PART 180–[AMENDED]

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

Authority: 21 U.S.C. 321 (q), 346 (a) and 374.

§ 180.1001 [Amended]

2. In subpart D, § 180.1001 is amended by:

i. Removing from the table in paragraph (c) the entry for urea ''use as a stabilizer and inhibitor.''

ii. Removing from the table in paragraph (d) the entry for urea ''use as an adjuvant/intensifier for herbicides.''

iii. Removing from the table in paragraph (e) the entry for urea ''use as a stabilizer and inhibitor.''

§ 180.1117 [Removed]

3. Section 180.1117 is removed.

[FR Doc. 02–32563 Filed 12–24–02; 8:45 a.m.]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2002–0277; FRL–7284–2]

Urea; 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 residues of urea when used in pesticide formulations. Ecolab, Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996, requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of urea. This final rule is being published in today's **Federal Register** with a companion Direct Final Rule entitled ''Urea: Revocation of Tolerance Exemptions''

DATES: This regulation is effective December 26, 2002. Objections and requests for hearings, identified by docket ID number OPP–2002–0277, must be received on or before February 24, 2003.

ADDRESSES: Written objections and hearing requests submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit VIII. of the **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Treva C. Alston, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8373; e-mail address: *alston.treva@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. Potentially affected categories and entities may include, but are not limited to:

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

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 table could also be affected. The North American Industrial Classification System (NAICS) codes have 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 person listed under **FOR FURTHER INFORMATION CONTACT.**

B. How Can I Get Copies of This Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP–2002–0277. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This 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.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/.* A frequently updated electronic version of 40 CFR part 180 is available at *http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html*, a beta site currently under development.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

II. Background and Statutory Findings

In the **Federal Register** of April 7, 2000 (65 FR 18324) (FRL–6499–7), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, as amended by the Food Quality Protection Act (FQPA) (Public Law 104–170), announcing the filing of a pesticide tolerance petition (PP 9E6028) by Ecolab, Inc., 370 N. Wabasha Street, St. Paul, MN 55102. This notice included a summary of the petition prepared by the petitioner Ecolab. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.1001 be amended by establishing an exemption from the requirement of a tolerance for residues of urea in or on raw agricultural commodities, in processed commodities, and in or on meat and meat by products of cattle, sheep, hogs, goats, horses, poultry, milk, dairy products, eggs, seafood and shellfish, and fruits and vegetables when such residues result from the use of urea as a component of a food contact surface sanitizing solution for use in food handling establishments.

Section 408(b)(2)(A)(i) of the 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 from tolerance is ''safe.'' Section 408(b)(2)(A)(ii) 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. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance 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. * * *''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Toxicological Profile

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by urea are discussed in this unit.

In the **Federal Register** of April 15, 2002 (67 FR 18197) (FRL–6860–6), the Agency published its report of the Tolerance Reassessment Decision for urea. This Report contained the hazard characterization of urea. For a complete description of the use summary, hazard characterization, exposure assessment and risk assessment findings, see the Notice of April 15, 2002. These data are considered by the Agency to be sufficient to assess the potential hazard to humans, including infants and children.

IV. Summary of Risk Assessment Findings

From the available animal studies and other data, EPA has concluded that urea exhibits a low toxicity and exposures to urea used either as an active or inert pesticide ingredient present a reasonable certainty of no harm to human health.

V. Cumulative Effects

Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify or revoke a tolerance, the Agency consider available information concerning the cumulative effects of a particular pesticide's residues and other substances that have a common mechanism of toxicity. Urea is a low toxicity chemical. EPA does not have, at this time, available data to determine whether urea has a common mechanism of toxicity with other subtances or how to include these pesticide chemicals in a cumulative risk assessment.

VI. Determination of Safety for U.S. Population, Infants and Children

Based on the available data, EPA concludes that urea does not pose a dietary risk under reasonable foreseeable circumstances. Accordingly, EPA finds that there is a reasonable certainty that no harm will result to the general population, and to infants and chldren from aggregate exposure to urea. Because of the low toxicity of urea, a safety factor analysis has not been used to assess the risk. For the same reason, the tenfold safety factor for the protection of infants and children is unnecessary.

VII. Other Considerations

A. Endocrine Disruptors

FQPA requires EPA to develop a screening program to determine whether certain substances, including all pesticide chemicals (both inert and active ingredients), may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect. EPA has been working with interested stakeholeders to develop a screening and testing program as well as a priority setting scheme. As the Agency proceeds with implementation of this program, further testing of products containing urea may be required.

B. Analytical Method(s)

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

C. Existing Tolerances

There are four existing tolerance exemptions for urea. They are as follows: § 180.1001(c), (d), and (e); and § 180.1117. However, in today's **Federal Register**, the Agency, acting on its on initiative, published a direct final rule revoking these four tolerance exemptions as they are no longer necessary. No uses are lost by revoking the above four tolerance exemptions, as the tolerance exemption established in this rule will cover these uses and the use requested by the petitioner.

D. International Tolerances

The Agency is not aware of any country requiring a tolerance for urea nor have any CODEX Maximum Residue Levels been established for any food crops at this time.

E. List 4A Classification

Based on its low toxicity, urea will be classified as a List 4A inert ingredient. List 4A inert ingredients are minimal risk inert ingredients. Minimal risk does not imply no risk under any circumstances. Every substance can present some risk in certain circumstances. Minimal risk is used to indicate a substance for which there is no information to indicate that there is a basis for concern. Thus, the tolerance exemption will be established in 40 CFR 180.950 which holds minimal risk chemicals instead of 40 CFR 180.1001 as requested by the petitioner, Ecolab.

VIII. Conclusions

Based on the information in the record, EPA concludes that there is a reasonable certainty of no harm from aggregate exposure to residues of urea. Accordingly, EPA finds that exempting urea from the requirement of a tolerance will be safe.

IX. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2002–0277 in the subject line on the first page of your submission. All

requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before February 24, 2003.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Rm.104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (703) 603–0061.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at *tompkins.jim@epa.gov,* or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit IX.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.1. Mail your copies, identified by docket ID number OPP–2002–0277, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.1. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov.* Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

X. Regulatory Assessment Requirements

This final rule establishes an exemption from the tolerance requirement under FFDCA section 408(d) in response to a petition submitted to the Agency. 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 rule has been exempted from review under Executive Order 12866, 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 final 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 tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance exemption in this final rule, 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. 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 final rule directly regulates growers, food processors, food handlers and food retailers, not States. 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). 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.

XI. Submission to Congress and the Comptroller General

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 to 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 this final rule in the **Federal Register**. This final rule 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: December 12, 2002.

Peter Caulkins,

Acting Director, Registration Division, 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), 346(a) and 371.

2. Section 180.950 is amended by adding alphabetically the following ingredient to the table in paragraph (e) to read as follows.

§ 180.950 Tolerance exemptions for minimal risk active and inert ingredients.

* * * * *

(e) * * *

Chemical	CAS No.
* * * * *	
Urea	57–13–6

[FR Doc. 02–32564 Filed 12–24–02; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 261

[FRL–7429–3]

RIN 2003–AA00

Regulatory Innovations: Pilot-Specific Rule for Electronic Materials in the EPA Region III Mid-Atlantic States; Hazardous Waste Management System; Modification of the Hazardous Waste Program; Cathode Ray Tubes

AGENCY: Environmental Protection Agency.

ACTION: Direct final rule.

SUMMARY: Many used cathode ray tubes (CRTs) are currently classified as characteristic hazardous wastes under the Resource Conservation and Recovery Act (RCRA). Such CRTs are therefore subject to the hazardous waste regulations of RCRA Subtitle C unless they come from a household or a conditionally exempt small quantity generator. Today EPA is taking direct final action on a revision to its hazardous waste program under RCRA to exclude used CRTs and glass removed from CRTs from the definition of ''solid waste'' in the EPA Region III Mid-Atlantic States (which include the States of Delaware, Maryland, and West Virginia, the Commonwealths of Pennsylvania and Virginia, and the District of Columbia). Additionally, the preamble to this rule clarifies when used CRTs and other used electronic equipment become a ''solid waste.'' This rule will support an ongoing e-Cycling Pilot Project of EPA Region III's Mid-Atlantic States, which is promoting reuse and recycling of electronics. EPA believes that today's direct final rule will encourage increased recycling and better management of these materials in Region III states.

EPA has proposed a similar, albeit broader, conditional exclusion for CRTs and certain other electronic materials that would be effective nationwide (June 12, 2002, 67 FR 40508–40528). EPA is promulgating this regional rule now because it believes that implementing the rule in the Region III states will produce information about the CRT conditional exclusion that will be useful to EPA as it assesses the appropriateness of adopting the RCRA exclusion nationally. EPA expects to withdraw the regional rule if and when a final national rule becomes effective.

DATES: This direct final rule is effective on February 24, 2003 without further notice, unless EPA receives adverse comment by January 27, 2003. If we receive such comment, EPA will publish a timely withdrawal in the **Federal Register** informing the public that this rule will not take effect.

ADDRESSES: Comments may be submitted by mail or electronically. Commenters must send an original and two copies of their comments referencing docket number III–02–OEI–01 to: Marie Holman (3EI00), U.S. EPA Region III, Office of Environmental Innovation, 1650 Arch Street, Philadelphia, PA 19103–2029 or *holman.marie@epa.gov.* Further