Procter & Gamble

The Procter & Gamble Company
General Offices
2 P&G Plaza, Cincinnati, Ohio 45202

July 3, 2003

1030 '03 JUL -7 P3:46

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: **Docket Number 02N-0277**
Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

Dear Sir or Madam:

The Procter and Gamble Company welcomes the opportunity to submit comments pertaining to FDA's Notice of Proposed Rulemaking for Establishment and Maintenance of Records for foods published on May 9, 2003 (FR Vol. 68, No. 90, pp. 25187-25240). The Procter & Gamble Company ("P&G") is an international consumer product company headquartered in Cincinnati, Ohio that markets consumer products in over 160 countries around the globe. In the United States, P&G products under FDA jurisdiction include those regulated as human and animal foods, dietary supplements, Rx and OTC drugs, cosmetics, and medical devices. P&G food products include Folgers coffee, Sunny Delight citrus beverages, Iams pet foods, and Pringles potato crisps.

On June 12, 2002, the President signed the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 into law. Section 306 of the Act requires domestic facilities and certain foreign facilities engaged in manufacturing, processing, packing or holding food for consumption in the U.S. to establish and maintain records for FDA access in the event the Agency has reason to believe a food is adulterated or may present a threat of serious adverse health consequences. P&G supports the goal of enhancing the security of the U.S. food supply and believes reasoned final regulations from FDA are essential for implementing the Act in an orderly manner that enhances food safety and food security while minimizing disruption to the U.S. food supply and to the parallel systems in place for nonfood consumer product import, manufacturing and distribution. P&G submitted comments on this important topic during FDA's initial open comment period in August, 2002 prior to drafting of this proposed regulation and we appreciate this opportunity to comment once more.

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Our Specific Comments are as follows:

1. The Proposed Timeframe for Making Records Available to FDA should be "As Soon as Possible but not to Exceed 24 Hours".

FDA's proposal to mandate that records be made available within 4 hours or 8 hours from when requested by the Agency does not reasonably reflect the scope of the records FDA has proposed must be made available, the number of systems these records are currently collected upon, the accessibility of all these systems, the degree of compatibility (or incompatibility) between record collection systems, the limitations on record maintenance some systems currently have, the limited physical access to non-electronic paper records, the time to retrieve records from archives, and the resources and time necessary to upgrade existing systems to try to achieve FDA's proposed objective. The key elements of the proposal—the number of records required, requiring them all to be available within 4 to 8 hours, maintaining them for 2 years, in a rule that takes effect in 6 months—are simply not achievable with current systems. Compliance with this rule as proposed would require significant investment in system capacity, system retention, and system compatibility, changes that could not be completed prior to when the rule takes effect. An analysis of the key elements of the FDA proposal indicates that the required short duration for producing records is the most significant and burdensome component of the rule, and the burden escalates significantly as the mandated time to provide records decreases from 24 hours. Its negative effects are compounded by the other key elements of the NPR, creating a proposal that appears largely untenable.

As a result, we recommend the Agency require record access to be "as quickly as possible but not to exceed 24 hours", an objective that most companies should be able to achieve by the time the recordkeeping rule does takes effect. This approach more equally balances the need to provide information quickly to the Agency with the availability of the information and with existing capability within the industry. Companies have a significant interest in acting as quickly as possible to identify suspect products and to provide relevant information to the Agency, even if all the actual records may not be available for almost 24 hours. This "As quickly as possible" mandate allows FDA to request specific information be provided more rapidly, depending on the nature of the Agency's concern, while giving the companies time to compile all the required records.

Many food manufacturing companies already have established product recall procedures in place to rapidly retrieve information about products and to locate and isolate product suspected of being adulterated or misbranded. Importantly, these systems track product moved through several facilities—from the manufacturing facility through one or more distribution centers to a wholesale or retail customer. These systems can track incoming raw materials through production and distribution and generally can provide this information within 24 to 48 hours.
Requiring companies to provide this information in only 4 to 8 hours is not feasible; the tracking takes too long. Nor is it practical to try to require these firms to produce a set of records specific to facilities in a one-by-one sequence every 4 hours. However, asking a firm for a limited amount of multi-facility information as quickly as possible to rapidly progress several steps through the facility-to-facility sequence while knowing the actual physical records will be provided later does appear to be reasonable progress when one firm's records encompass multiple facilities in the chain of custody.

Net, we believe FDA should initially encourage short timeframes to industry but to not mandate anytime shorter than 24 hours in regulation. We believe approach reasonably balances providing timely information to the Agency with requiring investment on the part of the food industry. We recommend implementing this approach, gaining experience with it and jointly assessing if further changes are needed to improve food security and protection of the public health.

2. Required Records Should be Limited to those Needed to Allow FDA to Move Quickly and Efficiently to Protect Public Health

Section 306 of the Bioterrorism Act specifies the establishment and maintenance of records to identify the immediate previous sources and the immediate subsequent recipients of food in order to address credible threats of adverse health consequences.

The Notice of Proposed Rulemaking proposes 16 mandatory chain of custody elements for each food item receipt and 16 more mandatory chain of custody elements for each food item shipped. We encourage the Agency to carefully consider the need for each element being required since each required element raises the burden of the regulation. Specifically, is each element proposed really needed to allow FDA to more quickly and efficiently protect public health? Does the public health benefit gained outweigh the increased burden placed on the food supply and the food industry? We believe this justification is essential to ensure the burden being borne the public is in the public's interest and not a needless burden. For example, FDA proposes a that nontransporter must maintain record of a responsible individual, fax number, and email address for 1) the facility that shipped product to your facility, 2) the transportation company that delivered the product, 3) the transportation company that picked up product from your facility, and 4) the facility where product is being shipped. Much of the facility information required here is already required by FDA when facilities register, making it unclear why nontransporters are also being required to maintain a duplicative record of this information and maintain it for two years. Furthermore, is the name, email, or phone number of a responsible person at a particular firm 2 years ago really important enough to require someone at another facility to maintain it for 2 years? We strongly encourage the Agency to require only those records essential to tracking credible threats.

3. Records should be Maintained 6 Months Beyond the "Sell By" Date or Expiration Date if Printed on the Package or for Two Years, Whichever is Shorter

The NPR proposes that records be maintained for 2 years on any food product with a shelf life longer than 7 days. This is based on the fact that foods with shelf lives longer than 7 days are not considered "perishable" foods. Basing the length of time for maintaining records for all food products based solely on whether a food has a shelf life of 7 days is not appear to utilize sound risk management principles. Many food products bear expiration dates or sell by dates on the product labels. Products bearing these labels are typically removed from store shelves on or before these dates and are returned to the manufacturer. Returned products are either destroyed, donated for immediate use to food stores and food kitchens, or if returned before the expiration date, they may be sold in thrift shops such as a bakery thrift shop.

Products are labeled with expiration or "sell by" dates because their quality is affected by time. Some products will spoil. Others products lose freshness or a key consumer preference attribute such as sweetness or flavor. Consumers know and recognize this and as a result, purchase these products with the intention of using them before they reach their expiry date. While there will

always be a few consumers who use the product after the expiry date, the vast majority of product will be consumed before the expiry date is reached. Therefore, if a threat or concern is going to be identified with a "nonperishable product", it is going to be identified by the time a product reaches its expiry date or very shortly thereafter. The threat is very highly unlikely to be emerge 15 months after the expiration date.

As a result, there is little risk management based rationale for requiring a "nonperishable" product with a 3-month expiration date to maintain records for two years. If there is an issue with that product, the issue will surface within 3-4 months of production. We recommend the Agency revise the regulation to better reflect this.

Our recommendation is to require records for any nonperishable food to be maintained 6 months beyond the "expiration" or "sell by" date or 2 years, whichever is shorter. This approach could be applied to "perishable" foods if desired, eliminating the need to distinguish between perishable and nonperishable foods in the regulation. Six months after product expiry date appears more than adequate for investigations of potential product threats. Since expanding system capacity to accommodate much longer record retention is a major cost associated with implementing this proposed rule, we believe the Agency should justify the value for longer record retention periods against the increased burden being placed on the industry or substantially decrease the number of records that must be retained for longer duration.

4. Emergency Contact Information may be More Useful than an Emergency Contact Name

The detailed facility emergency contact information proposed as mandatory may actually slow information flow to the facility from FDA. Many sites have 24-hour emergency numbers where someone is always on call. In some cases this number may be manned by security, by a rotation of certain facility staff or even by an answering service, but not one given person. The format of the emergency contact records that requires a person's name, email and phone number encourages the naming of an official whose immediate availability in the case of an emergency will depend on the time of day, meeting schedule, and travel schedules. We recommend allowing facilities greater flexibility in expressing how it they can be best contacted in an emergency.

5. Judgments Involving Manufacturing Facilities Where Raw Materials are Stored in Bulk Tanks/Silos Should be Based on Reasonably Available Information and Actual Risk.

We commend the Agency efforts in recognizing the recordkeeping complexities associated with bulk commodity and bulk raw material storage and seeking to find a reasonable approach for applying the Act in helping address some of the recordkeeping issues involved.

In the event that a threat to human health is associated with a bulk raw material, we encourage the Agency to use a risk management based approach in determining what actions are indicated. We believe the nature of the threat, the threat's health implications, evidence that a food product or food raw material has been adulterated, the health consequences of the adulteration, evidence of adulterating agent in the facility, and knowledge of manufacturing operations should all be considered in a risk management equation to determine if plant operations should be shutdown, temporarily halted, or continued; if equipment needs to be inspected or sanitized; or, if raw

materials should be analyzed, treated, or scrapped. These need to be handled on a case-by-case basis depending on the particular circumstances.

We encourage the Agency to elucidate its general approach in assessing risks of potential and actual food adulteration.

The Procter & Gamble Company appreciates the opportunity to comment on this proposed amendment and I would be happy to discuss any of these comments in more detail. I can be contacted at (513) 983-0530 or guay.cb@pg.com.

Sincerely,

THE PROCTER & GAMBLE COMPANY
North American External Relations

Christopher B. Guay
Legislative and Regulatory Affairs