



BILLING CODE 6560-50-P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2017-0080; FRL-9973-39]

### Lipochitooligosaccharide (LCO) SP104; Exemption from the Requirement of a Tolerance

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes an exemption from the requirement of a tolerance for lipochitooligosaccharide (LCO) SP104 in or on all food commodities when used in accordance with label directions and good agricultural practices. Monsanto Company submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA) requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of LCO SP104 under FFDCA.

**DATES:** This regulation is effective [*insert date of publication in the Federal Register*]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

**SUPPLEMENTARY INFORMATION).**

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2017-0080, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Robert McNally, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: [BPPDFRNotices@epa.gov](mailto:BPPDFRNotices@epa.gov).

## **SUPPLEMENTARY INFORMATION:**

### **I. General Information**

#### *A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

*B. How Can I Get Electronic Access to Other Related Information?*

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at [http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl).

*C. How Can I File an Objection or Hearing Request?*

Under FFDCFA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2017-0080 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the **Federal Register***]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information

not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2017-0080, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

## **II. Background**

In the **Federal Register** of June 8, 2017 (82 FR 26641) (FRL-9961-14), EPA issued a document pursuant to FFDCFA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 6F8520) by Monsanto Company, 1300 I (Eye) St. NW., Suite 450 East, Washington, DC 20005. The petition requested that 40 CFR 180 be amended by establishing an exemption from the requirement of a tolerance for residues of the plant growth regulator LCO SP104 in or on raw agricultural commodities and processed foods. That document referenced a summary

of the petition prepared by the petitioner, Monsanto Company, which is available in the docket via <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

### **III. Final Rule**

#### *A. EPA's Safety Determination*

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is “safe.” Section 408(c)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings but does not include occupational exposure. Pursuant to FFDCA section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C), which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance or tolerance exemption and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue . . . .” Additionally, FFDCA section 408(b)(2)(D) requires that EPA consider “available information concerning the cumulative effects of [a particular pesticide’s] . . . residues and other substances that have a common mechanism of toxicity.” FFDCA section 408(b)(2)(C) provides that EPA

shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

EPA evaluated the available toxicity and exposure data on LCO SP104 and considered their validity, completeness, and reliability, as well as the relationship of this information to human risk. EPA also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Lipochitooligosaccharides (LCOs) are signaling molecules produced by bacteria, which are involved in the initiation of plant-microbe endosymbiosis (the scenario when a microbe colonizes a plant) in an estimated 70-80% of terrestrial plants. As a pesticide, LCO SP104, a synthetically produced LCO, is intended for use as a plant growth regulator (PGR) to increase growth and decrease stress in growing crops. Typical of a PGR, LCO SP104 should be applied at low concentrations because use at high concentrations can result in detrimental effects to the plant. LCO SP104 is structurally similar to naturally occurring LCOs. Humans are exposed to naturally occurring LCOs as they are present in the roots of food crops and in the bacteria and fungi that are associated with the roots of these crops. Molecules identical to LCO breakdown products (such as

chitin) are also present in insects, crustaceans, fungi, bacteria, and humans, and are regularly consumed by humans as part of a normal diet.

Based on the data submitted in support of this petition (summarized in Unit II. B., below) and the comprehensive risk assessment conducted by the Agency (included in the Docket for this action), EPA concludes that there is a reasonable certainty of no harm from aggregate exposures to LCO SP104, including the consumption of food treated with this active ingredient in accordance with label directions and good agricultural practices. EPA has made this determination because available toxicology data indicate that the active ingredient is not acutely toxic and, based upon a weight of the evidence (WOE) approach, it has been determined not to be a developmental toxicant, a mutagen, or toxic via repeat oral exposure (ie. not subchronically toxic via the oral route). As such the Agency has not identified any endpoints of concern for LC SP104 and has conducted a qualitative assessment of exposure. The Agency has determined that residues of LCO SP104 in drinking water are not expected when products are used according to label instructions. The active ingredient is applied at low concentrations, is very soluble in water, and will dissociate within minutes once applied. Non-occupational exposures are not expected since LCO SP104 is not intended for residential use. A full explanation of the data upon which EPA relied and its risk assessment based on those data can be found within the January 22, 2018, document entitled “Federal Food, Drug, and Cosmetic Act (FFDCA) Considerations for Lipochitooligosaccharide (LCO) SP104.” This document, as well as other relevant information, is available in the docket for this action as described under **ADDRESSES**.

Based upon its evaluation, EPA concludes that LCO SP104 is of low acute toxicity and no toxicological endpoints have been identified for this compound. Therefore, EPA concludes that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of LCO SP104. Therefore, EPA is establishing an exemption from the requirement of a tolerance for residues of LCO SP104.

#### *B. Analytical Enforcement Methodology*

An analytical method is not required for enforcement purposes due to the lack of concern about safety for LCO SP104 at any exposure level.

### **IV. Statutory and Executive Order Reviews**

This action establishes a tolerance exemption under FFDCA section 408(d) in response to a petition submitted to EPA. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action 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) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997); nor is it considered a regulatory action under Executive Order 13771, entitled “Reducing Regulations and Controlling Regulatory Costs” (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act

(PRA), 44 U.S.C. 3501 *et seq.*, 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).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance exemption in this action, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes. As a result, this action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, EPA has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, EPA has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999), and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000), do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require EPA's consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

#### **V. Congressional Review Act**

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), 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 action is not a "major rule" as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 180**

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

Dated: February 23, 2018.

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Richard Keigwin, Jr.

*Director, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

**PART 180--[AMENDED]**

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

2. Add § 180.1353 to subpart D to read as follows:

**§ 180.1353 Lipochitooligosaccharide (LCO) SP104; exemption from the requirement of a tolerance.**

Residues of the biochemical pesticide Lipochitooligosaccharide (LCO) SP104 (which has been used in accordance with label directions and good agricultural practices) are exempt from the requirement of a tolerance in or on all food commodities.

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