Subpopulations to be covered in EFSA's risk assessments

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BACKGROUND

- Recent discussions with ANSES/BfR/DTU on considering target populations and population subgroups in the assessments carried out by EFSA.
- A general discussion with the Scientific Committee on:
  - Population sub-groups in EFSA's **safety** assessments
  - Population sub-groups in EFSA's **benefit/adequacy** assessments
- Scope: identification of population subgroups for hazard assessment and not exposure assessment.

DEFINITION OF GENERAL (HEALTHY) POPULATION AND ITS SUBGROUPS

- Normal healthy population comprises all life-stage groups
- The general healthy population or its sub-groups (e.g. infants) is the default target population for the vast majority of benefit and safety assessments in EFSA.
- Excludes sub-populations with extreme and distinct vulnerabilities due to genetic predisposition or disease
- Including these sub-populations would result in
  - safe levels that are significantly lower than needed to protect most people against adverse effects of high intakes
  - beneficial/adequate levels that are significantly higher than needed to achieve the desired effects/adequate levels

CONSIDERATION OF TARGET GROUPS OTHER THAN THE GENERAL HEALTHY POPULATION OR SUBGROUPS

1. **Subjects with food allergy and/or intolerance and subjects with certain errors of metabolism**
   - The only effective prevention: dietary exclusion
   - Food labelling and food information to the consumer
2. **Subjects at risk of disease**
   - For diseases with risk factors which can be modified by lifestyle or diet
   - Guidelines for primary prevention are issued by medical societies
   - **Challenges**: lack of studies for specific groups and consumer identification
3. **Subjects with a disease**
   - Normally under medical (dietary, lifestyle or pharmacological) treatment for the disease
   - Guidelines for the treatment and secondary prevention of diseases are issued by medical societies
   - **Challenges**: Identification of safe or beneficial/adequate levels of a food constituent

EXAMPLES

- **Perchlorate**

Most sensitive endpoint: iodine uptake in thyroid gland to cover subjects with mild iodine deficiency

- **Nickel**

Critical endpoint for chronic effects: reproductive/developmental toxicity in rats. Critical endpoint for acute effects: Systematic contact dermatitis elicitated in Ni-sensitive human (oral consumption)