Should allergic responses be expected when introducing edible insects in the diet? What are the consequences for allergenicity when genes are introduced or modified in crops? Is a specific infant formula safe for cow’s milk allergic babies? These are just a few of the many questions to address when developing (new) food products. TNO develops and implements, together with partners, strategies to assess and predict allergy risks early in the development phase of novel or modified food products.

In response to the continuous growth of the world population, strategies are being developed to create more sustainable agricultural practices. Current food production methods are being enhanced to develop climate-resistant crops and to ensure an adequate, safe, sustainable and nutritious food supply (e.g. alternative protein sources). Worldwide incidence of food allergies continues to rise and therefore allergy risk assessment is increasingly important for the food industry. Products should only be accepted and introduced to the market when they carry an acceptable allergy risk.

**ALLERGENICITY ASSESSMENT**

TNO offers the food and feed industries and governments tailor-made, advanced risk assessment support in two areas:

- Allergenicity assessment of new or modified food proteins;
- Hypoallergenicity assessment of infant formulae and protein hydrolysates.

**ALLERGENICITY ASSESSMENT OF NEW OR MODIFIED FOOD PROTEINS**

Until now, accurate assessment of the allergenicity of new or modified (e.g. alternatively processed) proteins, is unfeasible. A single definitive test to predict allergic responses in humans to a new or modified protein or protein source is not available. The current tests (weight of evidence approach), are not applicable for novel proteins. Furthermore, the outcome of the risk assessment relies on expert judgement since there is no generally accepted guidance on procedures and interpretation of the experimental results.
ALLERGENICITY ASSESSMENT

TAILOR-MADE ALLERGENICITY ASSESSMENT
At the present time, TNO offers tailor-made qualitative protein allergenicity assessments based on multiple hazard parameters regarding:

- **Product identification**
  (e.g. source of protein, evolutionary descent, amino acid composition, food matrix properties)

- **Physical and chemical properties**
  (e.g. structure, processed form, digestibility)

- **Biological properties**
  (e.g. in/ex vivo activity, cross-reactivity with other allergens)

RELATIVE ALLERGENICITY PREDICTION
TNO’s ambition is to develop a strategy to assess and predict the relative allergenicity of proteins in a quantitative way. To this end, a wide range of the established but also new hazard parameters are examined in known food allergens to assess their predictive power.

In this translational approach, we aim to statistically combine the hazard parameters that offer the best information on the allergenic potential of proteins and food products to develop a model that predicts the relative allergenicity of (new or modified) proteins (Figure 1). A comprehensive, quantitative risk assessment will become possible using multiple hazard parameters and will offer the best available information on the allergenic potential of proteins.

HYPOALLERGENICITY ASSESSMENT INFANT FORMULA
Cow’s milk based infant formulae are an important alternative to breast milk. Although most children benefit from standard cow’s milk-based formulae, some infants are allergic to the intact cow’s milk proteins. For these allergic infants, formulae have been developed based on hydrolysed cow’s milk proteins, which retain the high nutritional quality of the proteins, but have lower allergenic potential.

TNO’s advanced, case-by-case procedure determines the possible remaining sensitization or elicitation hazard presented by hypoallergenic formulae. To this end, the residual allergenicity of these hypoallergenic products is determined. The risk assessment procedure can cover a wide variety of studies such as immunogenic epitope analyses, in vitro challenge tests using human basophils or cell lines, and in vivo sensitization tests. These tests can be performed in compliance with the guidelines for Good Laboratory Practice (GLP) and conform to current legislation.

This approach may also be used to determine the hypoallergenicity of other alleged hypoallergenic proteins such as protein hydrolysates in clinical nutrition.

Figure 1. Conceptualized spectrum of relative allergenic potency of foods.