CBI or the procedures for claiming CBI, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

*E. What Should I Consider as I Prepare My Comments for EPA?*

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.

2. Describe any assumptions that you used.

3. Provide copies of any technical information and/or data you used that support your views.

4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.

5. Provide specific examples to illustrate your concerns.

6. Offer alternative ways to improve the notice.

7. Make sure to submit your comments by the deadline in this document.

8. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

**II. Background**

Monsanto Company has applied to amend their recently approved EUP number 524–EUP–93 amendment/extension in order to allow livestock feeding studies and a lifting of the crop destruct provisions. The recently approved EUP published in the **Federal Register** on July 27, 2001 (66 FR 39163) (FRL–6791–5). A tolerance exemption was established for *Bacillus thuringiensis* Cry3Bb1 protein and the genetic material necessary for its production in corn on May 11, 2001. The tolerance exemption published in the **Federal Register** on May 11, 2001 (66 FR 24061) (FRL–6781–6).

**III. What Action is the Agency Taking?**

Following the review of the Monsanto Company application and any comments and data received in response to this notice, EPA will decide whether to issue or deny the EUP request for this EUP program, and if issued, the conditions under which it is to be conducted. Any issuance of an EUP will be announced in the **Federal Register**.

**IV. What is the Agency's Authority for Taking this Action?**

The Agency's authority for taking this action is under 40 CFR part 172.

**List of Subjects**

Environmental protection, Experimental use permits.

Dated: August 29, 2001.

**Janet L. Andersen,**

*Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.*

[FR Doc. 01–22757 Filed 9–10–01; 8:45 am]

**BILLING CODE 6560–50–S**

## ENVIRONMENTAL PROTECTION AGENCY

**[OPP–34246; FRL–6796–3]**

## Butylate; Notice of Pesticide Report on FQPA Tolerance Reassessment Progress and Interim Risk Management Decision

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

**ACTION:** Notice.

**SUMMARY:** This notice constitutes the Agency's report on the Food Quality Protection Act (FQPA) tolerance reassessment progress and interim risk management decision for butylate, announces the Agency's decision, and releases the human health risk assessment and related documents supporting this decision to the public. The Agency's reassessment of dietary risk, including public exposure through food and drinking water as required by the Federal Food, Drug, and Cosmetic Act (FFDCA) as amended by FQPA, indicates that butylate, by itself, poses no risk concerns within the limits of the existing tolerances; therefore, no risk mitigation is needed, and no further actions are warranted at this time. The existing butylate tolerances remain in effect, until such time as a determination of whether a full reassessment of the cumulative risk from thiocarbamate pesticides, including butylate, may be needed and is considered.

**DATES:** Comments submitted on or before October 11, 2001 are most likely to be considered and will be included in the public docket.

**FOR FURTHER INFORMATION CONTACT:** Gary Mullins, Special Review and Reregistration Division (7508C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–8044; e-mail address: mullins.gary@epa.gov.

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Does this Action Apply to Me?*

This action is directed to the public in general, nevertheless, a wide range of stakeholders will be interested in obtaining information on the Agency's interim risk management and tolerance reassessment decision for butylate, including environmental, human health, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the use of pesticides on food. Since other entities also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. 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 Additional Information, Including Copies of this Document and Other Related Documents?*

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. On the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/. In addition, copies of documents related to the Agency's report on FQPA tolerance reassessment progress and interim risk management decision for butylate released to the public may also be accessed at: http://www.epa.gov/pesticides/reregistration/status.htm.

2. *In person.* The Agency has established an official record for this action under docket control numbers OPP–34246. The official record consists of the documents specifically referenced in this action, and other related information, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday,

excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

**II. How Can I Respond to this Action?**

*A. How and to Whom Do I Submit Comments?*

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number OPP–34246 in the subject line on the first page of your correspondence.

1. *By mail.* Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

3. *Electronically.* You may submit your comments and/or data electronically by e-mail to: opp-docket@epa.gov, or you can submit a computer disk as described in Units II.A.1. and 2 above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic comments may also be filed online at many Federal Depository Libraries.

*B. How Should I Handle CBI That I Want To Submit to the Agency?*

Do not submit any information electronically that you would consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI 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. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified under **FOR FURTHER INFORMATION CONTACT**.

**III. Report on FQPA Tolerance Reassessment Progress and Interim Risk Management Decision**

The Agency has completed its assessment of the dietary risk of butylate alone, and has determined that the level of dietary risk from exposure as a result of currently registered uses of butylate is not of concern. Therefore, no mitigation measures are needed and no further actions are warranted at this time. The Agency may find, however, that further action is necessary if it is determined that thiocarbamate pesticides, such as butylate, share a common mechanism of toxicity. Such an incremental approach to the tolerance reassessment process is consistent with the Agency's goal of improving transparency in implementing FFDCA, as amended. This interim tolerance reassessment and risk management decision does not specifically address the reassessment of the existing butylate food residue tolerances as called for by FFDCA, as amended, because the Agency has not yet determined that thiocarbamate pesticides have a common mechanism of toxicity, nor considered the cumulative risk for the thiocarbamates, if so warranted. When the Agency has determined whether the thiocarbamate group of pesticides have a common mechanism of toxicity and has considered the appropriate cumulative risks, the butylate tolerances will be reassessed in that light. At this time, the established tolerances for butylate remain in effect, until such time as a full reassessment of the cumulative risk from thiocarbamate pesticides, such as butylate, may be needed and is considered.

**IV. Background**

FFDCA, as amended requires EPA to review all the tolerances for registered chemicals in effect on or before the date of the enactment of FQPA. In reviewing these tolerances, the Agency must consider, among other things, aggregate risks from non-occupational sources of pesticide exposure, whether there is increased susceptibility to infants and children, and the cumulative effects of pesticides with a common mechanism of toxicity. The tolerances are considered reassessed once the safety finding has been made or a revocation occurs. A reregistration eligibility decision (RED) for butylate was completed in September 1993, prior to FQPA enactment, therefore, it needed to be updated to consider the provisions of the Act.

FFDCA, as amended, requires that the Agency, when considering whether to establish, modify, or revoke a tolerance, consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' The Agency is currently examining whether and to what extent thiocarbamate pesticides may share a common mechanism of toxicity. Preliminary determinations indicate that the potential to produce a common toxic effect, neuropathy (e.g., degeneration and demylination of the sciatic nerve), and the similarities in structure and metabolism, may support grouping of the thiocarbamates based on their ability to produce a common effect by a common mechanism. Assuming these assertions are correct, preliminary screening-level chronic cumulative dietary food risk analyses do not provide evidence that cumulative exposure of the human population, including infants and children, to the neuropathic thiocarbamates would raise concern of adversely affecting human health.

The preliminary determination of whether and to what extent thiocarbamates pesticides may share a common mechanism of toxicity, and accompanying screening-level cumulative dietary analyses are to be presented to the FIFRA Science Advisory Panel for peer review on September 7, 2001. Pending their review of the information, the Agency expects to complete the cumulative risk assessment for thiocarbamate pesticides, at which time, provided the risk analyses concludes chronic cumulative dietary risks are not of concern to the Agency, the butylate tolerances will be considered reassessed, in accordance with FFDCA, as amended.

The Agency's human health findings for the thiocarbamate pesticide butylate, dicussed below, are presented fully in the documents: Butylate-HED Revised Human Health Assessment, February 26, 2001; and: GENEEC and SCI-GROW2 EEC's for the Current Use of Butylate on Corn for the Purpose of Tolerance Reassessment, August 20, 1998. These risk assessments and other documents pertaining to the butylate tolerance reassessment decision are available on the Internet at: http://www.epa.gov/pesticides/reregistration/status.htm and the public docket for viewing (see Unit I.B.2).

**V. Use Summary**

Butylate (S-ethyl diisobutylthiocarbamate) is a soil incorporated herbicide registered for use on corn (field, sweet, and popcorn) for control of grassy and broadleaf weeds and nutsedge. There are no registered non-food/non-feed uses, and no existing or proposed residential uses of butylate products. Butylate is formulated as a liquid emulsifiable concentrate (85.1% active ingredient), and may be applied preplant, at plant, postplant, and after harvest (fall) at a maximum single and annual application rate of 6.3 pounds of active ingredient per acre (lb a.i./acre). Because butylate is highly volatile, applications are made by ground equipment, either broadcast or band, and are immediately incorporated into the soil. The type of equipment used to apply butylate include, boom sprayer; soil injection equipment; and center pivot irrigation. Usage of butylate has declined from approximately 15 million lb a.i. in 1991 to an estimated 950,000 lb a.i. in 1998. Butylate was not produced in 1998, and both usage and production are expected to continue to decline.

**VI. Dietary Food Risks**

Acute dietary risk from food is calculated considering what is eaten in one day (in this instance, the full range of consumption values as well as the range of residue values in food). A risk estimate that is less than 100% of the acute Population Adjusted Dose (PAD) (the dose at which an individual could be exposed on any given day and no adverse health effects would be expected) is not of concern to the Agency. Chronic dietary risk from food is calculated by using the average consumption values for food and average residue values for those foods over a 70–year lifetime. A risk estimate that is less than 100% of the chronic PAD (the dose at which an individual could be exposed over the course of a lifetime and no adverse health effects would be expected) is not of concern to the Agency.

For the general population, the acute no observed adverse effects level (NOAEL) of 600 milligrams/kilogram/day (mg/kg/day) was established, based on clinical signs and acute neurotoxic effects (i.e., neuronal cell necrosis in the brain and degeneration of sciatic nerve) in the acute rat neurotoxicity study at the lowest observed adverse effects level (LOAEL) of 2,000 mg/kg/day. For the females (13–50 years) population subgroup, the acute NOAEL of 40 mg/kg/day was established, based on decreased fetal weights and increased incidences of misaligned sterebrae in the rat developmental study at the LOAEL of 400 mg/kg/day. In this study, both maternal and developmental toxicity were observed at the same dose (400 mg/kg/day); therefore, no increased susceptibility to offspring was observed. The chronic NOAEL of 5 mg/kg/day was established, based on decreased body weight gain (not statistically significant) and increased relative liver weight in male dogs from a 12–month dog feeding study at the LOAEL of 25 mg/kg/day. Based on available data, butylate is not carcinogenic, and has been classified as a Group E ''not likely'' carcinogen; therefore, no chronic (cancer) dietary risk assessment was conducted.

An uncertainty factor of 100 was applied to risk assessments to account for interspecies extrapolation (10X) and intraspecies variability (10X). The FQPA safety factor to account for enhanced sensitivity of infants and children was removed (reduced to 1X) since: The toxicology data base is complete; the developmental and reproductive toxicity data did not indicate increased sensitivity or susceptibility of rats or rabbits to *in utero* and/or postnatal exposure; unrefined dietary exposure estimates (assuming all commodities contain tolerance level residues) will overestimate dietary exposure; modeling data are used for ground and surface source drinking water exposure assessments resulting in estimates considered to be upper-bound concentrations; and there are currently no registered residential uses for butylate. Additionally, there is no evidence to support a recommendation for a developmental neurotoxicity study.

The acute and chronic dietary exposure analyses are based on the Dietary Exposure Evaluation Model (DEEM™). The DEEM™ analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide Continuing Surveys for Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity.

The acute dietary (food) assessment for butylate is a Tier I deterministic analysis at the 95$^{th}$ percentile, and was conducted using tolerance level residues (0.1 ppm) and 100% crop treated. Tier I analysis was also conducted for chronic assessments using tolerance level residues and 100% crop treated. The estimated acute and chronic dietary (food) exposure consumed less than 1% of the respective acute and chronic PADs for all population subgroups; therefore, dietary (food) risk is not of concern to the Agency and no risk mitigation measures are necessary.

**VII. Dietary Drinking Water Risks**

Drinking water exposure to pesticides can occur through surface and/or ground water contamination. EPA considers acute (1–day) and chronic (lifetime) drinking water risks and uses either modeling or actual monitoring data, if available, to estimate those risks. Modeling is carried out in tiers of further refinement, and is designed to provide a high-end estimate of exposure.

Based on environmental fate data, butylate is mobile to slightly mobile in soil. However, significant residues of butylate are not expected to reach surface water under most conditions, because it is incorporated and partitions from soil to air readily. Although, soil incorporation favors downward movement to ground water over surface runoff, significant ground water contamination is still not expected under most conditions. Drinking water concentrations were estimated using GENEEC (Tier I-surface water) and SCI-GROW (Tier I-ground water) computer models. The drinking water assessment for butylate was conducted on parent butylate only, since no degradates of concern were identified. While limited monitoring data from surface and ground water sources are available on butylate and were lower than levels predicted by models, Tier I modeling estimates were used to assess exposure from both surface and ground water sources. These estimates were low and no further refinement was needed.

For acute drinking water risk, the potential (peak) concentrations of butylate in surface water sources is 33.1 parts per billion (ppb), and in ground water sources is 0.41 ppb. For chronic drinking water risk, potential (average) concentrations of butylate in surface water sources is 10 ppb, and in ground water sources is 0.41 ppb. Neither GENEEC nor SCI-GROW Tier I drinking water models take into account volatility from soil or water. Because butylate dissipates primarily by volatility from soil, actual butylate concentrations in drinking water predicted from either model are likely lower.

**VIII. Aggregate Risks**

Aggregate risk looks at the combined risk from exposure through food, drinking water, and residential uses. Generally, all risks from these exposures must be less than 100% of the acute and chronic PADs. For butylate, the aggregate risks are limited to food and

water exposure, because there are no residential uses.

To determine the maximum allowable contribution from water allowed in the diet, EPA first looks at how much of the overall allowable risk is contributed by food and then determines a ''drinking water level of comparison'' (DWLOC) to ascertain whether modeled or monitored concentrations in drinking water exceed this level. Drinking water concentrations that are above the corresponding DWLOC are of concern to the Agency. When the acute and chronic DWLOCs are compared with the estimated concentrations of butylate in drinking water using conservative modeling, surface and ground water concentrations are substantially lower than the DWLOCs for all populations. To assess aggregate risk, the acute and chronic dietary (food) risk estimates are combined with the corresponding surface and ground water (drinking water) estimated concentrations. For butylate, both the acute and chronic aggregate (food + drinking water) risks are less than 100% of the respective acute and chronic PADs, and therefore, are not of concern to the Agency, nor do they warrant risk mitigation measures.

**IX. Residential, Occupational, and Ecological Risk**

Residential risks were not assessed for butylate. Butylate is not registered for home use nor is it used in and around schools, or parks. Thus, there is no residential exposure to assess nor aggregate with the dietary exposure. Additionally, worker and ecological risks were not assessed for butylate, because butylate is under review for tolerance reassessment only. Occupational and ecological risk management decisions were made as part of the 1993 Butylate RED and have been implemented.

**X. Tolerance Reassessment Summary**

Tolerances are established for residues of butylate (S-ethyl diisobutylthiocarbamate) in/on raw agricultural commodities as defined in 40 CFR 180.232. Because there is no reasonable expectation of finite residues in meat, milk, poultry, and eggs; tolerances for residues of butylate in meat, milk, poultry, and eggs are not required. Further, no change in the 0.1 ppb commodity tolerance expression is required; however, the Agency intends to revise the commodity definitions. These tolerance commodity name revisions are given in the table below, and will be the subject of rulemaking. Based on a review of the residue data submitted, the established tolerances of butylate remain in effect at 0.1 ppm for all registered commodities, until such time as a determination of whether a full reassessment of the cumulative risk from thiocarbamate pesticides, such as butylate, may be needed and is considered. Tolerance commodity name revisions are given in the table below in accordance with current Agency administrative practice.

BUTYLATE TOLERANCES

| Commodity | Current Tolerance (ppm) | Reassessed Tolerance (ppm) | Corrected Commodity Definition |
|---|---|---|---|
| Corn, field, grain | 0.1 | 0.1 | |
| Corn, pop, grain | 0.1 | 0.1 | |
| Corn, sweet (kernels, plus cob with husk removed) | 0.1 | 0.1 | Corn, sweet, kernel plus cob with husks removed |
| Corn, field, fodder | 0.1 | 0.1 | Corn, field, stover |
| Corn, field, forage | 0.1 | 0.1 | |
| Corn, pop, forage | 0.1 | 0.1 | Corn, pop, stover |
| Corn, sweet, forage | 0.1 | 0.1 | |

**List of Subjects**

Environmental protection, Chemicals, Pesticides and pests.

Dated: August 29, 2001.

**Lois A. Rossi,**

*Director, Special Review and Reregistration Division, Office of Pesticide Programs.*

[FR Doc. 01–22754 Filed 9–10–01; 8:45 am]

**BILLING CODE 6560–50–S**

## ENVIRONMENTAL PROTECTION AGENCY

**[FRL–7051–7]**

### National Smelting and Refining Superfund Site/Atlanta, GA; Notice of Proposed Settlement

**AGENCY:** Environmental Protection Agency.

**ACTION:** Notice of proposed settlement.

**SUMMARY:** Under sections 104, 106(a), 107 and 122 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), NL Industries, Inc. and Norfolk Southern Railway Company (Respondents) entered into an Administrative Order on Consent (AOC) with the Environmental Protection Agency (EPA), whereby the Respondents agreed to perform response activities at the National Smelting and Refining Superfund Site (Site) located in Atlanta, Georgia. Section VII of the AOC provides for the reimbursement of EPA's past and future response costs by the Respondents. Under the terms of the AOC, section VII is subject to section 122(i) of CERCLA, which requires EPA to publish notice of the proposed settlement in the Federal Register for a thirty (30) day public comment period. EPA will consider public comments on section VII of the AOC for thirty days. EPA may withhold consent to all or part of section VII of the AOC if comments received disclose facts or considerations which indicate that section VII of the AOC is inappropriate, improper, or inadequate.

Copies of the proposed settlement are available from: Ms. Paula V. Batchelor, U.S. Environmental Protection Agency, Region IV, CERCLA Program Services Branch, Waste Management Division, 61 Forsyth Street, S.W., Atlanta, Georgia 30303, (404) 562–8887.

Written comment may be submitted to Mr. Greg Armstrong at the above address within 30 days of the date of publication.