

VI. Statutory and Executive Order Reviews

This proposed rule would add a new § 180.940 to 40 CFR part 180, subpart D, which lists the pesticide chemicals that are exempt from the requirement of a tolerance when used in food-contact surface sanitizing solutions. The initial list duplicates pesticide chemicals in 40 CFR 180.940 that are active and inert ingredients listed in 21 CFR 178.1010. Since this proposed rule does not impose any new requirements, it is not subject to review by the Office of Management and Budget (OMB) under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993).

Because this proposed rule has been exempted from review under Executive Order 12866 due to its lack of significance, this proposed 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 proposed rule does not 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).

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 proposed 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 section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this proposed 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 proposed 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 proposed rule.

Under section 605(b) of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency hereby certifies that the creation of a new section 180.940 will not have significant negative economic impact on a substantial number of small entities. The rationale supporting this conclusion is as follows. This proposed rule does not impose any requirements, it establishes exemptions from the requirement for a tolerance. The Agency is, however, also commencing a process whereby EPA will require certain persons to identify chemical substances considered to be GRAS (which could include self-affirmed GRAS chemicals), or permitted by prior sanction or approval in existing food contact surface sanitizing solutions. The information

available to the Agency indicates that fewer than 500 companies have approximately 1,300 products that could fall under this category. EPA anticipates the economic burden on small entities to be minor, since the Agency is only asking for confirmation that the chemical substances considered to be GRAS or permitted by prior sanction or approval in existing food contact surface sanitizing solutions are in fact part of an existing formulation, and information as to why the chemical is considered to be GRAS, or a copy of an FDA letter not objecting to the use of a chemical substance. By contrast, this proposed rule will be beneficial to the regulated community by increasing the number of inert ingredients for use in antimicrobial formulations and by reducing the regulatory burden on persons seeking to market new combinations of ingredients for certain hard surface sanitizing solutions. Additionally, this proposed rule will provide a more transparent listing of pesticide chemicals used in food-contact surface sanitizing solutions to the public.

According to the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, an Agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under the PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA’s regulations, after initial display in the preamble of the final rule and in addition to its display on any related collection instrument, are listed in 40 CFR part 9.

This proposed rule does not impose any new information collection requirements that would require separate approval by OMB under the PRA. Under 5 CFR 1320.3(h), the request for information discussed in Unit V. is not subject to approval under the PRA, and the information collection activities related to the Agency’s tolerance exemption process have already been approved by OMB under OMB control numbers 2070–0024 (EPA ICR No. 597). The annual “respondent” (petitioner) burden for the pesticide tolerance petitions program is estimated to average 1,726 hours per petition. According to the PRA, “burden” means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For this collection, it is the time reading the regulations, planning the necessary data collection activities, conducting tests, analyzing data, generating reports and completing other