

filing notice for a food additive petition filed by the National Fisheries Institute, to provide for the safe use of ionizing radiation for control of foodborne pathogens in crustaceans and processed crustaceans.

FOR FURTHER INFORMATION CONTACT:

Lane A. Highbarger, Center for Food Safety and Applied Nutrition (HFS-255), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1204.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), a notice was published in the **Federal Register** of February 6, 2001 (66 FR 9086) announcing that a food additive petition (FAP 1M4727) had been filed by the National Fisheries Institute, 7918 Jones Branch Dr., McLean, VA 22102, proposing that the food additive regulations in part 179 *Irradiation in the Production, Processing and Handling of Food* (21 CFR part 179) be amended to provide for the safe use of ionizing radiation for control of foodborne pathogens in raw-, frozen-, cooked-, partially cooked-, shelled-, or dried crustaceans, or cooked- or ready-to-cook crustaceans processed with batter, breading, spices, or small amounts of other food ingredients.

Subsequent to the publication of the filing notice, the National Fisheries Institute amended the scope of their petition so as to exclude the use of breading or batter. FDA received a letter from the National Fisheries Institute, dated July 16, 2009, asking FDA to modify the scope of the petition so that breading and batter are not included.

Therefore, FDA is amending the filing notice of February 6, 2001, to state that the National Fisheries Institute is proposing that the food additive regulations in part 179 be amended to provide for the use of ionizing radiation for the control of foodborne pathogens in raw-, frozen-, cooked-, partially cooked-, shelled-, or dried-crustaceans or cooked- or ready-to-cook crustaceans processed with spices or small amounts of other food ingredients.

The agency has determined under 21 CFR 25.32(i) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: September 4, 2009.

Laura M. Tarantino,

Director, Office of Food Safety, Center for Food Safety and Applied Nutrition.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket Number NIOSH-057]

Request for Information on 1-Bromopropane

AGENCY: National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of public comment period.

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) intends to evaluate the scientific data on the brominated organic solvent, 1-Bromopropane (1-BP, CAS # 106-94-5, also known as n-propyl bromide), and develop appropriate communication documents, such as a Current Intelligence Bulletin, Criteria Document and/or other informational products, and establish a Recommended Exposure Limit (REL) for 1-BP. NIOSH is requesting information on the following: (1) published and unpublished reports and findings from *in vitro* and *in vivo* toxicity studies with 1-BP, (2) information on possible health effects observed in workers exposed to 1-BP, (3) information on workplaces and products in which 1-BP can be found, (4) description of work tasks and scenarios with a potential for exposure to 1-BP, (5) workplace exposure data, and (6) information on control measures (e.g., engineering controls, work practices, personal protective equipment) that are being used in workplaces where potential exposures to 1-BP occur.

Public Comment Period: Comments must be received by December 14, 2009.

ADDRESSES: You may submit comments, identified by docket number NIOSH-057, by any of the following methods:

- **Mail:** NIOSH Docket Office, Robert A. Taft Laboratories, MS-C34, 4676 Columbia Parkway, Cincinnati, OH 45226.
- **Facsimile:** (513) 533-8285.
- **E-mail:** nioshdocket@cdc.gov.

All information received in response to this notice will be available for public examination and copying at the NIOSH Docket Office, 4676 Columbia Parkway, Cincinnati, Ohio 45226. A complete electronic docket containing all comments submitted will be available on the NIOSH Web page at <http://www.cdc.gov/niosh/docket>, and comments will be available in writing by request. NIOSH includes all comments received without change in the docket, including any personal information provided.

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FOR FURTHER INFORMATION CONTACT: G. Scott Dotson, PhD, NIOSH, Robert A Taft Laboratories, MS-C32, 4676 Columbia Parkway, Cincinnati, OH 45226, telephone (513) 533-8540.

SUPPLEMENTARY INFORMATION: 1-BP is a brominated organic solvent that has received increased global attention in recent years as a potential alternative for ozone depleting substances and other compounds with known adverse health effects, such as chlorofluorocarbons (CFC), hydrochlorofluorocarbons (HCFC), and methylene chloroform. 1-BP is used in multiple industrial processes including vapor and immersion degreasing operations, and as a solvent in industries using aerosol-applied adhesives; 1-BP is also proposed as a replacement solvent for perchloroethylene in the dry-cleaning sector. The National Toxicology Program (NTP) estimated that approximately 8.2 million pounds (lbs) of 1-BP were used in the United States (U.S.) in 2002. Estimates of the number of workers exposed to 1-BP are unavailable due to limited exposure data and its relatively recent introduction into domestic commerce.

The toxic nature of 1-BP is not fully understood. Recently published case reports describe possible adverse health effects, including neurotoxicity, following occupational exposures to 1-BP. The findings of animal toxicity studies in rats and mice indicate that 1-BP may be a reproductive and developmental toxicant, in addition a neurotoxicant. No occupational exposure limits for 1-BP have been established by NIOSH or the Occupational Safety and Health Administration (OSHA).

NIOSH seeks to obtain materials, including published and unpublished reports and research findings, to evaluate the possible health risks of occupational exposure to 1-BP. Examples of requested information include, but are not limited to, the following:

(1) Identification of industries or occupations in which exposures to 1-BP may occur.

(2) Trends in the production and use of 1-BP and 1-BP containing compounds.

(3) Description of work tasks and scenarios with a potential for exposure to 1-BP.

(4) Workplace exposure measurement data in various types of industries and jobs.

(5) Case reports or other health information demonstrating potential health effects in workers exposed to 1-BP.

(6) Research findings from *in vitro* and *in vivo* toxicity studies.

(7) Information on controls (*e.g.*, engineering controls, work practices, PPE) including costs and effectiveness of control measures being taken to minimize worker exposure to 1-BP.

(8) Educational materials for worker safety and training on the safe handling of 1-BP.

(9) Data pertaining to the feasibility of establishing a more protective REL for 1-BP including projected costs of control strategies considered.

(10) Names of substitute chemicals or processes being used in place of 1-BP and type of work tasks.

Dated: September 9, 2009.

John Howard,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. E9-22297 Filed 9-15-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket Number NIOSH-150]

Request for Information on Alternative Duty: Temporary Reassignment for Health Care Workers Who Work With Hazardous Drugs

AGENCY: National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of public comment period.

SUMMARY: NIOSH intends to publish a Current Intelligence Bulletin (CIB) on alternative duty and other forms of administrative controls for health care workers who work with hazardous drugs and are trying to conceive, are pregnant, and/or are breast feeding. Alternative duty involves transferring the worker to a similar position, but one in which they would not be required to handle hazardous drugs.

Exposure to certain hazardous drugs can affect reproduction and have adverse health effects on the developing fetus. Some hazardous drugs are known

to be present in the breast milk of patients treated with them [Briggs *et al.* 2005]. NIOSH plans to develop recommendations in this CIB on alternative duty and administrative controls that will protect the workers and their offspring from the potential adverse reproductive effects of hazardous drugs.

NIOSH is requesting (1) comments and information relevant to the potential reproductive effects of hazardous drugs, (2) reports or other data that investigate possible adverse reproductive effects in workers exposed to hazardous drugs, and (3) information pertaining to alternative duty policies and administrative controls for workers, particularly couples trying to conceive and women who are pregnant and breastfeeding, and who are exposed to hazardous drugs in health care and other industries.

Public Comment Period: Comments must be received within 60 calendar days of publication in the **Federal Register**.

ADDRESSES: You may submit comments, identified by docket number NIOSH-150, by any of the following methods:

- **Mail:** NIOSH Docket Office, Robert A. Taft Laboratories, MS-C34, 4676 Columbia Parkway, Cincinnati, OH 45226.
- **Facsimile:** (513) 533-8285.
- **E-mail:** nioshdocket@cdc.gov.

All information received in response to this notice will be available for public examination and copying at the NIOSH Docket Office, Room 111, 4676 Columbia Parkway, Cincinnati, Ohio 45226. A complete electronic docket containing all comments submitted will be available on the NIOSH Web page at <http://www.cdc.gov/niosh/docket>, and comments will be available in writing by request. NIOSH includes all comments received without change in the docket, including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Thomas Connor, PhD, NIOSH Robert A. Taft Laboratories, MS-C23, 4676 Columbia Parkway, Cincinnati, OH 45226, (513) 533-8399, e-mail tmc6@cdc.gov.

SUPPLEMENTARY INFORMATION: Drugs have a successful history in treating illnesses and injuries, and are responsible for many of our medical advances over the past century. However, virtually all drugs can have side effects associated with patient use [NIOSH 2004]. In addition to risks in patients, workers who handle them are at risk of suffering these effects. In addition, it is known that exposures to even very small concentrations of

certain drugs may be hazardous for workers who handle them or work near them. Occupational exposures to hazardous drugs can lead to adverse reproductive events [NIOSH 2004, Dranitsaris *et al.* 2005].

The term "*hazardous drugs*" was first used by the American Society of Hospital Pharmacists (ASHP) in 1990 and recent updates to their guidelines [ASHP 2006] and is currently used by NIOSH [2004] and the Occupational Safety and Health Administration (OSHA) [OSHA 1999]. Drugs are classified as hazardous if studies in animals or humans indicate that exposures to them have a potential for causing cancer, genotoxicity, developmental or reproductive toxicity, or harm to organs. Many drugs with a hazardous classification are used to treat illnesses such as cancer (antineoplastic drugs) or HIV infection (antiviral drugs). See Appendix A of the NIOSH Alert [NIOSH 2004] for examples of hazardous drugs and a full discussion of criteria used to define and classify them as hazardous.

The numbers and types of work environments containing antineoplastic drugs are expanding as these agents are used increasingly for nonmalignant rheumatologic and immunologic diseases [NIOSH 2004].

When exposed to hazardous drugs, health care workers face several health risks, including reproductive risks. A reproductive hazard affects the reproductive function of women or men or the ability of couples to have healthy children [HSE 2003]. Some chemicals, including many hazardous drugs, are considered reproductive hazards because studies in humans or animals show that exposure to them may affect fertility, pregnancy outcome, or cause birth defects.

Evidence shows that these drugs have caused adverse reproductive outcomes in health care workers. For example, nurses and pharmacists exposed to hazardous drugs at their worksite reported an increase in adverse reproductive events including spontaneous abortions, stillbirths, and congenital malformations when compared with unexposed health care workers [NIOSH 2004]. In addition, some drugs may negatively affect germ cell (sperm and egg) development [McInnes and Schilsky 1996].

In the United States, an estimated 8 million health care workers [BLS 2007] are potentially exposed to hazardous drugs at their worksites and may be vulnerable to reproductive risks. These workers include pharmacists and pharmacy technicians, nursing personnel, physicians, operating room