

### E. Safety Determination

1. *U.S. population.* Using the conservative exposure assumptions and the RfD described above, the aggregate exposure to spinosad use on existing crop uses utilizes 30% of the RfD for the U.S. population from a previous EPA assessment based on the chronic population adjusted dose (cPAD) (as posted in the **Federal Register** of September 27, 2002) (FRL-7199-5). EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. The new crop uses proposed in this notice are minor ones and are expected to contribute only a negligible impact to the RfD. Thus, it is clear that there is reasonable certainty that no harm will result from aggregate exposure to spinosad residues on existing and all pending crop uses listed in this notice.

2. *Infants and children.* In assessing the potential for additional sensitivity of infants and children to residues of spinosad, data from developmental toxicity studies in rats and rabbits and a 2-generation reproduction study in the rat are considered. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability and potential systemic toxicity of mating animals and on various parameters associated with the well-being of pups.

FFDCA section 408 provides that EPA may apply an additional safety factor for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base. Based on the current toxicological data requirements, the data base for spinosad relative to prenatal and postnatal effects for children is complete. Further, for spinosad, the NOELs in the dog chronic feeding study which was used to calculate the RfD (0.027 mg/kg/day) are already lower than the NOELs from the developmental studies in rats and rabbits by a factor of more than 10-fold. Concerning the reproduction study in rats, the pup effects shown at the highest dose tested were attributed to maternal toxicity. Therefore, it is concluded that an additional uncertainty factor is not needed and that the RfD at 0.027 mg/kg/day is appropriate for assessing risk to infants

and children. In addition, the EPA has determined that the 10X factor to account for enhanced sensitivity of infants and children is not needed because:

i. The data provided no indication of increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure to spinosad. In the prenatal developmental toxicity studies in rats and rabbits and two-generation reproduction in rats, effects in the offspring were observed only at or below treatment levels that resulted in evidence of parental toxicity.

ii. No neurotoxic signs have been observed in any of the standard required studies conducted.

iii. The toxicology data base is complete and there are no data gaps.

iv. Exposure data are complete or are estimated based on data that reasonably account for potential exposure.

Using the conservative exposure assumptions previously described (tolerance level residues), the percent RfD utilized by the aggregate exposure to residues of spinosad on existing crop uses is 69% for children 1-6 years old, the most sensitive population subgroup from an EPA assessment based on the chronic population adjusted dose (cPAD) (as posted in the **Federal Register** May 3, 2000. Additional refinements to the dietary exposure based on market share information would reduce the exposure of children 1-6 years old to less than 50% the cPAD. Grain treated under a tolerance is expected to have only a slight impact to the RfD since the vast majority of grain is untreated. Thus, based on the completeness and reliability of the toxicity data and the conservative exposure assessment, it is concluded, that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to spinosad residues on the above proposed uses including existing crop uses.

### F. International Tolerances

There is no Codex maximum residue levels established for residues of spinosad.

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## ENVIRONMENTAL PROTECTION AGENCY

[FRL-7778-6]

### Air Quality Criteria for Particulate Matter (External Review Draft)

AGENCY: Environmental Protection Agency (EPA).

**ACTION:** Notice of drafts of chapters for public review and comment.

**SUMMARY:** On or about June 21, 2004, the National Center for Environmental Assessment (NCEA), within EPA's Office of Research and Development, will make available for public review and comment revised drafts of Chapters 7, 8, and 9 of EPA's document *Air Quality Criteria for Particulate Matter*, which incorporate revisions made in response to earlier external review of those chapters. Under sections 108 and 109 of the Clean Air Act, the purpose of this document is to provide an assessment of the latest scientific information on the effects of airborne particulate matter (PM) on the public health and welfare for use in EPA's current review of the National Ambient Air Quality Standards (NAAQS) for PM.

**DATES:** Comments on the draft chapters must be submitted in writing no later than July 20, 2004. Send the written comments to the Project Manager for Particulate Matter, National Center for Environmental Assessment—RTP (B243-01), U.S. Environmental Protection Agency, Research Triangle Park, NC 27711.

**ADDRESSES:** The revised Chapters 7, 8, and 9 of the *Air Quality Criteria for Particulate Matter* will be available on CD ROM from NCEA-RTP. Contact Ms. Diane Ray by phone (919-541-3637), fax (919-541-1818), or e-mail ([ray.diane@epa.gov](mailto:ray.diane@epa.gov)) to request these chapters. Please provide the document's title, *Air Quality Criteria for Particulate Matter*, and the EPA numbers for each of the three revised chapters (EPA/600/P-99/002aE, EPA/600/P-99/002bE), as well as your name and address, to properly process your request. Internet users will be able to download a copy from the NCEA home page. The URL is <http://www.epa.gov/ncea/>. Hard copies of the revised chapters can also be made available upon request.

**FOR FURTHER INFORMATION CONTACT:** Dr. Robert Elias, National Center for Environmental Assessment—RTP (B243-01), U.S. Environmental Protection Agency, Research Triangle Park, NC 27711; telephone: 919-541-4167; fax: 919-541-1818; e-mail: [elias.robert@epa.gov](mailto:elias.robert@epa.gov).

**SUPPLEMENTARY INFORMATION:** EPA is in the process of updating and revising, where appropriate, its *Air Quality Criteria for Particulate Matter* as issued in 1996 (usually referred to as the "Criteria Document"). Sections 108 and 109 of the Clean Air Act require that EPA carry out a periodic review and revision, where appropriate, of the air quality criteria and national ambient air

quality standards (NAAQS) for "criteria" air pollutants such as PM. Details of EPA's plans for the review of the NAAQS for PM were initially announced in a previous **Federal Register** notice (62 FR 55201, October 23, 1997). EPA made a first external review draft of the updated *Air Quality Criteria for Particulate Matter* available for review by the Clean Air Act Scientific Advisory Committee (CASAC) and members of the public in October 1999 (64 FR 57884, October 27, 1999). Following that public review period and a meeting of the CASAC in December 1999 (64 FR 61875, November 15, 1999), EPA revised the document as appropriate to incorporate CASAC and public comments, as well as to reflect many new studies on the effects of PM that were not available in time for discussion in the first external review draft.

EPA then made a second external review draft of the *Air Quality Criteria for Particulate Matter* available for CASAC and public review in April 2001 (66 FR 18929, April 12, 2001). Following that public review period and a second CASAC meeting in July 2001 (66 FR 34924, July 2, 2001), EPA again revised the document as appropriate to incorporate changes in response to CASAC and public comments and also made further revisions reflecting new studies on effects of particulate matter that had become available between issuance of the first and second external review drafts.

EPA then made a third external review draft of the *Air Quality Criteria for Particulate Matter* available for CASAC and public review in May 2002 (67 FR 31303, May 9, 2002). Following that public review period and a third CASAC meeting in July 2002 (67 FR 41723, June 19, 2002), EPA again revised the document as appropriate to incorporate revisions in response to CASAC and public comments and also made further revisions reflecting new studies on effects of particulate matter that had become available between issuance of the second and third external review drafts, as well as re-analyses of certain existing studies occasioned after discovery of problems with applications of statistical software.

EPA made a fourth external review draft available for CASAC and public review in June 2003 (68 FR 36985, June 20, 2003). A public meeting with CASAC was held August 25–26, 2003 (68 FR 47061, August 7, 2003), during which CASAC reached closure on Chapters 1,2,3,4,5, and 6, with only relatively minor final revisions to be made. No further public review is requested on these chapters. However,

CASAC did not reach closure on Chapters 7 (toxicology), 8 (epidemiology), and 9 (integrative synthesis), each of which were to be more extensively revised or, in the case of Chapter 9, significantly restructured.

In December 2003, EPA made revised drafts of Chapters 7 and 8 available for CASAC and public review (68 FR 75240, December 30, 2003). These two revised draft chapters were reviewed by CASAC via a publically accessible teleconference call on February 3, 2004 (69 FR 657, January 6, 2004). However, CASAC did not reach closure on Chapters 7 or 8, leading to further revisions of each that are now being released for further public comment and CASAC review.

These three revised draft chapters will be reviewed by CASAC on July 20 and 21, 2004. The date and arrangements for the CASAC meeting were announced in the **Federal Register** on June 9, 2004 (69 FR 32344).

Dated: June 17, 2004.

**Peter W. Preuss,**

*Director, National Center for Environmental Assessment.*

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## FEDERAL MARITIME COMMISSION

### Notice of Agreements Filed

The Commission hereby gives notice of the filing of the following agreements under the Shipping Act of 1984. Interested parties can review or obtain copies of agreements at the Washington, DC, offices of the Commission, 800 North Capitol Street, NW., Room 940. Interested parties may submit comments on an agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within 10 days of the date this notice appears in the **Federal Register**.

*Agreement No.:* 011117–033.

*Title:* United States/Australasia Discussion Agreement.

*Parties:* P&O Nedlloyd Limited; Australia-New Zealand Direct Line; Hamburg-Sud; Compagnie Maritime Marfret, S.A.; Wallenius Wilhelmsen Lines AS; CMA CGM, S.A.; Fesco Ocean Management Limited; A.P. Moller-Maersk A/S; and Lykes Lines Limited, LLC.

*Synopsis:* The amendment deletes language regarding base ports and updates the addresses of two agreement parties.

*Agreement No.:* 011695–006.

*Title:* CMA CGM/Norasia Reciprocal Space Charter, Sailing and Cooperative Working Agreement.

*Parties:* CMA CGM, S.A. and Norasia Container Lines Limited.

*Synopsis:* The amendment provides for the substitution of a larger vessel for a smaller vessel currently deployed under the agreement. The parties request expedited review.

*Agreement No.:* 011814–003.

*Title:* HSDG/King Ocean Space Charter Agreement.

*Parties:* A.P. Moller-Maersk A/S; Hamburg-Südamerikanische Dampfschiffahrts-Gesellschaft KG; King Ocean Services Limited; and King Ocean Service de Venezuela, S.A.

*Synopsis:* The amendment revises the agreement to indicate that King Ocean will be providing both vessels, to change the space allocations under the agreement, to delete the Dominican Republic from the geographic scope, to add that Hamburg-Süd has the right to provide a vessel, to reflect the new duration of the agreement, and to delete existing Article 9.3 and replace it with a new provision. The amendment restates the agreement.

*Agreement No.:* 011852–008.

*Title:* Maritime Security Discussion Agreement.

*Parties:* American President Lines, Ltd.; APL Co. Pte Ltd.; Australia-New Zealand Direct Line; China Shipping Container Lines, Co., Ltd.; Canada Maritime; CMA–CGM S.A.; Contship Container Lines; COSCO Container Lines Company, Ltd.; CP Ships (UK) Limited; Evergreen Marine Corp.; Hanjin Shipping Company, Ltd.; Hapag Lloyd Container Linie GmbH; Italia di Navigazione, LLC; Kawasaki Kisen Kaisha Ltd.; Lykes Lines Limited, LLC; A.P. Moller-Maersk A/S, trading under the name of Maersk Sealand; Mitsui O.S.K. Lines, Ltd.; Nippon Yusen Kaisha; Orient Overseas Container Line Limited; Safmarine Container Line, NV; TMM Lines Limited, LLC; Yang Ming Marine Transport Corp.; Zim Israel Navigation Co., Ltd.; Alabama State Port Authority; APM Terminals North America, Inc.; Ceres Terminals, Inc.; Cooper/T. Smith Stevedoring Co., Inc.; Eagle Marine Services Ltd.; Global Terminal & Container Services, Inc.; Howland Hook Container Terminal, Inc.; Husky Terminal & Stevedoring, Inc.; International Shipping Agency; International Transportation Service, Inc.; Lambert's Point Docks Inc.; Long Beach Container Terminal, Inc.; Maersk Pacific Ltd.; Maher Terminals, Inc.; Marine Terminals Corp.; Maryland Port Administration; Massachusetts Port Authority (MASSPORT); Metropolitan Stevedore Co.; P&O Ports North American, Inc.; Port of Tacoma; South Carolina State Ports Authority;