

TABLE—EUP MICROBIAL PESTICIDES NONTARGET ORGANISMS AND ENVIRONMENTAL FATE DATA REQUIREMENTS

Guideline Number	Data Requirement	Use Patterns								Test Substance	Test Notes
		Aquatic		Terrestrial							
				Food/Feed/Nonfood	For-estry	Resi-dential	Green-house	Indoor	In-dus-trial		
Food/Feed	Nonfood	Out-door	Food/Nonfood			Food/Nonfood					
885.4050	Avian oral toxicity	NR	R	R	R	R	NR	NR	NR	TGAI	1, 2
885.4200	Freshwater fish toxicity/pathogenicity	NR	R	R	R	NR	NR	NR	NR	TGAI	1, 2, 3
885.4240	Freshwater invertebrate toxicity/pathogenicity	NR	R	R	R	NR	NR	NR	NR	TGAI	1, 2, 3
885.4300	Nontarget plant testing	NR	NR	NR	R	NR	NR	NR	NR	TEP	1, 4
885.4340	Nontarget insect testing	R	R	R	R	NR	NR	NR	NR	TGAI	1, 5
885.4380	Honey bee testing	R	R	R	R	NR	NR	NR	NR	TGAI	1

(e) *Test notes.* The following test notes are applicable to the data requirements for microbial pesticides nontarget organism and environmental fate as referenced in the last column of the table contained in paragraph (d) of this section.

1. Tests for pesticides intended solely for indoor application would be required on a case-by-case basis, depending on use pattern, production volume, and other pertinent factors. Tests to support EUP's are based on the application timing and acreage.

2. The preferred species for the avian oral study is either the upland game or waterfowl. The preferred species for the avian inhalation toxicity/pathogenicity study and the avian chronic toxicity/pathogenicity study is the upland game. There is also the option to test a passerine species if there is a concern. The coldwater fish is preferred for freshwater fish testing. However, two species (coldwater and warmwater fish are the preferred species) must be tested for uses involving direct freshwater exposure. Freshwater invertebrates are preferred for invertebrate testing.

3. Required when there will be significant exposure to aquatic organisms (fish and invertebrates).

4. Required if the microbial pesticide is taxonomically related to a known plant pathogen.

5. Data are not required unless an active microbial ingredient controls the target insect pest by a mechanism of infectivity; i.e. may create an epizootic condition in nontarget insects.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 152, 156, 159, 160, 168 and 172

[EPA-HQ-OPP-2004-0387; FRL-8114-1]

Pesticide Data Requirements; Technical Amendments

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This document makes technical changes and revises cross references in the Code of Federal Regulations (CFR) to reflect changes in pesticide data requirements being promulgated elsewhere in today's **Federal Register**. These technical changes are solely to conform other parts of the CFR to the new rules, and have no substantive impact on any requirements. This regulation is a technical amendment which requires no opportunity for comment or public participation.

DATES: This final rule is effective December 26, 2007.

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2004-0387. To access the electronic docket, go to <http://www.regulations.gov>, select "Advanced Search," then "Docket Search." Insert the docket ID number where indicated and select the "Submit" button. Follow the instructions on the www.regulations.gov web site to view the docket index or access available documents. All

documents in the docket are listed in the docket index available in www.regulations.gov. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Public Docket, in Rm. S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Jean Frane, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-5944; fax number: (703) 305-5884; e-mail address: frane.jean@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Does this Action Apply to Me

You may be potentially affected by this action if you are a producer or registrant of a pesticide product. This action may also affect any person or company who might petition the Agency for new tolerances, hold a pesticide registration with existing tolerances, or any person or company

who is interested in obtaining or retaining a tolerance in the absence of a registration, that is, an import tolerance. Potentially affected entities may include, but are not limited to:

- Pesticide Producers (NAICS code 32532), e.g., pesticide manufacturers or formulators of pesticide products, importers or any person or company who seeks to register a pesticide or to obtain a tolerance for a pesticide.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) code has been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the persons listed under **FOR FURTHER INFORMATION CONTACT**.

II. Background

In the **Federal Register** of March 11, 2005 [70 FR 12276] and March 8, 2006 [71 FR 12072], EPA proposed to amend pesticide data requirements in 40 CFR part 158 for conventional pesticides and for biochemical and microbial pesticides, respectively. EPA is today issuing final rules for both proposals. In order to preserve existing data requirements for antimicrobial pesticides, that were contained in part 158, but not proposed for revision, EPA issued a final rule on October 24, 2007, transferring the bulk of current part 158 to new part 161. Together part 158 and part 161 contain the entirety of pesticide data requirements previously contained only in part 158.

This final rule makes certain technical changes and corrects cross-references elsewhere in pesticide regulations to conform to new parts 161 and 158. By issuing a separate technical changes rule, EPA intends that the promulgation of the substantive revisions for conventional, biochemical and microbial pesticide data requirements will be straightforward without confusing technical changes. The key changes are:

1. *Formulators' Exemption*. EPA has consolidated requirements and policies for the formulators' exemption into part 152. EPA has combined existing material from § 152.85 and § 158.50 in one location (§ 152.85) and made minor conforming changes to reflect the consolidation. The consolidation is discussed in detail in the final rule for conventional pesticides.

2. *Cross-reference changes*. Cross-references in parts 152, 156, 159, 160, 168 and 172 are being revised to reflect the new data requirements structure of part 158 and part 161. The majority of these changes reflect the addition of new part 161 for antimicrobial pesticides. Others are revised to reflect the new definition of biochemical or microbial pesticide.

III. Why are these Technical Revisions Issued as a Final Rule?

Section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553(b)(B), provides that, when an Agency for good cause finds that notice and public procedure are impracticable, unnecessary or contrary to the public interest, the Agency may issue a final rule without providing notice and an opportunity for public comment. EPA has determined that it is unnecessary to make today's rule final without prior proposal and opportunity for comment, because EPA is simply making corrections to cross-references for accuracy. EPA finds that this constitutes good cause under 5 U.S.C. 553(b)(B).

IV. Regulatory Assessment Requirements

This rule makes technical changes and cross-reference corrections in the EPA regulations governing pesticides. The amendments are administrative in nature and, for the most part, amend the CFR so that it is consistent with regulations concerning data requirements being promulgated elsewhere in this issue of the **Federal Register**. Other than making EPA regulations more accurate, these amendments are not expected to have any impact on regulated parties or the public.

Accordingly, these amendments are not subject to review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), as a significant regulatory action. Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any special considerations under

Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Since this action is not subject to notice and comment requirements under the Administrative Procedure Act or any other statute, it is not subject to the regulatory flexibility provisions of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.).

In addition, the Agency has determined that this action will not have a substantial direct effect on 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, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 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 rule is directed at pesticide manufacturers and others who seek to register, amend or maintain a registration or to establish, modify, or revoke pesticide tolerances or exemptions, not States. For these same reasons, the Agency has determined that this rule does not have any "tribal implications" as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." "Policies that have tribal implications" is defined in the

Executive Order to include regulations that have “substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.” This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

V. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and the Comptroller General of the United States. EPA will submit 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 United States prior to publication of the rule in the **Federal Register**. This rule is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 152

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

List of Subjects in 40 CFR Part 156

Environmental protection, Labeling, Pesticides and pests, Reporting and recordkeeping requirements.

List of Subjects in 40 CFR Part 159

Environmental protection, Pesticides and pests, Reporting and recordkeeping requirements.

List of Subjects in 40 CFR Part 160

Environmental protection, Laboratories, Pesticides and pests, Reporting and recordkeeping requirements.

List of Subjects in 40 CFR Part 168

Environmental protection, Administrative practice and procedure, Advertising, Exports, Labeling, Pesticides and pests, Reporting and recordkeeping requirements.

List of Subjects in 40 CFR Part 172

Environmental protection, Intergovernmental relations, Labeling, Pesticides and pests, Reporting and recordkeeping requirements, Research.

Dated: October 11, 2007.

James B. Gulliford,

Assistant Administrator, Office of Prevention, Pesticides, and Toxic Substances.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 152—[AMENDED]

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

Authority: 7 U.S.C. 136–136y. Subpart U is also issued under 31 U.S.C. 9701.

■ 2. Section 152.20 is amended by revising paragraph (a)(3) to read as follows:

§ 152.20 Exemptions for pesticides regulated by another Federal agency.

* * * * *

(a) * * *

(3) The following biological control agents are not exempt from FIFRA requirements:

(i) A eucaryotic microorganism including, but not limited to, protozoa, algae and fungi;

(ii) A procaryotic microorganism including, but not limited to, Eubacteria and Archaeobacteria; or

(iii) A parasitically-replicating microscopic element, including, but not limited to, viruses.

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■ 3. Section 152.43 is amended by revising paragraph (b)(4) to read as follows:

§ 152.43 Alternative formulations.

* * * * *

(b) * * *

(4) The analytical method required under § 158.355 of this chapter must be suitable for use on both the basic formulation and the alternate formulation.

* * * * *

■ 4. Amend § 152.50 in paragraph (f)(1) by revising the reference to “FIFRA sec. 3(c)(1)(D)” to read “FIFRA sec. 3(c)(1)(F)”, and by revising paragraph (c) and paragraph (f)(2) to read as follows:

§ 152.50 Contents of application.

* * * * *

(c) *Summary of the application.* Each application must include a list of the data submitted with the application, together with a brief description of the results of the studies. The list of data submitted may be the same as the list

required by § 158.32 or § 161.32, as applicable, of this chapter. The summary must state that it is releasable to the public after registration in accordance with § 152.119.

* * * * *

(f) * * *

(2) An applicant must furnish any data specified in part 158 or part 161 of this chapter, as applicable, of this chapter which are required by the Agency to determine that the product meets the registration standards of FIFRA sec. 3(c)(5) or (7). Each study must comply with:

(i) Section 158.32 of this chapter, with respect to format of data submission.

(ii) Section 158.33 of this chapter, with respect to studies for which a claim of trade secret or confidential business information is made.

(iii) Section 158.34 of this chapter, with respect to flagging for potential adverse effects.

(iv) Section 160.12 of this chapter, with respect to a statement whether studies were conducted in accordance with Good Laboratory Practices of part 160.

* * * * *

■ 5. Revise § 152.85 to read as follows:

§ 152.85 Formulators' exemption.

(a) *Statutory provision.* FIFRA section 3(c)(2)(D) excuses an applicant from the requirement to submit or cite data pertaining to any pesticide contained in his product that is derived solely from one or more EPA-registered products which the applicant purchases from another person. This provision is commonly referred to as the formulators' exemption.

(b) *Applicability of the formulators' exemption.* (1) The formulators' exemption applies only to data concerning the purchased product or its ingredients. These data may include, but are not limited to, product chemistry, toxicology, residue chemistry, exposure, environmental fate, and ecological effects.

(2) The data to which the formulators' exemption applies usually will concern the safety of one or more of the product's active ingredients, specifically, those active ingredients which are contained in the purchased product. In general, data for which the required test substance is the technical grade of the active ingredient, the pure active ingredient, the radiolabeled pure active ingredient, or a typical end-use product are eligible for the formulators' exemption.

(3) The formulators' exemption generally does not apply to data on the applicant's product itself, including the

safety or efficacy of the product, unless the composition of the product is identical to the purchased product. In general, data for which the required test substance is the product proposed for registration are not eligible for the formulators' exemption.

(c) *Limitation of the formulators' exemption.* EPA interprets FIFRA section 3(c)(2)(D) as allowing an applicant to use the formulators' exemption with respect to data concerning an ingredient of his product only if:

(1) The application indicates that the ingredient's presence in the product is attributable solely to the purchase from another person of an identified, registered product containing that ingredient and the use of the purchased product in formulating the product; and

(2) The purchased product is a registered manufacturing-use product whose label does not prohibit its use for making an end-use product labeled for any use for which the applicant's product will be labeled; or

(3) The purchased product is a registered end-use product labeled for each use for which the applicant's product will be labeled.

(d) *Claiming eligibility for the exemption.* (1) If the product contains one or more ingredients eligible for the formulators' exemption, the applicant need not comply with the requirements of §§ 152.90 through 152.96 with respect to any data requirement pertaining to such ingredient, provided that he submits to the Agency a certification statement containing the following information (a form for this purpose is available from the Agency):

(i) Identification of the applicant, and of the product by EPA registration number or file symbol.

(ii) Identification of each ingredient in the pesticide that is eligible for the formulators' exemption, and the EPA registration number of the product that is the source of that ingredient.

(iii) A statement that the listed ingredients meet the requirements for the formulators' exemption.

(iv) A statement that the applicant has submitted (either previously or with the current application) a complete, accurate and current Confidential Statement of Formula.

(v) The name, title and signature of the applicant or his authorized representative and the date of signature.

(2) An applicant for amended registration is not required to submit a new formulators' exemption statement, if the current statement in Agency files is complete and accurate.

(e) *Approval of registration.* Notwithstanding FIFRA section

3(c)(2)(D), EPA will not approve an application unless there are available to EPA for its review all data that are necessary to make the required risk/benefit finding under FIFRA section 3(c)(5) or section 3(c)(7).

■ 6. Revise § 152.90(a)(2) to read as follows:

§ 152.90 The selective method.

* * * * *

(a) * * *

(2) If a Registration Standard has not been issued, or if an issued Registration Standard does not cover all data requirements for products containing the active ingredient in question, the applicant must list the applicable requirements as prescribed by 40 CFR part 158 or part 161, as applicable. All required (R) studies, and any studies that could be conditionally required (CR) based upon composition, use pattern, or the results of required studies, are to be listed. The applicant may demonstrate via the data gap procedures in § 152.96 that a conditional requirement need not be satisfied by the submission or citation of data at the time of application.

* * * * *

§ 152.91 [Amended]

■ 7. In § 152.91(b) revise the reference "40 CFR 158.45" to read "40 CFR 158.45 or 40 CFR 161.45".

■ 8. Revise § 152.97(a)(2)(iii) to read as follows:

§ 152.97 Rights and obligations of data submitters.

(a) * * *

(2) * * *

(iii) For each such active ingredient, the type(s) of study he has previously submitted (corresponding to Guidelines reference numbers given in tables in 40 CFR part 158 or part 161, as applicable), the date of submission, and the EPA registration number, file symbol, or other identifying reference for which it was submitted.

* * * * *

■ 9. Revise § 152.104 to read as follows:

§ 152.104 Completeness of applications.

The applicant is responsible for the accuracy and completeness of all information submitted in connection with the application. The Agency will review each application to determine whether it is complete. An application is incomplete if any pertinent item specified in § 152.50 has not been submitted, or has been incorrectly submitted (for example, data required by part 158, or part 161 of this chapter, as applicable, and not submitted in

accordance with the requirements for format, claims of confidential business information, or flagging).

§ 152.107 [Amended]

■ 10. In § 152.107(b)(3) revise the reference "\$ 158.34 of this chapter" to read "\$ 158.34 or § 161.34 of this chapter".

■ 11. Revise § 152.112(d) to read as follows:

§ 152.112 Approval of registration under FIFRA sec. 3(c)(5).

* * * * *

(d) The Agency has determined that the composition of the product is such as to warrant the proposed efficacy claims for it, if efficacy data are required to be submitted by part 158 or part 161, as applicable, of this chapter for the product.

* * * * *

■ 12. Revise § 152.403(b) to read as follows:

§ 152.403 Definitions of fee categories.

* * * * *

(b) *New biochemical and microbial registration review* means review of an application for registration of a biochemical or microbial pesticide product containing a biochemical or microbial active ingredient not contained in any other pesticide product that is registered under FIFRA at the time the application is made. For purposes of this subpart, the definitions of biochemical and microbial pesticides contained in § 158.2000 and § 158.2100, respectively, shall apply.

* * * * *

PART 156—[AMENDED]

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

Authority: 7 U.S.C. 136–136y.

§ 156.208 [Amended]

■ 14. In § 156.208(e)(1) revise the reference to "\$ 158.390" to read "\$ 158.1070 or § 161.390".

PART 159—[AMENDED]

■ 15. The authority citation for part 159 continues to read as follows:

Authority: 7 U.S.C. 136–136y.

§ 159.156 [Amended]

■ 16. Section 159.156 is amended as follows:

■ a. In paragraph (e) revise the reference to "\$ 158.32 of this chapter" to read "\$ 158.32 or § 161.32 of this chapter, as applicable".

■ b. In paragraph (g) revise the reference to “§ 158.33 of this chapter” to read “§ 158.33 or § 161.33 of this chapter, as applicable”.

■ c. In paragraph (h) revise the reference to “§ 158.34 of this chapter” to read “§ 158.34 or § 161.34 of this chapter, as applicable”.

■ 17. Revise § 159.188(a)(2) to read as follows:

§ 159.188 Failure of performance information.

(a) * * *

(2) A study which indicates that the pesticide may not perform in accordance with one or more claims made by the registrant regarding uses intended for control of microorganisms that may pose a risk to human health, including any of the public health antimicrobials identified in part 161 of this chapter.

* * * * *

PART 160—[AMENDED]

■ 18. The authority citation for part 160 continues to read as follows:

Authority: 7 U.S.C. 136a, 136c, 136d, 136f, 136j, 136v, 136w; 21 U.S.C. 346a, 348, 371, Reorganization Plan No. 3 of 1970.

■ 19. In § 160.3, revise the definition for the term “Study” to read as follows:

§ 160.3 Definitions.

* * * * *

Study means any experiment at one of more test sites, in which a test substance is studied in a test system under laboratory conditions or in the environment to determine or help predict its effects, metabolism, product performance (efficacy studies only as required by 40 CFR 158.400 or 161.640, as applicable), environmental and

chemical fate, persistence and residue, or other characteristics in humans, other living organisms, or media. The term “study” does not include basic exploratory studies carried out to determine whether a test substance or a test method has any potential utility.

* * * * *

PART 168—[AMENDED]

■ 20. The authority citation for part 168 continues to read as follows:

Authority: 7 U.S.C. 136–136y.

■ 21. Section 168.75 is amended by revising the reference in paragraph (b)(4)(ii) to “§ 158.640 of this chapter” to read “§ 158.400 or § 161.640 of this chapter, as applicable”, and by revising paragraph (b)(3)(ii) to read as set follows:

§ 168.75 Procedures for exporting unregistered pesticides—purchaser acknowledgement statements.

* * * * *

(b) * * *

(3) * * *

(ii) An exporter who is also the manufacturer of a U.S. registered pesticide may add new uses to the label of that product for export purposes, without triggering the requirements of section 17(a)(2), as long as the new uses are within the same general use patterns as those for the registered product. The general pesticide use patterns are: terrestrial food crop and terrestrial non-food crop; greenhouse food crop and greenhouse nonfood crop; aquatic food crop and aquatic nonfood crop; indoor use and forestry use. Adding new uses to the label which change the use pattern, such as changes from nonfood to food use, outdoor to indoor use, or terrestrial to aquatic use, render the

product unregistered and subject to the requirements of section 17 for unregistered products. If the new use added to the label is a food or feed use, a tolerance must already be established for the use of that pesticide in or on that commodity.

* * * * *

PART 172—[AMENDED]

■ 22. The Authority citation for part 172 continues to read as follows:

Authority: 7 U.S.C. 136c, 136w. Section 172.4 is also issued under 31 U.S.C. 9701.

■ 23. In § 172.43 revise the definition for “microbial pesticide” to read as follows:

§ 172.43 Definitions.

* * * * *

Microbial pesticide means a microbial agent intended for preventing, destroying, repelling, or mitigating any pest, or intended for use as a plant regulator, defoliant, or desiccant, that:

(1) Is a eucaryotic microorganism including, but not limited to, protozoa, algae and fungi;

(2) Is a procaryotic microorganism, including, but not limited to, Eubacteria and Archaeobacteria; or

(3) Is a parasitically replicating microscopic element, including, but not limited to, viruses.

* * * * *

§ 172.46 [Amended]

■ 24. In § 172.46(c) introductory text, revise the phrases “§§ 158.32 and 158.33 of this chapter” to read “§§ 158.32 and 158.33 or 161.31 and 161.33 of this chapter”

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