

TO: Distribution

FROM: T. G. Grumbles

DATE: July 16, 1987

Interoffice
Communication

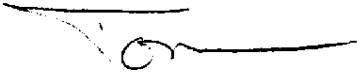
SUBJ: TSCA 8(D): LONZA CASE

VISTA

Regarding the proposed penalty against Lonza for not submitting an EO area monitoring report under Section 8(d), the agency has decided ... "never mind".

The agency is dropping the complaint. This decision (attached) is based on the agency receiving agency interpretation information from early in the 8(d) program, during the pre-trial hearing. The agency states they are investigating why they didn't find their own interpretations in the files, but feels this resulted from transfer of personnel.

EPA plans to publish further clarification and a proposed rulemaking regarding the status of monitoring studies under the 8(d) rule.


T. G. Grumbles

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Attachment

cc WLM

Dist: Safety Directors
Environmental Coordinators

VVV 000015203

UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

In the Matter of:

LONZA INCORPORATED

Respondent.

Docket No. TSCA-87-H-03

MOTION TO WITHDRAW COMPLAINT

Complainant U.S. Environmental Protection Agency (EPA) respectfully moves to withdraw the Complaint in the above-captioned matter, pursuant to 40 C.F.R. §22.14(e) of the Consolidated Rules of Practice.

In support of this Motion, Complainant files the attached Memorandum In Support of Motion To Withdraw Complaint, and proposed Order, incorporated herein by reference. Complainant is authorized to state that Respondent consents to the Motion to Withdraw Complaint, but has not reviewed and does not necessarily endorse the arguments in the Memorandum In Support of Motion to Withdraw Complaint.

Respectfully submitted,

Date

7/10/87


Jon D. Silberman, Esq.
Toxics Litigation Division
Office of Enforcement and Compliance
Monitoring

VVV 000015204

UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

07 JUL 1987 11:40

In the Matter of:

LONZA INCORPORATED

Respondent.

Docket No. TSCA-87-H-03

MEMORANDUM IN SUPPORT OF MOTION TO WITHDRAW COMPLAINT

I. INTRODUCTION

Complainant U.S. Environmental Protection Agency ("EPA or the Agency") respectfully moves to withdraw the Complaint in the above-captioned action, pursuant to 40 CFR 22.14(e) of the Consolidated Rules of Practice. It is appropriate to withdraw the Complaint in light of newly available information regarding the TSCA 1/ Section 8(d) rule 2/ at issue in this action. This information documents a pattern of interpretation of the rule by the original Agency staff responsible for developing and implementing the program supporting the conclusion that the rule does not require studies such as Respondent Lonza Incorporated's ethylene oxide monitoring study to be submitted to EPA.

Complainant is moving to withdraw the Complaint at this point in the proceedings because it now concludes, upon reviewing cumulatively all of the evidence before this Court, including previously unavailable evidence in Respondent's June 16, 1987 Prehearing Statement, that the intent of the rule was to exclude Respondent's study.

VVV 000015205

1/ Toxic Substances Control Act, 15 U.S.C. §§2601 et seq.
2/ 40 CFR 716.3(c), (e), and (j), 716.6, and 716.17 (a)(1).

As discussed below, this conclusion should not be interpreted as supporting the withdrawal of a Complaint in a case where EPA staff may have given informal guidance inconsistent with the official Agency interpretation of the rule.

Complainant regrets the necessity to have to terminate this action at this stage of the proceedings. However, as the duly authorized representative of the people of the United States, Complainant acknowledges its duty to review diligently, in good faith, and at any point in time, all information provided to it in an enforcement proceeding. Where the appropriate conclusion is that further action is not warranted, Complainant will act accordingly, even if this should necessitate withdrawing a filed Complaint.

II. HISTORY

This action is a civil administrative enforcement action, filed pursuant to TSCA section 16, naming Lonza Incorporated as the respondent. The Complaint sought civil penalties from the Respondent for violating TSCA section 8(d) and regulations thereunder. The violation arose from the Respondent's failure to submit to Complainant a copy of a specific monitoring study on a TSCA section 8(d)-listed chemical.

On September 26, 1985, an authorized EPA employee lawfully inspected Respondent's facility pursuant to TSCA Section 11. During this inspection, Respondent provided to EPA a copy of a study conducted for Respondent by John Kelse, Industrial Hygienist, The Hartford Insurance Group, entitled, "A Workplace Environmental

Study for Air Contaminants (Process Exposures and Fugitive Emissions)", on the chemical substance ethylene oxide (the "EtO study"). The study was completed on April 9, 1981, and provided to Respondent on June 24, 1981.

Pursuant to TSCA §8(d), and 40 CFR 716.3(c), (e), and (j), 716.6, and 716.17(a)(1), Respondent was required to submit to EPA a copy of any "health and safety study", in its possession, on ethylene oxide between October 4, 1982 and December 3, 1982. Respondent did not provide a copy of the EtO study to EPA within this time period. EPA filed a civil administrative Complaint against Respondent on October 23, 1986 seeking penalties for failing to submit the study. The factual and legal bases for the Complaint are described fully in the Complaint, incorporated herein by reference.

Respondent filed an Answer and Request for Hearing on April 6, 1987 (incorporated herein by reference). In Part II of the Answer, Respondent sets forth a number of "Affirmative Defenses". In Part II 1., Respondent argues that, for several reasons, the study does not constitute a "health and safety study" as per the section 8(d) rules. In Part II 2.(v), Respondent argues that "EPA never gave notice to Lonza or the chemical industry generally of the interpretation of Section 8(d) on which it relies this case, and that interpretation is not set forth in the text or preambles of EPA's proposed and final Section 8(d) regulations." Answer at 5.

Between April 6 and June 16, 1987, sundry motions and responses were filed by both parties to this action. On June 16, 1987, the Prehearing Exchange took place as directed by this Court. Respondent's Prehearing Statement includes, inter alia, 11 exhibits (num-

bered "2" through "12") documenting industry contacts with EPA staff regarding the interpretation and implementation of the section 8(d) rule. The exhibits include a letter on EPA stationary interpreting the rule as excluding 2 studies very similar in content to the Respondent's study. Respondent's Prehearing Statement, Exhibits 10 and 11. EPA had not located any records of these contacts prior to receiving Respondent's documentation.

III. ARGUMENT

Upon reviewing all available information, including the documentation appended to Respondent's Prehearing Statement, and analyzing further the utility of data in studies such as the Lonza study to EPA regulatory programs, the Agency has concluded that no penalty is warranted and accordingly moves to withdraw the Complaint in this action.

The most important factor justifying the withdrawal is the conclusion that the rule was intended to exclude the EtO study. 3/ This information, consisting of documentation of a pattern of interpretation of the section 8(d) rule by EPA staff early in the history of the program, was not available to EPA until supplied by Respondent in the June 16, 1987 Prehearing Exchange, and thus was not considered in the decisionmaking process culminating in the

3/ The EtO study consists of one-time area sampling to determine compliance with an OSHA or industry workplace standard on a given day. It states that contaminant levels are below the standard and that no specific recommendations appear warranted.

filing of the Complaint in this action. 4/

In moving to withdraw the Complaint, Complainant stresses the narrow ground upon which the withdrawal is predicated, viz. the fact that a review of the available evidence demonstrates that the proper interpretation of the section 8(d) rule is that Respondent's study is not reportable. Complainant notes that Respondent has not, at any point in this proceeding, claimed by way of defense to have relied detrimentally on any of the staff interpretations of the section 8(d) rule which it has documented. Indeed, even such persons would not be entitled to judgement against the United States where the unofficial advice was inconsistent with the regulations as interpreted officially by the Agency entrusted with their administration. E.g., Schweiker v. Hanson, 450 U.S. 785 (1981). Thus, the significance of the documentation of the Agency's original interpretation of the section 8(d) rule is to indicate the correct scope of that rule, and not to imply any right of estoppel against the United States as a result of inconsistent or erroneous staff

4/ EPA is presently investigating why this occurred. At present, the problem appears to have had its genesis in the Office of Toxic Substances' October 30, 1983 reorganization. One result of the reorganization, and certain contemporaneous reassignment of staff, was a transfer of section 8(d) responsibility from the staff originally responsible for its interpretation and implementation to new staff. While such reorganizations and reassignments are not uncommon and typically cause no significant regulatory problems, it appears that in this case certain section 8(d) records were not transferred to the new staff, and the new staff were not made aware of the prior pattern of interpretation of the rule by the original staff. As discussed above, EPA is taking immediate action to determine how and why this occurred and correct any problems uncovered.

guidance. 5/

In revisiting the interpretation of the section 8(d) rule with the original staff responsible for drafting and interpreting the language and implementing the program, Complainant also reviewed the utility of data such as those contained in the EtO study to EPA's regulatory programs and the burdens which the broad interpretation of the section 8(d) rule set forth in the Complaint would place on industry. These factors were considered by the original staff in developing the section 8(d) rule and program. Complainant has confirmed that the data contained in studies such as the EtO study would, in most cases, be of little value to EPA in its sections 4 ("Testing of chemical substances and mixtures"), 5 ("Manufacturing and processing notices"), and 6 ("Regulation of hazardous chemical substances and mixtures") programs. Though the data would be of value to the Agency in certain circumstances such as, for example, when investigating chemicals for which little or no monitoring data are available or for which the primary regulatory issue is whether systems claimed to be "closed" are functioning as described, such unusual cases do not appear to justify the burdens attendant with routinely submitting such information to EPA despite the grant of statutory authority to require such information to be submitted.

5/ It is common knowledge that employees of most, if not every government agency may occasionally provide informal guidance to regulated entities upon request. The United States, however, is a nation of law, and binding legal obligations are created solely by statute and regulation, not by informal staff opinions. For this reason, the law has always been clear that persons receiving such opinions rely on them at their own initiative and peril. See Schweiker, 450 U.S. 785.

Complainant recognizes the need to further clarify the scope of the section 8(d) rule. The Office of Toxic Substances (OTS) will therefore issue additional guidance in the near future discussing the status of monitoring studies under the section 8(d) rule. In addition, OTS is planning to initiate a rulemaking action to amend the section 8(d) rule to reflect these matters. EPA will provide public notice of any such rulemaking, and interested persons will be provided with an opportunity to participate.

III. CONCLUSION

The proposed withdrawal of the Complaint is justified under the circumstances and will not prejudice Respondent in any way. Accordingly, the Motion to Withdraw Complaint should be granted.

Respectfully submitted,

Date

7/10/87


Jon D. Silberman, Esq.
Toxics Litigation Division
Office of Enforcement and Compliance
Monitoring

VVV 000015211

In the Matter of:)
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)
LONZA INCORPORATED) Docket No. TSCA-87-H-03
)
Respondent.)
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By Motion dated July 10, 1987, Complainant U.S. Environmental Protection Agency (EPA) moves to withdraw the Complaint in the above-captioned action. I have carefully reviewed the filings in this matter and find that it is appropriate under the circumstances for the Complaint to be withdrawn.

Date _____

VVV 000015212

CERTIFICATION

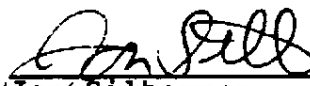
I hereby certify that the original of the foregoing Motion to Withdraw Complaint, Memorandum in Support of Motion to withdraw Complaint, and Order, Docket No. TSCA-87-H-03, have been filed with the Headquarters Hearing Clerk, and that copies were sent, registered or certified mail, return receipt requested, first class mail, or hand-delivered to:

Hon. Gerald Harwood
Chief Administrative Law Judge
Office of the Administrative Law Judges (A-110)
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

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7/10/87
Date


Jon Silberman
Toxics Litigation Division (LE-134P)
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

VVV 000015213

Interoffice
Communication

TO: Environmental Standards Team Meeting

FROM: T. G. Grumbles

DATE: July 14, 1987

SUBJ: JULY 23 MEETING

VISTA

The July 23 meeting will be held in Timberway I, Conference room 2A. At the last meeting we developed a goals statement, discussed goals and focus of our initial effort, how the guidelines would be used and interact with standards, and the benefits of the effort or "end product".

At this meeting, I would like to focus on the point in a project or the budget process the guidelines would be used and what is needed at those points. For instance, is a specific direction regarding a specification reference best or a general guideline regarding degree of environmental protection useful, when when no regulation is applicable. This will be done by reviewing the process used in two past projects. Hopefully this exercise will lead us to a clear idea of what the form of our "end-product" should be, and allow us to proceed with drafting the format and substance.

A draft agenda is attached. Please call if you have additions or other thoughts prior to the 23rd.



T. G. Grumbles

ajo

Attachment

Distribution: T. W. Heller / C. R. Dutra / J. O. Gibson
M. G. Hayes / J. D. Stone / R. T. Ferrell

VVV 000015214

AGENDA

JULY 23, 1987

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|--|-------|
| I. Review of Last Meeting Notes and Conclusions | TGG |
| II. Revisit/Reconfirm Goals Statement | Group |
| III. Review of Past Project Processes | |
| A. Baltimore Acid Sewer | JOG |
| B. VCM Acid Pits | TWH |
| IV. Review Above to Determine What Type of and Where
Guidelines Would Have Been Helpful | Group |
| V. Discuss and Formulate Guideline Format | Group |
| VI. Schedule and Process for Completion | |

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