

SAFETY & REGULATORY STRATEGY



TNO innovation
for life

Food and feed safety is strictly regulated within the EU. Our team of toxicologists, risk assessors and consultants offers strategic advice and valuable expertise in regulatory affairs and health risk assessment.

TNO CONSULTANCY AT ALL STAGES

The safety and regulatory compliance of food and feed products should be warranted and documented throughout their lifecycle. To this end, TNO performs evaluations covering hazard, exposure, risks and regulations in close consultation with their clients.

Often, a non-testing or minimal testing approach can be followed based on product characterization, data mining and up-to-date evaluation techniques. Sometimes, a health concern is identified that may warrant in-depth risk assessment or further testing. Since 2005, more than 150 food, feed and ingredient companies or their suppliers have called upon our safety and regulatory services.

TNO offers you broad and extensive experience in:

SUPPORT ON FOOD REGULATORY ASPECTS

- › Advice on regulatory feasibility, (testing) strategy and consequences of changes in legislation for both authorization and notification.
- › Preparation of regulatory dossiers for pre-market approval, post-market inspection or marketing support.
- › Preparation of product specifications and labeling information.
- › Peer review of statements and dossiers; second opinions.
- › Contacts with authorities and other relevant bodies.
- › Overall (multidisciplinary and/or multinational) project management and strategy.

TNO DEVELOPS ADVANCED METHODS FOR COST-EFFECTIVE SAFETY ASSESSMENT

SUPPORT ON FOOD SAFETY ASPECTS

- › Product safety: evaluations of scientific literature, safety studies and production processes and preparation of dossiers and product specifications.
- › Preparation of expert opinions and position papers on health effects.
- › Evaluation of residue fate and behavior in plants and livestock.
- › Residue analysis in various matrices*.
- › Evaluation of potentially hazardous compounds in poorly defined (food) matrices.
- › Experimental toxicity testing according to OECD, EC and other guidelines under GLP*.
- › Toxicological evaluation and risk assessment (experts available on each toxicological endpoint).
- › Estimation of potential and/or actual dietary exposure.
- › Quantitative prediction and health risk assessment of transfer of compounds from feed towards edible animal products.
- › Probabilistic food allergen risk assessment and management.

TNO has developed a computerized Expert System Food Safety in which our accumulated knowledge on food safety and legislation are integrated, which helps us to improve the speed, cost-effectiveness and quality of our services.

** performed at TNO Triskelion B.V., a TNO company*

REGULATORY ASSESSMENT

For a successful introduction of a new food product or ingredient, it is essential to consider the regulatory environment applicable to its target markets at an early stage of development.

The European Union has established a whole set of Regulations, Directives, Scientific opinions and guidance documents. Extensive expertise in legislation enables TNO to fully assist clients in key matters concerning international regulatory procedures for newly developed food and feed products. TNO has clear insight into the process of gaining approval for new products, new production processes, or new applications in food supply. Furthermore, TNO is able to advise on the possible consequences of changes in current legislation for existing products. We have a sound record of successful involvement in European regulatory procedures.

These include the following regulatory frameworks:

- › Functional Foods and Ingredients.
- › Novel Foods and Ingredients.
- › Genetically Modified Foods, Feeds and Ingredients.
- › Flavourings, Additives and Enzymes.
- › Feed Additives.
- › Food Supplements.
- › Foods for Particular Nutritional Uses (FPNU, Infant Nutrition and Foods for Special Medicinal Purposes).
- › Food Packaging*.
- › Nutrition Claims and Health Claims.
- › Non-food consumer products.

** In cooperation with TNO Triskelion B.V., a TNO company*





External partnerships are maintained with reputed consulting companies, who can be called upon when assistance is sought for tasks outside the EU, like US GRAS notifications. Regional differences are taken into account to develop an optimal, truly international regulatory strategy.

EXPOSURE ASSESSMENT

Determination of exposure of consumers to compounds in food is a critical aspect of risk assessment and may be required for registration. Consumer exposure data may also be necessary to substantiate the health benefit of a product.

To establish the correct and most efficient method for exposure assessment in a particular situation, TNO has developed a decision tree. Using the decision tree facilitates the choice between a more detailed probabilistic exposure assessment and a quick 'worst case' approach.

TRANSFER OF CHEMICALS FROM FEED TO ANIMAL PRODUCTS

Preventing consumer risk due to chemical contaminants or residues in animal feed

remains a point of attention. Often, consumer risk assessment has been hampered by a lack of knowledge on behavior of feed contaminants and residues. In particular, for many contaminants the transfer from feed consumed by livestock to edible animal commodities has not been quantified. TNO has developed a database on compound specific transfer factors, representative for the transfer from feed to animal products. The use of database-derived transfer factors enables a more realistic risk assessment compared to a worst-case approach. Even if little information is available, scientifically founded transfer factors can be derived using the data for comparable chemicals (in terms of either chemical group or physico-chemical properties). In cases where contaminated feed products are found, those animal products susceptible to contamination can be identified. The application of transfer factors in risk assessment also facilitates rapid risk management decision making or intervention.

SAFETY AND LEGALITY OF FOOD AND FEED PRODUCTS SHOULD BE WARRANTED



COMPLEX MATRICES

Food and feed are complex matrices containing hundreds of components. With a growing number of components, safety assessment may become even more complex. TNO has developed strategies to evaluate the safety of complex food and feed matrices, combining high-end sample preparation, fractionation and analytical techniques with state of the art data mining and risk assessment. Focusing on analysis of relevant compounds and selectively applying the Threshold of Toxicological Concern (TTC) concept, the safety of your product can be warranted in a responsible and acceptable manner.

ALLERGEN RISK ASSESSMENT

By our daily food, we are exposed to a variety of proteins, all of which may provoke allergic reactions in some of us. For risk assessment and in order to establish safe upper limits of these allergens, TNO has developed a method to quantify the number of allergic consumers who may react to specific concentrations of a known allergen present in a food product. This automated probabilistic method combines data on consumption of a wide range of food products with the sensitivity of allergic patients to food allergens. Currently, it is the most promising approach for risk management of allergens at the population level.

TNO.NL

HEALTHY LIVING

TNO initiates technological and social innovation for healthy living in a vital society.

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