

Patient Safety and Quality Improvement Final Rule, 42 CFR part 3 (Patient Safety Rule), published in the **Federal Register** on November 21, 2008, establish a framework by which hospitals, doctors, and other health care providers may voluntarily report information to Patient Safety Organizations (PSOs), on a privileged and confidential basis, for the aggregation and analysis of patient safety events. The Patient Safety Rule authorizes AHRQ, on behalf of the Secretary of HHS, to list as a PSO an entity that attests that it meets the statutory and regulatory requirements for listing. A PSO can be "delisted" by the Secretary if it is found to no longer meet the requirements of the Patient Safety Act and Patient Safety Rule, when a PSO chooses to voluntarily relinquish its status as a PSO for any reason, or when a PSO's listing expires. AHRQ has accepted a notification of voluntary relinquishment from the MagMutual Patient Safety Institute, LLC of its status as a PSO, and has delisted the PSO accordingly.

DATES: The directories for both listed and delisted PSOs are ongoing and reviewed weekly by AHRQ. The delisting was effective at 12:00 Midnight ET (2400) on February 21, 2017.

ADDRESSES: Both directories can be accessed electronically at the following HHS Web site: <http://www.pso.ahrq.gov/listed>.

FOR FURTHER INFORMATION CONTACT: Eileen Hogan, Center for Quality Improvement and Patient Safety, AHRQ, 5600 Fishers Lane, Room 06N94B, Rockville, MD 20857; Telephone (toll free): (866) 403-3697; Telephone (local): (301) 427-1111; TTY (toll free): (866) 438-7231; TTY (local): (301) 427-1130; Email: psa@ahrq.hhs.gov.

SUPPLEMENTARY INFORMATION:

Background

The Patient Safety Act, 42 U.S.C. 299b-21 to b-26, authorizes the listing of PSOs, which are entities or component organizations whose mission and primary activity are to conduct activities to improve patient safety and the quality of health care delivery.

HHS issued the Patient Safety Rule to implement the Patient Safety Act. AHRQ administers the provisions of the Patient Safety Act and Patient Safety Rule relating to the listing and operation of PSOs. The Patient Safety Rule authorizes AHRQ to list as a PSO an entity that attests that it meets the statutory and regulatory requirements for listing. A PSO can be "delisted" if it is found to no longer meet the requirements of the Patient Safety Act

and Patient Safety Rule, when a PSO chooses to voluntarily relinquish its status as a PSO for any reason, or when a PSO's listing expires. Section 3.108(d) of the Patient Safety Rule requires AHRQ to provide public notice when it removes an organization from the list of federally approved PSOs.

AHRQ has accepted a notification from the MagMutual Patient Safety Institute, LLC, a component entity of MAG Mutual Insurance Company, PSO number P0159, to voluntarily relinquish its status as a PSO. Accordingly, the MagMutual Patient Safety Institute, LLC was delisted effective at 12:00 Midnight ET (2400) on February 21, 2017.

The MagMutual Patient Safety Institute, LLC has patient safety work product (PSWP) in its possession. The PSO will meet the requirements of section 3.108(c)(2)(i) of the Patient Safety Rule regarding notification to providers that have reported to the PSO. In addition, according to sections 3.108(c)(2)(ii) and 3.108(b)(3) of the Patient Safety Rule regarding disposition of PSWP, the PSO has 90 days from the effective date of delisting and revocation to complete the disposition of PSWP that is currently in the PSO's possession.

More information on PSOs can be obtained through AHRQ's PSO Web site at <http://www.pso.ahrq.gov>.

Sharon B. Arnold,
Acting Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[CDC-2017-0028, Docket Number NIOSH-290]

Draft Current Intelligence Bulletin: The Occupational Exposure Banding Process: Guidance for the Evaluation of Chemical Hazards; Notice of Public Meeting; Request for Comments

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 meeting and availability of draft document for public comment.

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease

Control and Prevention (CDC) announces the availability of a draft Current Intelligence Bulletin entitled *The Occupational Exposure Banding Process: Guidance for the Evaluation of Chemical Hazards* for public comment. NIOSH is seeking comments on the draft document and plans to have a public meeting to discuss the document. The draft document can be found at www.regulations.gov by entering CDC-2017-0028 in the search field and clicking "Search."

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DATES: A public meeting will be held on Tuesday, May 23, 2016, from 9:00 a.m. to 3:00 p.m. Eastern Time, or until the last public presenter has spoken, whichever occurs first. Please note that public comments may end before the time indicated following the last call for comments. Members of the public who wish to provide public comments should plan to attend the meeting at the start time listed. Electronic or written comments must be received by June 13, 2017.

ADDRESSES: The public meeting will be held at the Robert A. Taft Laboratories, Auditorium, 1150 Tusculum Avenue, Cincinnati, Ohio 45226. The meeting will also be available through a conference call phone number and Webcast live on the Internet for a limited number of participants.

Written Comments: You may submit written comments, identified by CDC-2017-0028 and Docket Number NIOSH-290, by either of the following two methods:

- **Federal eRulemaking Portal:** www.regulations.gov. Follow the instructions for submitting comments.
- **Mail:** National Institute for Occupational Safety and Health, NIOSH Docket Office, 1090 Tusculum Avenue, MS C-34, Cincinnati, Ohio 45226-1998.

All information received in response to this notice must include the agency name and docket number [CDC-2017-0028; NIOSH-290]. All relevant comments received, including any personal information provided, will be posted without change to www.regulations.gov. To access the docket, read background documents or read comments, go to www.regulations.gov and enter CDC-2017-0028 in the search field and clicking "Search." All information received in response to this notice will be available for public examination and

copying at the NIOSH Docket Office, 1150 Tusculum Avenue, Room 155, Cincinnati, Ohio 45226-1998.

FOR FURTHER INFORMATION CONTACT:

Melissa Seaton, NIOSH, Education and Information Division, 1090 Tusculum Avenue, MS C-32, Cincinnati, OH 45226, telephone (513) 533-8248, Fax (513) 533-8230 (not toll free numbers), email MSeaton@cdc.gov.

SUPPLEMENTARY INFORMATION:

Registration: Notification of intent to attend the meeting, for both in-person and remote participation, or to provide oral comments must be made to the NIOSH Docket Office, at nioshdocket@cdc.gov, (513) 533-8611 (not a toll free number), no later than April 21, 2017 for U.S. citizens, and no later than April 7, 2017 for non-U.S. citizens, to allow sufficient time for mandatory facility security clearance procedures to be completed. Priority for attendance will be given to those providing oral comments. Other requests to attend the meeting will then be accommodated on a first-come, first-served basis. All requests to present should contain the name, address, telephone number, and relevant business affiliations of the presenter, topic of the presentation, whether you will be presenting in person or by phone, and the approximate time requested for the presentation. Oral presentations will be limited to 15 minutes per presenter. If additional time becomes available, presenters will be notified.

After reviewing the requests for presentations, NIOSH will notify the presenter when his/her presentation is scheduled. If a participant is not in attendance when his/her presentation is scheduled to begin, the remaining participants will be heard in order. After the last scheduled speaker is heard, participants who missed their assigned times may be allowed to speak, limited by time available. Oral comments given at the meeting will be recorded and included in the docket.

Attendees who wish to speak but did not submit a request for the opportunity to make a presentation may be given this opportunity after the scheduled speakers are heard, at the discretion of the presiding officer and limited by time available.

Status: The meeting is open to the public, limited only by the space available. The meeting space accommodates approximately 100 people. In addition, there will be an audio conference for those who cannot attend in person. There is no registration fee to attend this public meeting. However, those wishing to attend are encouraged to sign up by

April 21, 2017 with the contact person in this notice.

Security Considerations: Due to mandatory security clearance procedures at the Robert A Taft Laboratories, in-person attendees must present valid government-issued picture identification to security personnel upon entering the building and go through an airport-type security check.

Non-U.S. citizens: are encouraged to participate in the audio conferencing due to the extra clearance involved with in-person attendance. To attend in person, a non-U.S. citizen will have to call or send an email before April 7, 2017 to the contact person in this notice, and provide passport information. If clearance is received, you will be notified; otherwise, you will not be able to attend the meeting in person.

Non-U.S. Citizens must provide the following information in writing to the NIOSH Docket Office at the address above no later than April 7, 2017: Name; gender; date of birth; place of birth (city, province, state, country); citizenship; passport number; date of passport issue; date of passport expiration; type of visa; U.S. naturalization number (if a naturalized citizen); U.S. naturalization date (if a naturalized citizen); visitor's organization; organization address; organization telephone number; visitor's position/title within the organization. This information will be transmitted to the CDC Security Office for approval. Visitors will be notified as soon as approval has been obtained. If access approval is not granted to a non-U.S. Citizen, the individual may participate through a conference call phone number and Webcast live on the Internet.

Background

Occupational exposure banding is a process of quickly assigning chemicals into specific categories or bands. These bands are assigned based on a chemical's potency and the negative health outcomes associated with exposure to the chemical. The output of this process is an occupational exposure band (OEB), which corresponds to a range of exposure concentrations that is expected to be protective to worker health. Recently NIOSH has developed a process to apply the occupational exposure banding process to a broad spectrum of occupational settings. The NIOSH occupational exposure banding process uses available, but often limited, toxicological data to determine a potential range of chemical exposure levels that can be used as targets for exposure controls to reduce risk among workers.

The purpose of the public meeting and public comment period is to obtain comments on the draft document. Comments are being sought from individuals including scientists and representatives from various government agencies, industry, labor, and other stakeholders, and also the public. If there are errors of fact, unsubstantiated claims, evidence of careless experimental work, inclusion of too much information already in the literature, or statements that are inaccurate, please note such in your review comments.

I. Technical Review and Charge Questions. The authors ask that special emphasis be placed on technical review of the following issues:

1. If a chemical can cause an immediate effect (necrosis, sensitization, pulmonary edema, central nervous system (CNS) effects), should there be special guidelines for assigning a short term OEB or emphasizing the importance of keeping even short duration exposures below the OEB for those types of toxicants?

2. If a skin toxicant is a corrosive, irritant, or sensitizer, should there be any special designation assigned along with the occupational exposure band (OEB)? Additionally, please comment on the utility of using skin and eye effects to create inhalation based bands.

3. The comparison of Tier 1 and Tier 2 results for a set of chemicals showed that Tier 1 and Tier 2 produce the same band for 65% of the chemicals tested. Tier 1 is more protective for 17.5% of the chemicals, while Tier 2 is more protective for 17.5% of the chemicals. NIOSH currently recommends that both the tier 1 and tier 2 process be completed for a particular chemical. Do you agree with this recommendation? If not, what approach should NIOSH take?

4. NIOSH has proposed a number of sources of information for the different human health and toxicological endpoints under consideration. Are there other sources of information that should be recommended? Are there some sources that should be omitted?

5. In tier 1, the NIOSH method does not currently assign chemicals to an OEB based on H335 or H336 (drowsiness and dizziness). Should NIOSH include H335/H336 in the tier 1 methodology? If so, what criteria should be used for banding and why?

6. In Section 3.2 the process for assessing whether enough information is available to conduct occupational exposure banding is presented. Please comment on the use of a numerical scale (determinant scores) to document endpoint-specific data availability. Further, is the minimum value of 30 out

of a possible total of 125 (for the total determinant score) a suitable choice for the data sufficiency threshold? Is the relative weight for each score appropriate?

7. How should NIOSH consider data collected on structural analogs or related chemicals in the banding scheme?

8. Qualitative and quantitative technical criteria have been adopted for some endpoints. Is this approach adequately justified and suitably explained in the document? If not, how should the explanations be refined?

9. If a chemical has two forms (vapor or particulate) in the workplace, we have recommended that the most protective OEB take precedence. Please comment on the utility and adequacy of that recommendation.

10. Acute toxicity information may be presented in an array of different units. We have attempted to address those possibilities in the banding criteria for the acute toxicity endpoint, especially for inhalation exposures. Is this information sufficiently clear? Are suitable rubrics for unit conversions provided?

11. Does this draft document adequately describe the occupational exposure banding process in a way that supports its use in assigning ranges of exposure concentrations to protect worker health in the occupational setting?

Public Review

The external review of the draft document has been (1) developed in accordance with Office of Management and Budget (OMB) guidelines, (2) is consistent with NIOSH peer review practice, and (3) is meant to ensure that credible and appropriate science is reflected within the draft document.

Dated: March 10, 2017.

Frank Hearl,

Chief of Staff, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. 2017-05115 Filed 3-14-17; 8:45 am]

BILLING CODE 4163-19-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-1427]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Hazard Analysis and Critical Control Point Procedures for the Safe and Sanitary Processing and Importing of Juice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by April 14, 2017.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0466. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Hazard Analysis and Critical Control Point (HACCP) Procedures for the Safe and Sanitary Processing and Importing of Juice—21 CFR Part 120

OMB Control Number 0910-0466—Extension

FDA's regulations in part 120 (21 CFR part 120) mandate the application of HACCP procedures to the processing of fruit and vegetable juices. HACCP is a preventative system of hazard control designed to help ensure the safety of foods. The regulations were issued under FDA's statutory authority to regulate food safety under section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 342(a)(4)). Under section 402(a)(4) of the FD&C Act, a food is adulterated if it is prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth or rendered injurious to health. The Agency also has authority under section 361 of the Public Health Service Act (42 U.S.C. 264) to issue and enforce regulations to prevent the introduction, transmission, or spread of communicable diseases from one State, territory, or possession to another, or from outside the United States into this country. Under section 701(a) of the FD&C Act (21 U.S.C. 371(a)), FDA is authorized to issue regulations for the efficient enforcement of that act.

Under HACCP, processors of fruit and vegetable juices establish and follow a preplanned sequence of operations and observations (the HACCP plan) designed to avoid or eliminate one or more specific food hazards, and thereby ensure that their products are safe, wholesome, and not adulterated; in compliance with section 402 of the FD&C Act. Information development and recordkeeping are essential parts of any HACCP system. The information collection requirements are narrowly tailored to focus on the development of appropriate controls and document those aspects of processing that are critical to food safety.

In the **Federal Register** of August 30, 2016 (81 FR 59636), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows: