and Model A340–211, –212, –213, –311, –312, and –313 airplanes; certificated in any category; with hydraulic control block (HCB) part number (P/N) C24856000–9 or C24856001–7.

Unsafe Condition

(d) This AD was prompted by a report of an unexpected steering event (swerve) during the take-off roll of one affected airplane. We are issuing this AD to prevent loss of airplane steering while on the ground, which could result in the airplane going off the side of the runway.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Modification

(f) Within 30 months after the effective date of this AD: Modify the hydraulic control block (HCB) in accordance with the Accomplishment Instructions of the applicable service bulletin in paragraph (f)(1) or (f)(2) of this AD.

(1) Airbus Service Bulletin A330–32–3156, dated December 22, 2004, for Model A330–200 and A330–300 series airplanes.

(2) Airbus Service Bulletin A340–32–4194, dated December 22, 2004, for Model A340–200 and A340–300 series airplanes.

Note 1: The Airbus service bulletins refer to Messier-Bugatti Service Bulletin C24856–32–064, dated January 26, 2005, as an additional source of service information for doing the modification.

Parts Installation

(g) After the effective date of this AD, no person may install on any airplane an HCB having P/N C24856000–9 or C24856001–7, unless it has been modified in accordance with paragraph (f) of this AD.

Alternative Methods of Compliance (AMOCs)

(h) The Manager, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

Related Information

(i) French airworthiness directive F–2005–016, dated January 19, 2005, also addresses the subject of this AD.

Issued in Renton, Washington, on July 11, 2005.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 05–14172 Filed 7–18–05; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter I

[Docket No. 2005N–0279]

Food Labeling; Gluten-Free Labeling of Foods; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to obtain expert comment and consultation from stakeholders to help the agency to define and permit the voluntary use on food labeling of the term ''gluten-free''. The meeting will focus on food manufacturing, analytical methods, and consumer issues related to reduced levels of gluten in food. We request that those who wish to speak at the meeting, or otherwise provide FDA with their written or oral comments, focus on the questions set out in this document.

DATES: The public meeting will be held on Friday, August 19, 2005, from 8:30 a.m. to 5 p.m. All those attending the meeting must register by August 12, 2005. See the ''Registration'' heading of the **SUPPLEMENTARY INFORMATION** section of this document for details on how to register. Submit written or electronic comments by September 19, 2005.

ADDRESSES: The public meeting will be held at the Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy., Harvey W. Wiley Auditorium, College Park, MD 20740.

You may submit written comments, identified with Docket No. 2005N–0279, to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT:

For general questions about the meeting, to register, to request permission to speak at the meeting, to request onsite parking, or if you need special accommodations due to a disability: Marion V. Allen, Center for Food Safety and Applied Nutrition (HFS–32), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1584, FAX: 301–436–2605, e-mail: *marion.allen@fda.hhs.gov*.

For technical questions: Rhonda R. Kane, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2371, FAX: 301–436–2636, e-mail: *rhonda.kane@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Celiac disease (also known as celiac sprue) is a chronic inflammatory disorder of the small intestine triggered by ingesting certain storage proteins that naturally occur in cereal grains. Celiac disease is genetically inherited, and its prevalence in the United States is estimated to be slightly less than 1 percent of the general population (Ref. 1).

The grains that are considered to cause problems for persons with celiac disease are wheat, barley, and rye, their related species (e.g., durum wheat, spelt, kamut) and crossbred hybrids (e.g., triticale), and possibly oats (Ref. 2). The scientific literature includes reports of celiac disease patients who can tolerate oats (Refs. 3 through 5) and others who cannot (Refs. 6 and 7). This intolerance may be due to the possible presence in commercially available oat products of trace amounts of other grains that are harmful to persons who have celiac disease (e.g., wheat, rye, or barley) (Refs. 2 and 8). However, there is also some evidence that naturally occurring proteins in uncontaminated oats may cause adverse effects in some celiac disease patients (Ref. 7).

Technically, the term ''gluten'' applies to the combination of storage proteins found in wheat, the prolamin proteins called ''gliadins'' and the glutelin proteins called ''glutenins'' (Ref. 9). However, in the context of celiac disease, the term ''gluten'' is often used to refer collectively to any of the proteins in the grains that may cause harm. Currently, to prevent severe and sometimes life-threatening complications of celiac disease, sensitive individuals need to avoid all offending sources of gluten (Refs. 10 through 12). Life-threatening complications can affect multiple organs of the body (Refs. 10 through 12).

The Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) (Title II of Public Law 108–282) at *http://www.cfsan.fda.gov/~dms/alrgact.html* requires FDA to issue, within 2 years of the enactment date, a proposed rule to define, and permit the use of, the term ''gluten-free'' on food labeling and a final rule within 4 years of enactment. FALCPA requires FDA to

consult with appropriate experts and stakeholders during the agency's development of the proposed rule. Establishing a definition of ''gluten-free'' that is both protective of the celiac population and that uniformly applies to ''gluten-free'' labeling statements for foods marketed in the United States will assist Americans with celiac disease to make more informed food consumption decisions.

II. Purpose and Scope of Meeting

FDA is holding this meeting to solicit comments from appropriate experts and stakeholders to assist us in developing a proposed rule to define and permit the use of the term ''gluten-free,'' as required by FALCPA. The agency is interested in gathering information from the public, particularly the food industry on how ''gluten-free'' foods are manufactured, the analytical methods used to verify that foods are ''gluten-free,'' and related costs of manufacturing ''gluten-free'' foods. The agency is also interested in receiving research data or findings on the food purchasing practices of consumers with celiac disease and their caregivers related to packaged products labeled or marketed as ''gluten-free,'' compared to their purchasing practices of packaged products that are not so labeled.

The public meeting will not address issues regarding a threshold level of gluten (i.e., the amount of gluten below which it would be unlikely to elicit harmful effects in celiac disease patients) and the medical implications of celiac disease. These two issues were addressed at a meeting of FDA's Food Advisory Committee (FAC) on July 13 through 15, 2005 (70 FR 29528, May 23, 2005). The meeting agenda provided that the FAC would review and evaluate the Center for Food Safety and Applied Nutrition Threshold Working Group draft report entitled ''Approaches to Establish Thresholds for Major Food Allergens and for Gluten in Food,'' which may be found on the Internet at *http://www.cfsan.fda.gov/~dms/alrgn.html*. FDA will consider all pertinent information, including the recommendations of the FAC and comments from this public meeting, in developing a definition and establishing the permissible use of the term ''gluten-free'' in food labeling.

III. Questions

FDA has drafted a series of questions to help focus the comments presented at the public meeting or otherwise communicated to the agency. Those who comment are invited to address any or all of these questions. FDA is particularly interested in receiving related technical, scientific, and cost data from the food industry as well as research data or findings about the food purchasing practices of consumers with celiac disease or their caregivers. For the purpose of the list of questions in this document, FDA is using the following terms:

- ''Gluten'' refers to the proteins found in any of the grains that can cause harm to persons with celiac disease;
- ''Grains of concern'' refers to wheat, rye, barley, and oats, and their related species (e.g., durum, spelt, kamut) or crossbred hybrids (e.g., triticale); and
- ''Gluten-free foods'' refers to foods currently marketed in the United States that are either represented to be free of gluten or that contain statements or symbols on their labeling that identify the products as ones that do not contain gluten.

A. Definitions of ''Gluten-Free''

1. How do food manufacturers define ''gluten-free''? What is the generally accepted definition in the food industry of ''gluten-free''? Please identify any entities that ''certify'' finished foods or raw ingredients to be ''gluten-free''. Describe how they define ''gluten-free'' and how they determine whether a food product satisfies this definition.

B. ''Gluten-Free'' Product Development

2. How are ''gluten-free'' foods produced? For example, are ''gluten-free'' foods made by using only ingredients that do not contain any gluten (i.e., they are inherently ''gluten-free'') or are they made by processing ingredients or the finished food to remove gluten? What methods are most commonly used to remove gluten from food?

3. Due to potential grain cross-contact situations, is it technologically feasible to produce ''gluten-free'' flour from grains other than those of concern (e.g., corn, millet)? Is it technologically feasible to produce oat-based products that do not contain gluten from grains of concern other than oats (e.g., wheat)? If so, what additional measures in the milling or manufacturing process would be needed to produce these products? Is it economically feasible to produce such products, and if so, what would be the incremental costs?

C. Good Manufacturing Practices and Analytical Methods

4. What measures do you have in place during the manufacturing, packaging, or holding of ''gluten-free'' foods to prevent them from coming into contact with any grains of concern? For example, do you use dedicated facilities, dedicated equipment, or dedicated production lines?

5. What analytical method(s) do you use to evaluate your ''gluten-free'' products? How often to do you perform these analyses? For example, do you test every batch of finished product? Do you test bulk containers of each ingredient? What is the cost of such testing?

6. The following questions seek data and information about available gluten detection test kits or analytical methods to detect gluten:

- In what grains can the test kit or method detect gluten?
- What specific mechanism is used to indicate the presence or absence of gluten?
- What is the sensitivity or lowest level of detection of your test kit or method?
- Is your test kit or method qualitative (i.e., establishes only the presence or absence of gluten) or quantitative?
- If quantitative, what is the limit of quantification of your test kit or method?
- What is the false positive rate of your test kit or method? What is its false negative rate?
- Is the effectiveness of your test kit or method affected by the nature of the processing of the ''gluten-free'' food, and if so, how? Is it affected by the food matrix, and if so, how? (FDA is especially interested in information that addresses the influence of the presence of fermented or hydrolyzed proteins, of xanthan gum, of guar gum, or of any other dietary fibers.)
- If your test kit or method has been validated, please indicate by whom it was validated and the level (e.g., parts per million) of detection at which it was validated.
- If your test kit or method has not been validated, have the results of its performance or an evaluation of its performance been published in a peer-reviewed scientific journal?
- What is the cost of your test kit or the cost to perform your method of analysis?

7. What analytical methods are currently available or under development to detect the presence of oat proteins in food? Please specify which proteins. What is the cost to conduct such analyses? Have any of these methods been validated or published in a peer-reviewed scientific journal?

D. Foods Marketed as ''Gluten-Free''

8. Are there available research data or findings on what consumers with celiac disease or their caregivers believe the term ''gluten-free'' means? For example,

do the research data or findings show consumers' beliefs as to which specific grains or other ingredients are not present in foods labeled ''gluten-free''?

E. Consumer Purchasing Practices

9. Are there available research data or findings on how consumers with celiac disease or their caregivers identify packaged foods that do not contain gluten? Do the data establish how much time these consumers devote to identifying such foods?

10. Are there available research data or findings on whether the packaged foods consumers with celiac disease or their caregivers currently purchase or consume are primarily or exclusively those foods labeled ''gluten-free''? Do the research data or findings identify the types of ''gluten-free'' packaged foods (e.g., breads, dairy foods, canned vegetables) purchased or consumed by persons with celiac disease or their caregivers? Do the research data or findings show whether a ''gluten-free'' label influences the purchasing decision of persons with celiac disease or their caregivers when presented with products having identical ingredient lists?

IV. Registration

Please submit your registration information (including name, title, firm name (if applicable), address, telephone number, fax number (if available), and e-mail address (if available)) by August 12, 2005. We encourage you to register online at *http://www.cfsan.fda.gov/~comm/register.html* or by fax to Marion V. Allen at 301–436–2605. We will also accept registration onsite; however, space is limited and registration will be closed when the maximum seating capacity is reached. If you need special accommodations due to a disability (e.g., sign language interpreter), please inform Marion V. Allen (see **FOR FURTHER INFORMATION CONTACT**) no later than August 12, 2005, when you register. Please also specify whether you need onsite parking when you register.

If you wish to make a presentation, indicate this desire when registering and submit the following information by August 12, 2005: (1) A brief written statement about the general nature of the views you wish to present and (2) the names of any copresenters who must also register to attend. The amount of time allowed for each oral presentation at the public meeting may be limited (e.g., 5 minutes each), depending upon the number of persons who request to speak. Individuals and organizations that do not preregister to make a presentation may have the opportunity to speak if time permits.

Persons preregistered or wishing to register onsite should check in between 7:30 and 8:30 a.m. Because the meeting will be held in a Federal building, meeting participants must present photo identification and plan adequate time to pass through the security system.

V. Comments

In addition to attending or presenting oral comments at the meeting, interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments related to the questions and the focus of this public meeting. All relevant data and information should be submitted with the written comments. Submit a single copy of electronic comments or two paper copies of any mailed 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.

VI. Meeting Transcript

A transcript will be made of the meeting's proceedings. You may request a copy in writing from FDA's Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 30 working days after the public meeting at a cost of 10 cents per page. The transcript of public meeting and all comments submitted will be available for public examination at the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday, as well as on the FDA Web site at *http://www.fda.gov/ohrms/dockets/default.htm*.

VII. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSESS**) and may be viewed between 9 a.m. and 4 p.m., Monday through Friday.

1. National Institutes of Health, Consensus Development Conference Statement, Celiac Disease, June 28 through 30, 2004, accessible on June 2005 at *http://consensus.nih.gov/cons/118/118celiacPDF.pdf*. (FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.)

2. Kasarda, D.D., ''Grains in Relation to Celiac Disease,'' *Cereal Foods World*, 46(5):209–210, 2001.

3. Janatuinen, E.K., T.A. Kemppainen, R.J. Julkunen, et al., ''No Harm From Five Year Ingestion of Oats in Coeliac Disease,'' *Gut*, 50(3):332–335, 2002.

4. Janatuinen, E.K., T.A. Kemppainen, P.H. Pikkarainen, et al., ''Lack of Cellular and Humoral Immunological Responses to Oats in Adults With Coeliac Disease,'' *Gut*, 46(3):327–331, 2000.

5. Janatuinen, E.K., P.H. Pikkarainen, T.A. Kemppainen, et al., ''A Comparison of Diets With and Without Oats in Adults With Celiac Disease,'' *New England Journal of Medicine*, 333(16):1033–1037, 1995.

6. Lundin, K.E., E.M. Nilsen, H.G. Scott, et al., ''Oats Induced Villous Atrophy in Coeliac Disease,'' *Gut*, 52(11):1649–1652, 2003.

7. Arentz-Hansen, H., B. Fleckenstein, O. Molberg, et al., ''The Molecular Basis for Oat Intolerance in Patients With Celiac Disease,'' *PLoS Medicine*, 1:84–92, 2004.

8. Thompson, T., ''Gluten Contamination of Commercial Oat Products in the United States,'' *New England Journal of Medicine*, 351(19):2021–2022, 2004.

9. Brown A., *Understanding Food Principles and Preparation, Second Edition*, Wadsworth/Thomson Learning, Belmont CA, USA, pp. 402–403, 2004.

10. Corrao, G., G.R. Corazza, V. Bagnardi, et al., ''Mortality in Patients With Coeliac Disease and Their Relatives: A Cohort Study,'' *Lancet*, 358:356–361, 2001.

11. Dewar, D., S.P. Pereira, and P.J. Ciclitira, ''The Pathogenesis of Coeliac Disease,'' *International Journal of Biochemistry & Cell Biology*, 36:17–24, 2001.

12. Fasano, A. and C. Catassi, ''Current Approaches to Diagnosis and Treatment of Celiac Disease: An Evolving Spectrum,'' *Gastroenterology*, 120(3):636–651, 2001.

Dated: July 13, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–14196 Filed 7–14–05; 4:31 pm]

BILLING CODE 4160–01–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 261

[SW–FRL–7940–2]

Hazardous Waste Management System; Identification and Listing of Hazardous Waste; Proposed Exclusion

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule and request for comment.

SUMMARY: EPA is proposing to grant a petition submitted by General Motors Corporation-Arlington Truck Assembly Plant (GM-Arlington) to exclude (or delist) a wastewater treatment plant (WWTP) sludge generated by GM-Arlington in Arlington, TX. from the lists of hazardous wastes.

EPA used the Delisting Risk Assessment Software (DRAS) in the evaluation of the impact of the petitioned waste on human health and the environment.