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GENERAL MILLS

September 10, 2004

Division of Dockets Management  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, Maryland 20852

Re: Docket No. 2004N-0230; Food; Current Food Manufacturing Practice  
Regulations 69 *Federal Register* 40312; July 2, 2004

Dear Sir or Madam:

General Mills submits these comments to the Food and Drug Administration (FDA) concerning current good manufacturing practices and other controls used by food manufacturers and processors to prevent, reduce, control, or eliminate food borne hazards that can occur during food production, processing, and distribution.

General Mills is a Delaware Corporation with its general offices at No. 1 General Mills Boulevard, Minneapolis, MN 55426. General Mills is a major packaged-food manufacturer engaged for over 75 years in the development and production of food products including flour, ready-to-eat-cereals, refrigerated dough products, cake and other dessert mixes, soups, vegetables, snacks and numerous other products. We have long been a leader in the safe manufacture of food, identifying and promoting quality management principles, practices and technological advances, and implementing those advances through appropriate training, and organizational management policies and metrics.

We applaud FDA's action to review existing regulations as the food industry and scientific knowledge and understanding have undergone significant change since FDA last revised its Good Manufacturing Practice (cGMP) regulations. General Mills, as an industry leader in producing safe and wholesome foods, has strongly endorsed and utilized the fundamental principles embodied in the Good Manufacturing Practices outlined in 21 CFR Part 110. The cGMPs, when used in their totality, have served General Mills and the entire food industry well in assuring consumers, customers and regulatory agencies that we are producing safe, wholesome and compliant food.

The cGMPs provide critical and fundamental guidance applicable to the entire food and agricultural supply chain. They are clear and concise performance standards, covering

the many facets of food manufacturing. Their inherent flexibility and non-prescriptive nature has allowed new scientific discoveries and technical advances to be incorporated without need for frequent regulatory revision. As performance standards, the cGMPs have allowed processors and distributors the opportunity to develop the most efficient and cost effective programs and procedures necessary to achieve the objective and assure compliance. We would encourage FDA to assure any changes will enhance prevention of adulteration and misbranding without unduly burdening the food and agricultural supply chain. Any change to the regulations will impact not only our internal control programs, but the standards and requirements we place on our supply chain partners worldwide. Because of this, General Mills believes there are only limited areas calling for revision and enhancements.

### Allergens

An area that has garnered significant attention recently is allergen labeling and control. Allergen labeling is addressed in the recently passed Allergen Labeling Bill. Allergen control is an area properly addressed in the context of cGMP. That does not mean, however, that new regulations are necessary. Even though allergens were not a high profile issue at the time of the last revision, the cGMP's establish expectations for compliance with Section 402 (a) (4) of the Food Drug and Cosmetic Act, which indicates a food is adulterated if it is prepared, packed or held under insanitary conditions whereby it may have become contaminated with filth or been rendered injurious to health. As mentioned above, the non-prescriptive nature of cGMP's has afforded the regulations an ability to expand to meet the realities of a changing global landscape, including allergen control in an era of increasing attention of analytical sensitivity. General Mills has not experienced situations where controls for allergenic materials, or lack thereof, were not sufficiently addressed by our cGMP obligations under the current regulations. We would encourage continued adherence to this non-prescriptive approach as it has fostered innovation, critical thinking and allowed rapid adoption of new scientific discoveries without the need to routinely revise regulations. However, we do believe the term allergen should be incorporated into cGMPs where appropriate (e.g. chemical hazard such as an allergen).

We believe industry and regulators are both well served by guidance documents that can identify and facilitate an understanding of targeted areas of concern. This approach should be used for allergen management. The food industry undertook this approach, developing voluntary guidelines in late 2001. In addition, General Mills and the food industry have contributed significant resources training and educating our operations teams, as well as the food and agricultural supply chain, regulators, the medical profession and consumers to recognize and prevent risks associated with food allergens.

### Training

It has been our experience that training is the necessary foundation upon which a system for implementing food safety procedures and programs must be based. The strictest regulations and the most comprehensive internal food safety programs can be mooted

without appropriate training. It is for this reason that General Mills has always placed a strong emphasis on the proper training of all our food safety personnel. Recently, FDA has also adopted a progressive approach to training, by developing computer based training systems for its field personnel. This approach demonstrates FDA's recognition of the critical role training plays in ensuring the safety of the food supply.

Not all food manufacturers have the necessary internal resources to develop a robust internal training program. For that reason, FDA should consider making some form of their computer-based training modules available to industry, particularly to small manufacturers. This could make a significant step toward greater compliance and safety for the entire food supply. By allowing the food industry to utilize the powerful computer-based training tools, FDA could help facilitate a greater understanding of the processes and procedures necessary to ensure the safe manufacture of food.

### Responses to Specific Questions

As mentioned above, General Mills considers the current flexible regulatory approach to cGMPs to be an effective approach to ensuring food safety. Accordingly, in response to FDA's eleven questions, General Mills provides the following responses:

**1. Which practices specified in current part 110 are most effective at preventing each type of food hazard? Which practices are least effective at such prevention?**

General Mills believes that the current GMP's, as written, are broad enough to allow for the proper level of control based on the hazards specific to each plant and/or product line. It has been our experience that training is most important in fostering an understanding of the principles and goals of cGMPs as a performance standard.

It has been our experience that prescriptive programs can limit the need for personnel to understand what a specific control is needed and that they are inefficient and inflexible as situations and conditions change overtime. Due to the complexities inherent in each manufacturer's facility, it would be impractical to try to dictate significantly greater specificity in the regulations.

**2. In today's food manufacturing environment, what conditions, practices, or other factors are the principal contributors to each type of food hazard?**

General Mills believes that failure to follow the current GMP's and consistently assuring execution of adequate programs and procedures are the foremost contributors. This is further evidence of the importance of proper training for all personnel with respect to food safety. Other issues are product and process specific.

**3. If the CGMP regulations were revised, which type or types of food hazards could be most readily prevented through CGMP-type controls?**

We believe that the cGMPs cover physical, chemical and biological hazards as appropriate. We would suggest added examples behind each hazard (e.g. chemical – (e.g. allergens)).

**4. Are there preventive controls, in addition to those set out in part 110, needed to reduce, control, or eliminate each of the three types of food hazards? If yes, please identify the specific hazard and the particular controls, that would reduce, control, or eliminate the hazard.**

We believe that reduction and control are covered at a high level within the cGMP's. The specific values required are plant, product and process dependent. Due to the complexity, we believe that it would be impractical for the cGMP's to spell this out.

**5. What concepts or underlying principles should guide FDA's adoption of new preventive controls?**

General Mills believes that cGMPs should remain performance standards, setting Agency expectations and providing general guidance on how to meet them without mandating prescriptive requirements to comply. Preventative controls must be based on risk assessments.

**6. How should the effectiveness of preventive controls for each of the three types of hazards be most accurately measured?**

We believe each facility / company is in the best position to measure their own system effectiveness. We have found current FDA audits / inspections to be helpful in understanding Agency expectations.

**7. In today's food manufacturing environment, what are the principal contributors to the presence of undeclared allergens in food? For example, do labeling errors or cross-contamination contribute? Which preventive controls could help reduce, control, or eliminate the presence of undeclared allergens in food?**

General Mills has been an industry leader in allergen control programs. We have found that control begins at product and process design and goes all the way to shelf. While cross contamination is certainly a possibility, we have found errors in package ingredient declaration, carton handling practices and assuring proper match of formula to specific cartons to be the most common reason for the presence of undeclared allergens. Appropriate control by packaging vendors and our internal handling practices is critical in reducing the occurrence of these events. In addition, we have found a blend of training and technology (e.g. judicious use of bar code scanners, as appropriate) important tools at minimizing or eliminating these risks.

**8. Are there existing quality systems or standards (such as international standards) that FDA should consider as part of the agency's exploration of food CGMP modernization? Please identify these systems or standards and explain what their consideration might contribute to this effort.**

HACCP is a system in use today by most food manufacturers. This has been voluntary in the past in most sectors and we are in favor of it remaining voluntary. We believe that mandating HACCP across all sectors would dilute its effectiveness.

**9. There is a broad variation within the food manufacturing and processing industry, including variations in size of establishments, the nature of the food**

**produced, the degree to which the food is processed, and the vulnerability of a particular operation to physical, chemical, or microbial hazards. How, if at all, should the CGMP regulations be revised to take into account such variation? For example, should there be different sets of preventive controls for identifiable segments of the food industry, such as different storage temperature limits?**

We do not believe there should be different standards based on Plant size. The cGMP's as written can and should be used by all sizes of facilities. Implementation may be more complex and involved, but all food plants regardless of size should be in compliance with the cGMP's and control. The cGMPs allow for the variation in product risk and give the requirements needed to protect the consumer.

**10. There are a number of measures, procedures, and programs that help to ensure that preventive controls are carried out adequately. These include the following items:**

- \* **Training programs for managers and/or workers;**
- \* **Audit programs;**
- \* **Written records, e.g., batch records, sanitation records;**
- \* **Validation of control measures;**
- \* **Written sanitation standard operating procedures;**
- \* **Food label review and control program; and**
- \* **Testing of incoming raw materials, in process materials, or finished**

**products.**

**Which (if any) of these should be required practices for food and manufacturers and why? Which (if any) of these should be recommended practices for food manufacturers and processors and why?**

We believe that all of the programs mentioned, in the appropriate form, are critical to manufacturing a food product. We also believe that it should be left up to the plant and food industry to control and implement these areas based on the risk.

**11. Are there preventive controls in addition to those already set out in part 110 for food distributors, wholesalers, and warehouses that are needed to help ensure the safe and sanitary holding of food? If yes, please identify the controls by hazard and sector of the industry.**

We would encourage FDA to expand the section 110.93 Warehouse and distribution. We believe shipping vehicles deserve separate statements identifying the need for evaluation of overall condition to assure it is suitable for use in such a manner to prevent the food from becoming adulterated.

#### Suggested Revisions

The following is a list of areas where we believe the current GMP's could be strengthened.

#### 21CFR110.3 Definitions

(e) We would recommend that the definition of critical control point be modified to be more consistent with the HACCP definition. Our suggestion: “Critical Control Point means a step in the production, packaging, or distribution process at which control can be applied and is essential to prevent, eliminate or reduce a food safety hazard to an acceptable level.”

(l) We would recommend that the words “or misbranded” be inserted after the word adulterated. Statement would now read, “Quality control operations means a planned and systematic procedure for taking all actions necessary to prevent food from being adulterated or misbranded within the meaning of the act.”

(m) We would recommend a statement be added on control of rework as to not cause misbranding.

We would recommend the following definitions be added:

(s) Hazard Analysis is the process of collecting information on hazards and conditions leading to their presence to decide which are significant for food safety and therefore should be addressed.

(t) Hazardous is the potential to cause injury or illness.

(u) Allergen is a substance, typically a food protein, which can cause the body’s immune system to overreact and develop a potentially life-threatening autoimmune reaction.

#### **21CFR110.19 Exclusions**

(a) We would encourage FDA to issue some minimum guidance on raw agricultural commodities.

#### **21CFR110.20 Plant and grounds**

(b2) We would recommend that the statement “or cross contact with foods containing allergens” be inserted after the statement “Permit the taking of proper precautions to reduce the potential for contamination of food.”

#### **21CFR110.40 Equipment and utensils**

(a) We would recommend a statement be added that temporary repairs will not result in contamination.

(d) We would recommend a statement at the end of the existing statement that says, “and also prevent cross contact with unlabeled allergenic material.”

#### **21CFR110.80 Processes and controls**

(a5) We would recommend a statement be added at the end which says, “and be used in a manner that does not create an allergen cross contact situation.”

(b4) We would recommend that preservation systems or modified atmosphere packaging be added in the control of undesirable microorganisms.

(b5) We would recommend a statement be added at the end which says, “and allergen cross contact.”

(b7) We would recommend a statement be added at the end which says, “and cross contact of allergens when necessary.”

(b8) We would recommend the addition of X-Ray as a suitable means to prevent the inclusion of metal and other foreign material.

**21CFR110.93 Warehousing and distribution**

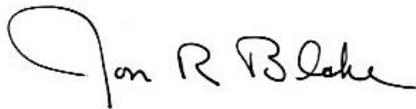
We would suggest that this might be a good area to provide guidance on Food Security.

We would recommend including some more focus and guidance on transportation vehicles. Issues we commonly encounter concern condition, cleanliness, previous loadings, LTL issues with co-mingling, and hauling of questionable previous loads. This rewrite is an opportunity to include some more wording- even if general- specifically targeting transportation vehicles and their acceptable sanitary condition.

In summary, we want to again compliment FDA for taking time to review the current GMP's and in looking for ways to update and improve them. As mentioned earlier, we believe that the current GMP's work well and only need minor revision.

We appreciate this opportunity to comment.

Sincerely,

A handwritten signature in black ink that reads "Jon R. Blake". The signature is written in a cursive, flowing style.

Jon R. Blake  
Vice President, Quality and Regulatory Operations  
General Mills, Inc.