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# **The Case of Continuing Use of Natural Rubber Latex Gloves**

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*Malaysian Rubber Export Promotion Council*

*Washington DC, USA*

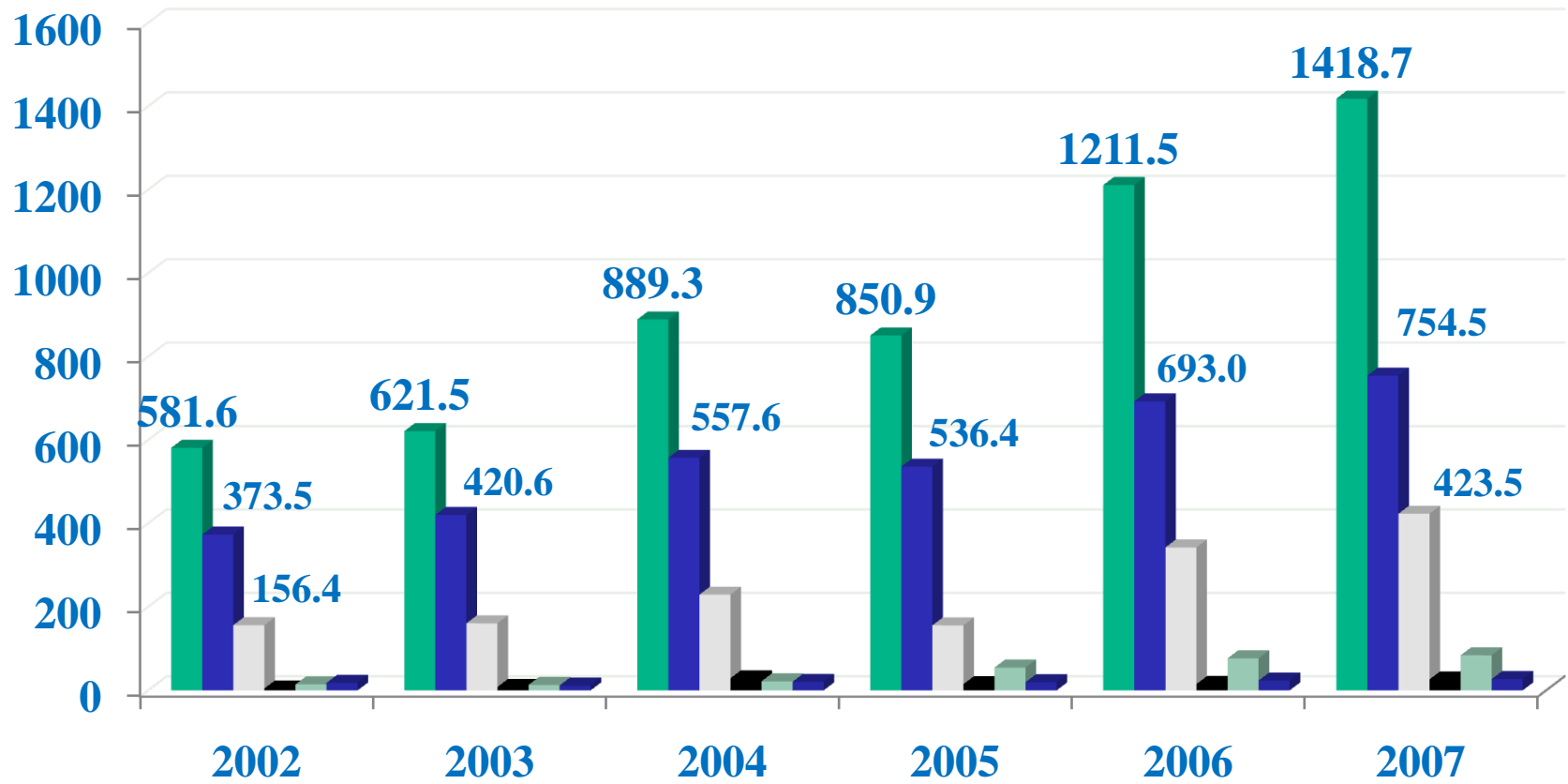
# World's Major Exporters of Rubber Gloves (2003-2007)

## Percentage Share



# Australia's Rubber Glove Imports (2003-2007)

*(Million Pairs)*



- World
- Malaysia
- Thailand
- United States
- China
- Sri Lanka

# Healthcare Professionals and Medical Gloves

- ❖ Constantly exposed to potentially harmful infectious agents, e.g. HIV, Hepatitis B & C.
- ❖ Need protection during their course of work, especially when in contact with contaminated blood and body fluids.
- ❖ One safety measure is the use of appropriate medical gloves.

# Medical Glove Types

```
graph TD; A[Medical Glove Types] --> B[Examination]; A --> C[Surgical]; B --- B1[Natural rubber latex]; B --- B2[Vinyl (PVC)]; B --- B3[Nitrile]; C --- C1[Natural rubber latex]; C --- C2[Polychloroprene]; C --- C3[Co-polymer]; C --- C4[Nitrile];
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## **Examination**

**Natural rubber latex**

**Vinyl (PVC)**

**Nitrile**

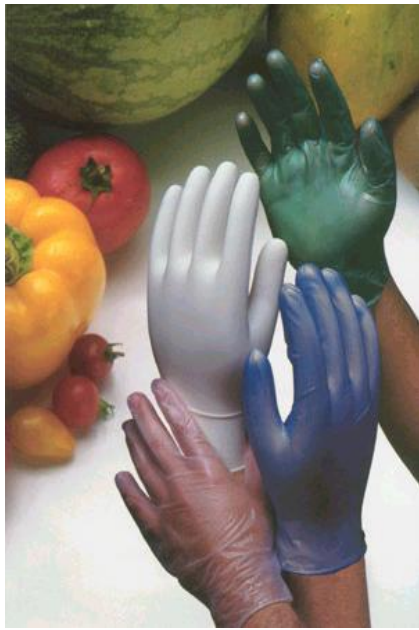
## **Surgical**

**Natural rubber latex**

**Polychloroprene**

**Co-polymer**

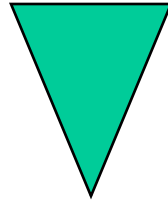
**Nitrile**



## Question

**Do ALL gloves provide the same degree of safety measure that healthcare professionals need??**

# *Different* **Glove Materials**



*Different* **barrier properties**

*&*

*Different* **glove qualities**

**Why**

**Natural**

**Rubber Latex Gloves?**



# *Aspects of Interest*

- ▶ **Barrier Properties:**
  - Barrier performance
  - Comfort, fit, durability
  - Tear resistance,
  - Tactile sensitivity
  
- ▶ **Potential Health Risks:**
  - Latex protein allergy
  - Chemical toxicity (DEHP)
  
- ▶ **Environmental Impact**
  
- ▶ **New Glove Certification Program**

# Barrier Protection

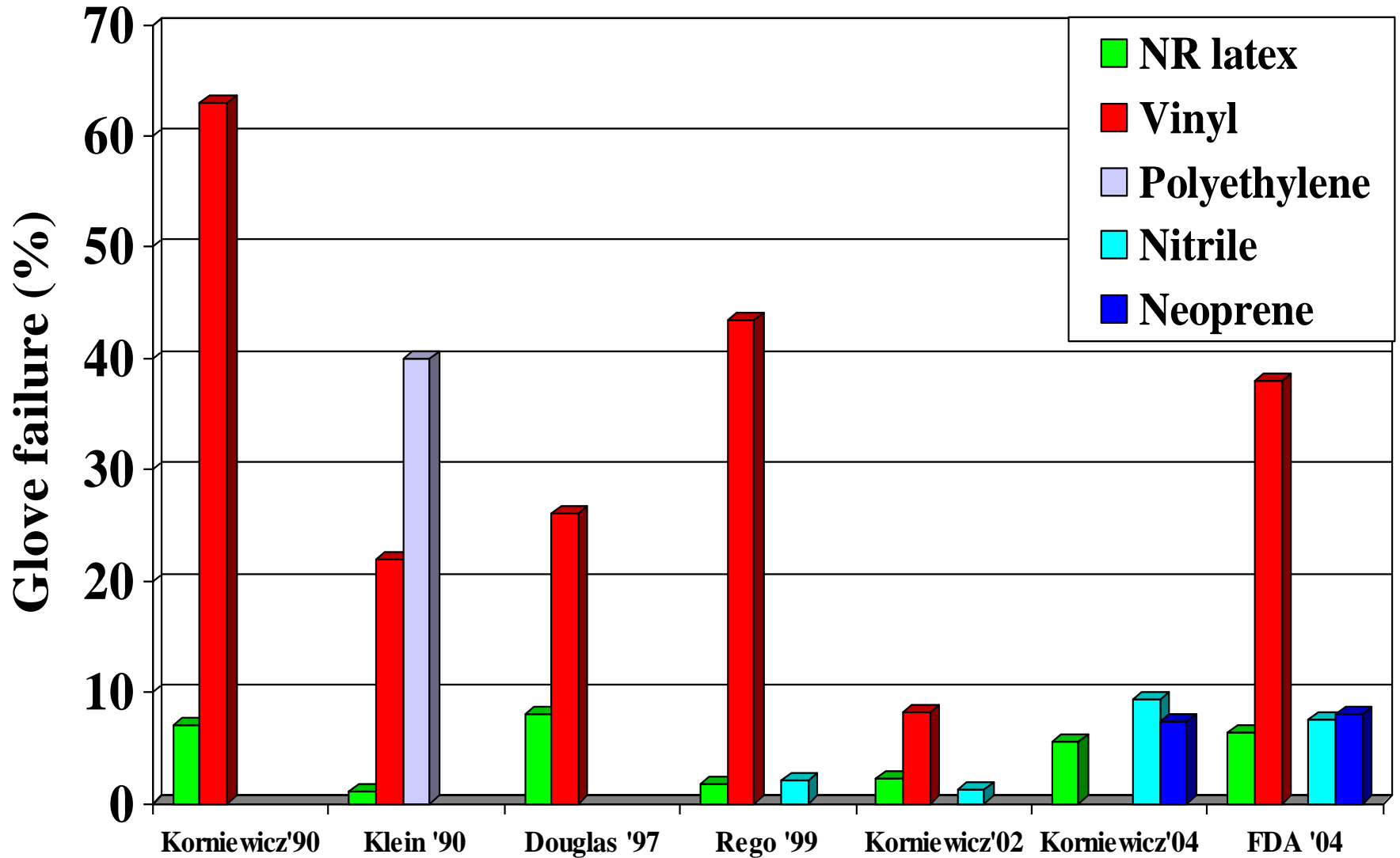
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*The single most important criterion:*

Ability to provide very effective barrier protection against blood pathogens and harmful infections

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# Barrier Integrity of Medical Gloves – “In-use”



# Barrier Effectiveness of *Punctured Gloves* Against Viral Penetration (Resealing Properties)

*Challenge virus - ΦX 174, diameter = 27 nm*

<b>Gloves</b>	Needle diameter = 0.22mm <b>Virus leak</b> (% of gloves)	Needle diameter = 0.45 mm <b>Virus leak</b> (Volume, ml)
<b>Vinyl</b>	<b>78%</b>	<b>3 – 18</b>
<b>Nitrile</b>	<b>53%</b>	<b>8 – 11</b>
<b>NR latex</b>	<b>Zero failure</b>	<b>0.013 – 0.023</b>

*(Hasma & Othman 2001)*

# Comfort and Fit

*Ability of gloves :*

- ▶ to stretch
- ▶ to remain soft
- ▶ conform to hand



**Latex > Nitrile, Neoprene > Vinyl**

# Durability of Medical Examination Gloves



**NR latex**

**Nitrile** > > > **Vinyl**

**Polychloroprene**

F.D.A. – “Assessment of the Durability of Medical Examination Gloves”, J. Occupational & Environmental Hygiene, 2004; 1: 607-612



## *Tactile Sensitivity*

**Latex >> Synthetics**

# ASTM Glove Standards –

## *Lower specifications for non-latex gloves*

Property	Surgical		Examination			
	NR	SR	NR	Vinyl	Nitrile	Poly-Chloroprene
Min. TS (MPa) (Strength)	24	17	18/14	9	14	14
Min. EB (%) (Elasticity)	750	650	650	300	500	500
	(ASTM D3577)		(D3578)	(D5250)	(D6319)	(D6977)

**NR** – natural rubber latex

**SR, Vinyl, Nitrile, Polychloroprene** – synthetic, non-latex

# ISO Glove Standards –

## *Lower specifications for non-latex gloves*

Property	Surgical		Examination		
	NR	SR	NR	SR	Vinyl
Min. Force-at-Break (Strength) -N	<b>12.5</b>	9.0	<b>7.0</b>	7.0	7.0
Min. EB (%) (Elasticity)	<b>700</b> (ISO 10282)	600	<b>650</b> (SO 11193-1)	500 (ISO11193-1)	350 (ISO 11193-2)

**NR** – natural rubber latex

**SR** (*Nitrile, Polychloroprene*), **Vinyl** – synthetic, non-latex

# EN Glove Standards –

*Lower specifications generally for non-latex gloves*

Property	Surgical		Examination	
	NR	SR	NR/SR	Others
Min.Force-at-Break (Strength) -N	$\geq 12$	$\geq 9.0$	$\geq 9.0$	$\geq 3.6$
	(EN 455-2-2000)		(EN 455-2-2000)	

**NR** – natural rubber latex

**SR** (*Nitrile, Polychloroprene*) – synthetic, non-latex

**Others** – vinyl

# AS/NZ Glove Standards –

## *Lower specifications for non-latex gloves*

Property	Surgical		Examination
	NR	SR	NR/SR
Min. TS (MPa) (Strength)	23	17	21
Min. EB (%) (Elasticity)	700 (AS/NZS 4179:1997)	550	700 (AS/NZS 4011:1997)

**NR** – natural rubber latex

**SR**, *Nitrile, Polychloroprene* – synthetic, non-latex

# Potential Health Risks

❖ **Latex Protein Allergy**

❖ **Chemical Toxicity**

*(DEHP in Vinyl products)*

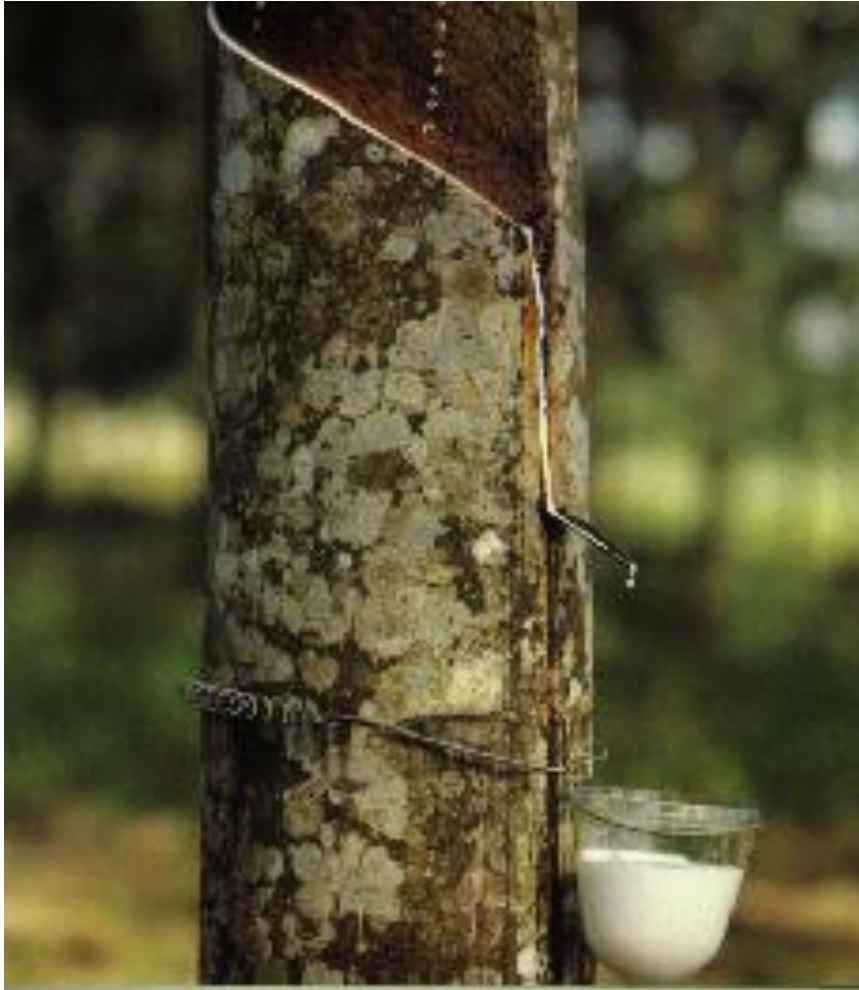
❖ Natural rubber latex gloves, with their excellent barrier protection, are preferred.



❖ However, latex allergy associated with their use in recent years – a concern

❖ Given rise to various synthetic alternatives, e.g. vinyl, nitrile, chloroprene (neoprene).

# Hevea Brasiliensis Latex



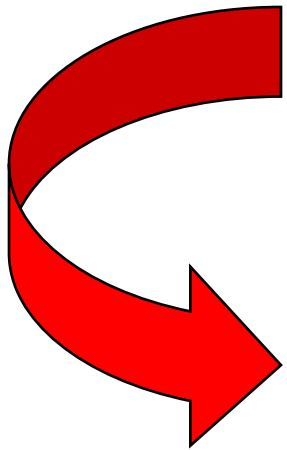
*It contains:*

- **Rubber particles**
- **Proteins**
- **Carbohydrates**
- **Inorganic constituents**
- **Water**

*Latex gloves with:*

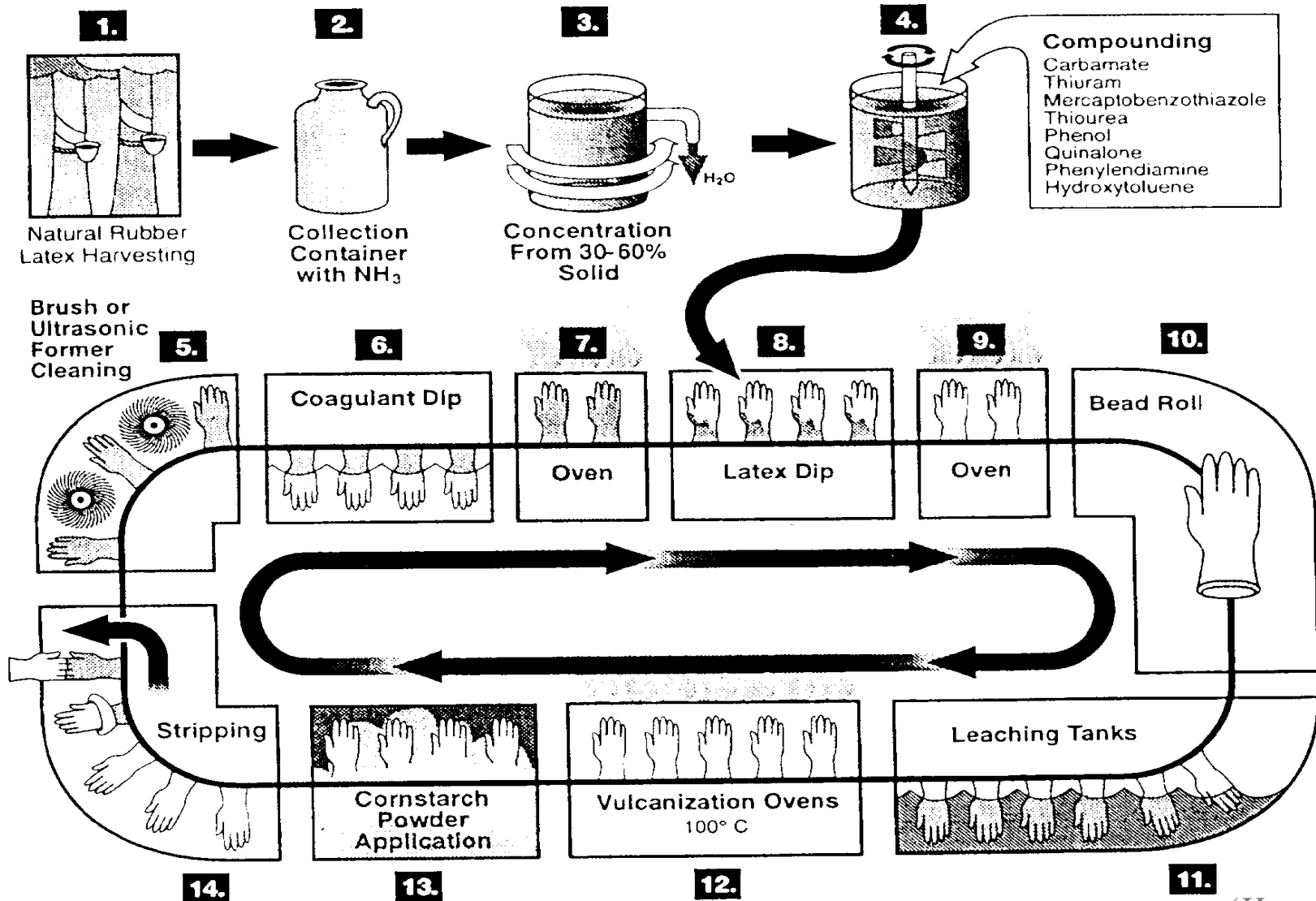
**High** residual proteins

**High** powder content



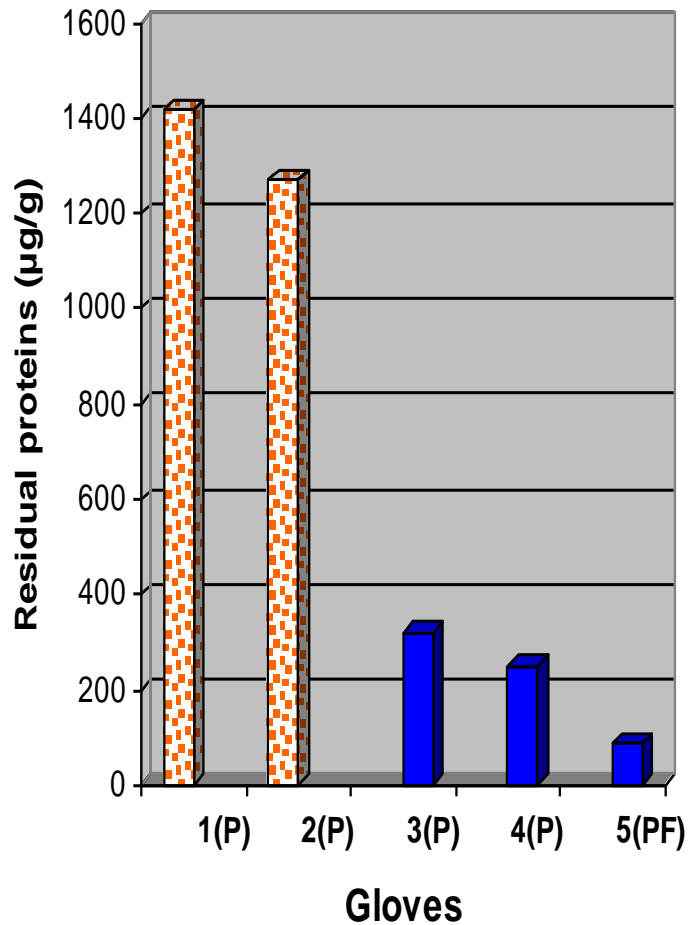
**Cause of allergy**

# Latex Glove Line (Schematic)

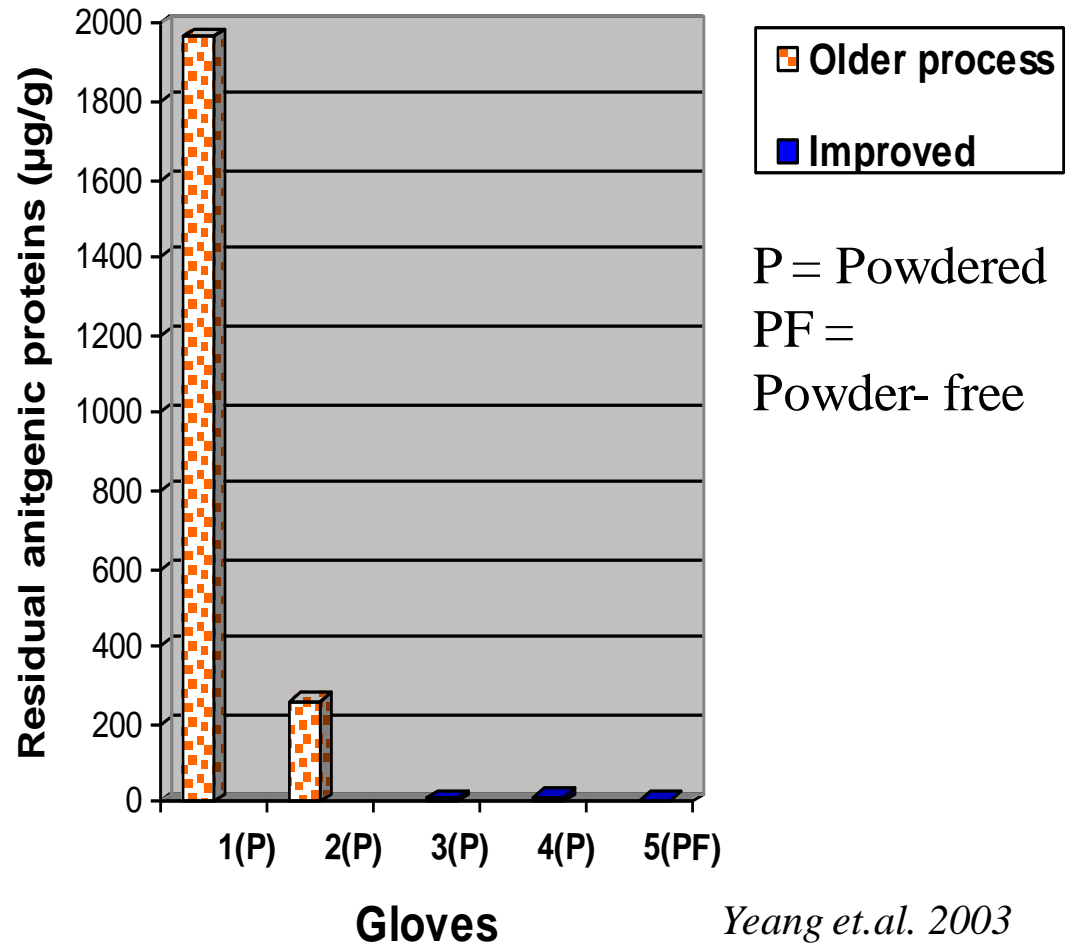


# Protein/Antigen Reduction by Improved Processes

## Protein content



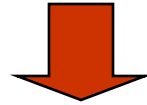
## Antigen level



Older process  
Improved

P = Powdered  
PF = Powder-free

# Residual Proteins with Allergens in Gloves



**Primary Sensitizer**  
*NOT* Powder



Need to avoid High Protein gloves with  
excessive glove powder

# *Adverse Reactions*

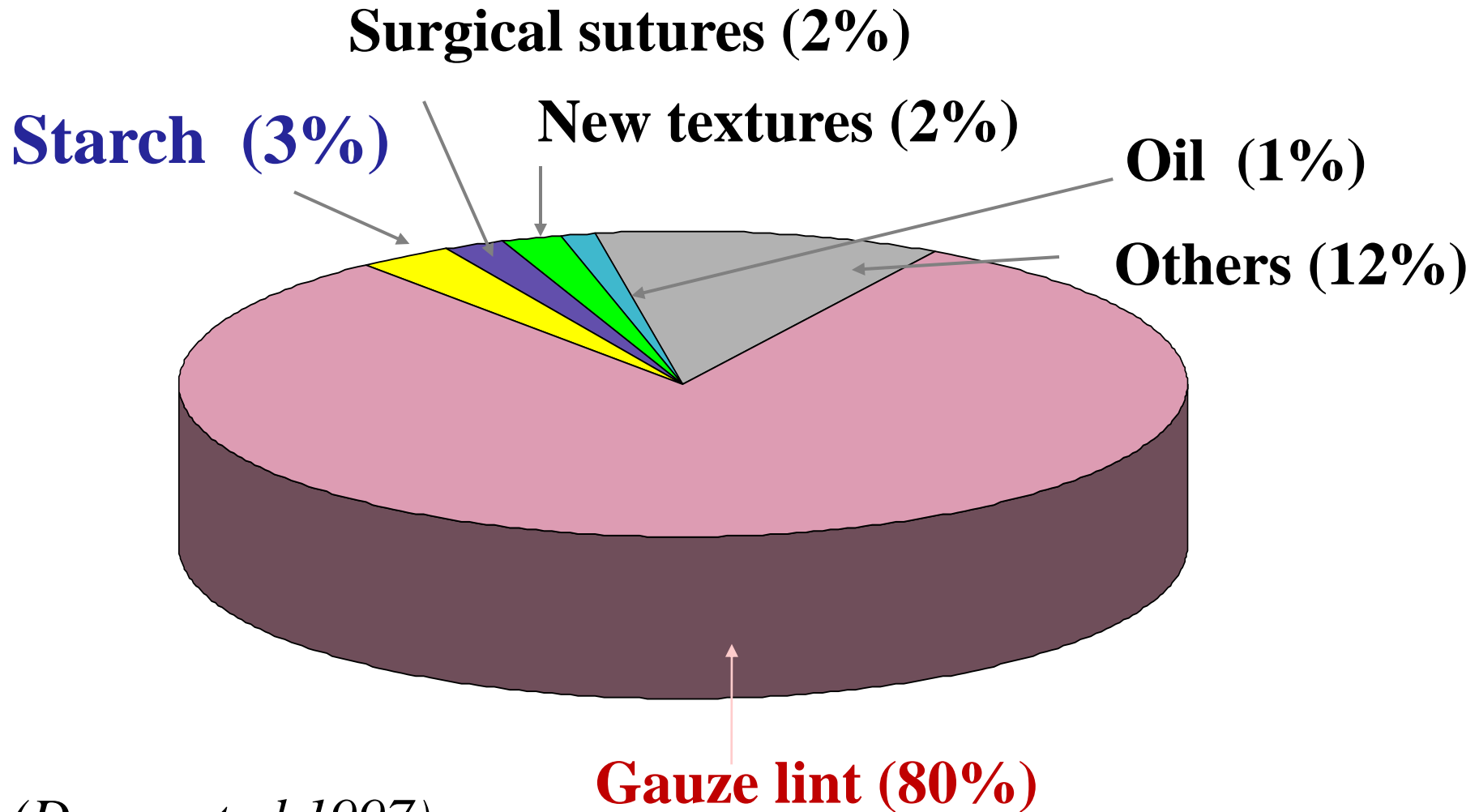
(Post operational)

- ▶ **Tissue adhesion**
- ▶ **Wound healing**
- ▶ **Granulomas**

*Cause :*

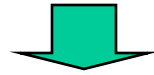
**Presence of foreign microbodies**

# Foreign micro-bodies associated with human adhesions



*(Duron et.al.1997)*

## Powder-free gloves

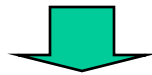


Low protein content –

Due to extensive washing, and chlorine treatment  
during processing

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## Powdered gloves



Can also have low protein content – using  
modern technologies

# Glove Intervention - Use of low protein/allergen gloves in place of high protein/allergen gloves

## *Ten Hospital Studies (1998 – 2006)*

- ▶ Dramatic drop in latex protein allergy incidence
- ▶ Latex allergic workers wearing synthetic gloves could work safely alongside their colleagues donning latex gloves
- ▶ Allergic individuals did not have to change jobs or retire because of latex allergy
- ▶ One reported no increased cost incurred, while Mayo Clinic had a saving of \$200,000 per year.

# Impact of Low-Protein Latex Gloves

**K.Kelly, MD.** *Former Chair of Latex Allergy Comm., AAAAI and Assoc. Dean of Clinical Affairs, Medical College of Wisconsin (HealthLink, August 2005) –*

- ▶ “Latex allergy episodes in decline, prevalence drops from 8%-12% in 1990’s to about 1% today”
- ▶ **“Mainly due to a change in way latex gloves are manufactured – a 1000-fold drop in allergen content of gloves.”**
- ▶ “Many HCW’s are back to work now, with no fear of allergic reactions,....patients don’t have to be afraid to go into the hospital.”
- ▶ “Latex allergic individuals wear medical bracelets, and avoid latex contact.”

# Impact of Low-Protein Latex Gloves

**D. Beezhold, PhD.(NIOSH) & G. Sussman, MD (University of Toronto)**, *Lessons Learned from Latex Allergies*, September 2005 :-

- ▶ “Low-protein, powder-free gloves have drastically reduced exposure to the healthcare setting.”
- ▶ “However, it is necessary for latex-allergic healthcare workers to only wear non-latex gloves.”

**J.N. Fink**, *Professor of Medicine, Medical College of Wisconsin;* *Latex Allergy in the Surgical Environment*, September 2005 -

- ▶ “....it appears that the epidemic has been eliminated.” -

# Chemical Toxicity

*[DEHP: 2 Di-ethyl hexyl phthalate]*

DEHP is a highly toxic plasticizer used in many **vinyl gloves** to make them more flexible

*Often 30-50% in vinyl products*



## ***DEHP can leach out from vinyl gloves:***

- ◆ **when in contact with blood or body fluids of patients during medical procedures**
- ◆ **when in contact with food during food handling**



# Adverse Effects of DEHP

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- ▶ **Toxic to liver, kidney and heart**
- ▶ **Causes reproductive problems:**
  - *Toxic to Sertoli cells (sperm production)*
  - *Reduced fertility*
  - *Ovarian dysfunction*
  - *Structural changes in testes*
- ▶ **Decrease hormone production in females**
- ▶ **Fetus malformation**
- ▶ **Listed as probable human carcinogen (EPA, NIOSH)**



# Infants, children, pregnant women and fetus – more sensitive to the effects of DEHP than others.

- Recent studies on human showed that prenatal exposure to phthalates lead to boys with subtle genital alternations –

*Environ. Health Perspectives, June 2005,*

*111:1719-1722*



➤ **Warning on Use of Vinyl (PVC)**

**Medical Devices – *FDA on 12 July 2002***

➤ **Vinyl Gloves with DEHP Not to be used  
in Food Handling - *Japanese Ministry of  
Health on 14 June 2001***

➤ **Ban on soft PVC toys with phthalates  
(DEHP) for young children –  
*EU Commission 1999***



# Environmental Impact

- *Raw materials*
- *Disposal of end-products*

# Natural Rubber Latex

Green material –  
*environmentally-friendly:*

- ▶ **Sustainable and renewable resource**
- ▶ **Biodegradable**

# Synthetic gloves

- ▶ Raw materials often toxic or carcinogenic
- ▶ **Not biodegradable**, disposal by burning releases harmful substances, e.g. dioxin, cyanide, HCl, etc.



# Disposal by Landfill –

leaching of chemicals into the soil,  
contaminating the ground waters, hence  
food supply chains



# **Many good reasons why Natural Rubber Latex Gloves should continue to be used**

## **The advent of low-protein latex gloves –**

- ❖ Alleviates latex allergy;
- ❖ Provides best possible barrier protection against dangerous infections.

**High protein latex gloves should be avoided**

❖ **NR latex gloves** have many superior critical glove properties that manufacturers of many synthetic alternatives are still trying to achieve.

❖ **Indiscriminatory replacement with vinyl gloves** in hospitals could expose healthcare professionals to undesirable health risks, and caution should be taken.

❖ Hospitals should make available suitable **synthetic gloves with effective barrier** for individuals who are latex allergic.

# *New Glove Certification Program*

## **SMG**



To help identify  
Quality Low-Protein Natural  
Rubber Latex Gloves

# Standard Malaysian Glove

## New Quality Certification Program

*To ensure the manufacture of quality latex examination gloves that are:*

- **High in barrier protection**
- **Low in protein and powder**



***Powder-free***



***Lightly Powdered***

# *SMG Program*

*for Examination Gloves developed  
through*

⇒ **R&D by RRIM\***

⇒ ***Consultation with U.S. FDA  
and other relevant authorities***

*\* RRIM – Rubber Research Institute of Malaysia*

# The SMG Program

([www.smg-gloves.com](http://www.smg-gloves.com))

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*Certifies Low-Protein latex gloves  
that:*

- **Meet stringent standards**
- **Low protein & powder limits**

# Barrier Performance

*[Acceptable Quality Level for Examination Gloves]*

*Standard*

*AQL requirement*

**AS/NZS**

**2.5**

**ASTM**

**2.5**

**ISO**

**2.5**

**SMG**

**1.5**

# Extractable Protein Level *Powder-free Gloves*

*Standard*

*Requirement  
[maximum]*

**FDA/ISO/EN**

*Not specified*

**ASTM**

**200  $\mu\text{g}/\text{dm}^2$**

**SMG**

**50  $\mu\text{g}/\text{dm}^2$**

# Cost

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**SMG gloves < synthetic alternatives,**  
*except for Vinyl –*  
*poor barrier*  
*properties*

**Certification of Quality Standard – No Additional Cost**

**ECRI** recommends  
the use of **Low-Protein Gloves**  
with label of low Protein Content  
or that SMG-Certified

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**Lower-Protein Latex Gloves**  
**A Way to Reduce Allergic Reactions**  
**in Hospital Staff**

*(Health Devices, May 2004, Vol.33, #5, 169-173)*

# *Conclusion*

## **Latex gloves** –

These remain the **gold standard** (superior barrier performance, durability, comfort, fit, tactile sensitivity, high tear resistance.)  
However, only *low-protein* gloves should be used.

## **Vinyl gloves** –

*Not* for medical procedures (high risks exposure to blood etc.)  
appropriate only for short-term low-risk tasks that involve minimal stress.

## **Nitrile and other synthetics** –

More superior than vinyl gloves, but may be more costly. They are recommended *for latex allergic individuals* who have to avoid latex proteins.

*For more information about NR latex  
medical gloves:*

**<http://www.latexglove.info>**

**<http://www.smg-gloves.com>**



*Thank you  
for your attention*

