ESTABLISHING EXEMPTIONS FROM MANDATORY DECLARATION FOR PRIORITY FOOD ALLERGENS

Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens - Meeting 4

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CCFL request:

Whether certain foods and ingredients, such as highly refined foods and ingredients, that are derived from the list of foods known to cause hypersensitivity, can be exempted from mandatory declaration.

Current exemptions

- high degree of concurrence between regions and countries for some foods & ingredients,
  - although precise exemption description/criteria may vary;
- Some exemptions specific to individual jurisdictions e.g.
  - ANZ –Gluten in beer, Coconut.
  - EU, Argentina, Paraguay – Tree nuts used to make distillates or ethanol.

Soybean Oil exemptions

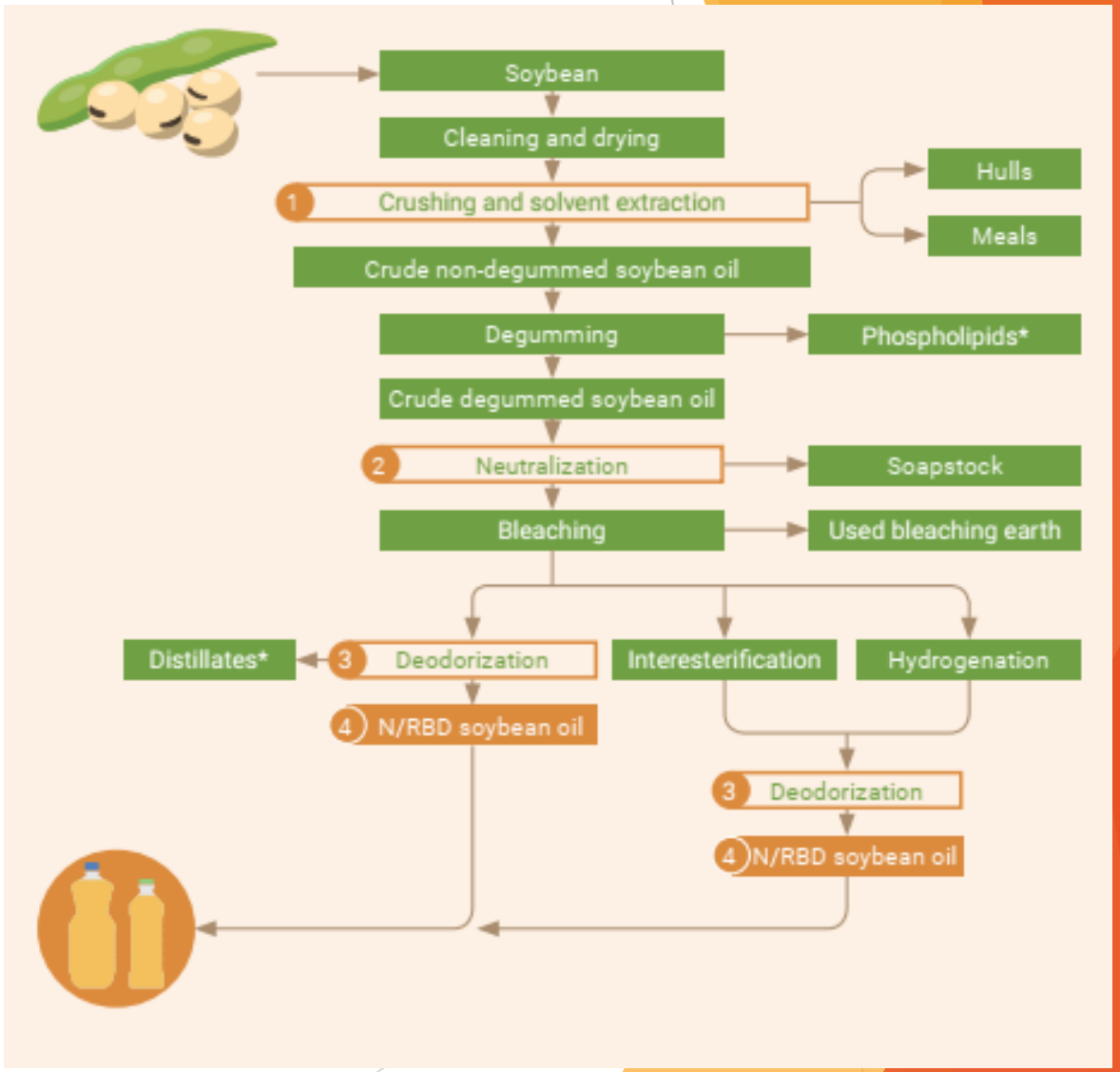
ANZ - degummed, neutralized, bleached and deodorized

EU, Argentina, Paraguay, Chile - Fully refined soybean oil and fat

USA - All highly refined* oils, including soy oil

** undergone refining, bleaching and deodorizing*

China - Soybean oil (refined) phospholipid

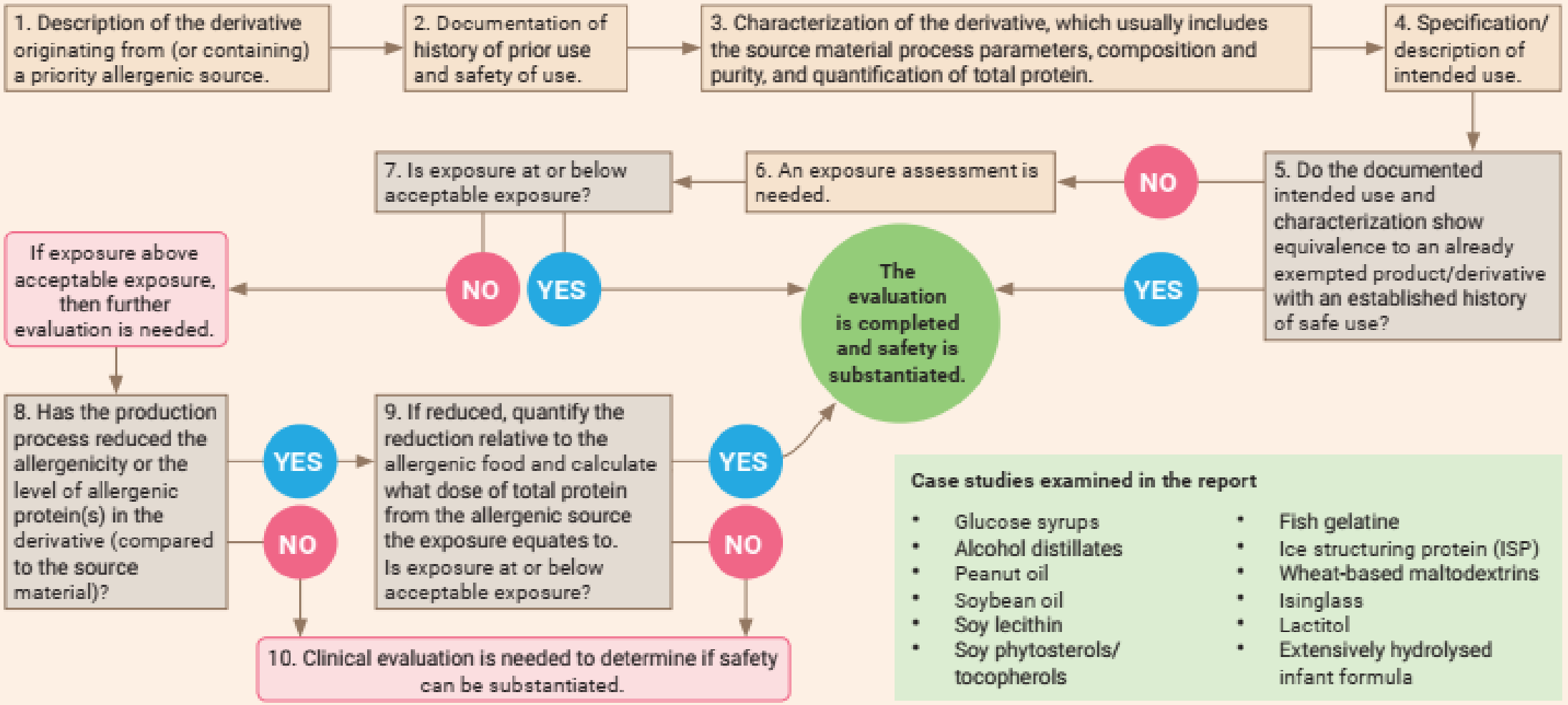


Three essential components to consider

1. characterization of the derivative,
   includes source and composition, existing uses, safety and reported adverse events;

2. exposure assessment from proposed exempt uses for verification against an acceptable marker of safety.
3. analysis of proteins from allergenic source;

Outline of the process for consideration of labelling exemptions for foods and ingredients derived from priority allergenic sources



1. Characterization of the derivative

1. Description
2. Documented history of prior safe use?
3. Characterization:
   source, process parameters,
   composition & purity, quantification of total protein.
4. Specification/description of intended use.
5. Is intended use and characterization equivalent to an already exempted safe product/derivative?

Yes - evaluation is completed and safe to exempt

No – proceed to exposure assessment

2. Exposure assessment

1. Is exposure at or below acceptable exposure?*

   Yes - evaluation is completed and safe to exempt

   No – further evaluation required

* *Based on current exemptions RfD/30 provides adequate margin of safety.*
* *Consideration should also be given to data & exposure assessment quality.*

Exposure assessment inputs

1. intended use levels for relevant food categories;
2. consumption values for relevant consumer groups per eating occasion;
3. analytical data or calculated equivalent of concentration of total protein allergenic source.

3. Potential reduction in allergenicity

1. Has production process reduced the allergenicity or the level of allergenic protein(s)?

2. If reduced, is exposure at or below acceptable exposure?

Yes - evaluation is completed and safe to exempt

No – Clinical evaluation required to determine if safety can be substantiated.

Total protein quantification

- Use more than one test method, each based on different principles
- Select suitable methods for protein levels based on the RfD/30
- Assessments of potential alterations in the allergenicity using weight of evidence approach based on data from:
  - allergen profiling assays (e.g. mass spectrometry or allergen molecule-specific assays), and
  - IgE-binding studies using sera from relevant food-allergic individuals

Clinical Evaluation

- When necessary, may require oral food challenge study

Case studies

- Exposure likely < RFD/30
  - Soy Phytosterols/Tocopherols
  - Soybean Oil
  - Peanut Oil
  - Soy Lecithin
  - Fish Gelatine & Isinglass
  - Ice-structuring protein (ISP)
- RfD/10 to RfD/30 but history of safe use
  - Wheat-based glucose syrups (including dextrose)
  - Whey derived ethanol
- Likely to exceed milk RfD/30. Clinical studies required
  - Extensively hydrolysed casein (EHC)

Conclusions

- the process developed by the FAO/WHO Expert Panel can be used to guide any future allergen labelling exemptions decisions both domestically and internationally.
- Establishment of safety is dependent upon consideration of data quality, outcome of the exposure assessment and review by relevant competent authorities.
- When safety is established, labelling exemption can be justified.

Thank You for Listening