



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
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OFFICE OF  
GENERAL COUNSEL

MEMORANDUM

TO : Deputy Assistant Administrator  
for Water Enforcement (EN-335)

FROM : Associate General Counsel *[Signature]*  
Water and Solid Waste Division (A-131)

SUBJECT: Use of Biomonitoring in the NPDES Permit Program

Your memorandum of August 31, 1978, requests the Office of General Counsel to address two questions as to the legal authority of EPA to impose toxicity test requirements in second round permits. Our conclusions are discussed below.\*

Question 1

Does EPA have the authority to require permittees whose effluent fails a toxicity test or whose waste contains known carcinogens, mutagens, or teratogens, etc. to prepare treatability studies and toxicity reduction plans?

Answer

Yes.

Discussion

EPA's authority to require submission of information in a permit under Section 402 of the Clean Water Act, as amended, is at least as broad as the authority conferred by Section 308 of the Act. Section 402(b)(2), see, Decision of the General Counsel No. 39, Issue I(b). Section 308 calls for point sources to conduct certain types of information gathering activities as necessary for specified purposes.

\* This memorandum supersedes an OGC memorandum of November 3, 1978, on this subject

Thus, if necessary, the Administrator must require the owner or operator of a point source to "install, use, and maintain such monitoring equipment or methods (including where appropriate, biological monitoring methods)," Section 308 (a)(A)(iii), and "provide such other information as he may reasonably require." Section 308(a)(A)(v). This authority must be exercised "whenever required to carry out the objective of this Act," including (1) "developing or assisting in the development of any effluent limitation . . . , (2) determining whether any person is in violation of any such effluent limitation . . . , or (3) carrying out sections . . . 402 . . . and 504." Section 308(a). The General Counsel has stated that under Section 308(a) it is only necessary, to support a permit data-gathering requirement, to find that the information is reasonably required to carry out the objective of the Act and is not unreasonable. Decision of the General Counsel No. 27, Issue V.

Reasonable biological monitoring requirements are clearly an appropriate permit condition. Biological monitoring is specifically authorized by Section 308. In addition, such monitoring is consistent with the section's criteria in that the requirement can provide information related to the restoration and maintenance of the biological integrity of the nation's waters; can be useful in the development of effluent limitations for the same or a subsequent NPDES permit, or may possibly be necessary to carry out the Section 504 emergency provisions.

Treatability studies and pollutant reduction plan requirements are also within the scope of Sections 308 and 402. Where a discharge is found to be toxic, it is not inherently unreasonable to require the discharger to develop additional information showing whether and how the toxicity can be controlled. The added information may be necessary in order to restore and maintain the waters involved, Section 308(a), Section 101(a), to develop effluent limitations for the source, Section 308(a)(1), and to carry out Section 402 Section 308(a)(4).

Such studies are further supported by Section 101(a)(3). That section establishes a policy, in order to achieve the Act's objective, that "the discharge of toxic pollutants in toxic amounts be prohibited." Toxicity reduction plans would be squarely in accord with that policy. Their development would assist the Administrator to implement the policy through the available statutory procedures.

This question is similar to the question addressed by Decision of the General Counsel No. 39, Issue I(b). There, the permittee was required to conduct treatment and control studies, including economic analyses of various alternatives, to determine the technical and economic feasibility of attaining BATEA as then estimated by EPA. No guidelines had been promulgated for the category of point sources in question. The General Counsel's decision upheld the permit terms under Sections 402 and 308, stating, "it just cannot be seriously contended that information directly relevant to establishment of effluent limitations reflecting BATEA for the very permittee from whom the information is obtained is not information required to carry out the objective of the Act' and neither to be used for developing effluent limitations or relevant to carrying out Section 402."

Here, it is not clear that the treatability studies and toxicity reduction plans to be supplied would be employed to promulgate industry-wide BAT. The information could nonetheless be "required to carry out the objective of the Act," to set Section 402(a)(1) effluent limitations for the individual permittee or to implement water quality standards. See discussion of question II, below.

It is therefore concluded that biomonitoring, treatability studies, and toxicity reduction plans may be included as terms of a NPDES permit. The specific requirements must of course be reasonable. The reasonableness of any requirement would have to be determined in each case.

#### Question II

Do EPA and NPDES States have the authority to require non-guidelines based toxicity limits in NPDES permits, and if so, what is the basis for that authority?

#### Answer

EPA and NPDES States have the authority to require non-guideline based toxicity limits in NPDES permits pursuant to Section 402(a)(1) or water quality standards, provided that the applicable requirements of Section 402(a)(1) are met or that the water quality standards supply a basis for the limits.

Discussion

Section 402(a)(1)

Section 402(a)(1) authorizes the Administrator to include in permits, prior to the implementing actions relating to Sections 301, 302, 306, 307, 308, and 403, such conditions as he determines are necessary to carry out the provisions of the Act. Where applicable effluent limitation guidelines and standards have not been promulgated, Section 402(a) authorizes the Administrator to include in permits effluent limitations based on best engineering judgment. Decision of the General Counsel No. 1, Issue I. The States authority is comparable. 40 CFR §124.42(6).

Promulgation of effluent limitations and guidelines for a category of sources does not prevent the Administrator from using Section 402(a)(1) to impose limitations on parameters not included in those guidelines. Decision of the General Counsel No. 54, Issue I. The omitted parameters are considered to be outside the scope of the regulation. In addition, in the case of a pollutant listed as a toxic pollutant under Section 307(a), the 402(a)(1) action could be justified as being action prior to implementing actions under Section 307(a). Id.; see also Decision of the General Counsel No. 2, Issue 3.

A determination under Section 402(a)(1) is an individual-case determination of "a uniform national standard for the class or category of plants of which the plant in question is a member." U.S. Steel Corp. v. EPA, \_\_\_ F.2d \_\_\_, 10 ERC 1001, 1016 (7th Cir. 1977). Toxicity limitations presumably would constitute individual-source BAT or 307(a) limitations and should be justifiable within the terms of Section 304(b)(2) or 307(a).

It has been proposed that toxicity limitations derived from biomonitoring could be stated in either of two ways. (1) Limitations could be established on specific waste parameters reflecting the levels of pollution achievable after completion of the toxicity reduction plan or (2) an LC50 limitation could be imposed on the total waste stream, after a toxicity reduction plan.

The first approach would impose numerical limitations on specific effluent characteristics. This is the usual practice in writing NPDES permits and is clearly acceptable

as long as the numbers are justified by technical, water-quality or 307(a) factors. Where the limitations are based on the discharger's own treatability studies and pollutant reduction plan, EPA may, after review of the studies and plan, be able to find that the results constitute an individually determined BAT for the source. The permit should then be able to withstand challenge and thus effectively limit the parameters covered.

Of course, the specific constituent approach has the practical drawback of requiring identification and limitation of each constituent to be regulated. It fails to take advantage of the capability of biological monitoring and general limitations to control unidentified pollutants. This purpose could be accomplished by the use of an LC50 permit limitation, if authorized by law.

Two possible approaches to a general toxicity condition have been identified. A straight LC50 limitation could be established. Alternatively, the permit might regulate the "lethal units" per gallon of discharge, using the "lethal unit" concept being developed in draft biomonitoring protocol guidance.

An initial question in determining whether such conditions could be upheld under Section 402(a)(1) is whether a lethal unit or LC50 limitation is an effluent limitation within the meaning of Section 502(11). That section defines the term "effluent limitation" as "... any restriction on quantities, rates, and concentrations of chemical, physical biological, and other constituents which are discharged. There is no indication in Section 502(11) that the restrictions contemplated must be numerical or that the constituents must be individually identified. A permit restriction phrased in terms of the biological results of the discharge of any constituents is comparable to a BOD limitation, which also indicates the effect of the overall discharge rather than the specific constituents. Such an effluent limitation should not be inherently improper.

An effluent limitation could be couched in terms of the effluent's LC50 or "lethal units." However, any permit condition must be sufficiently clear that the discharger can understand what the permit requires and what would constitute a violation. The problem of vagueness or uncertainty may be of more concern in setting general toxic limitations than

would be true in the case, for example, of BOD. BOD is a widely accepted measure of the oxygen required by living organisms (bacteria) to decompose organic material under aerobic conditions. A standard method for its analysis exists. See 40 C.F.R. §136.3. The methodology recognizes that BOD varies depending on a number of factors, and it specifies constant temperature and other conditions to assure a controlled environment.

At this time, EPA has not published toxicity test procedures under 40 C.F.R. §136. However, the Agency has published three methods manuals which are widely used by industry and regulatory agencies in testing for acute toxicity. 1/ Acute toxicity methods also are included in Standard Methods, 2/ which is recognized as an authoritative reference for chemical and biological methodology. 3/

1/ (a) IERL - RTP Procedures Manual, Level I Environmental Assessment: Biological Tests/or Pilot Studies.

(b) EPA-660/3-75-009, Methods for Acute Toxicity Tests with Fish, Macroinvertebrates and Amphibians.

(c) EPA-600/4-78-92, Methods for Measuring the Acute Toxicity of Effluent to Aquatic Organisms.

2/ APHA-1975. Standard Methods; 14th edition.

3/ Many NPDES states and regions, referencing the EPA and standard methods, are including acute and in some cases chronic toxicity test requirements in permits for industries suspected of discharging toxic substances. These requirements are generally used only for monitoring, but California and Washington also use acute toxicity test to establish permit effluent limitations. California uses the Toxicity Emission Rate (TER) as an effluent limitation. The TER is the product of the effluent toxicity (acute) concentration and the waste flow expressed as Mgd. The State of Washington limits acute toxicity in permits as a function of percent survival of test organisms in a percent concentration of effluent, i.e. 80 percent survival in 65 percent treated effluent.

While test procedures for acute toxicity may have reached a level of confidence adequate to support specific effluent limitations, it appears that testing methods to determine chronic toxicity are not so well established. Where procedures have not been refined to the point that results are fairly predictable and consistent, effluent requirements based on the results of the procedures might be challenged as uncertain or vague.

Where the testing method is generally recognized, lethal unit or LC50 effluent limitations based on a source's treatability studies and pollutant reduction plan may be upheld as a 402(a)(1) best engineering judgment as to BAT. The source's studies, if properly designed and conducted, could be considered as supplying the necessary engineering and other information for the Administrator to consider in keeping with Section 304(b)(2).

It must be emphasized that any 402(a)(1) best engineering judgment limitation must in fact be based on an evaluation of the technology available to achieve that limitation. If a discharger's study is to be employed to provide the engineering data, the permit writer cannot depart from the results of the study to impose requirements more stringent than those indicated by the study unless other defensible technical studies support the alternative requirements. This is true irrespective of the permit writer's views of the discharger's studies. Whether a given discharger's studies correctly identify the best available technology for reducing its toxic effluents may be a practical issue, but inadequacies of the study, whether done in good faith or otherwise, will not justify writing a 402(a)(1) permit that goes beyond the available engineering data.

Section 307(a) focusses on individual pollutants. It would be inappropriate to base a 402(a)(1) lethal unit or LC50 condition on a 307(a) rationale. If the conditions can be justified as individual-source-BAT—no-307(a) justification would be necessary.

#### Water Quality Standards

State water quality standards have for years included general narrative criteria to limit certain water quality

characteristics resulting from other than natural causes. These criteria include variously phrased criteria prohibiting the discharge of toxic substances in toxic amounts. 4/

Previous decisions of the General Counsel have established that narrative criteria in State water quality standards may be used in imposing conditions in NPDES permits. Thus, Decision of the General Counsel No. 13, Issue 1, upholds imposition of numerical limits on the total residual chlorine discharged based on State toxic water quality standards, consisting of a general narrative and a median tolerance limit numerical standard. The decision indicates that the appropriate numerical chlorine limitation would be a question of fact.

Further, the permit's effluent limitations derived from the State's narrative criteria do not have to be expressed in quantitative terms. See Decision of the General Counsel No. 65, upholding a limitation that "there shall be no discharge of visible foam or floating solids in other than trace amounts," based on the State's narrative standard to that effect.

It follows from these decisions that the Act would not bar the Administrator from issuing permits that include LC50 or "lethal unit" effluent limitations based on a narrative criterion included in a duly adopted State water quality standard. Indeed, where a water quality standard for toxicity exists and a source's biomonitoring indicates that its discharge is toxic, the Administrator would have a duty to establish effluent limitations to assure compliance with the State's established criteria. See Decision of the General

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4/ Many State standards were modeled on the Water Quality Criteria (1968) ("Green Book") recommendations. The Green Book recommended, p. 3, that standards should provide that all waters should be free from "materials, including radionuclides, in concentrations or combinations which are toxic or which produce undesirable physiological responses in human, fish, and other animal life and plants." Similarly, Quality Criteria for Water (1976), p. 6, recommends that waters should be free from substances attributable to discharges that "injure or are toxic or produce adverse physiological responses in humans, animals, or plants."



Counsel No. 13, Issue I; Decision of the General Counsel No. 54, Issue IV, and Decision of the General Counsel No. 58 Issue I. 5/ In that case, the Administrator's choices would be to compel analysis and identification of the individual constituents accounting for the toxicity or to impose a general toxic limitation. Particularly since technical feasibility of compliance is not an issue in the case of water quality standards compliance, the latter response is reasonable.

It might be argued that imposition of a general control on the effluent in order to implement a water quality criterion which is non-numerical, with compliance measured through relatively new and uncertain techniques, contains too many uncertainties to form a part of a regulatory program -- the same vagueness/uncertainty concerns raised in connection with the Section 402(a)(1) discussion. However, the translation of effluent characteristics to receiving water quality and determination of appropriate effluent limitations to assure compliance with water quality standards is generally imprecise. Where the toxicity criterion is a State water quality standard, Section 301(b)(1)(C) requires that it be met. Although the standard is phrased in narrative terms, its intent is clear, and there is an obvious close relationship between the water quality criterion and the effluent limitation. The permit process may provide a forum for translating the imprecise standard into more precise effluent limitations. It is concluded that effluent limitations reasonably designed to result in achievement of the duly-adopted narrative water quality standard should be defensible.

Where the water quality standard is completely narrative, the measure of compliance becomes judgmental. (Compare, e.g., the Illinois standard considered in Decision of the General Counsel No. 13, Issue I, which defined toxicity as 1/10 of the 48-hour TLM for native fish or essential fish food organisms, with the more general prohibitions modelled after the recommendations quoted in footnote 4, above.

5/ A State's 401 certification, failure to certify, or certification of a less stringent limitation would not alter the Administrator's independent responsibility. Decision of the General Counsel No. 13, Issue I, and Decision of the General Counsel No. 58, Issue I.

It is cautioned that where EPA is operating the permit program and the State standards are silent as to the measure of toxicity, the Administrator may be forced to determine acceptable concentrations, thus issuing "interpretations" of State law and regulations in an important area of emerging policies. 6/

### Conclusion

There are over 12,000 suspected toxic chemical compounds in commercial use. It is, if not impossible, at least enormously expensive to identify and establish appropriate prohibitions or limitations on every substance which, if discharged to the navigable waters, may in some concentration, singly or in combination with other substances, injure or be toxic to humans or aquatic biota. Creative and at times technology-forcing solutions are needed. It is believed that the efforts discussed in this memorandum can be supported under the Clean Water Act.

At the same time, the imperfections of these approaches are clear. Continuing work on identification and more precise definition of the acute and long-term lethal and sub-lethal effects of toxic constituents will be an important complement to the biomonitoring and general toxicity limitation approach.

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6/ Of course, the State may participate in the permit determinations, and if the State objects to an EPA interpretation of its narrative toxicity standard, the State may suggest an effluent limitation or adopt a standard reflecting the State's preferences.