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## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Parts 152 and 156

**[OPP–300890A; FRL–6752–1]**

**RIN 2070–AD14**

## Pesticide Labeling and Other Regulatory Revisions

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** EPA is revising certain labeling regulations for pesticide products for clarity. EPA is also interpreting the Federal Insecticide, Fungicide and Rodenticide Act as it applies to nitrogen stabilizers, and revising regulations that contain statutory provisions excluding certain types of products from regulation of pesticides. These topics were part of a larger proposal concerning antimicrobial products, and are being promulgated separately for convenience.

**EFFECTIVE DATE:** This rule is effective on February 12, 2002.

**FOR FURTHER INFORMATION CONTACT:** Jean M. Frane, Field and External Affairs Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Building, 1200 Pennsylvania Ave., NW., Washington DC 20460; telephone: (703) 305–5944; and e-mail address: frane.jean@epa.gov.

**SUPPLEMENTARY INFORMATION:**

### I. General Information

*A. Does this Action Apply to Me?*

You may be affected by this action if you are an agricultural producer, food manufacturer or importer, or pesticide manufacturer. Potentially affected categories and entities may include but are not limited to:

| Category | NAICS Code | Examples |
|---|---|---|
| Producers | 32531 | Nitrogen stabilizer products |
| | 32532 | Pesticide products |
| | 32561 | Antimicrobial products |
| Wholesalers | 42269 | Antimicrobial products |
| | 42291 | Pesticide products |

This table is not exhaustive, but is intended as a guide to entities likely to be regulated by this action. The North American Industrial Classification System codes have been provided to assist you in determining whether this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

*B. How Can I Get Additional Information or Copies of Support Documents?*

1. *Electronically*. You may obtain electronic copies of this document and various support documents are available from the EPA Home page at http://www.epa.gov/. On the Home Page, select ''Laws and Regulations,'' ''Regulations and Proposed Rules'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.''

2. *In person*. The Agency has established an official record for this action under docket control number OPP–36195. The official records consists of the documents specifically referred to in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). The official record includes documents that are physically located in the docket, as well as documents that are referred to in those documents. The public version of the official record does not include any information claimed as CBI. The public version of this record, including printed versions of any electronic comments, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

### II. EPA Proposal

In the **Federal Register** of September 17, 1999 (64 FR 50672) (FRL–5770–6), EPA issued a proposed rule entitled ''Registration Requirements for Antimicrobial Pesticide Products and Other Pesticide Regulatory Changes.'' The proposal was primarily directed at implementing provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requiring EPA to issue regulations streamlining its management of the registration process for antimicrobial pesticides, and the main body of the proposal addressed antimicrobial procedures and policies.

At the same time, EPA chose to include additional proposals.

1. EPA proposed to codify a statutory provision excluding from regulation under FIFRA certain liquid chemical sterilants. The effect of the statutory exclusion was to eliminate double jurisdiction over liquid chemical sterilants by EPA and the Food and Drug Administration (FDA).

2. EPA proposed to exempt from FIFRA regulation under section 25(b) non-liquid chemical sterilants that met essentially the same criteria as those statutorily excluded. This proposal was intended to supplement the statutory exclusion to give FDA jurisdiction over all chemical sterilants for similar purposes.

3. EPA proposed to permit consolidated applications for amendment of several products at one time, under prescribed conditions.

4. EPA proposed to interpret a new provision of FIFRA defining certain nitrogen stabilizer products as pesticides, thus subjecting them to regulation under FIFRA.

5. EPA proposed to reformat, clarify, and make minor revisions to its labeling regulations that affect all pesticide products, including antimicrobial pesticides.

EPA is promulgating a final rule on the topics enumerated above separately from the main body of the antimicrobial proposal. EPA's decision is based partly on the fact that these proposals are general for all pesticides and are not limited to antimicrobial pesticides. Moreover, they were non-controversial and received little comment in proposal.

With few exceptions, noted in Unit III. of this Preamble, EPA is adopting the changes as proposed.

EPA is not at this time promulgating any of the core antimicrobial proposals, which were comprised of procedural regulations for registration, labeling requirements pertaining to the efficacy of public health products, and associated revisions to accommodate the new antimicrobial provisions.

### III. Comments

In this unit, EPA will discuss briefly the major comments received on the topics listed above and any resulting revisions. Of the 20 sets of comments received on the entire proposal, the vast majority were directed to the antimicrobial provisions. Most comments on the topics being promulgated today came from major trade associations and large producers of antimicrobial products. They were, by and large, editorial or clarifying. A

number of commenters also misconstrued EPA's proposals, or suggested revisions in areas that EPA did not propose to modify. Comments not discussed in the preamble are responded to in the docket.

*A. Chemical Sterilants*

EPA proposed to codify the statutory provisions excluding from regulation liquid chemical sterilants intended for use on critical or semi-critical medical devices, and further proposed to exempt under the authority of section 25(b) FIFRA non-liquid sterilants for the same uses. To accommodate the statutory exclusion for liquid chemical sterilants, and others scattered throughout the regulations, EPA proposed to create a new § 152.6 in which to locate all statutory exclusions from regulation. EPA also proposed to revise § § 152.8 and 152.25 by moving existing statutory exclusions into the new § 152.6. In addition, EPA would add the section 25(b) exemption for non-liquid chemical sterilants to existing § 152.20, which contains exemptions for pesticides adequately regulated by another Federal agency. No comments were received on any of these proposals, and they are adopted as proposed.

*B. Consolidation of Amendments*

EPA proposed to allow registrants of products who wish to make identical amendments to multiple registrations to do so with one application, provided that no data are needed to support the amendment. Although this situation occurs informally for some amendments, registrants had informed the Agency that it was not clear in the regulations that the practice was permitted. No comments were received on this proposal, and it is adopted as proposed.

EPA emphasizes that consolidated amendments under this provision must be identical, and must not require supporting data. The types of amendments EPA envisions being most appropriate are labeling changes, such as revision of precautionary statements to add a specific type of statement. Another area where a consolidated application may be useful would be to accomplish EPA-requested changes made by notice to registrants. Changes in composition are unlikely to be eligible for consolidated applications because composition changes will generally not apply to multiple products.

*C. Nitrogen Stabilizers*

FIFRA, as amended in 1996, generally subjected nitrogen stabilizers to FIFRA regulation by defining them as pesticides. EPA proposed an interpretation of the term ''nitrogen stabilizer'' that would codify the statutory definition and explain how the Agency would determine that a product was or was not a nitrogen stabilizer subject to FIFRA regulation. In proposed § 152.6, EPA structured the requirement as an exclusion from regulation, since the statutory definition of nitrogen stabilizer is a loosely framed set of exclusions.

In the final rule, EPA has incorporated all of the exclusion criteria that were clearly delineated in section 2(hh) of FIFRA, including specific chemicals that were excluded, and dates of commercial introduction of the nitrogen stabilizer. In the area of claims, where the statute was not explicit, EPA proposed a common sense interpretation of the types of claims that EPA would regard as nitrogen stabilization claims. EPA received two comments on its interpretation.

The first commenter noted that, while the regulatory text is clear, EPA's preamble appeared to imply that products that make ammonia volatilization claims might be considered nitrogen stabilizers even though they do not act upon soil bacteria. The commenter requested clarification in the final rule. EPA emphasizes that unless a product functions by acting upon soil bacteria, it would not be regarded as a nitrogen stabilizer product upon examination by EPA. This point is clear in § 152.6, so EPA has not revised the text.

However, with the complex interactions affecting nitrogen uptake and utilization, it is not always possible to discern the mechanism of action of a product, particularly if a product makes claims that could otherwise be construed as nitrogen stabilizer claims. In its proposal, EPA identified types of claims that it would deem to be nitrogen stabilizer claims. Claims alone would not definitively identify a product as a nitrogen stabilizer, but in the absence of confirmation that the product does not act upon soil bacteria, claims that appear to be nitrogen stabilization claims would be a trigger for EPA evaluation of the product's pesticide status. By considering the claims along with the composition and mode of action of a product, EPA ultimately would be able to determine whether a product bearing such claims was a nitrogen stabilizer.

Any product that makes what appear to be nitrogen stabilization claims as listed in § 152.6 will be presumed in the first instance to be a nitrogen stabilizer. The producers of such products bear the burden of demonstrating that the product accomplishes the claimed effect without having an effect on soil bacteria.

The second commenter noted that some vitamin-hormone horticultural products currently make claims that EPA might regard as nitrogen stabilization claims. The result, it was asserted, would be that products specifically excluded from FIFRA would be drawn in by virtue of the nitrogen-related claims. With respect to vitamin-hormone products, EPA believes such products do not contain ingredients that would achieve the effects of a nitrogen stabilizer, i.e, an effect upon soil bacteria leading to greater nitrogen availability to plants. EPA plant pathologists believe, based upon their experience, that vitamin-hormone products contain no more than their names suggest—vitamins and hormones, which are not known to function as nitrogen stabilizers via effects upon soil bacteria. EPA has not revised the rule as a result of this comment.

This same commenter raised a second concern, which EPA agrees has merit. Certain fungi known as *mycorrhizae* have a symbiotic relationship with plant roots in the soil and are believed to have an effect on macronutrient uptake into plants. Products containing *mycorrhizae* are sold to enhance such uptake, which might include nitrogen uptake. The effect is believed not to result from action on soil bacteria, although EPA has not evaluated such products. The significant difference between *mycorrhizae* and a nitrogen stabilizer as defined in § 152.6 is that a *mycorrhizae* is a living organism, while a nitrogen stabilizer is a chemical substance. EPA has in the final rule revised § 152.6(b)(1) to exclude living organisms, which should ensure that the presence of *mycorrhizae* does not itself make a product a nitrogen stabilizer within the meaning of the Act.

*D. Labeling Revisions*

EPA proposed a number of minor revisions to its pesticide labeling regulations in 40 CFR part 156. EPA views these revisions as ''housekeeping'' provisions, intended primarily to improve the structure of the regulations to make them more understandable to users, and to clarify some requirements currently in effect but not stated in the regulations. With one exception, EPA is adopting its proposal unchanged.

1. *First aid heading.* The single area that EPA is revising as a result of comments concerns first aid statements. EPA proposed to require that the heading ''First Aid'' be used for all

products, instead of the current ''Statement of Practical Treatment.'' Agricultural product registrants who commented were concerned that they might be compelled to revise their labels for what they viewed as an unnecessarily rigid requirement They noted that the current ''Statement of Practical Treatment'' heading has been in use since 1975, and that agricultural users are familiar with the heading. EPA's research under the Consumer Labeling Initiative, on which its proposal was based, was limited to consumer products such as household cleaners, insecticides, and garden products. EPA agrees that the results may not be representative of agricultural product users, and has revised § 156.68 to allow the use of either heading. EPA encourages the use of ''First Aid'' as the heading on consumer and residential/household products, because research conducted under the Agency's Consumer Labeling Initiative revealed that consumers understood the phrase ''First Aid'' better than ''Statement of Practical Treatment.''

2. *Proposals adopted without change.* Table 1 in this unit lists the EPA proposed revisions, which, after consideration of comments, the Agency is adopting without change.

TABLE1.—PROPOSALS ADOPTED WITHOUT CHANGE

| Proposed revision | Change |
|---|---|
| Reformatting and upgrading structure of part 156 | Human hazard and precautionary statements will be located in subpart D (§ § 156.60–156.79). Environmental hazard and precautionary statements will be located in subpart E(§ § 156.80–156.99). |
| Signal word | Products in Toxicity Category IV will no longer be required to bear a signal word. The Child Hazard Warning is still required on such products. |
| Signal word | A product may not bear a signal word reflecting higher or lower toxicity than demonstrated by testing of the product as distributed and sold |
| Child Hazard Warning (Keep Out of Reach of Children) | Variations on the standard statement may be approved or required by EPA |
| Use dilution statements | Products may bear additional information in the precautionary statements and in the first aid instructions concerning the product as diluted for use. These instructions augment, but do not replace, statements concerning the product as sold or distributed. |
| First Aid Statement | All products assigned to Toxicity Category I by any route of exposure would be required to bear a First Aid or Statement of Practical Treatment on the front panel of the label. (Products assigned to Toxicity Category II or III could bear the statement on any panel of the label.) |

3. *Additional comments received.* In proposing to upgrade the codified structure, EPA included the entire content of the new subparts for convenience, including many provisions for which no substantive change was proposed. Nonetheless, some commenters suggested changes in addition to those EPA proposed. EPA has not changed the rule based on those comments. Detailed responses to all comments are contained in the public docket for this rulemaking, OPP–36195, at the location given under **ADDRESSES**.

The thrust of several comments was that EPA regulations should be made consistent with the Agency's Label Review Manual (LRM). Commenters generally ascribed to the LRM more regulatory standing than it has.

Because of the variety of pesticide products, purposes and uses, it is impossible for EPA to describe in regulatory form the majority of the individual labeling decisions that are required under the licensing scheme of FIFRA. EPA's labeling regulations in part 156 are of necessity general, serving as a framework for individual decisions and allowing flexibility for both the Agency and applicants to tailor actual labeling to the extent practicable to a particular product and its uses. The labeling regulations clearly specify in many cases that the statements provided are examples— representative or typical of the types of statements that EPA may require.

The LRM is a non-regulatory guidance document to assist applicants and the Agency in developing and reviewing labeling submitted for approval. It reflects, but does not supersede or change the underlying regulations. Its purpose is to elaborate on how the labeling regulations in part 156 can be applied in individual product decisions. EPA does not revise its regulations to conform to the LRM; rather, the LRM reflects the regulations.

## IV. Correction

In its proposal, EPA intended to reorganize existing material concerning statutory exceptions, now scattered both in FIFRA and its regulations, into a single location, new § 152.6. To accomplish this, EPA proposed to move material from existing § § 152.8, 152.20, and 152.25 to the new section. However, EPA inadvertently proposed to remove material from § 152.8 without concurrently including it in new § 152.6. The text in question concerned the statutory exclusion as ''plant regulators'' of plant nutrients, trace elements, plant inoculants and soil amendments. In this final rule, EPA has corrected this omission. Former paragraphs 152.8(c)(1), (2) and (3) now appear in § 152.6(g).

## V. Summary of Sections Affected

Table 2 in this unit summarizes the sections in the Code of Federal Regulation that are affected by this final rule, and the nature of the change.

TABLE 2.—CFR PARTS AND SECTIONS AFFECTED BY THIS FINAL RULE.

| CFR part or section number | Title | Action |
|---|---|---|
| 152.6 | Substances excluded from regulation by FIFRA | New. Material incorporated from § § 152.8, 152.20 and 152.25; Chemical sterilants added; nitrogen stabilizers added. |
| 152.8 | Products that are not pesticides because they are not for use against pests | Material moved to § 152.6. |

TABLE 2.—CFR PARTS AND SECTIONS AFFECTED BY THIS FINAL RULE.—Continued

| CFR part or section number | Title | Action |
|---|---|---|
| 152.20 | Exemptions for pesticides regulated by another Federal agency | Material moved to § 152.6; chemical sterilants added |
| 152.25 | Exemptions for pesticides of a character not requiring FIFRA regulation | Material moved to § 152.6 |
| 152.44 | Application for amended registration | Clarification and reformatting |
| 156.10 | Labeling requirements | Material moved to new subparts D and E; conforming changes |
| Part 156, subpart D (§ § 156.60–156.78) | Human Hazard and Precautionary Statements | Reorganized material from § 156.10. New material added. |
| Part 156, subpart E (§ § 156.80–156 85) | Environmental Hazards and Precautionary Statements | Reorganized material from § 156.10. No change in substance. |

## VI. Implementation of this Rule

The revisions being promulgated today will be (or have been) implemented as described in this unit. Portions of the regulations being promulgated today have been in place for some time, and are included to provide context for the reorganized and reformatted elements and for the convenience of readers.

The exclusion for liquid chemical sterilants was effective on August 3, 1996, when FIFRA was amended by the Food Quality Protection Act (FQPA). Since August 3, 1996, FDA has been responsible for the regulation of liquid chemical sterilants described by § 152.6. Codifying the exclusion is merely for the convenience of sterilant producers, and is not required for the exclusion to be effective.

The companion exemption for non-liquid chemical sterilants is self-implementing. The exemption removes the dual jurisdiction which has existed for these products, and which is being relinquished by EPA. After the effective date of this rule, non-liquid chemical sterilants described in § 152.20 will be regulated solely by FDA.

The provisions pertaining to nitrogen stabilizers were effective on August 3, 1996, when nitrogen stabilizers were made subject to FIFRA regulation. Although EPA is unaware of any products currently being marketed that are subject to this rule, it will identify such products through its compliance and inspection initiatives in the marketplace, and will apply the interpretation in § 152.6 to determine whether the products are subject to FIFRA regulation.

The provision for consolidated amendment applications is self-implementing. Applications that meet the criteria for consolidated amendments in § 152.44 may be submitted at any time.

Labeling provisions will be implemented by the Agency on a case-by-case basis, as applications for registration, amended registration, or reregistration are submitted. No specific action by any registrant is required because of the issuance of this final rule. Registrants who wish to avail themselves of any of the provisions must submit an application for amended registration to the Agency, in accordance with normal application procedures.

## VII. Statutory Requirements

In accordance with section 25 of FIFRA, a draft of this final rule was provided to the Secretary of Agriculture and to appropriate Committees of Congress. Neither had comments on the final rule. The FIFRA Scientific Advisory Panel previously had waived its review of the proposed and final rules.

## VIII. Regulatory Assessment Requirements

### *A. Executive Order 12866*

Under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' subject to review by the Office of Management and Budget (OMB). There are no costs or burdens associated with this rule. In most cases, this final rule provides regulatory relief or flexibility for pesticide producers. In the case of nitrogen stabilizer products, where the statute and this final rule potentially subject products to FIFRA regulation, EPA is not aware of any affected entities, and consequently has not identified or evaluated any costs. The Economic Analysis for the proposed rule identified costs and burdens solely associated with the antimicrobial provisions, which are being promulgated separately.

### *B. Regulatory Flexibility Act*

Under section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Agency hereby certifies that this action will not have a significant economic impact on a substantial number of small entities. Today's rule for the most part clarifies and reformats existing labeling requirements. The provisions addressing nitrogen stabilizers potentially affect small businesses, but EPA is not aware of any business entities that currently produce nitrogen stabilizer products subject to regulation under the provisions of the rule.

Information relating to this determination is provided upon request to the Chief Counsel for Advocacy of the Small Business Administration, and is included in the docket for this rulemaking. No comments were received on this determination in response to the proposal.

### *C. Paperwork Reduction Act*

This regulatory action does not contain any information collection requirements requiring approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

### *D. Unfunded Mandates Reform Act*

Under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). This action does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any one year. The cost associated with this action are described in Unit VI.A. Therefore, this action is not subject to the requirements of sections 202 and 205 of the UMRA.

### *E. Environmental Justice*

Under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), the Agency has considered environmental justice related issues with regard to the potential impacts of this action on the environmental and health conditions in low-income and

minority communities. This rule does not affect minority or low income populations.

*F. Children's Health Protection*

This action is not an economically significant action (i.e., it is not expected to have an annual adverse impact of $100 million or more) that would require additional OMB review under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

*G. Federalism*

Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

This final rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of governments specified in Executive Order 13132. Thus, Executive Order 13132 does not apply to this rule.

*H. Consultation and Coordination with Indian Tribal Governments*

This rule does not have tribal implications because it is not expected to have substantial direct effects on Indian Tribes. This does not significantly or uniquely affect the communities of Indian trial governments, nor does it involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 276755, May 19, 1998), do not apply to this rule. Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000), which took effect on January 6, 2001, revokes Executive Order 13084 as of that date. EPA developed this rulemaking, however, during the period when Executive Order 13084 was in effect; thus, EPA addressed tribal considerations under Executive Order 13084. For the same reasons stated for Executive Order 13084, the requirements of Executive Order 10175 do not apply to this rule either.

*I. Energy Effects*

This rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

**IX. Submission to Congress and the General Accounting Office**

Under 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, the Agency has submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the General Accounting Office prior to publication of this rule in today's **Federal Register**. This is not a major rule as defined by 5 U.S.C. 804(2).

**List of Subjects**

*40 CFR Part 152*

Environmental protection, Administrative practice and procedure, Pesticides and pests, Reporting and recordkeeping requirements

*40 CFR Part 156*

Environmental protection, Labeling, Occupational safety and health, Pesticides and pests, Reporting and recordkeeping requirements

Dated: November 29, 2001.

**Christine T. Whitman,**

*Administrator.*

Therefore, 40 CFR chapter I, subchapter E is amended as follows:

## PART 152—[AMENDED]

1. In part 152:

a. The authority citation for part 152 continues to read as follows:

**Authority:** 7 U.S.C. 136–136y.

b. Section 152.6 is added, to read as follows:

### § 152.6 Substances excluded from regulation by FIFRA.

Products and substances listed in this section are excluded from FIFRA regulation if they meet the specified conditions or criteria.

(a) *Liquid chemical sterilants.* A liquid chemical sterilant product is not a pesticide under section 2(u) of FIFRA if it meets all of the following criteria. Excluded products are regulated by the Food and Drug Administration (FDA). Products excluded are those meeting all of the following criteria:

(1) *Composition*. The product must be in liquid form as sold or distributed. Pressurized gases or products in dry or semi-solid form are not excluded by this provision. Ethylene oxide products are not liquid products and are not excluded by this provision.

(2) *Claims*. The product must bear a sterilant claim, or a sterilant plus subordinate level disinfection claim. Products that bear antimicrobial claims solely at a level less than ''sterilant'' are not excluded and are jointly regulated by EPA and FDA. ''Sterilant'' is defined in § 156.441 of this chapter.

(3) *Use site*. (i) The product must be intended and labeled only for use on ''critical or semi-critical devices.'' A ''critical device'' is any device which is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body. A *semi-critical device* is any device which contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body.

(ii) Liquid chemical sterilants that bear claims solely for use on non-critical medical devices are jointly regulated by EPA and FDA.

(iii) Liquid chemical sterilants that bear claims solely for use on sites that are not medical devices, such as veterinary equipment, are not excluded and are regulated solely by EPA.

(b) *Nitrogen stabilizers*. A nitrogen stabilizer is excluded from regulation under FIFRA if it is a substance (or mixture of substances), meeting all of the following criteria:

(1) The substance prevents or hinders the process of nitrification, denitrification, ammonia volatilization, or urease production through action affecting soil bacteria and is distributed and sold solely for those purposes and no other pesticidal purposes. For purposes of this section, living organisms are not considered to be substances, and the actions of living organisms are not relevant to whether a substance is deemed to be a nitrogen stabilizer.

(2) The substance was in ''commercial agronomic use'' in the United States before January 1, 1992. EPA considers a substance to be in commercial agronomic use if it is available for sale or distribution to users for direct agronomic benefit, as opposed to limited research, experimental or demonstration use.

(3) The substance was not registered under FIFRA before January 1, 1992.

(4) Since January 1, 1992, the distributor or seller has made no claim that the product prevents or hinders the process of nitrification, denitrification, ammonia volatilization or urease production. EPA considers any of the following claims (or their equivalents) to be a claim that the product prevents or hinders nitrification, denitrification, ammonia volatilization or urease production:

(i) Improves crop utilization of applied nitrogen.

(ii) Reduces leaching of applied nitrogen or reduces groundwater nitrogen contamination.

(iii) Prevents nitrogen loss.

(iv) Prolongs availability of nitrogen.

(v) Increases nitrogen uptake, availability, usage, or efficiency.

(5) A product will be considered to have met the criterion of paragraph (b)(4) of this section that no nitrogen stabilization claim has been made if:

(i) The nitrogen stabilization claim, in whatever terms expressed, is made solely in compliance with a State requirement to include the claim in materials required to be submitted to a State legislative or regulatory authority, or in the labeling or other literature accompanying the product; and

(ii) The State requirement to include the claim was in effect both before the product bearing the claim was introduced into commercial agronomic use, and before the effective date of this rule.

(6) A product that meets all of the criteria of this paragraph with respect to one State is not thereby excluded from FIFRA regulation if distributed and sold in another State whose nitrogen stabilization statement requirement does not meet the requirements of paragraph (b)(5)(ii) of this section.

(c) *Human drugs.* Fungi, bacteria, viruses or other microorganisms in or on living man are not ''pests'' as defined in section 2(t) of FIFRA. Products intended and labeled for use against such organisms are human drugs subject to regulation by the FDA under the FFDCA.

(d) *Animal drugs*—(1) Fungi, viruses, bacteria or other microorganisms on or in living animals are not ''pests'' under section 2(t) of FIFRA. Products intended for use against such organisms are ''animal drugs'' regulated by the FDA under the FFDCA.

(2) A ''new animal drug'' as defined in section 201(w) of the FFDCA, or an animal drug that FDA has determined is not a ''new animal drug'' is not a pesticide under section 2(u) of FIFRA. Animal drugs are regulated by the FDA under the FFDCA.

(e) *Animal feeds.* An animal feed containing a new animal drug is not a pesticide under section 2(u) of FIFRA. An animal feed containing a new animal drug is subject to regulation by the FDA under the FFDCA.

(f) *Vitamin hormone products.* A product consisting of a mixture of plant hormones, plant nutrients, inoculants, or soil amendments is not a ''plant regulator'' under section 2(v) of FIFRA, provided it meets the following criteria:

(1) The product, in the undiluted package concentration at which it is distributed or sold, meets the criteria of § 156.62 of this chapter for Toxicity Category III or IV; and

(2) The product is not intended for use on food crop sites, and is labeled accordingly.

(g) *Products intended to aid the growth of desirable plants.* A product of any of the following types, intended only to aid the growth of desirable plants, is not a ''plant regulator'' under section 2(v) of FIFRA, and therefore is not a pesticide:

(1) A plant nutrient product, consisting of one or more macronutrients or micronutrient trace elements necessary to normal growth of plants and in a form readily usable by plants.

(2) A plant inoculant product consisting of microorganisms to be applied to the plant or soil for the purpose of enhancing the availability or uptake of plant nutrients through the root system.

(3) A soil amendment product containing a substance or substances intended for the purpose of improving soil characteristics favorable for plant growth.

**§ 152.8 [Amended]**

c. In § 152.8, by removing paragraphs (a), (b), (c) introductory text, (c)(2), (c)(3) and (c)(4), and redesignating paragraph (c)(1) as paragraph (a) and paragraph (d) as paragraph (b).

d. In § 152.20, by revising paragraph (b) to read as follows:

**§ 152.20 Exemptions for pesticides regulated by another Federal agency.**

* * * * *

(b) *Non-liquid chemical sterilants.* A non-liquid chemical sterilant, except ethylene oxide, that meets the criteria of § 152.6(a)(2) with respect to its claims and § 152.6(a)(3) with respect to its use sites is exempted from regulation under FIFRA.

**§ 152.25 [Amended]**

e. Section 152.25 is amended by removing paragraph (d) and redesignating paragraphs (e) through (g) as (d) through (f).

f. Section 152.44 is amended by removing paragraph (b)(3), redesignating paragraph (b)(4) as paragraph (b)(3), and adding new paragraph (c), to read as follows:

**§ 152.44 Application for amended registration.**

* * * * *

(c) A registrant may at any time submit identical minor labeling amendments affecting a number of products as a single application if no data are required for EPA to approve the amendment (for example, a change in the wording of a storage statement for designated residential use products). A consolidated application must clearly identify the labeling modification(s) to be made (which must be identical for all products included in the application), list the registration number of each product for which the modification is requested, and provide required supporting materials (for example, labeling) for each affected product.

## PART 156—[AMENDED]

2. In part 156:

a. The authority citation for part 156 continues to read as follows:

**Authority:** 7 U.S.C. 136–136y.

b. In § 156.10, by revising paragraph (a)(1)(vii) and removing paragraph (h), to read as follows:

**§ 156.10 Labeling requirements.**

(a) * * *

(1) * * *

(vii) Hazard and precautionary statements as prescribed in subpart D of this part for human and domestic animal hazards and subpart E of this part for environmental hazards.

* * * * *

c. By adding new subpart D, to read as follows:

**Subpart D—Human Hazard and Precautionary Statements**

Sec.

## Subpart D—Human Hazard and Precautionary Statements

### § 156.60 General.

Each product label is required to bear hazard and precautionary statements for humans and domestic animals (if applicable) as prescribed in this subpart. Hazard statements describe the type of hazard that may occur, while precautionary statements will either direct or inform the user of actions to take to avoid the hazard or mitigate its effects.

(a) *Location of statements*—(1) *Front panel statements.* The signal word, child hazard warning, and, in certain cases, the first aid statement are required to appear on the front panel of the label, and also in any supplemental labeling intended to accompany the product in distribution or sale.

(2) *Statements elsewhere on label.* Hazard and precautionary statements not required on the front panel may appear on other panels of the label, and may be required also in supplemental labeling. These include, but are not limited to, the human hazard and precautionary statements, domestic animal statements if applicable, a Note to Physician, and physical or chemical hazard statements.

(b) *Placement and prominence*—(1) *Front panel statements.* All required front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The table below shows the minimum type size requirements for the front panel warning statements for various front panel sizes.

TYPE SIZES FOR FRONT PANEL WARNING STATEMENTS

| Size of Label Front Panel (Square Inches) | Point Size | |
|---|---|---|
| | Signal Word (All Capital Letters) | Child Hazard Warning |
| 5 and under .... | 6 | 6 |
| Over 5 to 10 .... | 10 | 6 |
| Over 10 to 15 .. | 12 | 8 |
| Over 15 to 30 .. | 14 | 10 |
| Over 30 ..... | 18 | 12 |

(2) *Other required statements.* All other hazard and precautionary statements must be at least 6 point type.

### § 156.62 Toxicity Category.

This section establishes four Toxicity Categories for acute hazards of pesticide products, Category I being the highest toxicity category. Most human hazard, precautionary statements, and human personal protective equipment statements are based upon the Toxicity Category of the pesticide product as sold or distributed. In addition, toxicity categories may be used for regulatory purposes other than labeling, such as classification for restricted use and requirements for child-resistant packaging. In certain cases, statements based upon the Toxicity Category of the product as diluted for use are also permitted. A Toxicity Category is assigned for each of five types of acute exposure, as specified in the table in this paragraph.

ACUTE TOXICITY CATEGORIES FOR PESTICIDE PRODUCTS

| Hazard Indicators | I | II | III | IV |
|---|---|---|---|---|
| Oral $LD_{50}$ ..... | Up to and including 50 mg/kg | >50 thru 500 mg/kg | >500 thru 5,000 mg/kg | >5,000 mg/kg |
| Dermal $LD_{50}$ ..... | Up to and including 200 mg/kg | >200 thru 2000 mg/kg | >2000 thru 20,000 mg/kg | >20,000 mg/kg |
| Inhalation $LC_{50}$ ..... | Up to and including 0.2 mg/liter | >0.2 thru 2 mg/liter | >2 thru 20 mg/liter | >20 mg/liter |
| Eye irritation ..... | Corrosive; corneal opacity not reversible within 7 days | Corneal opacity reversible within 7 days; irritation persisting for 7 days | No corneal opacity; irritation reversible within 7 days | No irritation |
| Skin irritation ..... | Corrosive | Severe irritation at 72 hours | Moderate irritation at 72 hours | Mild or slight irritation at 72 hours |

### § 156.64 Signal word.

(a) *Requirement.* Except as provided in paragraph (a)(4), each pesticide product must bear on the front panel a signal word, reflecting the highest Toxicity Category (Category I is the highest toxicity category) to which the product is assigned by any of the five routes of exposure in § 156.62. The signal word must also appear together with the heading for the human precautionary statement section of the labeling (see § 156.70).

(1) *Toxicity Category I.* Any pesticide product meeting the criteria of Toxicity Category I for any route of exposure must bear on the front panel the signal word ''DANGER.'' In addition, if the product is assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye irritation), the word ''Poison'' must appear in red on a background of distinctly contrasting color, and the skull and crossbones symbol must appear in immediate proximity to the word ''Poison.''

(2) *Toxicity Category II.* Any pesticide product meeting the criteria of Toxicity Category II as the highest category by any route of exposure must bear on the front panel the signal word ''WARNING.''

(3) *Toxicity Category III.* Any pesticide product meeting the criteria of Toxicity Category III as the highest category by any route of exposure must bear on the front panel the signal word ''CAUTION.''

(4) *Toxicity Category IV.* A pesticide product meeting the criteria of Toxicity Category IV by all routes of exposure is not required to bear a signal word. If a signal word is used, it must be ''CAUTION.''

(b) *Use of signal words.* In no case may a product:

(1) Bear a signal word reflecting a higher Toxicity Category than indicated by the route of exposure of highest toxicity, unless the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment;

(2) Bear a signal word reflecting a lesser Toxicity Category associated with a diluted product. Although precautionary statements for use dilutions may be included on label, the signal word must reflect the toxicity of the product as distributed or sold; or

(3) Bear different signal words on different parts of the label.

**§ 156.66 Child hazard warning.**

(a) Each pesticide product must bear on the front panel of the label the statement ''Keep Out of Reach of Children.'' That statement, or any alternative statement approved by EPA, must appear on a separate line in close proximity to the signal word, if required. The statement is required on Toxicity Category IV products that do not otherwise require a signal word.

(b) In its discretion, EPA may waive the requirement, or require or permit an alternative child hazard warning, if:

(1) The applicant can demonstrate that the likelihood of exposure of children to the pesticide during distribution, marketing, storage or use is remote (for example, an industrial use product); or

(2) The pesticide is approved for use on children (for example, an insect repellent).

(c) EPA may approve an alternative child hazard warning that more appropriately reflects the nature of the pesticide product to which children may be exposed (for example, an impregnated pet collar). In this case, EPA may also approve placement on other than the front panel.

**§ 156.68 First aid statement.**

(a) *Product as sold and distributed.* Each product must bear a first aid statement if the product has systemic effects in Category I, II, or III, or skin or eye irritation effects in Category I or II.

(b) *Product as diluted for use.* If the product labeling bears directions for dilution with water prior to use, the label may also include a statement describing how the first aid measures may be modified for the diluted product. Such a statement must reflect the Toxicity Category(ies) of the diluted product, based upon data for the route of exposure (or calculations if appropriate). If the labeling provides for a range of use dilutions, only that use dilution representing the highest concentration allowed by labeling may be used as the basis for a statement pertaining to the diluted product. The statement for a diluted product may not substitute for the statement for the concentrate, but augments the information provided for the concentrate.

(c) *Heading.* The heading of the statement may be ''First Aid'' or ''Statement of Practical Treatment.''

(d) *Location of first aid statement.* The first aid statement must appear on the front panel of the label of all products assigned to Toxicity Category I by any route of exposure. Upon review, the Agency may permit reasonable variations in the placement of the first aid statement if a reference such as ''See first aid statement on back panel'' appears on the front panel. The first aid statement for products assigned to Toxicity Categories II or III may appear on any panel of the label.

**§ 156.70 Precautionary statements for human hazards.**

(a) *Requirement.* Human hazard and precautionary statements as required must appear together on the label or labeling under the general heading ''Precautionary Statements'' and under appropriate subheadings similar to ''Humans and Domestic Animals,'' ''Environmental Hazards'' (see subpart E of this part) and ''Physical or Chemical Hazards.'' The phrase ''and Domestic Animals'' may be omitted from the heading if domestic animals will not be exposed to the product.

(b) *Content of statements.* When data or other information show that an acute hazard may exist to humans or domestic animals, the label must bear precautionary statements describing the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or toxic effect or to mitigate the effect. The precautionary paragraph must be immediately preceded by the appropriate signal word.

(c) *Typical precautionary statements.* The table below presents typical hazard and precautionary statements. Specific statements pertaining to the hazards of the product and its uses must be approved by the Agency. With Agency approval, statements may be augmented to reflect the hazards and precautions associated with the product as diluted for use. Refer to § 156.68(b) for requirements for use dilution statements.

TYPICAL HUMAN HAZARD AND PRECAUTIONARY STATEMENTS

| Toxicity Category | Systemic effects (oral, dermal, inhalation toxicity) | Irritation effects (skin and eye) | Sensitizer (There are no categories of sensitization.) |
|---|---|---|---|
| I | Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Front panel first aid statement required.] | Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Front panel first aid statement required.] | If product is a sensitizer: Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. |
| II | May be fatal if swallowed, [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statement required.] | Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.] | |
| III | Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.] | Avoid contact with skin, eyes or clothing. | |
| IV | No precautionary statements required | No precautionary statements required. | |

**§ 156.78 Precautionary statements for physical or chemical hazards.**

(a) *Requirement.* Warning statements on the flammability or explosive characteristics of the pesticide product are required if a product meets the criteria in this section. Warning statements pertaining to other physical/chemical hazards (e.g., oxidizing potential, conductivity, chemical reactions leading to production of toxic substances) may be required on a case-by-case basis.

(b) *Pressurized products.* The table below sets out the required flammability label statements for pressurized products.

FLAMMABILITY STATEMENTS FOR PRESSURIZED PRODUCTS

| Flash point/flame extension of product | Required labeling statement |
|---|---|
| —Flash point at or below 20° F<br><br>OR<br><br>—Flashback at any valve opening | *Extremely flammable*. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting. |
| —Flash point >20° F to 80° F<br><br>OR<br><br>—Flame extension more than 18 in. long at a distance of 6 in from the flame | *Flammable*. Contents under pressure. Keep away from heat, sparks and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting. |
| All other pressurized products | *Contents under pressure*. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting. |

(c) *Non-pressurized products.* The table below sets out the required flammability label statements for non-pressurized products.

FLAMMABILITY STATEMENTS FOR NON-PRESSURIZED PRODUCTS

| Flash point | Required labeling statement |
|---|---|
| At or below 20° F | *Extremely flammable*. Keep away from fire, sparks and heated surfaces. |
| Greater than 20° F to 80° F | *Flammable*. Keep away from heat and open flame. |
| Greater than 80° F to 150° F | *Combustible*. Do not use or store near heat or open flame. |

(d) *Total release fogger products.* (1) A *total release fogger* is defined as a pesticide product in a pressurized container designed to automatically release the total contents in one operation, for the purpose of creating a permeating fog within a confined space to deliver the pesticide throughout the space.

(2) If a pesticide product is a total release fogger containing a propellant with a flash point at or below 20° F, then the following special instructions must be added to the ''Physical and Chemical Hazards'' warning statement, in addition to any flammability statement required by paragraph (b) of this section:

This product contains a highly flammable ingredient. It may cause a fire or explosion if not used properly. Follow the Directions for Use on this label very carefully.

(3) A graphic symbol depicting fire, such as illustrated in this paragraph, or an equivalent symbol, must be displayed along with the required language adjoining the ''Physical and Chemical Hazards'' warning statement. The graphic symbol must be no smaller than twice the size of the first character of the human hazard signal word.

Highly Flammable Ingredient

Ingrediente Altamente Inflamable

d. By adding new subpart E, to read as follows:

**Subpart E—Environmental Hazard and Precautionary Statements**

Sec.



## Subpart E—Environmental Hazard and Precautionary Statements

**§ 156.80 General.**

(a) *Requirement.* Each product is required to bear hazard and precautionary statements for environmental hazards, including hazards to non-target organisms, as prescribed in this subpart. Hazard statements describe the type of hazard that may be present, while precautionary statements direct or inform the user of actions to take to avoid the hazard or mitigate its effects.

(b) *Location of statements.* Environmental hazard and precautionary statements may appear on any panel of the label and may be required also in supplemental labeling. The environmental hazard statements must appear together under the heading ''Environmental Hazards.'' Typically the statements are grouped as a sub-category within the ''Precautionary Statements'' section of the labeling.

(c) *Type size.* All environmental hazard and precautionary statements must be at least 6 point type.

**§ 156.85 Non-target organisms.**

(a) *Requirement.* Where a hazard exists to non-target organisms, EPA may require precautionary statements of the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage.

(b) *Examples.* The statements in this paragraph illustrate the types of hazard statements that EPA may require and the circumstances under which they are typically required. These statements are not comprehensive; other statements may be required if more appropriate to the formulation or use.

(1) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral $LD_{50}$ of 100 mg/kg or less, the statement, ''This pesticide is toxic to wildlife'' is required.

(2) If a pesticide intended for outdoor use contains an active ingredient with a fish acute $LC_{50}$ of 1 ppm or less, the statement, ''This pesticide is toxic to fish'' is required.

(3) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral $LD_{50}$ of 100 mg/kg or less, or a subacute dietary $LC_{50}$ of 500 ppm or less, the statement, ''This pesticide is toxic to wildlife'' is required.

(4) If either accident history or field studies demonstrate that the use of the pesticide may result in fatality to birds, fish or mammals, the statement, ''This pesticide is extremely toxic to wildlife (fish)'' is required.

(5) If a product is intended for or involves foliar application to agricultural crops, forests or shade trees, or mosquito abatement treatments, and contains a pesticide toxic to pollinating insects, the label must bear appropriate label cautions.

(6) If a product is intended for outdoor use other than aquatic applications, the label must bear the caution, ''Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes.''

[FR Doc. 01–30820 Filed 12–13–01; 8:45 am]

BILLING CODE 6560–50–S

## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Part 180

**[OPP–301194; FRL–6814–2]**

**RIN 2070–AB78**

## Extension of Tolerances for Emergency Exemptions; Multiple Chemicals

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation extends time-limited tolerances for the various pesticides listed in this document. These actions are in response to EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of these pesticides. Section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA) requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA.

**DATES:** This regulation is effective December 14, 2001. Objections and requests for hearings, identified by docket control number OPP–301194, must be received by EPA on or before January 14, 2002.

**ADDRESSES:** Written objections and hearing requests may be submitted by mail, electronically, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit III. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301194 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** See the listing below for the name of a specific contact person. The following information applies to all contact persons: Emergency Response Team, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–9366.

| Pesticide/CFR cite | Contact person |
|---|---|
| Maneb, 180.110<br>Zinc phosphide, 180.284<br>Clopyralid, 180.431<br>Propiconazole, 180.434<br>Fenpropathrin, 180.466<br>Imazapic-ammonium, 180.490 | Libby Pemberton<br>pemberton.libby@epa.gov |
| Avermectin, 180.449<br>Difenoconazole, 180.475 | Dan Rosenblatt<br>rosenblatt.dan@epa.gov |
| Carboxin, 180.301<br>Propyzamide, 180.317<br>Metolachlor, 180.368<br>Metsulfuron-methyl, 180.428<br>Bifenthrin, 180.442<br>HOE 107892, 180.509<br>Fludioxonil, 180. 516 | Andrew Ertman<br>ertman.andrew@epa.gov |
| Fenbuconazole, 40 CFR 180.480 | Shaja R. Brothers<br>brothers.shaja @epa.gov |
| Cyprodinil, 180.532<br>Desmidipham, 180.353 | Stephen Schaible<br>schaible.stephen@epa.gov |
| Mancozeb, 180.176<br>Thiabendazole, 180.242<br>Emamectin benzoate, 180.505 | Meredith Laws<br>laws.meredith@epa.gov |
| Tebuconazole, 180.474 | Andrea Conrath<br>conrath.andrea@epa.gov |

**SUPPLEMENTARY INFORMATION:**

### I. General Information

*A. Does this Action Apply to Me?*

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to: