the-shelf software has these capabilities. Compliance will require wholesale overhaul of computer systems -- Y2K all over again, possibly worse.

CROMERRR is "intended to be consistent" with, and is closely modeled on, an FDA rule issued about four years ago that was also described as voluntary and cost-saving.[3] Instead, the FDA rule has turned out to be mandatory for anyone who maintains data electronically. It has also turned out to be horrendously complicated and expensive to comply with. Four years later, pharmaceutical companies are still struggling to comply. Fundamental principles of administrative law suggest that where one federal agency interprets a given set of words in a particular way, another agency adopting the same language is going to be held to the first agency's interpretation, at least until the second agency can offer good reasons for a different interpretation.

Increasingly, policymakers are calling for more and better information about environmental quality and the performance of individual facilities. It is ironic that EPA's Office of Environmental Information has proposed a rule that will force regulated entities to spend their limited information resources on procedures that generate no new information, but only guard against risks that have not been adequately characterized.

EPA's own cost/benefit analysis concluded that the costs of implementing CROMERRR exceed the benefits. Very few companies would implement it voluntarily. This result does not comport with EPA's stated intention to "reduce the burden of compliance."[4]

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[3] 66 Fed. Reg. 46170.
[4] 66 Fed. Reg. 46163.

As explained below, CROMERRR is "significant" within the meaning of Executive Order 12866 not only because it involves "novel legal or policy issues," as recognized by EPA, but also because it is likely to have an annual effect on the economy of $100 million or more. More important to this Committee, CROMERRR clearly would trigger the Regulatory Flexibility Act and the Small Business Regulatory Enforcement Fairness Act. EPA has not complied with any of these authorities, however, because it has taken the unsustainable position that CROMERRR is voluntary and would actually save companies money. But it won't. The balance of this testimony will explain (i) why CROMERRR is not voluntary, (ii) why it would be so costly to comply with, and (iii) why EPA should withdraw at least the recordkeeping provisions of CROMERRR. The American Chemistry Council is prepared to work with EPA to improve them.

CROMERRR is mandatory, as a practical matter, and would apply to most records at most EPA-regulated facilities

The scope of CROMERRR is so vast that it would apply to essentially all organizations subject to federal environmental laws. About 1.2 million entities file reports under EPA regulations, either directly or via delegated state programs. Virtually all of these entities are required by some EPA rule to keep records. I am attaching to my testimony a very recent compilation, prepared by the American Chemistry Council, of EPA recordkeeping requirements. As you can see, there is an astonishing multitude of them. Even this document, 208 pages long, omits many – for example, the pesticide law called FIFRA.[5]

Even where rules don't require records to be kept, the possibility of enforcement makes it necessary. Many EPA rules don't apply to facilities or operations if they fall below certain thresholds for releases, inventories, etc. Needless to say, these exemptions are vital to small businesses – in general, they reflect EPA's judgment that the costs of compliance are not justified by the small environmental effects involved. Most of these exemptions operate on the honor system – if you determine that a rule doesn't apply, you don't have to report that conclusion to EPA or the state. But if one of those authorities challenges your determination, you had better have some records to document how you made your decision. We can envision facilities being challenged if those records don't satisfy CROMERRR.

So almost every facility regulated by our environmental laws has to maintain some records. CROMERRR would govern most of them. While it applies nominally to "electronic records," these are defined as "any combination of text, graphics, data, audio, pictorial, or other information represented in digital form that is created, modified, maintained, archived, retrieved or distributed by a computer system."[6] In other words, so long as a piece of information passes through a computer at any stage in its life cycle – from generation to archiving and retrieving – it is an electronic record.

[5] The Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. §§ 136-136y.
[6] Proposed 40 C.F.R. § 3.3, 66 Fed. Reg. 46189.

This definition is taken virtually word for word from the FDA's electronic records rule, and that's how the FDA has interpreted it.[7]

Unfortunately, right now, much if not most of the information that facilities maintain to comply with EPA rules passes through a computer at some point, and hence meets this definition of an electronic record. By and large, regulated entities do not operate in a purely paper world. In fact, much regulatory information is generated by computers in the first instance, and can *only* be electronic. Some significant examples include:

- continuous emissions monitors;
- hand-held fugitive emissions data loggers;
- gas chromatograph/mass spectrometers and other analytical equipment; and
- temperature and flow meters.

Even very small chemical companies run their machinery by distributed control systems, complex integrated systems for collecting, analyzing and presenting information on operating parameters of equipment and processes. For many companies, the outputs of these systems serve as the basis for much of their reporting on emissions, releases, etc. Other companies have developed customized software for special purposes, such as:

- screening export orders for reporting obligations under Section 12(b) of TSCA;[8] and
- recording hazardous waste generation and management data (used to prepare RCRA biennial reports, annual Toxic Release Inventory reports and other filings)
- entering, analyzing data from toxicological and epidemiological studies.

All of these systems would generate "electronic records." Under CROMERRR, these records would satisfy the recordkeeping requirements of EPA rules *only* if they satisfied all the requirements of CROMERRR.[9] If a particular record doesn't meet CROMERRR, then the facility is in violation of the underlying recordkeeping requirement.

Simply printing out a record does not seem to be an adequate solution. For one thing, the data will have existed for some period of time in electronic form. If that electronic system does not meet CROMERRR requirements, then theoretically it could have been tampered with before it was printed. But even if you could avoid CROMERRR by printing out data as soon as it was generated, that would hardly be a helpful solution. In that case, a rule designed to "remove . . . obstacles to electronic . . . recordkeeping"[10] would be forcing facilities to print out all their records onto paper – including records they are now keeping electronically. This would be an ironic result, clearly inconsistent with a statute entitled the Government *Paperwork Elimination* Act.

Again, the foregoing is not paranoid speculation -- the FDA has interpreted its functionally identical rule to mean that if data ever pass through a computer, that

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[7] *See* 62 Fed. Reg. 13437 (Mar. 20, 1997), discussing 21 C.F.R. Part 11.
[8] The Toxic Substances Control Act, 15 U.S.C. §§ 2601-2692.
[9] *See* proposed 40 C.F.R. § 3.100(a), 66 Fed. Reg. 46190.
[10] 66 Fed. Reg. 46163.

computer must comply with the FDA rule, even if the data are printed out. EPA intends CROMERRR to be consistent with the FDA rule. And complying with CROMERRR, like complying with the FDA rule, would be a major nightmare.

CROMERRR's requirements are very demanding and very expensive

As mentioned before, electronic reporting and recordkeeping have already demonstrated great savings and convenience in the commercial world. Why, then, would anyone be concerned about switching from paper to electronic records? The answer, in a word, is fraud. Paper records have an inherent connotation of authenticity, even though forgery is as old as handwriting. In the electronic world, though, data are simply miniscule electrical charges that can vanish - or be changed - with a keystroke. Any organization that relies on electronic data has some legitimate concern about preserving the integrity of that data — about ensuring that unauthorized people can't make changes to data, and that authorized people can't make improper changes without detection.

But ensuring integrity has an impact on the scope and effectiveness of the system. The extent of this impact depends on how secure the system needs to be. That's why OMB's implementing guidance for the Government Paperwork Elimination Act calls for agencies to do a risk analysis for each type of recordkeeping requirement to assess:

- how likely is it that fraud will occur?
- how bad are the consequences if it does?
- how much will differing degrees of security cost?[11]

OMB's guidance instructs agencies to adopt the appropriate level of protection, based on this analysis. It specifically admonishes them not to adopt a one-size-fits-all approach.[12]

We have been unable to find any evidence that EPA ever performed this analysis - not in the preamble to CROMERRR, not in the Agency's cost-benefit analysis, or anywhere else. It appears that EPA simply took the highest degree of security - the one used by FDA -- and imposed many aspects of this far-reaching system on *all* EPA recordkeeping. The elements of this level of security are substantial:

- *Audit trails*. Records must have secure, computer-generated, time-stamped audit trails that automatically record the date and time of operator key entries and actions that create, modify or delete electronic records.
- *Archiving*. The records must be stored in such a way that completely preserve the context in which the document was prepared, the associated metadata (i.e., information about the data) and the audit trail.
- *Migration*. If a facility ever migrates an electronic record from one medium or format to another, EPA expects each record, plus all of its metadata, to be transferred from the original to the new format so that the entire body of

[11] *See* "OMB Procedures and Guidance on Implementing the Government Paperwork Elimination Act," Part II, § 3, 65 Fed. Reg. 25514 (May 2, 2000).
[12] *Id.* at 25510. The guidance also admonishes agencies to continually assess the risks to their own computer systems and to maintain adequate security. *Id.*

information is moved without modification. Error checking functionality would be required to verify that this occurred.

- *Ready onsite availability*. The record, and all of its meta data, must be "readily available" at any time for onsite inspection and offsite review.

The net, intended result of these requirements is an essentially tamper-proof system, in which any attempt to compromise data will leave indelible traces for prosecutors. EPA also requested comment on a range of other security features of the FDA rule (e.g., validation, training, operational and authority checks) that would only further increase the burden of CROMERRR.[13]

Moreover, CROMERRR requires facilities to comply with these requirements for the life of record, which is defined by the underlying recordkeeping requirement. While some of these are only 3-5 years, many are much longer. For example:

- The operating log maintained by a hazardous waste treatment, storage or disposal facility must be kept for the life of the facility, which could be decades.[14] When you consider that a hazardous waste incinerator may be required to monitor air emissions every six minutes, and that these monitoring data must go into the operating log, you can see the daunting challenge of CROMERRR.
- Data supporting a pesticide registration must be kept for the life of the registration, which again can be decades. These supporting data -- primarily involving toxicology studies - are also exceedingly voluminous.

Meeting CROMERRR requirements would often mean complete overhauls of computer systems, at huge costs. No commercially available, off-the-shelf software package meets these requirements. While some vendors claim they have patches to make popular software compliant, these patches are generally still in beta form, and not available off-the-shelf. Companies are not going to want to stake their legal liabilities (and reputations) on these products. Questions have also been raised about the extent to which the licenses under which regulated entities use software would allow them, or their contractors, to modify that software. Many and perhaps most corporate information systems are already customized to the company or facility to the point where they may not be "patchable." Such systems might have to be completely redeveloped from ground up.

Software evolves rapidly. The costs and technical challenges of migrating enormous, CROMERRR-compliant data sets to new formats and systems so that they retain the required functionality will often be prohibitive. Companies may be compelled to leave those data on old, "legacy" systems that might have no other function but to maintain old electronic records. It would be extremely costly to maintain such old systems, and very difficult to retain information technology staff willing to work on such a dead-end career path.

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[13] *See* 66 Fed. Reg. 46171-72.

[14] *See, e.g*, 40 C.F.R. §§ 264.347(d), 264.73(d).

The lessons learned from the FDA rule should not be forgotten. As noted above, the FDA adopted essentially the same rule as CROMERRR in 1997.[15] Four years later, the Food & Drug Law Institute notes that "many [companies] are still struggling to understand and implement it" and have been forced to "develop a compliance plan" with the FDA to come into compliance years after the effective date.[16] Many drug companies are spending in excess of $100 million *each* to comply. The FDA, like EPA, advertised its rule as voluntary and cost-saving.[17] It has turned out to be dramatically otherwise. Let's not make the same mistake twice.

The theme of this hearing is whether bad analyses lead to irrational rules. In a very vital respect, EPA has *done* an analysis, but then ignored it. The preamble to CROMERRR mixes reporting and recordkeeping together and declares that, combined, they will save the regulated community over $300 million/year.[18] But combining the two obscures the findings of EPA's own cost/benefit analysis, which looked separately at reporting and recordkeeping. It assumes that *only one half of one percent* of the 1.2 million facilities that file reports under EPA administered laws would implement the recordkeeping provisions, due to their "very significant" costs.[19] EPA's estimated costs include first-year implementation costs of $40,000, and $17,000 annual operating costs, per facility.[20] Compared to the costs that these 6,000 facilities would otherwise have incurred for recordkeeping, the analysis concludes that these facilities would incur additional net costs for every year of CROMERRR implementation. In the second year, the cost for just these 6,000 facilities would be $14.69 million.[21] So electronic recordkeeping will not reduce costs.

But even this analysis assumes that facilities have a choice, which is an incorrect assumption. CROMERRR is likely to apply to most, if not all, of the 1.2 million facilities reporting under EPA-administered laws, and possibly others who don't report but who keep records documenting that they don't have to report. In that event, the costs identified in the cost-benefit report would be staggering - in the tens of billions of dollars annually. Even small businesses are going to face major costs from CROMERRR; there can be no question that the rule would produce a significant impact on a substantial number of small entities. EPA's claim to the contrary is wrong, and it will need to comply with the Regulatory Flexibility Act and the Small Business Regulatory Enforcement Fairness Act if it proceeds.

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[15] 62 Fed. Reg. 13430 (Mar. 20, 1997).

[16] See www.fdli.org/pubs/audio/electronic.html. The FDA was forced to issue enforcement guidance recognizing that firms would need "a reasonable timetable for promptly modifying any systems not in compliance (including legacy systems) to make them Part 11 compliant," and deferring enforcement where firms could "demonstrate progress in implementing their timetable." 64 Fed. Reg. 39147 (July 21, 1999).

[17] *See* 62 Fed. Reg. 13431, 13434.

[18] 66 Fed. Reg. 46186.

[19] Logistics Management Institute, "Cross-Media Electronic Reporting and Records Rule; Cost-Benefit Analysis" (March 2001), at 3-7.

[20] *Id.* The preamble to the proposed rule repeats the $40,000 implementation cost, but claims facilities would save $23, 080 annually in operating costs. 66 Fed. Reg. 476178. We cannot see where EPA derived that number, which conflicts with its own cost-benefit analysis.

[21] *Id.* at 3-8.

Solutions

Mr. Chairman, it is important to remember that CROMERRR is intended to implement the Government Paperwork Elimination Act. That law says only two things about recordkeeping:

- Agencies must "provide . . . for the option of the electronic maintenance . . . of information, when practicable as a substitute for paper";[22] and
- Electronic records . . . maintained in accordance with procedures developed under this [law] shall not be denied legal effect, validity or enforceability because such records are in electronic form."[23]

Regulated entities already have the option of keeping records electronically. They have been doing so for years. In our experience, no one in federal or state government has attempted to deny the legal effect, validity or enforceability of these records. In fact, many EPA rules expect records to be kept electronically. For example, the Hazardous Waste Combustor MACT standard – issued two years ago - specifically authorizes facilities to use data compression, a concept that only makes sense when one is talking about electronic data.[24]

By its terms, then, the GPEA doesn't really require EPA to do *anything* regarding electronic recordkeeping. But if CROMERRR goes final, it will have the paradoxical effect of current electronic records being denied legal effect, unless companies (i) spend huge sums of money to comply or (ii) go back to paper, where that's possible. This result conflicts with and frustrates Congressional intent. It is an irrational result.

We also note that GPEA provides agencies with no authorization to "improve the level of corporate individual responsibility and accountability . . . that currently exists in the paper environment," which is one of the asserted purposes of CROMERRR.[25] EPA's proposed requirements would greatly exceed reliability associated with paper records, rather than being "generally equivalent."[26]

Mr. Chairman, we appreciate and fully support the federal government's legitimate concerns about fraud occurring with electronic records. But the Office of Management & Budget, in its GPEA guidance, has dealt with this issue. As discussed above, the guidance instructs agencies to conduct a risk analysis, but EPA apparently has not done so. While it may be an open question whether bad analyses lead to irrational rules, this rulemaking demonstrates that doing *no* analysis surely does.

We urge EPA to conduct this analysis. We also urge them to note OMB's finding that the risk of fraud is highest in cases of one-time transactions between strangers involving

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[22] Section 1704(1), codified at 44 U.S.C. § 3504 note.
[23] Section 1707, *id.*
[24] *See* 64 Fed. Reg. 52961 (Sept. 30, 1999).
[25] *See* 66 Fed. Reg. 46166.
[26] *Id.*