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REGULATORY GUIDE

OFFICE OF STANDARDS DEVELOPMENT

REGULATORY GUIDE 6.7

PREPARATION OF AN ENVIRONMENTAL REPORT TO SUPPORT A RULE MAKING PETITION SEEKING AN EXEMPTION FOR A RADIONUCLIDE-CONTAINING PRODUCT

A. INTRODUCTION

1. Purpose of This Regulatory Guide

The National Environmental Policy Act of 1969 (83 Stat. 852), implemented by Executive Order 11514 and the Council on Environmental Quality's Guidelines of August 1, 1973 (38 FR 20550), requires that all agencies of the Federal Government prepare detailed environmental statements on proposals for legislation and other major federal actions significantly affecting the quality of the human environment. The principal objective of the National Environmental Policy Act of 1969 is to build into the agency decision-making process an appropriate and careful consideration of environmental aspects of proposed actions.

As part of its policy and procedures for achieving this objective, the U.S. Nuclear Regulatory Commission (NRC) requires (see 10 CFR § 51.~~20~~25) that an environmental report be submitted by any person petitioning the NRC to establish an exemption from licensing for the use of radioactive material in a product. The purpose of this guide is to provide assistance to petitioners in their development of environmental reports.

This guide is intended to be quite comprehensive in scope. However, the petitioner may need additional clarification. Therefore, if a petitioner or a person considering submission of a petition has questions about the applicability of certain recommendations of this guide to his product, he is encouraged to contact the ~~Office of Standards Development~~, U.S. Nuclear Regulatory Commission. ^Rules and Directives Branch,

2. Preparation of Environmental Reports

Part 51 of 10 CFR provides regulatory requirements for the content of a petitioner's environmental report. Specific and detailed guidance is provided in Section B, "Standard Format and Content of an Environmental Report to Support a Rule Making Petition Seeking an Exemption for a Radionuclide-Containing Product," of this guide.

A number of the topics discussed in Section B may apply only in part, or not at all. The petitioner should apply the guidelines appropriate to the product for which the licensing exemption is sought; any topic that is not relevant to the particular product being discussed should be so identified.

Descriptive or narrative text as well as tables, charts, graphs, etc. should be used in the report. Each subject should be treated in sufficient depth and should provide sufficient documentation to permit the NRC to evaluate independently the extent of the environmental impact. Tables, line drawings, and photographs should be used wherever they contribute to the clarity of the report. Descriptive and narrative passages should be brief and concise. The number of significant figures stated in numerical data should reflect the accuracy of the data; wherever practical the degree of accuracy should be indicated by plus or minus values.

Pertinent published information relating to the product and to its distribution, use, and disposal should be referenced or included as appendices.

Some of the information to be included in the environmental report may have been prepared by the petitioner during consideration of the safety and marketing aspects of the product. Where appropriate, this information (in the form of text, tables, or figures) should be incorporated in, or appended to, the environmental report in order to provide a complete document.

If the petitioner considers any information requested by this guide to be a trade secret or commercial or financial information submitted in confidence, the requested information should be submitted as a separate document with a written request that NRC withhold the information from public disclosure in accordance with 10 CFR § 2.790 on the grounds that it is proprietary data.

3. Commission Action on Environmental Reports

The environmental report submitted by the petitioner is placed ~~in the Commission's Public Document Room at 1717 H Street NW., Washington, D.C.~~ on NRC's website at http://www.nrc.gov. At the same time, NRC issues a public announcement and publishes a summary notice in the *Federal Register.*

The petitioner's environmental report, relevant published information, and any comments received from interested persons are considered by the staff in preparing a "Draft Environmental Statement" concerning the proposed rule making action. The staff's draft statement and the petitioner's environmental report are transmitted for information to the Council on Environmental Quality and for comment to appropriate federal agencies and state officials. The draft statement is also made available to the general public. Comments on both the environmental report and the draft statement are requested within a specified time interval.

As described in detail in § § 51.~~22~~70 through 51.~~25~~77 of 10 CFR Part 51, the staff considers the comments on the environmental report and on the draft statement and prepares a "Final Environmental Statement" (FES). This final statement is then transmitted to the Council on Environmental Quality and made available to appropriate state agencies. NRC issues a public announcement and publishes a notice of availability in the *Federal Register.*

Subsequent hearings, if required, on the environmental aspects involved in rule making on an exemption from licensing requirements are based on the petitioner's environmental report and NRC's Final Environmental Statement. The FES takes into account information from many sources, including the petitioner's environmental report and its supplements and the comments of the various governmental agencies, private organizations, and individuals.

The environmental statement prepared by the staff is intended to provide a generic treatment of the product. This treatment is appropriate for a rule making procedure involving a licensing exemption that permits distribution of products by any person who satisfies the conditions of the regulations. In this regard, in the absence of information to the contrary, the staff will view the petitioner's particular product as typical of all products likely to be distributed for use under the exemption. Accordingly, detailed and complete information on the petitioner's particular product and on the petitioner's planned distribution system is important to consideration of the petition.

The petitioner's environmental report is not expected to address the impact of manufacturing the product. Accordingly, the possible creation of manufacturing jobs at the petitioner's plant and the possible radiation exposures to individuals who may perform those jobs should not be treated in the petitioner's environmental report. In most instances the manufacturing impact will be negligible. In those few instances where it is not, NRC will assess the manufacturing impact when considering issuance of the materials license that authorizes manufacture of the product.

B. STANDARD FORMAT AND CONTENT OF AN ENVIRONMENTAL REPORT TO SUPPORT A RULE MAKING PETITION SEEKING AN EXEMPTION FOR A RADIONUCLIDE-CONTAINING PRODUCT

SUMMARY

The summary should support a conclusion that adoption of the requested rule change would be consistent with the national environmental goals. In preparing the summary and much of the remainder of the report, the petitioner should assume the requested rule change to be in effect and assess the impacts accordingly. Since the rule change would permit any person who satisfied the specific licensing requirements to distribute products for use under the exemption, the scope of the report should go beyond the petitioner's own particular product. For most types of products the report should show that the petitioner's particular product and means of distribution should be viewed as "typical examples" of models and distribution systems that can reasonably be expected to develop if the requested rule change is made.

The summary should include the following information:

1. A concise description of the specific product, including specific design features, intended use, and methods of use, operation, distribution, and disposal or recycle.

2. A brief comparison of alternative product designs (both radioactive and nonradioactive); of alternative methods of use, distribution, and disposal; and of alternative actions as extracted from the material prepared for Chapter 6 of this guide.

3. A brief listing of significant environmental impacts associated with the product as extracted from the benefit-cost analysis of Chapter 7 of this guide. The listing should include both adverse and beneficial environmental and socioeconomic impacts that would occur if the Commission takes the action proposed by the petitioner.

Chapter 1

INTRODUCTION

1.1 The Petition for Rule Making

The petitioner should give the substance or text of the proposed rule change in this section. He should elaborate on the purpose to be served by the rule change requested in the petition, provide pros and cons for the change, and indicate why he believes the change should be made.

1.2 The Petitioner

1.2.1 Description

The petitioner should identify himself by name and address and should describe his business and the types of products he manufactures. He should also estimate the number of persons (i.e., competitors) who can reasonably be expected to request regulatory approval to distribute products similar to the petitioner's if the rule change is accomplished.

1.2.2 Relationship to *(specific name of product)*

A clear statement of the petitioner's interest in the distribution of such a product should be provided. Also state whether the petitioner will manufacture, subcontract the manufacture, purchase, or import the product and whether the manufacturer or importer will distribute the product directly or through others.

Chapter 2

DESCRIPTION AND USE OF *(SPECIFIC NAME OF PRODUCT)* THAT CONTAINS *(NAMES OF RADIONUCLIDES)*

This section should describe the product; how it works; what it will be used for; how it will be used, distributed, installed, serviced, and repaired; and the method of its disposal. In the absence of information to the contrary, NRC may consider this information to be "typical" for all such products, whether distributed by the petitioner or by his competitors.

2.1 Description

2.1.1 General Construction

The petitioner should describe how the product is constructed, emphasizing particularly how the radioactive material is incorporated. The following information is needed:

1. Identity of all radioactive materials contained in the product.

2. Description and drawing of the product, including all designs. Indicate the maximum and average amount of radioactive material used and its chemical and physical form. Show how the radioactive material is incorporated into the product. Include drawings. The composition, dimensions, density, thickness, and location of any substrates, coatings, or sandwich material should be specified. The measured radiation dose rates at the surface and at specified distances from the product should be indicated. Also specify the measured radiation dose rates at the surface and at specified distances from separable components such as pieces that could be replaced or repaired or parts that could be disassembled. Give the results of any tests (wipe, leak-rate, leach-rate, combustion, vibration, abrasion, etc.) that show the degree of integrity of the containment and shielding of the radioactive material in the product under expected conditions of use. A description of the test procedures * | and radiation measuring instruments should also be provided.

2.1.2 The Radionuclides

The petitioner should describe in detail the radioactive material used, including all radionuclides (parents, daughters, and contaminants) present and their nuclear properties and abundances. Give pertinent chemical, biological, and physical data. The availability and cost of the material should also be indicated.

2.2 Operations

The petitioner should discuss how the product functions, giving particular emphasis to its unique features and the function of the radioactive material. Typical operating conditions and environments should be described, for example, temperature and gas or air flows. Describe typical labels and instructions as they relate to safety and operation of the product.

2.3 Uses

The use for which the product is designed should be discussed, along with possible uses unintended by the manufacturer but which the product may experience after distribution. Emphasize how the radioactive material facilitates such uses.

2.4 Methods of Use

The petitioner should describe how, where (geographic locations, facilities, homes, etc.), and by whom the product will be used. The expected useful life of the product under the various use conditions should be specified. Include descriptions and numbers of persons, other than actual users, who might be affected by use of the product.

2.5 Distribution

2.5.1 Packaging

For each package design that will contain the product, the petitioner should give the number and arrangement of:

- Units per package;
- Packages per box;
- Boxes per carton.

The petitioner should also discuss the geometry and composition of construction materials for boxes, packages, and cartons. Describe labeling, markings, and instructions–both outside and inside the container. The radiation dose rates at specified distances from packages, boxes, and cartons should also be indicated.

2.5.2 Distribution

The petitioner should characterize the sites (such as warehouses, freight terminals, or large or small retail stores) where the product will be temporarily located during distribution. Estimate the number of units, packages, boxes, cartons, or shipments that will pass

*Lines indicate substantive changes from previous issue.

through each site; how long they will remain there; how they will be handled and stored at each site; and all important environmental factors, e.g., temperature ranges in freight terminals and probability and consequences of accidents or fires.

2.5.3 Transport

A list should be provided concerning the modes of transport (long-haul or local-delivery truck, rail, mail, etc.) that will be used to transfer the product from its place of manufacture to the sites described above and, ultimately, to the user. For each mode, give the size of a shipment (number of cartons), number and frequency of shipments, likely routes of shipments, and average distance and environment. The radiation dose rate at a specified distance from the shipping vehicle should also be provided for each mode.

2.6 Installation, Maintenance, and Repair

The petitioner should describe the intended methods of performing installation, maintenance, and repair activities relating to radiation safety features of the product. Also indicate methods precluded by design and methods that are possible and likely to be performed, but not specifically planned or recommended. Include the frequency of the installation, maintenance, and repair activities; the time required; and the general operations to be performed. Emphasize any operations during which persons will come into contact with the radioactive material or during which the shielding of the radioactive material might be significantly reduced or the radioactive material released.

2.7 Disposal

The petitioner should describe likely methods of disposal of the product and predicted percentages for each method. These methods may include disposal as domestic, commercial, or industrial solid or liquid waste. Identify any efforts made to encourage return of the product to the manufacturer for controlled disposal as radioactive waste.

Define any disposal procedures during which persons will come into contact with the product and any conditions under which the radioactive material may be released from the product.

Chapter 3

MARKET FOR *(NAME OF PRODUCT)* THAT CONTAINS *(NAMES OF RADIONUCLIDES)*

The petitioner should demonstrate that the product is needed, should describe the need, and should indicate how the need is presently being filled. He should also provide estimates of the demand for the product and should indicate how the demand will be met.

3.1 Need

This section should describe the need for the general and specific product.

3.1.1 For *(general name of product)*

Identify the need for the product to be provided by the petitioner and for similar products. Describe how the need is presently being met and how it would be met in the future without the product.

3.1.2 For *(name of specific product)*

The petitioner should describe how the specific product that he will provide will fill the need for products of this type. Identify and discuss those aspects of the product that will fill the need differently from existing or planned products (new, better, worse, etc.) of the same general type.

3.2 The *(name)* Industry

The petitioner should characterize the likely manufacturers and distributors of the product (e.g., timepiece manufacturers, medical device manufacturers, firearms manufacturers). Discuss their normal manufacturing business transactions, products manufactured, and inter- and intra-industry practices (for example, purchase components such as small sealed sources of radioactive material and assemble the components to make the final product).

3.3 Demand

This section should provide estimates of historical demand for the product – both the general type and the specific product. It should also project estimates of demand for the short term (1 to 10 years) and the long term (10, 20, 30, 40, and 50 years). Bases should be provided for the estimates.

3.3.1 For *(general name of product)*

Past, present, and future short- and long-term demands for the general type of product should be discussed.

3.3.2 For *(specific name of product)*

The petitioner should estimate the demand (present and future) for the specific product. Relate the demand for the specific product to the demand for the general type of product, as described in Section 3.3.1, and show how the demands will interact.

3.4 Supply

This section should show how the demands given in Section 3.3 have been, are being, and will be met.

3.4.1 Of *(general name of product)*

Identify and quantify past, present, and future sources and means of satisfying the demands for the general type of product.

Chapter 4

ENVIRONMENTAL EFFECTS OF NORMAL DISTRIBUTION, USE, AND DISPOSAL OF *(NAME OF PRODUCT)*

The distribution, use, and disposal of the product will inevitably affect the environment. Effects are considered adverse if the environmental change provides an added stress that lessens a desirable characteristic of an important biotic population or natural resource (e.g., safety, health, abundance, and productivity); if the change provides an added stress that tends to lower the quality of renewable resources or to impair the recycling of depletable resources; or if the change provides an added stress that reduces the diversity and variety of individual choice, the standard of living, or the extent of sharing life's amenities. Effects are considered beneficial if they enhance the characteristics just enumerated. Both adverse and beneficial effects should be discussed in this section.

The petitioner should use the information presented in Chapters 2 and 3 to describe the environments and populations that will be affected by the distribution, use, and disposal of the product. Include the effects of transportation and storage as they relate to wholesale and retail marketing.

Any impacts arising from interactions of the product with the environment and the populations should be quantified and systematically presented. In the discussion of each impact, the petitioner should make clear whether the supporting evidence is based on theoretical, laboratory, or field studies. The source of each impact and the population or resource affected should be made clear. Impacts on water, land, air, and biota should be distinguished, and any changes that may be brought about in the ecological system due to these impacts should be defined.

Radiological, economic, technological, social, ecological, aesthetic, and any other impacts should be identified and quantified. These impacts should address both a single product and multiple products. The numbers used for multiple products should be consistent with the demand estimated in Chapter 3.

4.1 Environments and Populations Affected

This section is intended to provide the scenarios from which the impacts discussed in Sections 4.2 to 4.4 are determined. For each stage in the life span of the product (as described in Sections 2.3 to 2.7) describe the following:

1. Geographic locations;

2. Site and environments;

3. Persons involved directly with the stage and their actions;

4. Bystanders or persons not involved directly with, but affected by, the stage and their actions.

The above should be discussed under the following topics:

4.1.1 During Distribution

4.1.2 During Use

4.1.3 During Installation, Maintenance, and Repair

4.1.4 Due to Disposal

4.2 Radiological Impacts

This section should contain detailed, quantified estimates of the radiation doses (both external doses and dose commitments) to individuals and to the population. Include any radiological consideration affecting the use of land, air, water, or other resources. These estimates are to be based on the scenarios given in Section 4.1.

The petitioner should consider the radiological effects of distribution, use, and disposal of the product on man and important biota. Provide estimates of the radiological impact on man, both to individuals and to population groups, via various exposure pathways. The various pathways for external and internal exposure should be identified and described in textual and flowchart format.

4.2.1 On Man

In each of the following sections estimate radiation doses to all exposed persons.

4.2.1.1 During Distribution

4.2.1.2 During Use

4.2.1.3 During Installation, Maintenance, and Repair

4.2.1.4 Due to Disposal

4.2.2 On Terrestrial and Aquatic Ecology

In each of the following sections estimate radiation doses to and contamination of terrestrial and aquatic flora and fauna.

4.2.2.1 During Distribution

4.2.2.2 During Use

4.2.2.3 During Installation, Maintenance, and Repair

4.2.2.4 Due to Disposal

4.2.3 On Land, Air, and Water Use

In each of the following sections estimate contamination of or restrictions placed on the use of land, air, water, and other resources.

4.2.3.1 During Distribution

4.2.3.2 During Use

4.2.3.3 During Installation, Maintenance, and Repair

4.2.3.4 Due to Disposal

4.3 Nonradiological Impacts

This section should contain detailed estimates of any nonradiological impacts on man, on terrestrial and aquatic ecology, and on the use of land, air, water and other resources for the stages in the life span and disposal of the product. It should include evaluations of any toxic substances and alterations of existing environments or resources.

The structure of this section should be the same as that of Section 4.2.

4.4 Impacts on the Community

The petitioner should describe and estimate the expected magnitude of impacts of the product, both beneficial and adverse.

4.4.1 Economic

In each of the sections indicated below, discuss:

1. Employment–new jobs, transfer of jobs from one location (or country) to another, job improvement, effects of product on job market, etc.;

2. Secondary effects–such as crime reduction, energy conservation, etc.;

3. Tax revenues–if applicable;

4. Service revenues–to transporters, users, repairers, nonusers (general economic benefit or cost);

5. Use of resources;

6. Improved service–costs that the product eliminates by providing a better service and costs that the product imposes.

The above should be discussed in the following sections:

4.4.1.1 During Distribution

4.4.1.2 During Use

4.4.1.3 During Installation, Maintenance, and Repair

4.4.1.4 Due to Disposal

4.4.2 Social

In each of the sections listed below, discuss:

1. Community services–the need for more or fewer services such as housing, schools, hospitals, police and fire protection, recreation areas, and other institutions;

2. National goals and security–energy conservation, new technologies, improved (or reduced) national security, balance of payments, more or less efficient use of resources;

3. Concern about introducing radionuclides into the environment.

The above should be discussed in the folloiwng sections:

4.4.2.1 During Distribution

4.4.2.2 During Use

4.4.2.3 During Installation, Maintenance, and Repair

4.4.2.4 Due to Disposal

4.5 Resources Committed

The petitioner should discuss any irreversible commitments of resources involved in manufacturing the product and in its distribution, use, repair, and disposal. The discussion should include both direct commitments and irreversible environmental losses and natural resource uses.

In this discussion, the petitioner should consider lost resources from the viewpoint of both relative impacts and long-term net effects. As an example of a relative impact assessment, the commitment of a given resource to the manufacture, distribution, use, and disposal of the product should be given as the percentage of the total available resource committed and should be discussed in terms of the resources that would be committed to provide an equivalent service by an alternative means.

Chapter 5

ENVIRONMENTAL EFFECTS OF POSTULATED ACCIDENTS OR MISUSE

The petitioner should postulate, describe, and indicate the probability of occurrence of all credible accidents or misuses of the product. Describe the effects of each, and assess the impacts associated therewith. Each accident or misuse should be described and assessed in the same manner as the normal events discussed in Chapter 4. Accidents may involve fire, explosion, submersion (flooding), mechanical failure, abrasion, wind, shredding, etc.

5.1 Radiological Impacts of Accidents

In each of the following sections, accidents or misuses in which exposure to or release of the radioactive material is a significant factor should be described and assessed. Exposure conditions and modes of release (to air from rupture or fire, to water, to land) and the quantity of radioactive material released should be stated.

5.1.1 During Distribution

5.1.2 During Use

5.1.3 During Installation, Maintenance, and Repair

5.1.4 During Disposal

5.2 Nonradiological Impacts of Accidents

Each of the following sections should describe and assess accidents or misuses in which exposure to or release of the radioactive material is not a significant factor, but in which significant personal injury or property loss may occur. Special attention should be given to potential chemical effects of such occurrences.

5.2.1 During Distribution

5.2.2 During Use

5.2.3 During Installation, Maintenance, and Repair

5.2.4 During Disposal

Chapter 6

ALTERNATIVES

This section should identify and discuss feasible alternatives related to (1) the design, distribution, use, and disposal of the product and (2) the licensing requirements for the product. Reasons for rejecting the alternatives should be clearly stated.

6.1 Alternatives Related to *(specific name of product)*

Alternatives to the specific product and to its design, distribution, use, and disposal should be described and compared with those proposed in Chapter 2. The discussion should show which alternative is best and the bases for the decision (environmental, technical, economic, etc.).

6.1.1 Alternative Radionuclides

The petitioner should discuss all feasible alternative radionuclides and indicate why they are not being used.

6.1.2 Other Products or Designs

In this section the petitioner should discuss feasible alternative designs of the specific product, the advantages and disadvantages of those designs, and the reasons why they are not used. Discuss all alternative products, both radioactive and nonradioactive, that could be used in place of the proposed product and compare them with the product. The petitioner should consider both his own products and those manufactured by other companies.

6.1.3 Other Means of Distribution, Use, and Disposal

Discuss feasible alternatives to the proposed methods of packaging, labeling, transport, routing, storage, sales, intended use, unintended use, return for disposal, disposal, installation, maintenance, and repair. Compare these alternatives with the proposed methods.

6.2 Alternatives Related to Licensing Requirements for *(name of product)*

The petitioner should indicate what the effects (administrative, economic, psychological, etc.) of a different licensing action would be if applied to the product (i.e., the effects of an action other than an exemption from licensing and regulatory requirements).

6.2.1 General License

This alternative to a license exemption normally would require issuance of a general license that would (1) authorize the receipt, possession, use, export, ownership, and acquisition of the radioactive material in the product and (2) control the use, transfer, and disposal of the radioactive material in the product. The petitioner should discuss the administrative and other effects of such a license. For example, detailed records of product purchases and transfers would probably be required to facilitate verification that the distributor and the purchaser have complied with the use, transfer, and disposal requirements of the general license.

6.2.2 Specific License

This alternative normally would require each purchaser or user of the product to obtain a specific license. An application would have to be filed and a specific license issued to a named person (user) prior to the receipt of the radioactive material contained in the product. Possession, use, transfer, and disposal of the radioactive material would be controlled under the terms and conditions of the specific licenses. The petitioner should provide a discussion of these and other implications of obtaining a specific license.

Chapter 7

SUMMARY OF POTENTIAL BENEFITS AND POSSIBLE COSTS

In this section the petitioner should provide a summary of the potential benefits and costs associated with the distribution, use, and disposal of the product. Significant benefits and costs identified in previous sections should be listed, summarized briefly, and quantified in the text.

A table (see example in Table 7.1) should summarize and quantify the impacts. Emphasis should be placed on environmental and societal benefits and costs, but private (producer-consumer) benefits and costs should be considered as well. Some benefits could become costs, and vice versa, depending on the particular way in which the impact is imposed. Such factors should be identified and the probability that they will be costs or will be benefits should be stated. If significant changes in the numbers of products distributed annually are expected, multiple entries (e.g., short-term, long-term) should be made for many of the impacts.

Table 7.1

SUMMARY OF POTENTIAL BENEFITS (AND COSTS) DUE TO THE INTRODUCTION OF THE (SPECIFIC NAME OF PRODUCT)

Impact	*Means of Describing Impact*
Radiological	
Potential radiation doses to individuals under:	
Normal conditions	millirems/year
Accident conditions	millirems/year
Potential radiation doses to population	person-rems/year
Introduction of radioactive materials into the environment	μCi/year
Potential contamination of the environment (disposal sites, etc.)	$\mu Ci/m^3$ or $\mu Ci/m^2$ and total volumes or areas
Socioeconomic	
Provision of new or better product	Summarize implications of product availability, e.g., improved safety
Savings from new or better product	Money, energy, etc. per year
Uses of resources	Summarize; provide estimates of relative efficiency of resource use and magnitude of use.
Employment	Summarize and quantify jobs made available, lost, or upgraded.
Stimulation of competition within industry	Summarize effect of proposed product.

Table 7.1 (Continued)

Impact	*Means of Describing Impact*
Socioeconomic (continued)	
National security	Summarize potential contributions of product.
Balance of payments	Summarize potential effects of product; include import and export estimates.
Effects on existing products	Summarize effects on utilization of existing products.
Technological	
Introduction of new or improved product	Summarize implications.
Other	Identify and discuss any other important technological factors.
Ecological and other	Summarize any important effects or impacts on air, land, water, and biota.