

Docket Management

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Comment Record			
Commentor	Dr. Lise C. Borel	Date/Time	2001-09-16 09:46:37
Organization	The National Latex Allergy Network (ELASTIC Inc.)		
Category	Consumer Group		
Comments for FDA General			
Questions			
1. General Comments	<p>On behalf of the estimated 2.3 million Americans affected by latex allergy and the members of the National Latex Allergy Network (ELASTIC Inc.), I am requesting that the FDA Center for Food Safety and Applied Nutrition place the issue of latex glove use by food handlers and auxiliary food service workers on the A Priority List, that is those issues to be resolved in 2002. In recognition of the hidden hazards associated with latex glove use posed to consumers and workers, FDA published the following warning in the 1999 Food Code Annex 3 3-3-4.15; 3-304.15 - Gloves, Use Limitation – “Natural rubber latex gloves have been reported to cause allergic reactions in some individuals who wear latex gloves during food preparation, and even in individuals eating food prepared by food employees wearing latex gloves.” To resolve this issue, the FDA must implement rulemaking process to amend or modify existing regulations for natural rubber latex established in 1963 to prohibit the use of NRL gloves for any aspect of food production, processing, preparation, handling, retail sales and service – from farm to table. The following information was previously submitted to the FDA, upon request, in July 2001 and is presented here as a matter of public record. The</p>		

original document was prepared and reviewed as a collaborative effort by members of the National Latex Allergy Network. July 2001 NATURAL RUBBER LATEX AS A FOOD ALLERGEN - ACTION PLAN

Proposed action plan submitted to the Office of Scientific Analysis and Support - FDA Center for Food Safety and Applied Nutrition LATEX GLOVE USE BY FOOD HANDLERS – THE HIDDEN FOOD ALLERGEN

Issues: The prevalent use of latex gloves by food handlers results in the contamination of foods by latex allergens. Research demonstrates that natural rubber latex gloves used by food handlers, from farm to table, are a direct source of food adulteration caused by the migration of allergenic proteins from the glove surface to food products. When a person with latex protein allergy comes into contact with or ingests food that has been handled by latex gloves, that individual is at risk for an allergic reaction. When the original regulation establishing natural rubber latex as an approved indirect food additive in 1963, latex protein allergy was virtually unheard of. Increased use of latex, most notably, latex gloves, to prevent infectious diseases has been followed by an increase in the number of people affected by latex allergy. At least 2.3 million Americans are affected by latex protein allergy. Thousands of adverse event reports describing allergic reactions and anaphylaxis caused by medical gloves and other devices made from natural rubber latex have been sent to FDA

MedWatch. These reports relate both to patients and users of natural rubber latex products and include at least 21 deaths 5 of which were associated with exposure to latex gloves. According to the FDA policy on food allergens: “Production practices that lead to unintentional addition of allergens to food may be considered insanitary conditions that may render the food injurious to health and cause the food product to be adulterated under section 402(a)(4) of the Act.” Natural

rubber latex gloves, commonly utilized by food handlers, are a source of indirect food additives which violate Section 402(a)(1) of the FDA Food Regulations which state: "A food is illegal (adulterated) if it bears or contains an added poisonous or deleterious (harmful) substance which may render it injurious to health. The conditions under which pre-market approval was extended to NRL products commonly used in the processing and handling of food, have radically changed and must be amended to reflect these changes. The emergence of latex allergy in the late 1980's and the prevalent use NRL gloves manufactured from NRL to food production and handling practices necessitates prompt action by the FDA. Due to food and food preparation and serving surface contamination, latex gloves, must be declared an unsuitable utensil for any use associated within the food industry. PROPOSED ACTION PLAN FOR NATURAL RUBBER LATEX AS A FOOD ALLERGEN 1. The Commissioner shall implement rulemaking process to amend or modify existing regulations for natural rubber latex established in 1963 to prohibit the use of NRL gloves for any aspect of food production, processing, preparation, handling, retail sales and service – from farm to table. 2. Verify latex protein allergy as a FDA CFSAN Priority for the fiscal year 2002. 3. The 2001 Food Code shall include the 1999 Food Code references to NRL gloves in the main text of the code and will include references to worker safety citing the NIOSH Alert and OSHA TIB publications. 4. Identify and communicate with all government offices, administrations and agencies this rulemaking will affect. (HHS, USDA, FSIS etc.) 5. Publish information regarding safety issues associated with latex glove use by food handlers (1999 Food Code Annex 3 3-3-4.15; 3-304.15 - Gloves, Use Limitation – "Natural rubber latex gloves have been reported to cause allergic reactions in some individuals

who wear latex gloves during food preparation, and even in individuals eating food prepared by food employees wearing latex gloves.”) in the form of Releases, Alerts and Fact Sheets. FDA and other suitable government Internet sites must provide this material to consumers and industry as is currently done for other food allergen issues. In addition, these releases need to be distributed to pertinent print media sources including the FDA Consumer and other similar publications. 6. Amend the FDA Compliance Policy Guide (CPG) focus list of allergens (milk, eggs, fish, crustacea, mollusks, tree nuts, wheat and legumes), to include natural rubber latex. 7. Maintain open communications and free exchange of information between the Center for Food Safety and Applied Nutrition, stakeholders and legislative representatives. Expand stakeholder list to include representatives from the National Latex Allergy Network. 8. Develop a compliance policy including a reporting program for illegal use of latex glove use within the food industry.