ENVIRONMENTAL EVALUATION — PRODUCTS AND PROCESSES

I. PURPOSE

This bulletin assigns responsibilities and describes the procedure for conducting environmental impact assessments of new products and processes before commercialization is approved and of existing products and processes as significant changes in application or manufacture are undertaken.

II. POLICY

The Organic Division recognizes the need for control and reduction of environmental degradation and thoroughly assesses the impact of proposed products and processes on the environment before commercialization and of proposed changes in existing product usage or manufacture.

III. SCOPE

This bulletin applies to proposed new products, new formulations and new applications of existing products.

This bulletin also applies to new processes and to process and/or equipment modifications when the proposed change is estimated to increase either the total volume or the concentration of any

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component in the water effluent or air emmission streams: (1) by 25% or (2) any lower percentage increase which might exceed prescribed limits for any components of waste streams, or (3) any change from zero. Changes in water, nitrogen, oxygen or carbon dioxide concentrations are exempt from these considerations.

IV. RESPONSIBILITIES

A. PRODUCT EVALUATIONS

1. Director, Business Group	Shall be responsible for assuring that no new product, new formulation or new application of an existing product is commercialized by his group unless a positive environmental impact assessment has been determined.
2. Manager, Research & Development	Shall be responsible for pursuing, through his Research Group Leaders,

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	the assessment of the environmental impact of new products, new formulations or new applications of existing products which are conceived within the Research function.
3. Manager, Commercial Development	Shall be responsible for pursuing, through his Project Managers, the assessment of the environmental impact of new products, new formulations or new applications of existing products which are conceived within the Commercial Development function.
4. Sales Director	Shall be responsible for pursuing through his Product/ Market Managers, the assessment of the environmental impact of

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new products, new formulations or new applications of existing products which are conceived within the Marketing function.

5. Manager, Environmental Protection — Shall be responsible for coordinating the product environmental evaluation activities in the division.

B. PROCESS EVALUATIONS

1. Director, Manufacturing — Shall be responsible for assuring that no new process or change in process is accepted for operating manufacturing facilities until a positive environmental impact assessment is determined.

2. Manager, Research & Development — Shall be responsible for initiating, through his Research Group Leaders, the preliminary

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environmental evaluation of the process or process change conceived within the Research function and for participating in subsequent more definitive evaluations.

3. Manufacturing Manager — Shall be responsible for initiating, through the General Superintendents, Technical Services and the Guest Superintendents, the preliminary environmental evaluation of the process or process change conceived within the Manufacturing function. He shall also be responsible for initiating the more definitive evaluations made before implementation of those projects handled by Manufacturing.

4.	Engineering Manager	Shall be responsible for initiating, through his Project Managers, the more definitive evaluations made before implementation of those projects handled by CED.
5.	Manager, Environmental Protection-Manufacturing	Shall be responsible for coordinating the process environmental evaluation activities in the division.

V. PROCEDURE

A. PRODUCTS

1. The Research Group Leader, Commercial Development Project Manager, or Product/Market Manager, who is primarily responsible for the development of a new product, new formulation or new application of an existing product, must initiate a preliminary environmental evaluation as soon as the proposed product is identified and the end uses visualized by completing

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data sheet EC-201 (Appendix A) after conducting a literature search and consulting with others. He forwards copies of data sheet EC-201 with a statement of his principal sources of information, environmental problems visualized, probable end uses, and a request for a preliminary evaluation to the Medical Director and to the Manager, Environmental Protection.

2. The Medical Director will respond regarding the environmental problems foreseen and information required before samples are forwarded to potential users.

3. Upon receiving Medical Department concurrence, the Research Group Leader, Development Project Manager or Product/Market Manager involved may release shipment of samples.

4. Based on the results of the preliminary environmental assessment, the Research Group Leader, Development Project Manager or Product/Market Manager concerned will arrange for appropriate studies; e.g., toxicity,

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biodegradation, to develop additional environmental information.

5. Before commercialization, the Research Group Leader, Development Project Manager or Product/Market Manager concerned must initiate a final environmental evaluation by completing data sheet EC-202. He forwards copies of data sheet EC-202 (Appendix B)with a listing of the principal sources of information, the intended product uses and a request for an environmental evaluation with intent to commercialize to the Medical Director and to the Manager, Environmental Protection.

6. The Medical Director will respond regarding the environmental acceptability, restrictions or additional information required.

7. When a positive environmental assessment is achieved the Business Director will approve commercialization.

8. The Manager, Environmental Protection, will maintain suitable records, issue appropriate reports and co-ordinate the environmental evaluation activities to

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assure that assessments are processed thoroughly and quickly and that new products, new formulations and new applications of existing products meet the standards of environmental acceptability.

B. PROCESSES (NEW OR CHANGED) AND EQUIPMENT MODIFICATIONS

Intent

This procedure applies to all new processes and process and/or equipment modifications which are estimated to increase either the total volume or the concentration of any component in the water effluent or air emission streams by:

(a) 25% or more, or

(b) any lower percentage increase which may cause exceeding emission or effluent regulations (or Monsanto standards, if more stringent) by any component of the waste streams or

(c) any change from zero.

Changes in water, nitrogen, oxygen or carbon dioxide concentrations are not significant and are therefore exempt.

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Steps applying to new processes and/or process changes are detailed in 1 through 7 below. Steps applying to equipment modifications (or de-bottlenecking) where no process changes are involved are detailed in 4 through 7 below.

1. The Research Group Leader, General Superintendent, Technical Services, or Guest Superintendent, who is primarily responsible for the development of a new process or process change, will arrange for a preliminary environment evaluation review (see CED Procedure #602, Section V Procedure - Research LP & EC Review, pages 2, 3 of 7). This will be made along with a loss prevention review and will be coordinated with the Director of Safety and Property Protection. An Environmental Control Review Check List (EC-27, Appendix C) will be used to insure that all pertinent items are considered.

2. A report summarizing the review and defining problems requiring particular attention during subsequent

process development work is prepared and copies are sent to appropriate division management and to the Medical Director, Director of Safety and Property Protection and Manager, Environmental Protection, Manufacturing.

3. Appropriate comments resulting from this review are included in the Suggested Procedure or Tentative Process which will be used during the development period.

4. Following the decision to implement the process or process change and/or in cases involving equipment modifications, three definitive environmental evaluations are made along with the loss prevention reviews. (See CED Procedure #602, Section V Procedure, pages 3, 4 and 5 of 7.)

   a. Pre-project review - made prior to preparing the appropriation request.

   b. Project design review - made after the appropriation

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has been approved and the process design is sufficiently advanced.

c. Pre-startup review - made when the plant operating manual is completed and before plant startup.

5. These evaluation reviews are initiated by the appropriate project manager or engineer. Representatives of concerned groups including plant, division and CED personnel participate. The Environmental Control Check List, EC-27 (Appendix C) is used as a guide. Plants will develop and implement "Environmental Review" procedures similar to present "Safety Project Reviews" for their Operations on Procedure Manuals. Reports summarizing the evaluations are sent to all participants, appropriate division management, Medical Director, Director of Safety and Property Protection and the Manager, Environmental Protection, Manufacturing.

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6. Appropriate comments resulting from these definitive reviews are included in the Tentative Process, Interim Process or Standard Manufacturing Process.

7. The Manager, Environmental Protection, Manufacturing, will maintain suitable records, issue appropriate reports and coordinate the process environmental assessment reviews to assure timeliness and thoroughness.

VI. REFERENCE PROCEDURES AND BULLETINS

Corporate Procedure	- Evaluation of Proposed New Products and Processes.
CED Procedure 602	- Loss Prevention and Environmental Control Reviews.
Organic Division Bulletin O-18	- Procedure for Toxicological Testing.
Organic Division Bulletin O-36	- Process Documentation.
Organic Research Reference OR-16	- Suggested Procedures.
Organic Research Reference E-10	- Tentative Process.
Organic Manufacturing Procedure Procedure OM-13	- Standard Manufacturing Process.

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APPENDIX A

BULLETIN

Data Sheet EC-201

NEW PRODUCTS

Preliminary Environmental Compatability Assessment

The following Environmental Compatability Assessment Scheme includes some procedures similar to those now used by the Medical Department to assess the potential hazard of new materials to humans. This systematic scheme is being adopted to ensure insofar as possible that our products are not hazardous to the public or the environment.

The scheme is designed to elicit the information needed to protect people who come in contact with large or small amounts of a material, occasionally or continually, and all aspects of the environment which may contact or accumulate it or its degradation products. It takes the form of a series of questions to be asked about the material which can be answered simply "yes" or "no". However, as will be obvious from consideration of the questions, considerable knowledge will be required to provide satisfactory answers.

As provided for in corporate procedures (D-II-8 in Management Guide), the division in the company responsible for a new product must obtain a preliminary environmental evaluation, as soon as the proposed product is identified and the end uses visualized.

To initiate this evaluation the individual responsible for the product consults the literature and obtains the best answers he can by consultation with others and completes data sheet EC-201. He sends this to the Medical Department along with a statement of his principal sources of information and a request for a preliminary environmental evaluation.

The Medical Director will respond as to the environmental problems foreseen and information required, if any, before sending out trial samples.

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Environmental Compatability Assessment - Data Sheet EC-201 (cont.)

Description of the Product -

Probable End Uses -

A. Is the acute toxicity (via oral ingestion, skin absorption, inhalation) known or can it be estimated by analogy based on data for chemically related compounds? Indicate below:

	Known		Estimated
1) oral LD_{50}-rats	_____	or	_____ mg/kg
2) skin absorption MLD-rabbits	_____	or	_____ mg/kg
3) inhalation effect	_____	or	_____
4) skin irritation potential	_____	or	_____
5) eye irritation potential	_____	or	_____

B. Are harmful effects from repeated or chronic exposures known or can they be predicted by analogy?

C. Will 1) wastes from manufacturing
2) anticipated use, and/or
3) ultimate disposal of end product create environmental problems because product fails to readily degrade or decompose?

D. Is there an indication based on data or analogy, that the product can be stored or concentrated in biological systems?

E. Is it likely that harmful secondary reaction products will arise from a harmless-appearing parent as a result of chemical, biochemical, or biological activity in the environment?

NOTE: The Medical Department should be consulted for answers to Questions A and B. Questions C - E require speculation by people knowledgeable about the process and end use.

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BULLETIN

Data Sheet EC-202

NEW PRODUCTS

Final Environmental Compatibility Assessment

As provided for in corporate procedures (D-II-8 in Management Guide and Medical Department Bulletin EC-201) the division in the company responsible for a new product must obtain a final environmental evaluation before commercialization.

To obtain this evaluation, the individual responsible for the product reviews the Preliminary Environmental Compatibility Assessment (EC-201) form, consults the literature, obtains the best answers he can by consultation with others, and completes Data Sheet EC-202. He sends this to the Medical Director along with a statement of his principal sources of information, the intended product uses and a request for a final environmental evaluation with intent to commercialize.

The Medical Director will respond as to the environmental acceptability, restrictions, or additional information needed, if any, or if unacceptable, the reasons why.

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Environmental Compatibility Assessment Scheme

Instructions:

Answer each question in turn, "yes" or "no". Each answer is provided with a directive concerning the question to be answered next: the logic of the scheme assumes that questions skipped would be answered "no" and can thus be ignored. The last question, No. 12, should be considered if it is decided to make and sell materials which are very useful but potentially dangerous to man or his environment. When applying this form, consideration must be given to the product Monsanto supplies, product impurities, as well as thefinal or end product that enters the environment.

ITEMS 1 THROUGH 3 ARE TO ESTABLISH THE HAZARDS TO HUMANS OF PRODUCTS, PRODUCT IMPURITIES, BY-PRODUCTS OR MANUFACTURING AND DEGRADATION PRODUCTS.

	If	Go to:
1. Is the material so physiologically inert that there need be no concern about health hazards to humans?	Yes	4
	No	2 & 3
2. a) Is the material toxic to persons as a result of a single contact with high concentrations?		
b) Is the material toxic to persons at lesser concentrations following repeated or prolonged exposure?		
c) Is the material likely to be carcinogenic, teratogenic or mutagenic?		
3. Recognizing the hazards to people, can procedures be devised for safe handling at reasonable cost?	Yes	4
	No	-Do Not Sell

ITEMS 4 THROUGH 6 ARE TO ESTABLISH IF CONSIDERATION HAS BEEN GIVEN TO DISPOSAL, DEGRADATION PRODUCTS OF DISPOSAL AND ENVIRONMENTAL DEGRADABILITY.

	If	Go to:
4. Can "closed-loop" disposal provisions be developed for the product so it will never reach the environment?	Yes	5
	No	6

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	If	Go to:
5. Is it likely the degradation products from the "closed-loop" disposal system could be harmful to humans?	Yes	-Recycle Degradation Products to 2. Continue at 6.
	No	7
6. Is it likely that the product will degrade in the environment or in any of the currently used disposal systems?	Yes	-Recycle Degradation Products to 1. Continue at 7.
	No	7

ITEMS 7 THROUGH 10 ARE TO ESTABLISH HAZARDS OF PRODUCTS AND DEGRADATION PRODUCTS TO PLANTS, ANIMALS OR ECOSYSTEMS.

7. Is it probable that the product or degradation products are harmful to plants and animals at concentrations to which they are likely to be exposed?	Yes	8
	No	9
8. Recognizing the hazards to plants and animals, can procedures be devised at reasonable costs to render the material innocuous?	Yes	9
	No	-Do Not Sell
9. Is it likely that harmful secondary reaction products could be formed from the harmless parent material as a result of a chemical, biochemical, or biological activity in the environment?	Yes	-Recycle the By-product at 1 & 7. Continue at 10.
	No	10
10. Is there reason to suppose that the material could have deleterious effect on the ecosystem, e.g., through concentration in the food chain, antagonism, synergism, abiotic reactions, chelation or plain physical concentration even though the material was not directly toxic to the biota?	Yes	-Recycle to 8. Continue at 11.
	No	11
11. Have procedures been devized to handle catastrophes in the production, storage, or transportation of the product?	Yes	-Sell
12. Is it necessary to restrict sales to specific end uses?		

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