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December 28, 1971

Mr. Robert M. Miller
Hercules, Inc.
Delaware Trust Building
Wilmington, Delaware 19899

Dear Bob:

I suppose the best way to characterize this letter, which is being sent to you and the other members of the Food, Drug and Cosmetic Packaging Materials Committee simultaneously with our separate letter on H.R. 12316, is to say that this is the "bad news" to go with the "good news" on developing trends which will undoubtedly command some of our attention in the coming year.

For the benefit of those who do not subscribe to Food Chemical News, we have obtained the usual permission from our good friend, Lou Rothschild, to reproduce pages 25 through 27 of the December 27 issue of his publication. As you will see in reviewing this report, the Food and Drug Administration appears to be moving away from an earlier position and in a direction which might well require the preparation of so-called "environmental impact statements" vis a vis future clearances of products, including packaging materials components. Having recently had occasion to try to be of some assistance to the Alcohol, Tobacco and Firearms Division of the Internal Revenue Service in connection with its attempts to prepare an environmental statement relative to the possible "regularizing" of the use of PVC bottles for alcoholic beverages, we can tell you that if FDA were to decide that it must comply with all of the requirements of the National Environmental Policy Act of 1970 with respect to food packaging materials clearances, the amount of effort involved would be

truly mind-boggling. Furthermore, the delay that anyone filing a Food Additive Petition would have to expect would seem to us to mean that only the heartiest of souls would ever consider development of a new material of any importance whatsoever.

The Food Chemical News article will give you some idea of how FDA is now considering the problem. Also enclosed, however, to give you a more complete concept of what the NEPA requires is a briefing memorandum we had occasion to prepare on this subject some time ago. I think this memorandum will give you an idea of why we say that the presently intolerable time situation involved in the processing of Food Additive Petitions could easily become completely unbearable if the NEPA requirements are brought to bear. I think that if I were an FDA Staffer with this prospect facing me, I would prepare to resign.

It is probably a little too early to give up all hope on the basis of the Food Chemical News report alone since the guidelines Peter Hutt is said to be preparing might be more encouraging. In any event, we thought we should advise you fully about this matter so that you will be aware of what is "in the wind." We shall continue to watch the situation and keep you posted on further developments.

Cordially yours,

Jerome H. Heckman

Enclosures

cc: SPI Food, Drug and Cosmetic
Packaging Materials Committee

to state any factors which might be prejudicial to a committee's work and noted:

> "Some of those who examine such a report may question whether personal factors might have influenced the judgments of the authors of the report. An allegation, however unwarranted, that the objectivity of the authors is questionable because of current or previous affiliations, activities or significant financial interest, can all too readily impugn the work of the committee."

The letter might give strength to the arguments of groups which sought to eliminate NAS Committees from review of pesticide cancellation proceedings under the pending pesticides law (See FOOD CHEMICAL NEWS, Oct. 18, Page 16). But it could also make the organization less vulnerable to the charges that can be expected from a study by Ralph Nader's Center for the Study of Responsive Law. The study is expected to be released in January (See FOOD CHEMICAL NEWS, May 17, Page 2). Industry groups also have challenged the biases of members of NAS committees, a recent example being the objections by Montrose Chemical to a member of NAS' committee on DDT (See FOOD CHEMICAL NEWS, June 7, Page 22).

Going beyond traditional "conflict of interest" statements, which require listing of financial ties, the NAS statements of bias go into opinions held by the scientists. Handler noted that it is not possible in many cases to "construct a competent committee exclusively of individuals who have had no meaningful experience immediately relevant to the subject problem." He continued:

> "It may, indeed, be imperative that the committee represent a balance of interests or opinions known to be in conflict. The mere fact that a committee member is known to have been involved in related endeavors is generally not likely to lead to charges of bias that need to be taken seriously. However, if the Academy, or fellow committee members, were unaware of such involvement, a gross disservice could be done to the individual concerned as well as to the committee report and to the Academy."

The letter stopped short of promising that the statements would not be released to the public by the Academy, which has not considered itself to be covered by the government's Freedom of Information Law. Handler said: "Only under unusual circumstances will such information be included in a committee report or otherwise made public, and then, only after consultation with the committee member concerned."

FDA TO ISSUE GUIDELINES FOR ENVIRONMENTAL IMPACT STATEMENTS

The Food and Drug Administration is in the final stages of preparing agency guidelines for issuing environmental impact statements required under the National Environmental Policy Act.

FDA's decision to reverse its position on the necessity for issuing the statements was disclosed by Health, Education, and Welfare General Counsel for FDA Peter B. Hutt in a letter to David Hawkins of the Natural Resources Defense Council.

FDA had earlier announced it was not going to issue impact statements.

Hawkins had complained to Chairman Russell E. Train, Chairman of the Council on Environmental Quality, after learning from former FDA General Counsel William W. Goodrich, and Robert N. Anderson, FDA attorney who has since left FDA, that in their view the impact statements of NEPA did not apply to FDA's activities.

Train Listed FDA Among Agencies Failing to Comply with NEPA

Train had listed FDA among the recalcitrant agencies in a May memorandum urging all Government Departments to comply with NEPA. He singled out the agency again in a November directive, pointing out that "continued failure of any agency to establish these procedures can only attract unfavorable Congressional and public comment and possible legal difficulties."

In his letter last week to Hawkins, Hutt wrote that the "two attorneys to whom your letter refers are, as you know, no longer with the Division."

Averring that he has not been able to determine whether or not Hawkins' complaints that FDA was not intending to comply with NEPA were accurate, Hutt responded, "I can, however, assure you that we have been taking steps during the past two months to bring FDA into full compliance with NEPA."

He said FDA has participated, since November, in the development of final HEW guidelines for compliance with NEPA, pointing out it was necessary to complete these guidelines before FDA could begin drafting its own regulations. He said FDA is now in the final stages of drafting its own version, and, as soon as they are approved, they will be published in the Federal Register for comment.

Hawkins had complained to Train that FDA had "totally disregarded" NEPA, despite the fact the agency "engages in a number of activities which significantly affect the quality of the human environment."

He cited FDA's approval of New Animal Drug Applications, which he said affect the environment from excretion through animal wastes or because of residues in edible food from treated animals.

The NDRC has a suit pending against FDA and the Department of Agriculture to ban the use of DES in animal feeds (See story, Page 36).

"In spite of these actual and potential environmental impacts," Hawkins wrote, "FDA refuses to accompany animal drug approvals with the 'environmental impact statement' required by . . . NEPA. Nor does FDA otherwise adequately evaluate these impacts."

He also charged that FDA's approval of indirect food additive packaging materials should be covered because the "compounds approved in packaging may, when incinerated, cause air pollution." He added:

> "Packaging which is not bio-degradable contributes inordinately to the problem of solid waste disposal. FDA does not recognize NEPA's applicability to these actions."

The NDRC official also asked for impact statements on new drugs for humans, and for all Food Additive Orders, declaring that "FDA analyses of the safety of food additives and drugs are kept secret as a matter of policy" in contrast to the "procedural and public notice guarantees of NEPA."

90 PESTICIDE ADJUVANTS GRANTED TOLERANCE EXEMPTIONS

The Environmental Protection Agency on Dec. 22 finalized a proposal to grant exemptions from tolerance requirements to 90 inert adjuvants used in pesticide formulations.

Few changes were made in exemptions proposed by the Food and Drug Administration (See FOOD CHEMICAL NEWS, Dec. 14, 1970, Page 19). Since the proposal was made, jurisdiction shifted from FDA to EPA.

The final order exempted 34 adjuvants which may be used in formulations applied to growing crops or to raw agricultural commodities after harvest. Fifty-six adjuvants used in formulations applied to growing crops only received exemptions. The list of adjuvants exempted last week appear on this and the following page of this issue of FOOD CHEMICAL NEWS.

FOR USE IN FORMULATIONS APPLIED TO GROWING CROPS OR TO RAW AGRICULTURAL COMMODITIES AFTER HARVEST:

Inert ingredients	Limits	Uses
• • •	• • •	• • •
Acetic anhydride		Solvent, cosolvent.
• • •	• • •	• • •
Ammonium sulfate		Solid diluent, carrier.
• • •	• • •	• • •
Calcium citrate		Solid diluent, carrier.
• • •	• • •	• • •
Calcium phosphate		Do.
• • •	• • •	• • •
α-Cellulose		Do.
• • •	• • •	• • •
Citrus meal		Do.
• • •	• • •	• • •
Cod liver oil		Solvent, cosolvent.
• • •	• • •	• • •
Corn meal		Solid diluent, carrier.
Corn oil		Solvent, cosolvent.
• • •	• • •	• • •
Dimethylpolysiloxane (as defined in § 121.1099)		Defoaming agent.
• • •	• • •	• • •
Ferric sulfate		Solid diluent, carrier.
Fish meal		Do.
Fish oil		Solvent, cosolvent.
• • •	• • •	• • •
Hydroxypropyl methylcellulose		Thickener.
• • •	• • •	• • •
Lard		Solid diluent, carrier.
• • •	• • •	• • •
Magnesium oxide		Do.
• • •	• • •	• • •
Magnesium stearate		Surfactant.
• • •	• • •	• • •

Inert ingredients	Limits	Uses
Oats		Do.
• • •	• • •	• • •
Palmitic acid		Diluent.
• • •	• • •	• • •
Polymerized sodium methacrylate		pH control.
• • •	• • •	• • •
Potassium chloride		Solid diluent, c
• • •	• • •	• • •
Potassium phosphate		Buffer.
Propionic acid		Catalyst.
• • •	• • •	• • •
Propylene glycol alginate (as defined in § 121.1015)		Defoaming agen
• • •	• • •	• • •
Sand		Solid diluent, c
• • •	• • •	• • •
Sodium bicarbonate		Neutralizer.
• • •	• • •	• • •
Sodium chloride		Solid diluent, c
• • •	• • •	• • •
Sorbitan fatty acid esters (fatty acids limited to C_{12}, C_{14}, C_{16}, and C_{18} containing minor amounts of associated fatty acids) and their poly(oxyethylene) derivatives; the poly(oxyethylene) content averages 16–20 moles.		Surfactants. adjuvants surfactants.
• • •	• • •	• • •
Soybean oil		Solvent, c
Starch (potato, tapioca, and wheat)		Solid diluent
Stearic acid		Diluent.
• • •	• • •	• • •
1, 1, 1-Trichloroethane		Solvent, co
• • •	• • •	• • •
Xanthan gum		Thickener.
• • •	• • •	• • •

M E M O R A N D U M

Re: The Procedure Involved in Filing a §102(2)(C) (Environmental Impact) Statement

1. All federal agencies must submit a final environmental impact statement as required by the National Environmental Policy Act §102(2)(C), 42 U.S.C. §4332(2)(C), to the Council on Environmental Quality (CEQ) whenever the lead agency takes any major action significantly affecting the quality of the human environment. The nature of this whole process is to make public proposed federal governmental actions that will have an impact on the environment. The burden is on the federal agency to file this statement and not on the private party to be regulated.

2. The objective of a statement must be to provide a basis for evaluating impact on the environment of proposed federal agency actions so such statements must include:

(a) a technical description of the proposed action,

(b) the probable impact of the proposed action on the environment including primary and secondary consequences,

(c) any probable adverse environmental effects which cannot be avoided,

(d) alternatives to the proposed action,

(e) the relationship between local short-term uses of the environment and the maintenance of long-term productivity,

(f) any irreversible commitments of resources, and

(g) after circulation of the draft statement to appropriate governmental agencies, private organizations and individuals, (as discussed below) a discussion, when necessary of any problems or objections raised by these appropriate parties.

3. The 102(2)(C) procedure is initiated by the lead federal agency (e.g. FDA, FCC, IRS etc., as the case may be) which is required to write a draft environmental statement to CEQ and any other appropriate governmental agency (federal, state and local), private organization or individual that has jurisdiction by law or special expertise over the subject matter so that they can comment on the lead agency's proposed action. This draft statement must also be made available to the public.

4. The secondary agencies then have a specific time period in which to comment upon the proposed action of the lead agency. That time period must be established by the lead agency, and may differ among the agencies, but shall not be less than 30 days. Extensions of time for comment may be sought by the secondary agencies whereby the lead agencies may grant such extensions for periods of time up to 15 days. If the secondary agency comments upon the proposed action of the lead agency, the secondary agency must return those comments, in writing, to the lead agency and then send ten copies of those comments to CEQ. Upon the expiration of the time for comment with no response from secondary agencies, the lead agency may assume that no comments will be forthcoming and may proceed to the next step.

5. Upon receiving comments, if any, from appropriate parties, which also must be made available to the public by those parties, the lead agency may then alter its draft environmental impact statement to reflect these comments. In any event, the lead agency must then write a final environmental impact statement and submit ten copies of this statement, which also must be made available to the public, to CEQ. There is no time limit placed on the lead agency to draft this final statement.

6. The CEQ then reviews the final 102(2)(C) statement to insure that the proposed agency action is consistent with the stated environmental policies of the federal government. However, CEQ has no veto power over the lead agency's action and can only make further comments on the proposed action to the lead agency

or to the President. The lead agency still has the ultimate authority to grant or deny its own proposed agency action in question. There is no limit to the time in which the CEQ may make comments but the lead agency should not take any final action until 30 days have elapsed from the time the final environmental impact statement was filed with CEQ, and until 90 days have elapsed from the time the initial draft statement was filed with CEQ.

COUNCIL ON ENVIRONMENTAL QUALITY

STATEMENTS ON PROPOSED FEDERAL ACTIONS AFFECTING THE ENVIRONMENT

Guidelines

1. *Purpose.* This memorandum provides guidelines to Federal departments, agencies, and establishments for preparing detailed environmental statements on proposals for legislation and other major Federal actions significantly affecting the quality of the human environment as required by section 102(2)(C) of the National Environmental Policy Act (Public Law 91-190) (hereafter "the Act"). Underlying the preparation of such environmental statements is the mandate of both the Act and Executive Order 11514 (35 F.R. 4247) of March 4, 1970, that all Federal agencies, to the fullest extent possible, direct their policies, plans and programs so as to meet national environmental goals. The objective of section 102(2)(C) of the Act and of these guidelines is to build into the agency decision making process an appropriate and careful consideration of the environmental aspects of proposed action and to assist agencies in implementing not only the letter, but the spirit, of the Act. This memorandum also provides guidance on implementation of section 309 of the Clean Air Act, as amended (42 U.S.C. 1857 et seq.).

2. *Policy.* As early as possible and in all cases prior to agency decision concerning major action or recommendation or a favorable report on legislation that significantly affects the environment, Federal agencies will, in consultation with other appropriate Federal, State, and local agencies, assess in detail the potential environmental impact in order that adverse effects are avoided, and environmental quality is restored or enhanced, to the fullest extent practicable. In particular, alternative actions that will minimize adverse impact should be explored and both the long- and short-range implications to man, his physical and social surroundings, and to nature, should be evaluated in order to avoid to the fullest extent practicable undesirable consequences for the environment.

3. *Agency and OMB procedures.* (a) Pursuant to section 2(f) of Executive Order 11514, the heads of Federal agencies have been directed to proceed with measures required by section 102(2)(C) of the Act. Consequently, each agency will establish, in consultation with the Council on Environmental Quality, not later than June 1, 1970 (and by July 1, 1971, with respect to requirements imposed by revisions in these guidelines, which will apply to draft environmental statements circulated after June 30, 1971), its own formal procedures for (1) identifying those agency actions requiring environmental statements, the appropriate time prior to decision for the consultations required by section 102(2)(C), and the agency review process for which environmental statements are to be available, (2) obtaining information required in their preparation, (3) designating the officials who are to be responsible for the statements, (4) consulting with and taking account of the comments of appropriate Federal, State, and local agencies, including obtaining the comment of the Administrator of the Environmental Protection Agency, whether or not an environmental statement is prepared, when required under section 309 of the Clean Air Act, as amended, and section 8 of these guidelines, and (5) meeting the requirements of section 2(b) of Executive Order 11514 for providing timely public information on Federal plans and programs with environmental impact including procedures responsive to section 10 of these guidelines. These procedures should be consonant with the guidelines contained herein. Each agency should file seven (7) copies of all such procedures with the Council on Environmental Quality, which will provide advice to agencies in the preparation of their procedures and guidance on the application and interpretation of the Council's guidelines. The Environmental Protection Agency will assist in resolving any question relating to section 309 of the Clean Air Act, as amended.

(b) Each Federal agency should consult, with the assistance of the Council on Environmental Quality and the Office of Management and Budget if desired, with other appropriate Federal agencies in the development of the above procedures so as to achieve consistency in dealing with similar activities and to assure effective coordination among agencies in their review of proposed activities.

(c) State and local review of agency procedures, regulations, and policies for the administration of Federal programs of assistance to State and local governments will be conducted pursuant to procedures established by the Office of Management and Budget Circular No. A-85. For agency procedures subject to OMB Circular No. A-85 a 30-day extension in the July 1, 1971, deadline set in section 3(a) is granted.

(d) It is imperative that existing mechanisms for obtaining the views of Federal, State, and local agencies on proposed Federal actions be utilized to the extent practicable in dealing with environmental matters. The Office of Management and Budget will issue instructions, as necessary, to take full advantage of existing mechanisms (relating to procedures for handling legislation, preparation of budgetary materials, new procedures, water resource and other projects, etc.).

4. *Federal agencies included.* Section 102(2)(C) applies to all agencies of the Federal Government with respect to recommendations or favorable reports on proposals for (i) legislation and (ii) other major Federal actions significantly affecting the quality of the human environment. The phrase "to the fullest extent possible" in section 102(2)(C) is meant to make clear that each agency of the Federal Government shall comply with the requirement unless existing law applicable to the agency's operations expressly prohibits or makes compliance impossible. (Section 105 of the Act provides that "The policies and goals set forth in this Act are supplementary to those set forth in existing authorizations of Federal agencies.")

5. *Actions included.* The following criteria will be employed by agencies in deciding whether a proposed action requires the preparation of an environmental statement:

(a) "Actions" include but are not limited to:

(i) Recommendations or favorable reports relating to legislation including that for appropriations. The requirement for following the section 102(2)(C) procedure as elaborated in these guidelines applies to both (i) agency recommendations on their own proposals for legislation and (ii) agency reports on legislation initiated elsewhere. (In the latter case only the agency which has primary responsibility for the subject matter involved will prepare an environmental statement.) The Office of Management and Budget will supplement these general guidelines with specific instructions relating to the way in which the section 102(2)(C) procedure fits into its legislative clearance process;

(ii) Projects and continuing activities: directly undertaken by Federal agencies; supported in whole or in part through Federal contracts, grants, [illegible] [illegible] [illegible] lease, permit, license, certificate or other entitlement for use;

(iii) Policy, regulations, and procedure-making.

(b) The statutory clause "major Federal actions significantly affecting the quality of the human environment" is to be construed by agencies with a view to the overall, cumulative impact of the action proposed (and of further actions contemplated). Such actions may be localized in their impact, but if there is potential that the environment may be significantly affected, the statement is to be prepared. Proposed actions, the environmental impact of which is likely to be highly controversial, should be covered in all cases. In considering what constitutes major action significantly affecting the environment, agencies should bear in mind that the effect of many Federal decisions about a project or complex of projects can be individually limited but cumulatively considerable. This can occur when one or more agencies over a period of years puts into a project individually minor but collectively major resources, when one decision involving a limited amount of money is a precedent for action in much larger cases or represents a decision in principle about a future major course of action, or when several Government agencies individually make decisions about partial aspects of a major action. The lead agency

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should prepare an environmental statement if it is reasonable to anticipate a cumulatively significant impact on the environment from Federal action. "Lead agency" refers to the Federal agency which has primary authority for committing the Federal Government to a course of action with significant environmental impact. As necessary, the Council on Environmental Quality will assist in resolving questions of lead agency determination.

(c) Section 101(b) of the Act indicates the broad range of aspects of the environment to be surveyed in any assessment of significant effect. The Act also indicates that adverse significant effects include those that degrade the quality of the environment, curtail the range of beneficial uses of the environment and serve short-term, to the disadvantage of long-term, environmental goals. Significant effects can also include actions which may have both beneficial and detrimental effects, even if on balance, the agency believes that the effect will be beneficial. Significant adverse effects on the quality of the human environment include both those that directly affect human beings and those that indirectly affect human beings through adverse effects on the environment.

(d) Because of the Act's legislative history, environmental protective regulatory activities concurred in or taken by the Environmental Protection Agency are not deemed actions which require the preparation of environmental statements under section 102(2)(C) of the Act.

6. *Content of environmental statement.* (a) The following points are to be covered:

(i) A description of the proposed action including information and technical data adequate to permit a careful assessment of environmental impact by commenting agencies. Where relevant, maps should be provided.

(ii) The probable impact of the proposed action on the environment, including impact on ecological systems such as wildlife, fish, and marine life. Both primary and secondary significant consequences for the environment should be included in the analysis. For example, the implications, if any, of the action for population distribution or concentration should be estimated and an assessment made of the effect of any possible change in population patterns upon the resource base, including land use, water, and public services, of the area in question.

(iii) Any probable adverse environmental effects which cannot be avoided (such as water or air pollution, undesirable land use patterns, damage to life systems, urban congestion, threats to health or other consequences adverse to the environmental goals set out in section 101(b) of the Act).

(iv) Alternatives to the proposed action (section 102(2)(D) of the Act requires the responsible agency to "study, develop, and describe appropriate alternatives to recommended courses of action in any proposal which involves unresolved conflicts concerning alternative uses of available resources"). A rigorous exploration and objective evaluation of alternative actions that might avoid some or all of the adverse environmental effects is essential. Sufficient analysis of such alternatives and their costs and impact on the environment should accompany the proposed action through the agency review process in order not to foreclose prematurely options which might have less detrimental effects.

(v) The relationship between local short-term uses of man's environment and the maintenance and enhancement of long-term productivity. This in essence requires the agency to assess the action for cumulative and long-term effects from the perspective that each generation is trustee of the environment for succeeding generations.

(vi) Any irreversible and irretrievable commitments of resources which would be involved in the proposed action should it be implemented. This requires the agency to identify the extent to which the action curtails the range of beneficial uses of the environment.

(vii) Where appropriate, a discussion of problems and objections raised by other Federal, State, and local agencies and by private organizations and individuals in the review process and the disposition of the issues involved. (This section may be added at the end of the review process in the final text of the environmental statement.)

(b) With respect to water quality aspects of the proposed action which have been previously certified by the appropriate State or interstate organization as being in substantial compliance with applicable water quality standards, the comment of the Environmental Protection Agency should also be requested.

(c) Each environmental statement should be prepared in accordance with the precept in section 102(2)(A) of the Act that all agencies of the Federal Government "utilize a systematic, interdisciplinary approach which will insure the integrated use of the natural and social sciences and the environmental design arts in planning and decisionmaking which may have an impact on man's environment."

(d) Where an agency follows a practice of declining to favor an alternative until public hearings have been held on a proposed action, a draft environmental statement may be prepared and circulated indicating that two or more alternatives are under consideration.

(e) Appendix I prescribes the form of the summary sheet which should accompany each draft and final environmental statement.

7. Federal agencies to be consulted in connection with preparation of environmental statement. A Federal agency considering an action requiring an environmental statement, on the basis of (i) a draft environmental statement for which it takes responsibility or (ii) comparable information followed by a hearing subject to the provisions of the Administrative Procedure Act, should consult with, and obtain the comment on the environmental impact of the action of, Federal agencies with jurisdiction by law or special expertise with respect to any environmental impact involved. These Federal agencies include components of (depending on the aspect or aspects of the environment):

Advisory Council on Historic Preservation.
Department of Agriculture.
Department of Commerce.
Department of Defense.
Department of Health, Education, and Welfare.
Department of Housing and Urban Development.
Department of the Interior.
Department of State.
Department of Transportation.
Atomic Energy Commission.
Federal Power Commission.
Environmental Protection Agency.
Office of Economic Opportunity.

For actions specifically affecting the environment of their geographic jurisdictions, the following Federal and Federal-State agencies are also to be consulted:

Tennessee Valley Authority.
Appalachian Regional Commission.
Delaware River Basin Commission.
Susquehanna River Basin Commission.

Agencies seeking comment should determine which one or more of the above listed agencies are appropriate to consult on the basis of the areas of expertise identified in Appendix II to these guidelines. It is recommended that the above listed departments and agencies establish contact points, which often are most appropriately regional offices, for providing comments on the environmental statements. The requirement in section 102(2)(C) to obtain comment from Federal agencies having jurisdiction or special expertise is in addition to any specific statutory obligation of any Federal agency to coordinate or consult with any other Federal or State agency. Agencies seeking comment may establish time limits of not less than thirty (30) days for reply, after which it may be presumed, unless the agency consulted requests a specified extension of time, that the agency consulted has no comment to make. Agencies seeking comment should endeavor to comply with requests for extensions of time of up to fifteen (15) days.

8. *Interim EPA procedures for implementation of section 309 of the Clean Air Act, as amended.* (a) Section 309 of the Clean Air Act, as amended, provides:

SEC. 309. (a) The Administrator shall review and comment in writing on the environmental impact of any matter relating to duties and responsibilities granted pursuant to this Act or other provisions of the authority of the Administrator, contained in any (1) legislation proposed by any Federal department or agency, (2) newly authorized Federal projects for construction and any major Federal agency action (other than a project for construction) to which section 102(2)(C) of Public Law 91-190 applies, and (3) proposed regulations published by any

department or agency of the Federal Government. Such written comment shall be made public at the conclusion of any such review.

(b) In the event the Administrator determines that any such legislation, action, or regulation is unsatisfactory from the standpoint of public health or welfare or environmental quality, he shall publish his determination and the matter shall be referred to the Council on Environmental Quality.

(b) Accordingly, wherever an agency action related to air or water quality, noise abatement and control, pesticide regulation, solid waste disposal, radiation criteria and standards, or other provisions of the authority of the Administrator of the Environmental Protection Agency is involved, including his enforcement authority, Federal agencies are required to submit for review and comment by the Administrator in writing: (i) proposals for new Federal construction projects and other major Federal agency actions to which section 102(2)(C) of the National Environmental Policy Act applies and (ii) proposed legislation and regulations, whether or not section 102(2)(C) of the National Environmental Policy Act applies. (Actions requiring review by the Administrator do not include litigation or enforcement proceedings.) The Administrator's comments shall constitute his comments for the purposes of both section 309 of the Clean Air Act and section 102(2)(C) of the National Environmental Policy Act. A period of 45 days shall be allowed for such review. The Administrator's written comment shall be furnished to the responsible Federal department or agency, to the Council on Environmental Quality and summarized in a notice published in the FEDERAL REGISTER. The public may obtain copies of such comment on request from the Environmental Protection Agency.

9. *State and local review.* Where no public hearing has been held on the proposed action at which the appropriate State and local review has been invited, and where review of the environmental impact of the proposed action by State and local agencies authorized to develop and enforce environmental standards is relevant, such State and local review shall be provided as follows:

(a) For direct Federal development projects and projects assisted under programs listed in Attachment D of the Office of Management and Budget Circular No. A–95, review of draft environmental statements by State and local governments will be through procedures set forth under Part 1 of Circular No. A–95.

(b) Where these procedures are not appropriate and where the proposed action affects matters within their jurisdiction, review of the draft environmental statement on a proposed action by State and local agencies authorized to develop and enforce environmental standards and their comments on the environmental impact of the proposed action may be obtained directly or by sending the draft environmental statement to the appropriate State, regional and metropolitan clearinghouses, unless the Governor of the State involved has designated some other point for obtaining this review.

10. *Use of statements in agency review processes; distribution to Council on Environmental Quality.* (a) Agencies will need to identify at what stage or stages of a series of actions relating to a particular matter the environmental statement procedures of this directive will be applied. It will often be necessary to use the procedures both in the development of a national program and in the review of proposed projects within the national program. However, where a [illegible] [illegible] prior [illegible] be [illegible] of specific projects the view of Federal, State, and local agencies in the legislative process may have to suffice. The principle to be applied is to obtain views of other agencies at the earliest feasible time in the development of program and project proposals. Care should be exercised so as not to duplicate the clearance process, but when actions being considered differ significantly from those that have already been reviewed pursuant to section 102(2)(C) of the Act an environmental statement should be provided.

(b) Ten (10) copies of draft environmental statements (when prepared), ten (10) copies of all comments made thereon (to be forwarded to the Council by the entity making comment at the time comment is forwarded to the responsible agency), and ten (10) copies of the final text of environmental statements (together with all comments received thereon by the responsible agency from Federal, State, and local agencies and from private organizations and individuals) shall be supplied to the Council on Environmental Quality in the Executive Office of the President (this will serve as making environmental statements available to the President). It is important that draft environmental statements be prepared and circulated for comment and furnished to the Council early enough in the agency review process before an action is taken in order to permit meaningful consideration of the environmental issues involved. To the maximum extent practicable no administrative action (i.e., any proposed action to be taken by the agency other than agency proposals for legislation to Congress or agency reports on legislation) subject to section 102(2)(C) is to be taken sooner than ninety (90) days after a draft environmental statement has been circulated for comment, furnished to the Council and, except where advance public disclosure will result in significantly increased costs of procurement to the Government, made available to the public pursuant to these guidelines; neither should such administrative action be taken sooner than thirty (30) days after the final text of an environmental statement (together with comments) has been made available to the Council and the public. If the final text of an environmental statement is filed within ninety (90) days after a draft statement has been circulated for comment, furnished to the Council and made public pursuant to [illegible] the [illegible] the [illegible] period [illegible] concurrently to the extent that they overlap.

(c) With respect to recommendations or reports on proposals for legislation to which section 102(2)(C) applies, the final text of the environmental statement and comments thereon should be available to the Congress and to the public in the consideration of the proposed legislation or report. In cases where the scheduling of congressional hearings on recommendations or reports on proposals for legislation which the Federal agency has forwarded to the Congress does not allow adequate time for the completion of a final text of an environmental statement (together with comments), a draft environmental statement may be furnished to the Congress and made available to the public pending transmittal of the comments as received and the final text.

(d) Where emergency circumstances make it necessary to take an action with significant environmental impact without observing the provisions of these guidelines concerning minimum periods for agency review and advance availability of environmental statements, the Federal agency proposing to take the action should consult with the Council on Environmental Quality about alternative arrangements. Similarly, where there are overriding considerations of expense to the Government or impaired program effectiveness, the responsible agency should consult with the Council concerning appropriate modifications of the minimum periods.

(e) In accord with the policy of the National Environmental Policy Act and Executive Order 11514 agencies have a responsibility to develop procedures to insure the fullest practicable provision of timely public information and understanding of Federal plans and programs with environmental impact in order to obtain the views of interested parties. These procedures shall include, whenever appropriate, provision for public hearings, and shall provide the public with relevant information, including information on alternative courses of action. Agencies which hold hearings on proposed administrative actions or legislation should make the draft environmental statement available to the public at least fifteen (15) days prior to the time of the relevant hearings except where the agency prepares the draft statement on the basis of a hearing subject to the Administrative Procedure Act and preceded by adequate public notice and information to identify the issues and obtain the comments provided for in sections 6–9 of these guidelines.

(f) [illegible] environmental [illegible] for [illegible] ments received [illegible] pursuant to the [illegible] dom of Information Act [illegible] 552), [illegible] interagency memoranda when [illegible]

memoranda transmit comments of Federal agencies listed in section 7 of these guidelines on the environmental impact of proposed actions subject to section 102(2)(C).

(e) Agency procedures prepared pursuant to section 3 of these guidelines shall make [illegible] public information [illegible] environmental statements [illegible] the head [illegible] of the responsible agency and, if appropriate, [illegible] the Governor of the State [illegible] point for [illegible] of this information.

11. *Application of section 102(2)(C) procedure to existing projects and programs.* To the maximum extent practicable the section 102(2)(C) procedure should be applied to further major Federal actions having a significant effect on the environment even though they arise from projects or programs initiated prior to enactment of the Act on January 1, 1970. Where it is not practicable to reassess the basic course of action, it is still important that further incremental major actions be shaped so as to minimize adverse environmental consequences. It is also important in further action that account be taken of environmental consequences not fully evaluated at the outset of the project or program.

12. *Supplementary guidelines; evaluation of procedures.* (a) The Council on Environmental Quality after examining environmental statements and agency procedures with respect to such statements will issue such supplements to these guidelines as are necessary.

(b) Agencies will continue to assess their experience in the implementation of the section 102(2)(C) provisions of the Act and in conforming with these guidelines and report thereon to the Council on Environmental Quality by December 1, 1971. Such report should include an identification of the problem areas and suggestions for revision or clarification of these guidelines to achieve effective coordination of views on environmental aspects (and alternatives, where appropriate) of proposed actions without imposing unproductive administrative procedures.

RUSSELL E. TRAIN,
Chairman.

APPENDIX I

(Check one) ( ) Draft. ( ) Final Environmental Statement.

Name of Responsible Federal Agency (with name of operating division where appropriate).

1. Name of Action. (Check one) ( ) Administrative Action. ( ) Legislative Action.

2. Brief description of action indicating what States (and counties) particularly affected.

3. Summary of environmental impact and adverse environmental effects.

4. List alternatives considered.

5. a. (For draft statements) List all Federal, State, and local agencies from which comments have been requested.

b. (For final statements) List all Federal, State, and local agencies and other sources from which written comments have been received.

6. Dates draft statement and final statement made available to Council on Environmental Quality and public.

APPENDIX II—FEDERAL AGENCIES WITH JURISDICTION BY LAW OR SPECIAL EXPERTISE TO COMMENT ON VARIOUS TYPES OF ENVIRONMENTAL IMPACTS

AIR

Air Quality and Air Pollution Control

Department of Agriculture—
  Forest Service (effects on vegetation).
Department of Health, Education, and Welfare (health aspects).
Environmental Protection Agency—
  Air Pollution Control Office.
Department of the Interior—
  Bureau of Mines (fossil and gaseous fuel combustion).
  Bureau of Sport Fisheries and Wildlife (wildlife).
Department of Transportation—
  Assistant Secretary for Systems Development and Technology (auto emissions).
  Coast Guard (vessel emissions).
  Federal Aviation Administration (aircraft emissions).

Weather Modification

Department of Commerce—
  National Oceanic and Atmospheric Administration.
Department of Defense—
  Department of the Air Force.
Department of the Interior—
  Bureau of Reclamation.

ENERGY

Environmental Aspects of Electric Energy Generation and Transmission

Atomic Energy Commission (nuclear power).
Environmental Protection Agency—
  Water Quality Office.
  Air Pollution Control Office.
Department of Agriculture—
  Rural Electrification Administration (rural areas).
Department of Defense—
  Army Corps of Engineers (hydro-facilities).
Federal Power Commission (hydro-facilities and transmission lines).
Department of Housing and Urban Development (urban areas).
Department of the Interior—(facilities on Government lands).

Natural Gas Energy Development, Transmission and Generation

Federal Power Commission (natural gas production, transmission and supply).
Department of the Interior—
  Geological Survey.
  Bureau of Mines.

HAZARDOUS SUBSTANCES

Toxic Materials

Department of Commerce—
  National Oceanic and Atmospheric Administration.
Department of Health, Education and Welfare (Health aspects).
Environmental Protection Agency.
Department of Agriculture—
  Agricultural Research Service.
  Consumer and Marketing Service.
Department of Defense.
Department of the Interior—
  Bureau of Sport Fisheries and Wildlife.

Pesticides

Department of Agriculture—
  Agricultural Research Service (biological controls, food and fiber production).
  Consumer and Marketing Service.
  Forest Service.
Department of Commerce—
  National Marine Fisheries Service.
  National Oceanic and Atmospheric Administration.
Environmental Protection Agency—
  Office of Pesticides.
Department of the Interior—
  Bureau of Sport Fisheries and Wildlife (effects on fish and wildlife).
  Bureau of Land Management.
Department of Health, Education, and Welfare (Health aspects).

Herbicides

Department of Agriculture—
  Agricultural Research Service.
  Forest Service.
Environmental Protection Agency—
  Office of Pesticides.
Department of Health, Education, and Welfare (Health aspects).
Department of the Interior—
  Bureau of Sport Fisheries and Wildlife.
  Bureau of Land Management.
  Bureau of Reclamation.

Transportation and Handling of Hazardous Materials

Department of Commerce—
  Maritime Administration.
  National Marine Fisheries Service.
  National Oceanic and Atmospheric Administration (impact on marine life).
Department of Defense—
  Armed Services Explosive Safety Board.
  Army Corps of Engineers (navigable waterways).
Department of Health, Education, and Welfare—
  Office of the Surgeon General (Health aspects).
Department of Transportation—
  Federal Highway Administration Bureau of Motor Carrier Safety.
  Coast Guard.
  Federal Railroad Administration.
  Federal Aviation Administration.
  Assistant Secretary for Systems Development and Technology.
  Office of Hazardous Materials.
  Office of Pipeline Safety.
Environmental Protection Agency (hazardous substances).
Atomic Energy Commission (radioactive substances).

LAND USE AND MANAGEMENT

Coastal Areas: Wetlands, Estuaries, Waterfowl Refuges, and Beaches

Department of Agriculture—
  Forest Service.
Department of Commerce—
  National Marine Fisheries Service (impact on marine life).
  National Oceanic and Atmospheric Administration (impact on marine life).
Department of Transportation—
  Coast Guard (bridges, navigation).
Department of Defense—
  Army Corps of Engineers (beaches, dredge and fill permits, Refuse Act permits).
Department of the Interior—
  Bureau of Sport Fisheries and Wildlife.
  National Park Service.
  U.S. Geological Survey (coastal geology).
  Bureau of Outdoor Recreation (beaches).
Department of Agriculture—
  Soil Conservation Service (soil stability, hydrology).
Environmental Protection Agency—
  Water Quality Office.

Historic and Archeological Sites

Department of the Interior—
  National Park Service.
Advisory Council on Historic Preservation.

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