

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Interim Safety and Risk Assessment of Melamine and Its Analogues in Food for Humans; Availability

AGENCY: Food and Drug Administration, HHS

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled "Interim Safety and Risk Assessment of Melamine and Its Analogues in Food for Humans." The interim safety/risk assessment evaluated exposure to melamine and its analogues (cyanuric acid,ammelide and ammeline) in infant formula and other foods to identify, where possible, a level of exposure that would not raise public health concerns. FDA is seeking public comment on the interim safety/risk assessment.

DATES: Comments on the interim safety/risk assessment must be submitted by *[insert date 60 days after date of publication in the Federal Register]*.

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Annette McCarthy, Center for Food Safety and Applied Nutrition (HFS-205), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1057, FAX: 301-436-2973, or e-mail: Annette.McCarthy@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:**I. Background**

The purpose of the interim safety/risk assessment is to identify the level of melamine and melamine-related compounds in food which would not raise public health concerns. On September 11, 2008, FDA learned that melamine may be contained in an infant formula manufactured by a firm in China. As of September 21, 2008, FDA learned that a total of 52,857 cases of nephrolithiasis (and, in some instances, renal failure) had been reported in China linked to consumption of this contaminated powdered formula. There have been approximately 13,000 hospitalizations, and at least 3 deaths have been confirmed to date. The results of an investigation conducted in China indicated that Chinese-produced powdered infant formula was linked to these illnesses; no cases were associated with liquid infant formula. Test results conducted in China on samples of the powdered infant formula showed that they contained a wide range of concentrations (0.1 parts per million (ppm) to greater than 2,500 ppm melamine). In addition, other countries have reported detection of melamine in other product categories, such as confections and beverages.

The interim safety/risk assessment concludes that, based on currently available data and information, there is too much uncertainty for FDA to establish a level of melamine and its analogues in infant formula that does not raise public health concerns. In foods other than infant formula, FDA concludes that levels of melamine and melamine-related compounds below 2.5 ppm do not raise public health concerns. This interim safety/risk assessment was developed rapidly due to the extremely time-sensitive need to understand

the nature of the potential risk. We are seeking public comment on this interim safety/risk assessment. In addition, it will undergo expert peer review.

II. Safety/Risk Assessment

A human health safety/risk assessment is a scientifically-based methodology used to estimate risk to human health from exposure to specific compounds such as contaminant(s) in food. The interim safety/risk assessment of melamine and its analogues builds upon the 2007 Melamine Safety/Risk Assessment and considers the toxicological profile of melamine and its analogues, including the observed results from controlled animal studies conducted with melamine.

For infant formula, there are gaps in our scientific knowledge about the toxicity of melamine and its analogues in infants, including:

1. The consequences of the continuous use of infant formulas as the sole source of nutrition;
2. The uncertainties associated with the possible presence and co-ingestion of more than one melamine analogue; and
3. For premature infants with immature kidney function, the possibility that they may be fed these formulas as the sole source of nutrition and thus on a body weight basis experience greater levels of intake for a longer time than is experienced by term infants. For these reasons, there is too much uncertainty for FDA to establish a level of melamine and its analogues in infant formula that does not raise public health concerns. However, it is important to understand that this does not mean that any exposure to any detectable level of melamine and melamine-related compounds in formula will result in harm to infants.

In food products other than infant formula, to estimate the level of melamine that does not raise public health concerns, FDA used a worst case

exposure scenario in which one-half of a person's total daily dietary intake (Tolerable Daily Intake (TDI), an estimate of the maximum amount of an agent to which an individual could be exposed on a daily basis over the course of a lifetime without appreciable health risk) is contaminated with melamine and its analogues. The TDI used, 0.63 milligrams/kilogram (mg/kg) body weight/day (bw/d), was developed in 2007 in collaboration with the Food Safety and Inspection Service of the Department of Agriculture and in consultation with the Centers for Disease Control and Prevention, the Environmental Protection Agency, and the Department of Homeland Security.¹ In the present interim safety/risk assessment, we estimated that if 50 percent of the diet were contaminated at a level of 2.5 ppm of melamine and its analogues, a person's daily intake would equal 0.063 mg/kg bw/d—a level 10-fold below the TDI. Therefore, FDA concludes that levels of melamine and melamine-related compounds below 2.5 ppm do not raise public health concerns in food other than infant formula.

Recognizing the time-sensitive need for the safety/risk assessment, FDA invites comments concerning:

1. The assessment approach used;
2. The assumptions made;
3. The data used; and
4. The transparency and clarity of the report.

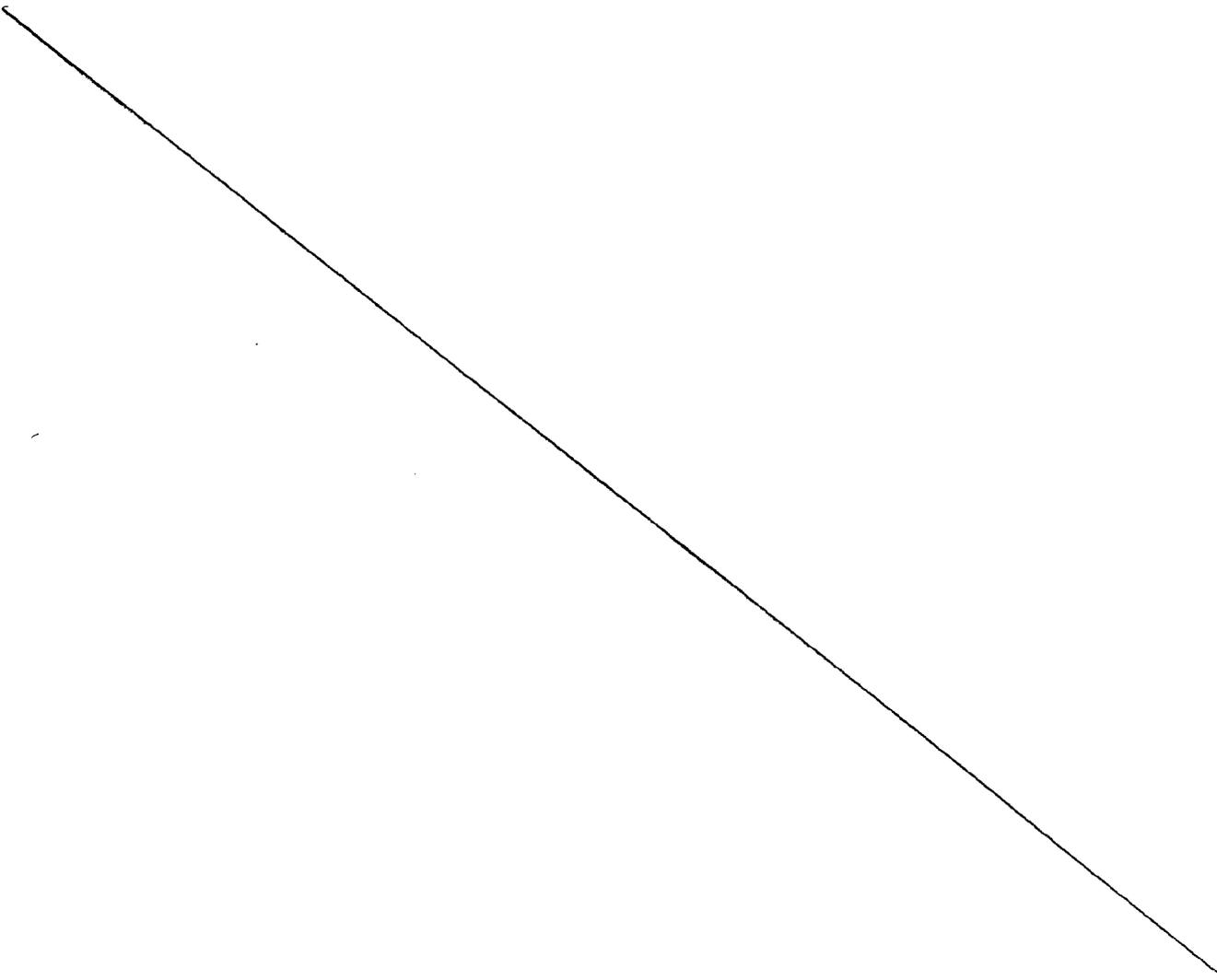
III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed

¹Interim Melamine and Analogues Safety/Risk Assessment, May 25, 2007 (<http://www.cfsan.fda.gov/~dms/melamra.html>).

comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

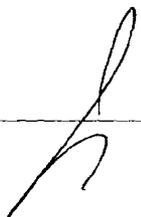
Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.



IV. Electronic Access

The interim safety/risk assessment is available electronically at <http://www.cfsan.fda.gov/~dms/melamra3.html>.

Dated: 11/5/08
November 5, 2008.



Jeffrey Shuren,
Associate Commissioner for Policy and Planning.

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Dawn P. Hawkins