

Allergens and the Confectionery Industry

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National Confectioners Association

- Over 300 manufacturing confectionery company members
- Interest in allergens for past 15 years
- Participant in Food Allergy Issues Alliance
- Goal is to best protect the consumer

Topics to Cover

- Industry Overview
- Circumstances that influence use of advisory labeling
- Guidance for industry
- Relevance of company size
- Unique challenges

Industry Overview

Major Food Allergens used in candy

- Peanuts
- Milk
- Eggs
- Soy (lecithin)
- Wheat
- Fish (gelatin, omega-3 fa)
- Almonds
- Walnuts
- Macadamia Nuts
- Pecans
- Cashews
- Hazelnuts
- Pistachios
- Coconut

What manufacturing circumstances prompt manufacturers to place advisory statements on a food label?

Influencing Factors

- Ingredient procurement
- Physical characteristics of allergen
- Manufacturing one or more allergens in the same facility
- Manufacturing one or more allergens on the same equipment
- Chocolate GMPs

Particulate Matter vs Readily Dispersible Proteins

Particulate

- Peanuts, Tree nuts
- Particulate matter gets caught in equipment
- No certainty of cleaning technique, testing not appropriate
- Risk of significant quantity of protein reaching consumer in small serving

Dispersible Proteins

- Milk, whey, soy, egg, etc
- Residual levels affected by type of candy, time, equipment
- Bound by chocolate; impossible to rid from some systems

Shared Facility

Dedicated facility is not a realistic expectation.

- Very few candy companies in the industry have dedicated facilities that isolate allergens
- Many allergens often used in same facility
- Barriers to cross contact not foolproof
- Risk of human error, even with employee education and allergen control plans in place

Shared Equipment

Dedicated equipment is not a realistic expectation.

- Most confectioners use the same equipment to produce many different candies
- Constraints include space, cost, efficiencies
- Those who use shared equipment have an allergen clean-up strategy and are more likely to use advisory labeling.

Unavoidable Cross-contact:

- Inaccessible Equipment
 - Equipment not intended to be dismantled.
 - Many systems or components of systems are closed
- Shared equipment that cannot be wet cleaned
 - For chocolate operations, carbon steel equipment often used. Can be corrosive with water system.

**Difficult to achieve certainty
that allergens are eliminated.**

Chocolate

Manufacturing in a Dry Environment

Water and Pathogens

- Chocolate is very viscous and adheres in thick layers to machinery, pipes
 - Flushing is very difficult
- Chocolate + water = stiffness
- These pockets of water can foster microbial growth
- Cannot guarantee dryness in system

Basic GMP principle:

Avoid water-cleaning systems for most *chocolate* equipment

Dry Clean and Flush

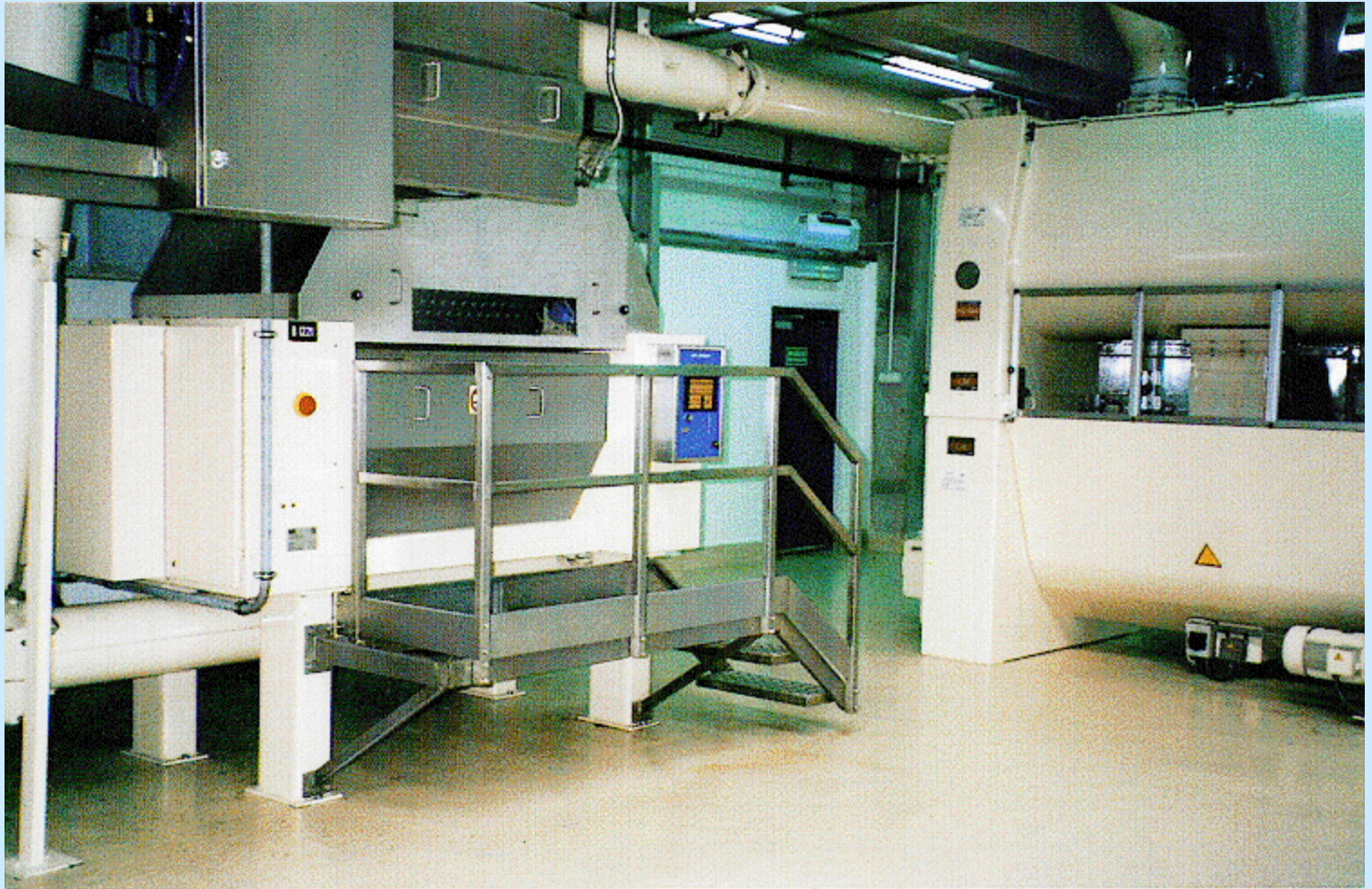
Dry Clean

- Depends on accessibility of equipment
- Extremely labor intensive
- Not able to rid many systems of allergen proteins

Flush

- Chocolate clings to pipes
- Flushed chocolate must be reworked. Introduces new risk.
- Does not eliminate risk of allergen protein.
- Does not eliminate need for advisory labeling.

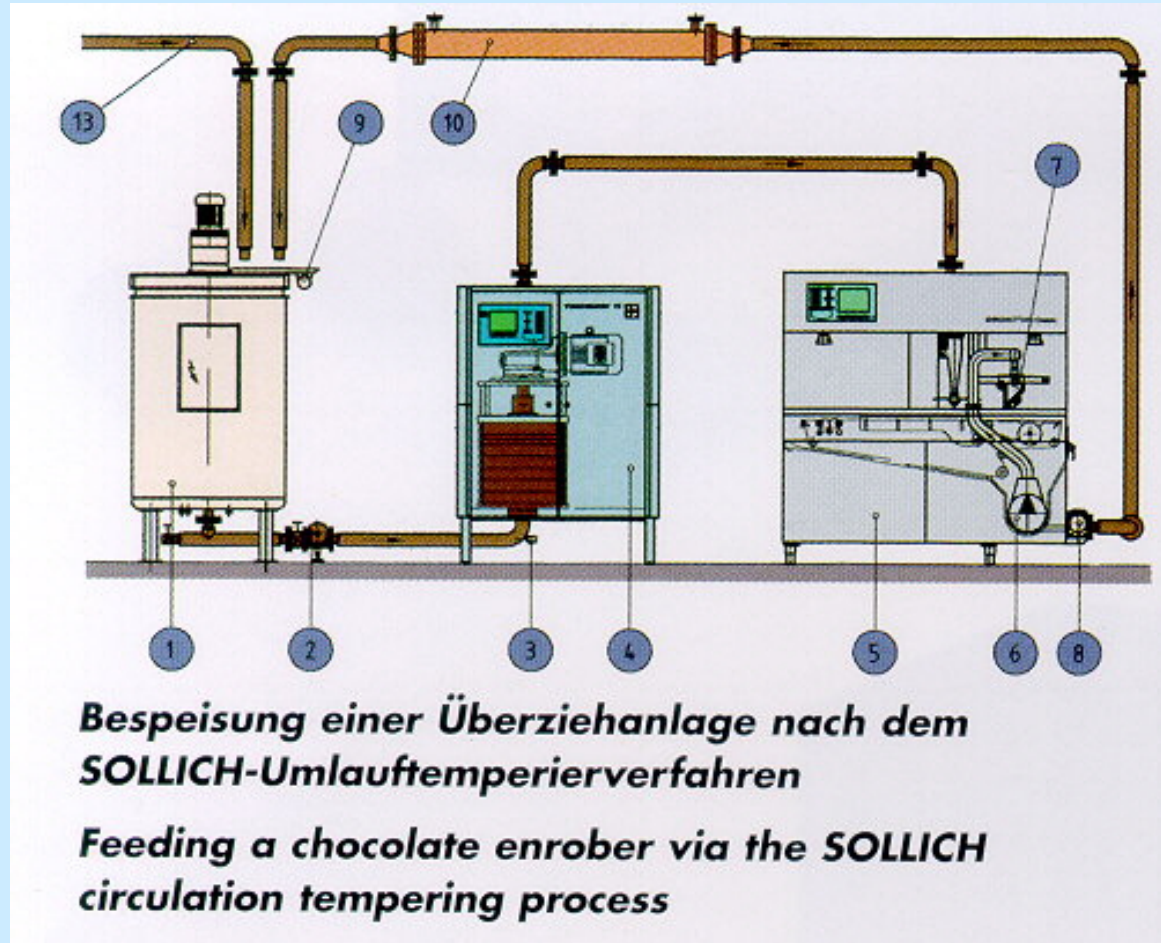
Mixing and Pre-refining Room



Liquid Phase Conching



Chocolate Feed to Enrober



Typical Points of Cross Contact: Chocolate and Other Confections

- Ingredient feed systems, pipes
- Conveyors, tunnels
- Mixing Equipment
- Release agent reservoirs
- Tempering units
- Depositors
- Vacuum cook kettles
- Cutting equipment
- Wire belts
- Rework vessels, grinders
- Enrobers
- Extruders
- Panners
- Utensils, gloves, clothes
- Wrapping equipment

Ingredient Procurement

- Reliance on operations of suppliers
- Carry-forward principle for labeling, if verified
 - Multiple peanuts and tree nuts processed by same suppliers
 - Dark chocolate with milk protein

Testing

- Use visual inspection and analytical testing to facilitate the design of the clean-up procedure
 - Used to validate a sanitation procedure
 - Doesn't measure “hung-up” product that can later dislodge
 - Cannot guarantee safety
- Need analytical methods for some allergens and validation of other methods.
- Industry needs FDA to establish thresholds

Guidance for Industry: Advisory Allergen Labeling

Food Allergen Issues Alliance Labeling Guidelines

- Recommend using advisory statements for unavoidable cross contact when all of the following exist:
 - Allergen presence is documented - visual, analytical, etc.
 - Risk is unavoidable even when current GMPs followed
 - Allergen present in some, but not all, products
 - Presence is potentially hazardous

Relevance of Company Size

Small companies	= 100 employees or less
Medium companies	= 101 to 500 employees
Large companies	= 500 to 1000+ employees

- Similar proportion of shared facilities and shared manufacturing lines
- Labeling criteria and considerations of small companies similar to medium and large companies
- Frequency of advisory labeling is similar, based on limited NCA survey data
- Small companies possibly less likely to document presence of allergen via analytical or visual testing
 - Issue of resources, expertise?

Candy companies support...

Additional “Alliance” Guidelines:

- Advisory statements should be accurate and conspicuous.
- Advisory statements should be placed at the end of, or in close proximity to, the ingredient declaration.
- When using an ingredient that utilizes an advisory statement, the food processor should carry that statement forward to the label of its food, when risk verified.
- Food processors should strive to label the same product consistently, even if produced in different locations or in different package sizes.

Typical Common Advisory Label Approaches for Confectionery

- May contain X. (or May contain traces of X.)
- Manufactured on equipment that also processes X.
- Manufactured in a facility that processes X.

What do advisory statements on candy mean?

- No confectionery industry agreement on levels of risk associated with different statements
- An advisory statement is intended to indicate **risk** to the allergic consumer
- **An advisory statement -of any kind- means that allergic consumers should not eat the product.**

Challenges

- Is it possible to convey a level of risk to the consumer?
- Industry needs FDA to establish thresholds/action levels.
- How do we communicate risk of a particulate allergen?
- Need to account for variability in allergen levels, depending on allergen characteristic, processing system and sanitation capabilities.
- Companies will err on the side of over protecting the consumer.

Additional Confectionery Concerns

- Label carryover from ingredient suppliers
 - Chocolate with milk or nut proteins
 - Peanuts and tree nuts are often processed in same facility
- Limited label space / smaller formats
- Recommend same labeling for brand manufactured in different plants regardless of manufacturing conditions and size variations.

Summary:

Advisory labeling is important tool that confectionery manufacturers use to help allergic consumers make an informed choice.