

Regulated Precautionary Allergen Labelling

The South African approach
Lessons learned, challenges and successes

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SA FOOD REGULSTIONS



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DTIC

Promote fair trade and economic development.



DALRRD

Health, nutrition and quality of plants & animal products.



DoH

Health of SA population at large, including safety of food.



DTIC

**Consumer Protection
Act**

(Act No. 68 of 2008)



DoH

**Regulations relating to
the Labelling &
Advertising of Foodstuffs
(R.146/2010)**

Consumer Protection Act

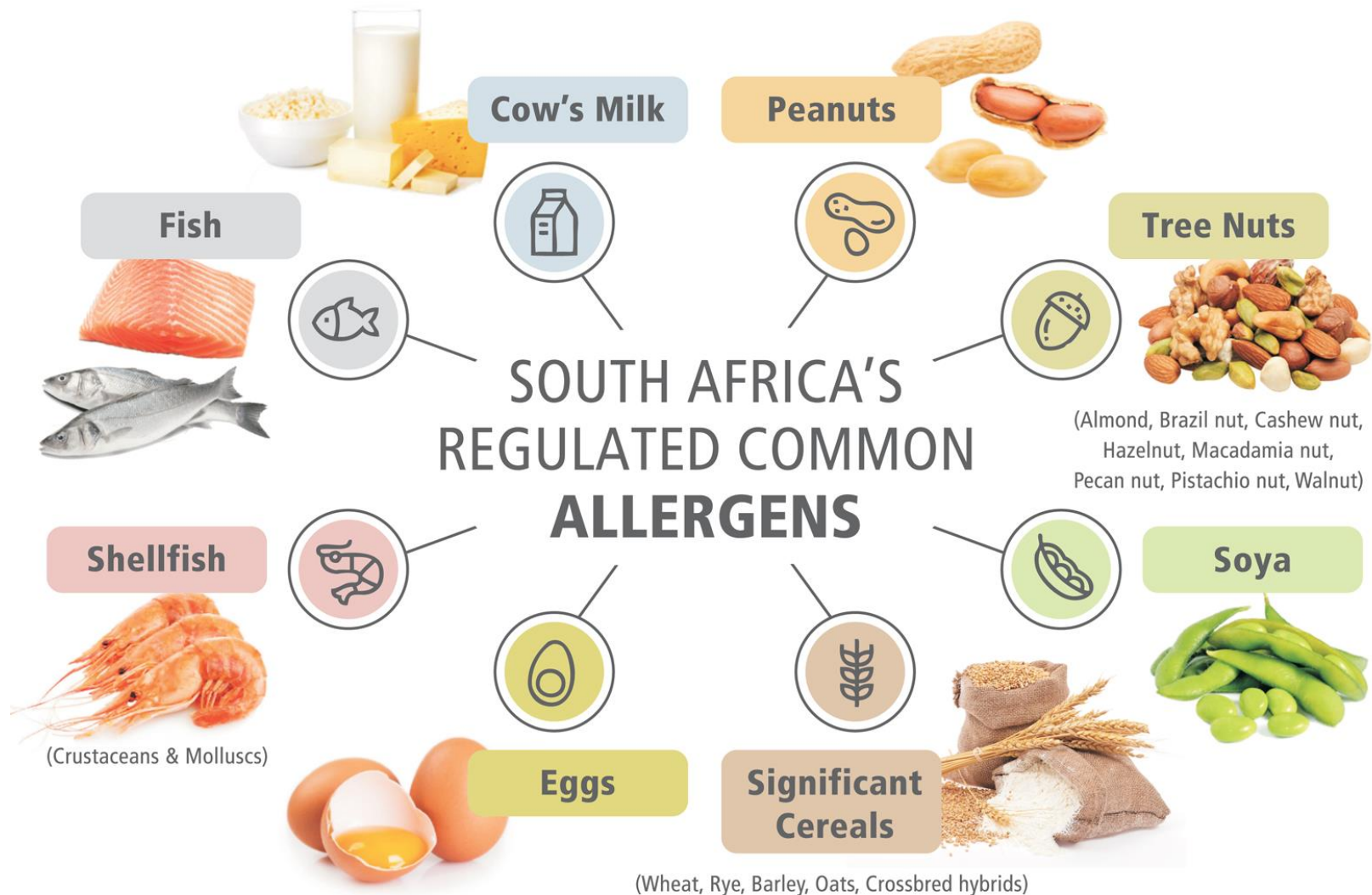
- Indirectly address allergens labelling.
- Protect consumers from:
 - exploitation & unfair marketing practices.
 - unusual hazards.
- Consumers have the right to information in plain, understandable language.

Regulations relating to the Labelling & Advertising of Foodstuffs

- Directly address allergen labelling.
- The objective is to give clear, concise information to protect consumers' health.
- Regulations are mandated from the top but enforced from the bottom up.

Regulations relating to the Labelling & Advertising of Foodstuffs





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Ingredient Declaration

Common Allergens

1. Self-evident from the name and/or
2. In parenthesis after ingredient and/or
3. 'Contains' directly after ingredient list

Examples:

1. Soya lecithin
2. Lecithin (soya)
3. Lecithin...
Contains: Soya

Significant Cereals

1. Indicate the species
2. Indicate 'gluten' in parenthesis

Examples:

Wheat cake flour (gluten)

Optional:

Contains: Wheat, Gluten

Additives

Declare when derived from an allergen, even in the case of:

1. Carry-over additives
2. Solvents and carriers
3. Processing aids



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Precautionary Allergen Labelling (PAL)

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Claims

(Common Allergen)-Free

- Name the common allergen e.g.: cow's milk-free, wheat-free
- Must be proven by testing

Gluten-Free

- ≤ 20 ppm (mg/kg) gluten
- Must be proven by testing
- 'By its nature gluten-free' if applicable and tested (e.g.: 'Maize is by its nature gluten-free')

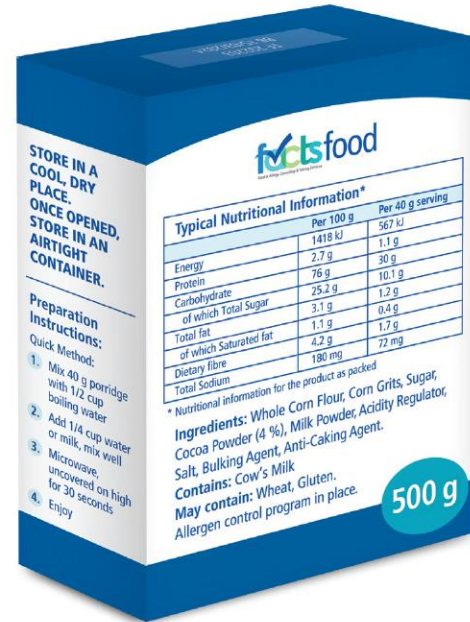
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- Use the terms 'milk-free' or 'dairy-free' in the case of 'cow's milk-free' claims
- Make '(allergen)-free' claims where they may be misleading

'Small packages', i.e.:

- pre-packed foodstuffs, with total exterior area of $\leq 2000\text{mm}^2$
- single once-off-use herbs and spices ($\leq 10\text{g}$)

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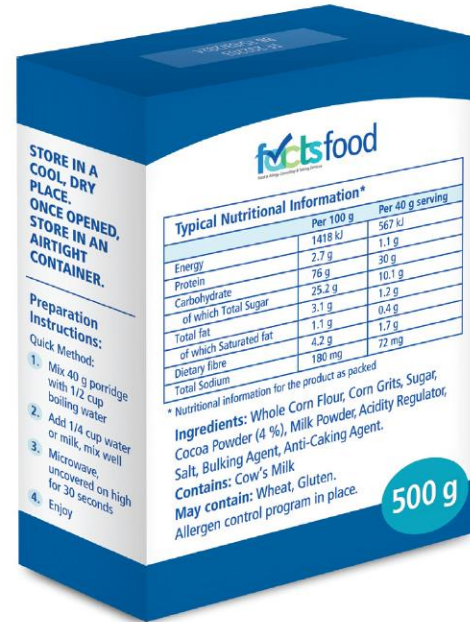
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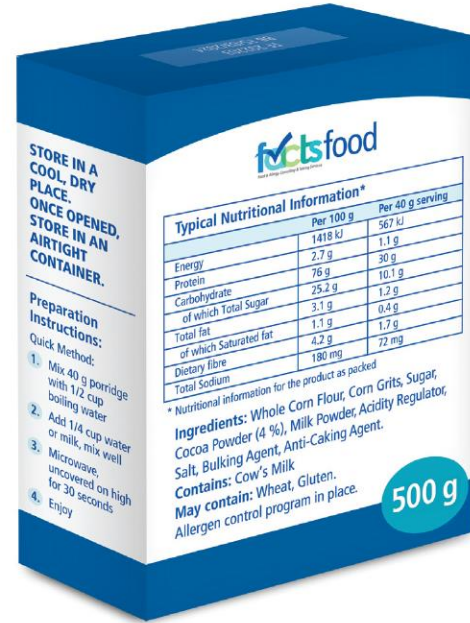
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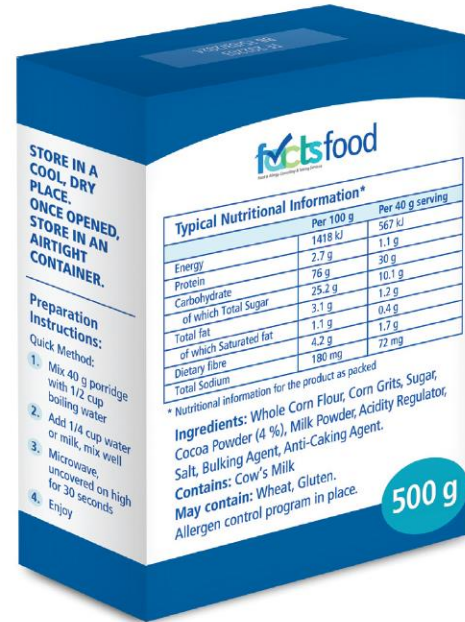
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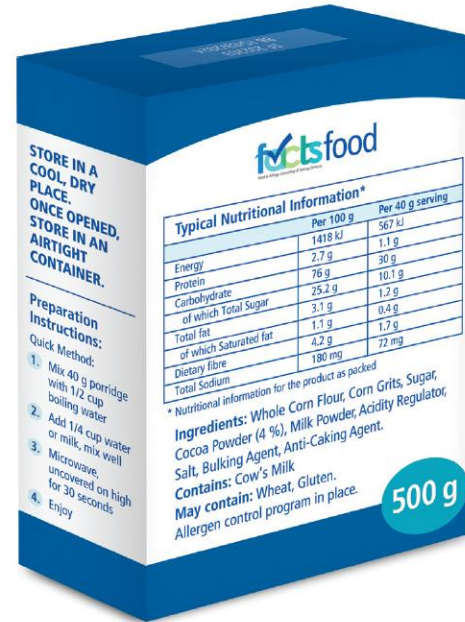
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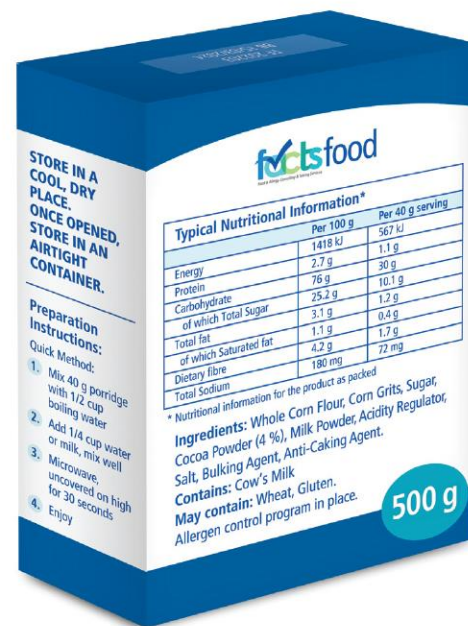
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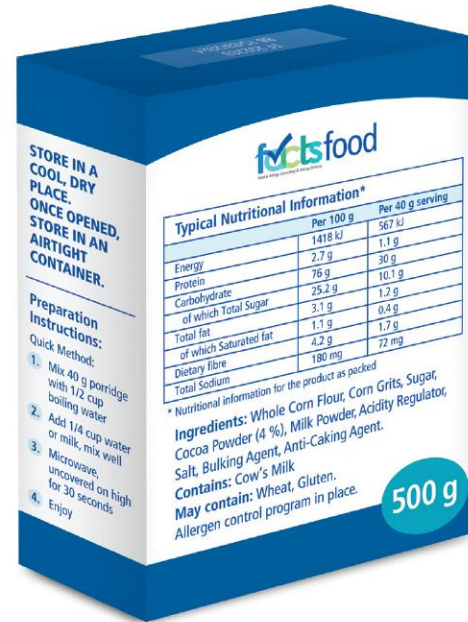
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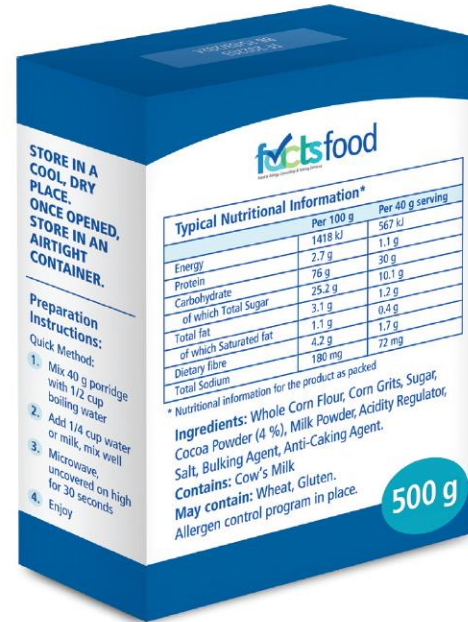
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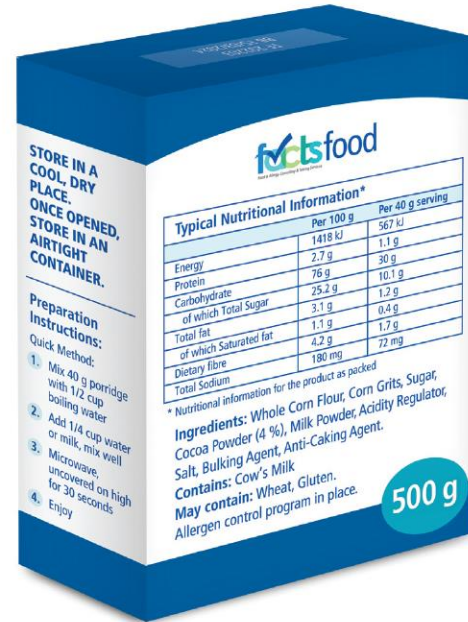
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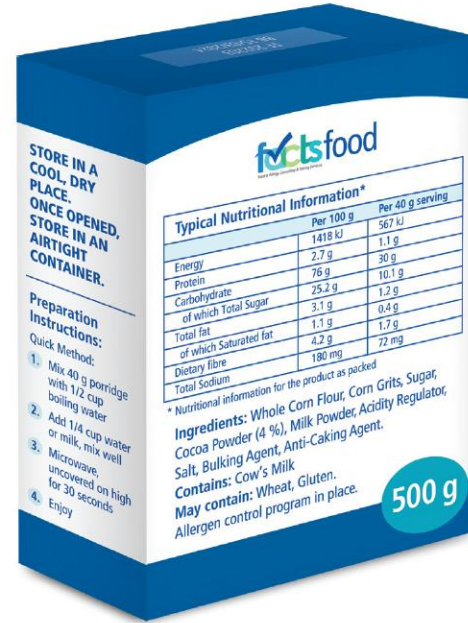
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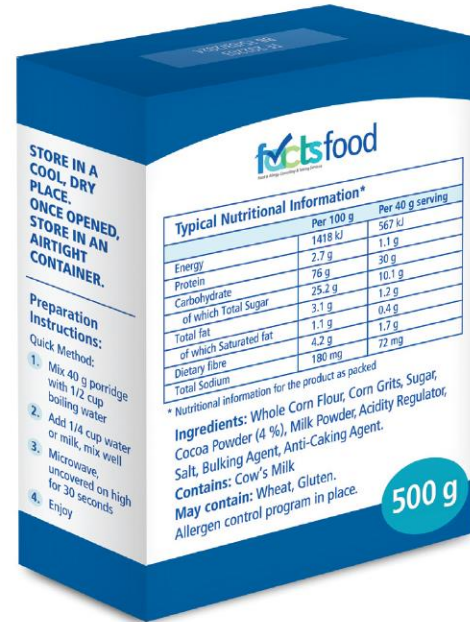


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 - Use the statement 'May contain...'
 - Statement must be in direct proximity to the ingredient declaration
 - In addition, 'Allergen control program in place' may be used



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3

Claims

(Common Allergen)-Free

- Name the common allergen e.g.: cow's milk-free, wheat-free
- Must be proven by testing

Gluten-Free

- ≤ 20 ppm (mg/kg) gluten
- Must be proven by testing
- 'By its nature gluten-free' if applicable and tested (e.g.: 'Maize is by its nature gluten-free')

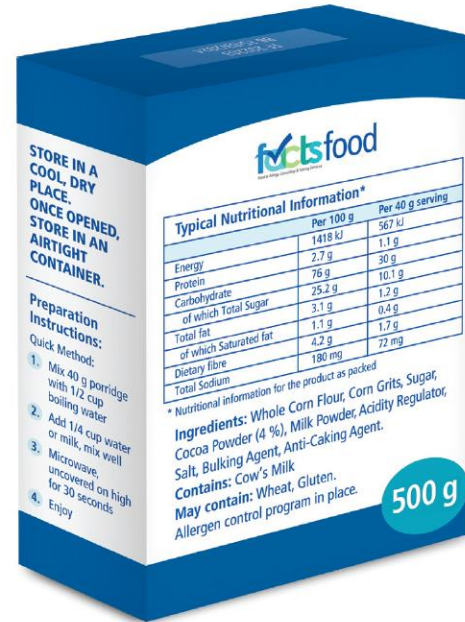
Do not:

- Make generic 'allergen-free', 'non-allergenic' or 'hypoallergenic' claims.
- Use the terms 'milk-free' or 'dairy-free' in the case of 'cow's milk-free' claims
- Make '(allergen)-free' claims where they may be misleading

'Small packages', i.e.:

- pre-packed foodstuffs, with total exterior area of ≤ 2000 mm²
- single once-off-use herbs and spices (≤ 10 g)

Although small packages are exempt from ingredient declaration, common allergens must be indicated on packaging.





If there is a risk for cross-contamination in a food processing facility:

- a) **Due diligence** shall be exercised to prevent the occurrence of such contamination and **an allergen control policy (ACP)** shall be implemented.*
- b) In the case where precautionary labelling is utilised, this shall not be used to circumvent **GMPs** and **an effective ACP**.*
- c) In the case where precautionary labelling is utilised, the risk, the manner of **assessing the risk and the steps taken to avoid the risk of allergen cross-contamination**, shall be documented.*



Guidelines to R146:

- Provide guidance on allergen management and risk assessment.
- It gives preference to the “May contain” phraseology for PAL.
- Give guidance on the role of allergen thresholds/reference doses in allergen risk assessment and PAL decision-making.
- Refers to the VITAL[®] to guide PAL decision-making.

IMPLICATIONS FOR FOOD INDUSTRY?

- Food manufacturers are required to manage allergens and show due diligence.
- Document allergen management plan in place, including risk assessments.
- Not allowed to PAL without trying to prevent and manage allergen cross-contact.
- PAL must be based on risk.





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FOOD INDUSTRY

- Knowledge/expertise in risk assessment.
- Confusion - which RfDs?
- Discomfort PAL based on RfDs.
- Compliance with single phraseology.



STRUCTURAL

- State has limited resources for enforcement.
- No surveillance framework.
- No recalls notification and trending framework.



KNOWLEDGE AND DATA

- Limited SA specific research.
 - Prevalence
 - Sensitivity
 - Consumption data
 - Perception of PAL





- Sourcing good quality raw material information.
- Varying global allergen labelling requirements.
- Complexity in testing and quantifying allergens.
- Sampling to detect and quantify cross-contact.



SUCCESSSES



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REGULATIONS

- Created a solid foundation for PAL.
 - in line with WHO/FAO Expert Consultation recommendations.
- Promotes mandatory PAL coupled with due diligence.
- Regulations + uptake in GFSI standards + Retailer pressure = SA industry very aware of the importance of allergen management and PAL.



TESTING CAPABILITIES

- Growing and maturing testing capabilities and knowledge.
- ELISA, PCR and LC-MS/MS.
- Cross-check results.
- Detect allergens that may go undetected.
- Provide additional information on what may be present.
- Detect, speciate and quantify gluten in one test.





LESSONS LEARNED



Effects of Food
Fraud on
allergen
management.



Change in diet trends.

Vegan / Alternative protein sources



Rfd used to
support free-
from claims or
not to declare.



**ALLERGEN
FREE**



Wheat vs Gluten

Separate risk
assessments
and PAL.





CLOSING



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SA is a good case study to support that risk-based PAL is feasible.

We all have similar challenges.

Together, we will succeed.





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