



**Statement of The Dow Chemical Company**  
**FDA Public Meeting, June 11, 2004**  
**Electronic Records; Electronic Signature**  
**Docket No. 2004N-0133**

Good morning. My name is Mark Duvall. I am an attorney with The Dow Chemical Company. Dow is a global manufacturer of chemicals and plastics with many facilities that are subject to FDA recordkeeping requirements. We welcome the opportunity to provide our views on how FDA should revise Part 11.

**Summary**

Today I would like to make several brief points, which Dow will address in greater detail in its written comments:

1. FDA should revise Part 11 through rulemaking, because the current rule is very costly and inhibits innovation while providing few benefits.
2. FDA should conduct a risk assessment for all aspects of Part 11, as required by the Government Paperwork Reduction Act.
3. FDA should delete the Part 11 validation requirements because they duplicate provisions in predicate rules.
4. FDA should require audit trails only where justified by an individualized risk assessment and cost-benefit analysis.
5. Part 11 should permit conversion of electronic records into other media.
6. Legacy systems that have been modified since 1997 should be exempt.
7. FDA should clarify that API and excipient manufacturing is not subject to Part 11.

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1. **FDA Should Review All Aspects of Part 11**

First, Dow supports FDA in considering rulemaking to overhaul Part 11. FDA adopted Part 11 in 1997 on the basis of several misunderstandings that new rulemaking can address, including:

- That electronic recordkeeping would be voluntary, not indispensable.
- That Part 11 would only apply to about 100 facilities, not thousands.
- That the cost of Part 11 would be trivial because most regulated entities already met its requirements.

Due to these misunderstandings, FDA performed no cost-benefit analysis for Part 11. It also conducted no risk assessment to determine the need for Part 11.

The years since 1997 have shown that the underlying assumptions were incorrect. Electronic recordkeeping is critical to modern drug and medical device processing. Few companies would voluntarily choose to adopt Part 11 requirements, such as computer-generated audit trails and long-term electronic retention of records. Yet those who have been compelled to do so by Part 11 have spent over \$2 billion. Many companies have yet to invest the millions required to retrofit their computer systems to meet Part 11. This large investment in Part 11 compliance necessarily restricts the resources available for innovation in drug and device development. In addition, the burdensome cost for complying with Part 11 has deterred companies from investing in new equipment and systems that would be more accurate and reliable, and thus increase the quality and safety of FDA-regulated products. Accordingly, in at least some aspects, Part 11 is actually counterproductive. Moreover, no compelling case has been made that Part 11 is needed to deter and detect fraud in electronic recordkeeping and reporting.

## 2. Risk Assessment

Dow supports FDA's decision to make at least parts of Part 11 risk-based. Dow believes that all of Part 11 should be risk-based.

The "risk" addressed by Part 11 is primarily the risk of fraud, of deliberate changes in electronic records with the intent to deceive that might not be as easily detected as corresponding changes in paper documents. That risk is addressed by the 1999 Government Paperwork Elimination Act, which directed all federal agencies to accept electronic recordkeeping and reporting "when practicable". OMB told agencies that in doing so they must "weigh costs and benefits and involve an appropriate risk analysis, recognizing that low-risk information processes may need only minimal consideration, while high-risk processes may need extensive analysis."

To date, FDA has not conducted that cost-benefit and risk analysis. Part 11 was already promulgated, and it essentially placed all electronic records required by predicate rules in the "high risk" category and required all of them to meet virtually all Part 11 requirements, regardless of the actual risk of fraud. OMB warned federal agencies not to prescribe "one-size-fits-all" regulations on electronic recordkeeping and reporting. Unfortunately, "one-size-fits all" exactly describes Part 11 today.

Thus, FDA should examine every aspect of Part 11 in terms of costs and benefits and risk of fraud. Every other federal agency that has made such an examination of its own electronic recordkeeping and reporting rules has found that in most cases only very limited controls are justified. For example, the Nuclear Regulatory Commission has very simple, performance-oriented requirements, despite its public health responsibilities. EPA has allowed electronic recordkeeping for many years without Part 11-type

restrictions. A couple of years ago EPA considered adopting a much more stringent rule based explicitly on Part 11. Once it recognized that it had failed to justify the costs versus benefits and to evaluate the risk of fraud, EPA decided to defer any action on electronic recordkeeping, and to proceed only on electronic reporting. FDA should make its own examination and scrutinize how much of Part 11 is really necessary.

**3. Validation**

FDA should delete the validation requirement from Part 11. Validation asks whether uncompromised records are accurate and reliable. While that is a legitimate agency concern, the predicate rules already address validation where necessary. Thus, the Part 11 validation requirement is duplicative of predicate rule requirements.

**4. Audit Trails**

The audit trail requirement is a particularly expensive requirement in Part 11 because most existing systems cannot generate audit trails. The reason for this is that, aside from Part 11 compliance, the marketplace does not see sufficient value in that electronic capability to justify the cost. Some vendors have offered computer-generated audit trail capability at a significant cost to facilitate Part 11 compliance, but those packages must be integrated with existing systems at an even greater cost. The need to maintain metadata generated by audit trails is yet another substantial cost.

FDA allows manual audit trails in its GLP regulations and does not require audit trails at all in its GMP regulations. Most federal agencies have no requirement for audit trails of any kind. FDA should allow regulated entities to determine through a risk assessment if audit trails are necessary for their particular applications.

## 5. Conversion to Other Media

Until FDA announced enforcement guidance on Part 11 last year, it required all electronic records subject to Part 11 to be maintained in electronic form until the expiration of the record retention period. For some records, that can be decades. Thus, but for enforcement discretion, Part 11 requires either conversion of data to new hardware and software without data loss (virtually impossible to achieve), or else maintenance of computer museums where superseded computer systems remain operational solely to permit FDA inspections of old electronic records. FDA should change this requirement in Part 11.

FDA's GLP and GMP regulations allow records to be maintained in any format. Virtually every other federal agency does the same thing. FDA should delete this requirement altogether.

## 6. Legacy Systems

The 1997 preamble to Part 11 states that the regulation applies to legacy systems. FDA's enforcement discretion says that FDA will not enforce Part 11 with respect to systems that were operational as of the effective date of 1997, unless they have been significantly upgraded since then. The exception swallows the rule. The seven years since Part 11 took effect are multiple lifetimes for much computer hardware and software. Thus, the legacy systems exception announced by FDA has little meaning.

That exception is also based on the false assumption that as soon as the rule took effect, regulated entities could upgrade their systems to meet Part 11 requirements. The reality is that (1) options such as computer-generated audit trails were simply unavailable until years later for most applications, and (2) no one actually knew what Part 11

required. In 1997 FDA promised guidance, which companies such as Dow awaited before investing heavily in possibly unnecessary add-ons. FDA never did issue final Part 11 guidance until September 2003, and in February 2003 it revoked what draft guidance it had issued over the years.

Thus, the legacy systems exception only makes sense with respect to systems operational at the time that either FDA issues final guidance or revises the substantive requirements of Part 11. FDA should revise the exception accordingly.

#### 7. Predicate Rules

FDA should clarify that Part 11 does not apply to the manufacturing of active pharmaceutical ingredients or excipients, because FDA has no rulemaking regulations applicable to those activities.

Instead of promulgating regulations, FDA has issued guidance, such as Q7A, "Good Manufacturing Practices for Active Pharmaceutical Ingredients". Since Part 11 is triggered by recordkeeping regulations (or reporting to FDA), FDA should clarify that Part 11 does not apply to either API or excipient manufacturing. Some of the draft guidance previously issued (and later withdrawn) could be read to suggest that FDA does regard API and excipient manufacturing to be covered by Part 11. FDA's cGMP guidance for API manufacturing addresses electronic recordkeeping. It is that guidance, not Part 11, that API manufacturers should follow.

#### Conclusion

Dow will expand upon these and other points in our written comments, which are due by July 9. Thank you for your attention.