

January 8, 2003

NSF Protocol P155 Disposable Food Contact Gloves



January 8, 2003

NSF International, an independent, not-for-profit organization, is dedicated to public health safety and protection of the environment by developing standards, by providing education and by providing superior third-party conformity assessment services while representing the interest of all stakeholders.

This Protocol is subject to revision.
Contact NSF to confirm this revision is current.

Users of this Protocol may request clarifications and interpretations, or propose revisions by contacting:

NSF International
Engineering & Research Services
789 N. Dixboro Road
Ann Arbor, MI 48105
Phone: (734)769-8010 Telex: 753215 NSF INTL
FAX: (734)769-0109 E-mail: info@nsf.org
Web: <http://www.nsf.org>

January 8, 2003

NSF Protocol P155 Disposable Food Contact Gloves

Protocol Developer
NSF International
Engineering & Research Services

Prepared by NSF Engineering & Research Services staff with assistance from NSF Protocol Development Panel members shown below:

Mr. Frank Arcuri, Quality Control Field Inspector, Blimpie International

Dr. Lise C. Borel, National Director, Education for Latex Allergy Support Team & Information Coalition (ELASTIC)

Mr. Robert A. Bova, President BB & Associates, Inc. - President International Dairy, Deli and Bakery Association (IDDBA) 2000.

Ms. Kristie Grzywinski, National Restaurant Association (NRA) Education Foundation

Dr. Ernie Julian, Rhode Island Department of Health

Mr. Mike Kissel, Carl's Jr. Restaurants, Carl Karcher Enterprises

Ms. Glenda Lewis, Center for Food Safety and Applied Nutrition (CFSAN), U.S. Food and Drug Administration (FDA)

Dr. Hugh Mainzer, Medical Epidemiologist, National Center for Environmental Health Centers for Disease Control and Prevention (CDC)

Dr. Robert Post and Mr. Bill Jones, Labeling and Additives Policy Division, Food Safety and Inspection Services, U.S. Department of Agriculture (USDA)

Mr. Arthur Yellin, Center for Devices and Radiological Health (CDRH), U.S. Food and Drug Administration.

Published by
NSF International
789 N. Dixboro Road, Ann Arbor, Michigan 48105

For ordering copies or for making inquiries with regard to this Protocol, please reference the protocol title.

Copyright 2003 NSF International

Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from NSF International.

Printed in the United States of America.

Disclaimers

NSF International (NSF), in performing its functions in accordance with its objectives, does not assume or undertake to discharge any responsibility of the manufacturer or any other party. The opinions and findings of NSF represent its professional judgment. NSF shall not be responsible to anyone for the use of or reliance upon this protocol by anyone. NSF shall not incur any obligations or liability for damages, including consequential damages, arising out of or in connection with the use, interpretation of, or reliance upon this protocol.

Participation in NSF's protocol development activities by a representative of a regulatory agency (Federal, state, local) shall not be construed as the agency's endorsement of NSF, its policies, or any of its protocols.

NSF Protocols provide basic criteria to promote and protect public health.

Unless otherwise referenced as normative, the appendices are not considered an integral part of NSF protocols. They are provided as general guidelines to the manufacturer, regulatory agency, user, or certifying organization.

Table of Contents

1	General	1
1.1	Introduction	1
1.2	Scope	1
1.3	Certification policies	2
1.4	Limitations	2
2	References	2
3	Definitions	3
3.1	Acceptable Quality Level	3
3.2	Barrier integrity	3
3.3	Bioburden	3
3.4	Ready-to-eat foods	3
3.5	Single-task disposable gloves	3
4	General Requirements For All Gloves	4
4.1	Materials	4
4.1.1	Toxicology	4
4.1.2	Biocompatibility	4
4.2	Glove powder	4
4.3	Bioburden	4
4.4	Visual inspection	5
4.5	Labeling	5
4.5.1	Natural rubber latex labeling	5
4.6	ISO compliance	5
5	Material-Specific Requirements	5
5.1	Polyethylene gloves	5
5.2	Vinyl and vinyl blend gloves	6
5.3	Natural rubber latex gloves	6
5.4	Nitrile gloves	6
5.5	Other glove materials	6
6	Test Methods	8
6.1	Materials	8
6.2	Glove powder	8
6.2.1	Initial qualification	8
6.2.2	Ongoing quality assurance	8
6.3	Bioburden	8
6.3.1	Initial qualification	8
6.3.2	Ongoing quality assurance	8
6.3.3	Test method specifics	9

6.4	Extractable protein content (NRL gloves only)	9
6.4.1	Initial qualification.....	9
6.4.2	Ongoing quality assurance	9
6.5	Barrier Integrity.....	9
6.5.1	Initial qualification.....	9
6.5.2	Ongoing quality assurance	11
6.6	Dimensions	11
6.6.1	Initial qualification.....	11
6.6.2	Ongoing quality assurance	11
6.7	Tensile properties	12
6.7.1	Initial qualification.....	12
6.7.2	Ongoing quality assurance	13
Annex A	– Program Specific Policies	A1
A.1	Marking the products	A1
A.2	Audits	A1
A.3	Re-testing	A1
Annex B	– Guidance Document for Disposable Glove Usage.....	B1
Annex C	– Standards Organizations and Document Sources.....	C1
Annex D	– Expert Panel Comments Found Non-Persuasive with Rationale for Not Including in Protocol	D1

NSF Protocol P155

Disposable Food Contact Gloves

1 General

1.1 Introduction

Disposable gloves are used in numerous applications in food preparation, handling, and service. In the 1999 U.S. Food and Drug Administration (FDA) Food Code, single-use gloves are one of a number of suitable utensils for use by employees when handling exposed, ready-to-eat foods. Food contact gloves are used in the industry for tasks requiring different physical properties, dexterity, puncture, and chemical resistance characteristics. Although not regulated by FDA as medical devices, many of the requirements for medical gloves are applicable to food contact gloves. Using medical glove guidelines in combination with food-specific requirements, this protocol intends to be the first comprehensive protocol for disposable food contact gloves.

Prevention of the spread of foodborne disease requires adherence to several key preventative practices to interrupt routes of pathogen transmission. The National Advisory Committee on Microbiological Criteria for Foods concluded that gloves, or other suitable utensils, are only one barrier and must be used in conjunction with other barriers such as frequent handwashing, the exclusion/restriction of ill food workers from contact with ready-to-eat foods and food-contact surfaces, and minimizing bare-hand contact with exposed, ready-to-eat food (i.e. food that is edible without washing or is not subsequently subjected to a pathogen kill step – items such as salads, fruits, sandwiches, cooked meats, breads or ice).

Food workers must be educated about the vital importance of hand washing, glove selection, and the correct usage and limitations of all barriers and utensils. The basis for any training of food workers about optimum usage of all barriers, including gloves, should take into account the FDA Food Code's prohibition of bare-hand contact with exposed, raw, ready-to-eat foods and the reasoning behind it (see informational Annex B for more information). Ongoing food worker and management training is highly recommended and should explain the link between foodborne disease, protective barriers, and basic personal hygiene to reduce the risk of transmission of pathogens to foods via the food workers hands.

1.2 Scope

This protocol covers disposable single-task gloves typically used for food handling, preparation, and service tasks. This protocol establishes criteria for product quality in terms of toxicology (indirect food additive), physical properties (tensile strength, elongation), barrier resistance (leakage), and sanitation (bioburden). The criteria in the protocol are divided into general requirements for all gloves and material-specific requirements that apply to the major material-types used in food contact gloves: polyethylene, vinyl, natural rubber latex, nitrile, and other synthetic blends. As new materials are developed in the industry, material-specific requirements may be added in subsequent revisions of the protocol. As new test methods and regulatory requirements (e.g. ASTM, FDA) are developed dealing with durability or other