Dietary Risk Assessment of Nitrates in Cyprus and the relevant uncertainties

Georgios Stavroulakis, Maria Christofidou, Maro Christodoulidou, Popi Nicolaidou Kanari

Risk Assessment Unit
State General Laboratory (SGL)
Ministry of Health, Cyprus
gstavroulakis@sgl.moh.gov.cy

Eleni Ioannou-Kakouri (ex-Head of RA Unit)
Lefkios Paikousis (Improvast Ltd)

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Overview

- SGL's role in risk assessment
- Databases for exposure assessment
- Preparation of Chemical Occurrence Data
- The ImproRisk model
- Dietary risk assessment of nitrates
- Uncertainties
- Conclusions and final remarks.

SGL's role in risk assessment

- **The SGL supports all Competent Authorities of the Food Safety Council (FSC) in Cyprus as it has established a Risk Assessment Unit to assist FSC's work to carry out the necessary risk assessment**

Risk Assessment capacity at SGL has been built through :

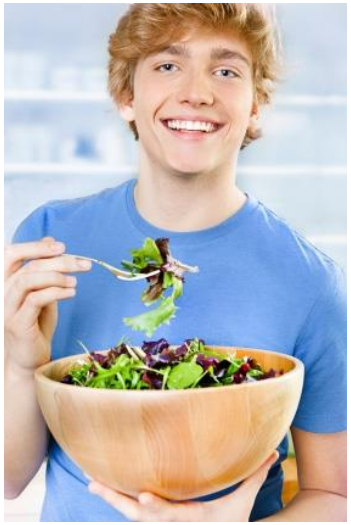
- **EFSA's guest scientist scheme**
- **Local Training by BfR experts, after signing a MOA with BfR – Germany**
- **Training in BfR Summer workshop**
- **BTSF trainings**
- **Participation in the research project ACROPOLIS (aggregate and cumulative exposure of pesticide residues) under FP7 coordinated by RIVM in the Netherlands**

- **SGL is now participating in a new research project EUROMIX under Horizon 2020 on new tools on Risk Assessment**
- **Cyprus closely collaborates with EFSA, who is considered as a Driving Force in these efforts and a platform for support.**

Dietary Exposure Assessment

Chemical occurrence

Food consumption



Dietary Intake assessment

Databases for exposure assessment of nitrates

Consumption data

- Food Consumption Data for **adolescents** (303 participants, 11-15 years old, 3-day dietary record) at individual level from "Child Health" Database (part of the **EFSA Comprehensive European Food Consumption Database**), with FoodEx coding at 4 levels

Occurrence data

- Concentration levels of nitrates from the analysis of foodstuffs & water for the years 2006-2015, stored in the LIMS Database of SGL
- Validated and harmonized data according to EFSA requirements (Standard Sample Description (SSD), FoodEx etc.) and based on SGL's participation in relevant EFSA projects
- Accredited Laboratories of SGL according to **CYS EN ISO/IEC 17025:2005**
- Accredited analytical methods: HPLC/Conductivity & Spectrophotometry

Dietary Exposure Calculation (mg/kg b.w. per day)

Exposure = concentration of chemical (mg/kg) x food consumption (g/day)/body weight(kg)

- The results of the calculations are compared with the respective toxicological reference value, in this case Acceptable Daily Intake (**ADI**=3.7 mg/kg b.w. per day).

Preparation of Chemical Occurrence Data

- Nitrate occurrence data in food (n=684) and drinking water (n=6424) were extracted from LIMS for the years 2006-2015

- Sample results below the limit of detection (LOD) or the limit of quantification (LOQ) were expressed as the upper bound (UB) value, i.e. the actual LOD or LOQ values were used for the calculations

- According to EFSA opinion on nitrates (EFSA, 2010a), the nitrate occurrence results were split into five main groups including:
  - Lettuce
  - Other leafy vegetables (spinach, rocket/rucola, purslane, beet leaves)
  - Potatoes and potato products
  - Other vegetables
  - Other foods (including water)

- Under "Other foods", preserved meat and cheese were used as the food categories for which nitrates are added intentionally (as a preservative agent).

The exposure assessment model- ImproRisk

ImproRisk: Deterministic model using food consumption data at individual level

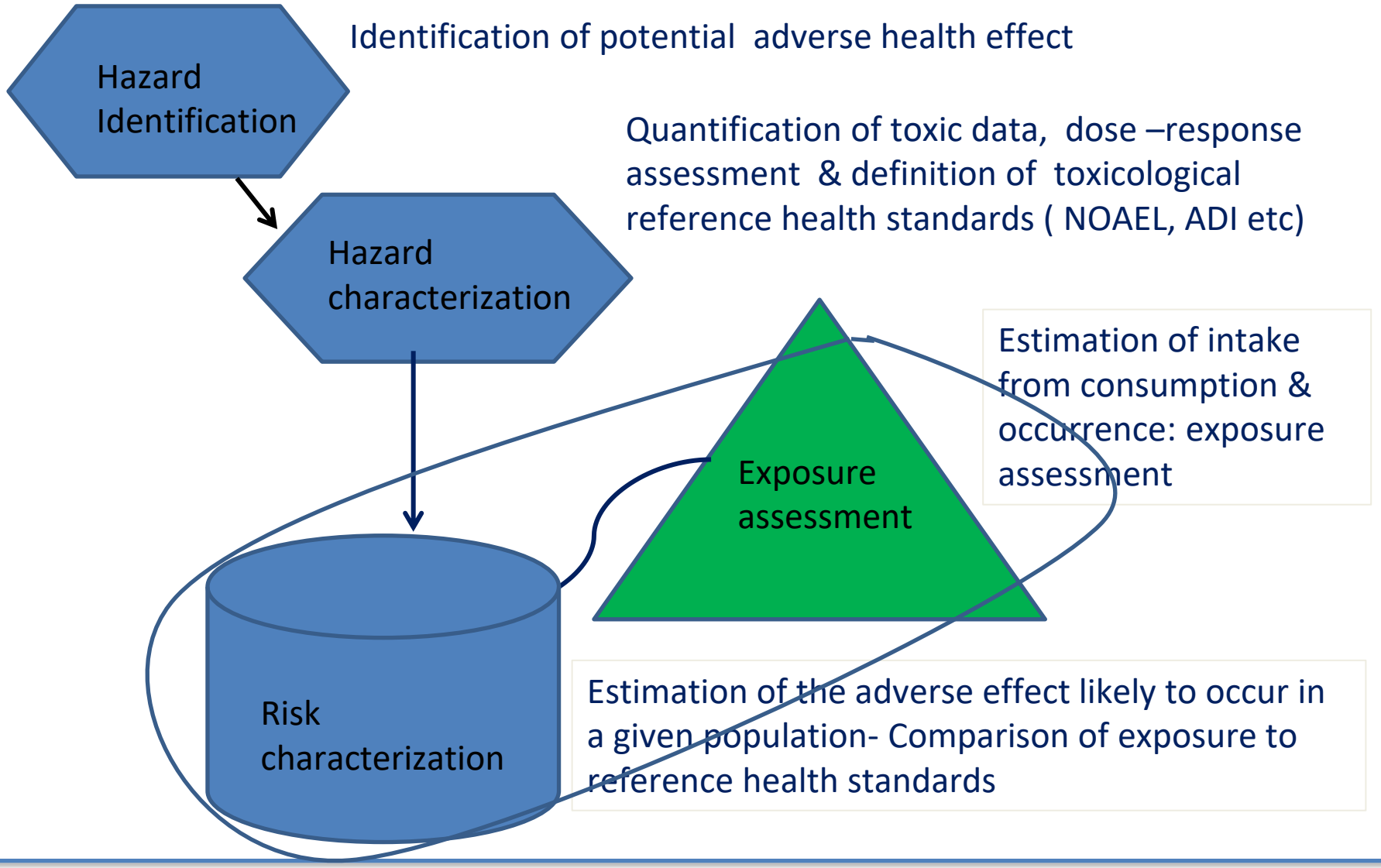
- It was developed for SGL by IMPROVAST (www.improvast.com)
- Implemented in MS Excel (Supported by the 2010 version or later)
- An empirical distribution model, which produces the probability & cumulative distributions of the exposure
- Consumption Data and Occurrence Data are matched to calculate the individual intake level
- Matching is done at each food consumption occasion

ImproRisk

In this study:

- Chronic nitrate exposure was calculated using median nitrate concentrations and individual body weights and consumption amounts averaged over the three days of the survey for each adolescent
- The matching was done by using the food names of the EFSA FoodEx1 at Level 2 and Level 3 (in the case of lettuce)

4 steps of Risk Assessment (EFSA, 2010b)



Dietary risk assessment of nitrates

A) Exposure Assessment

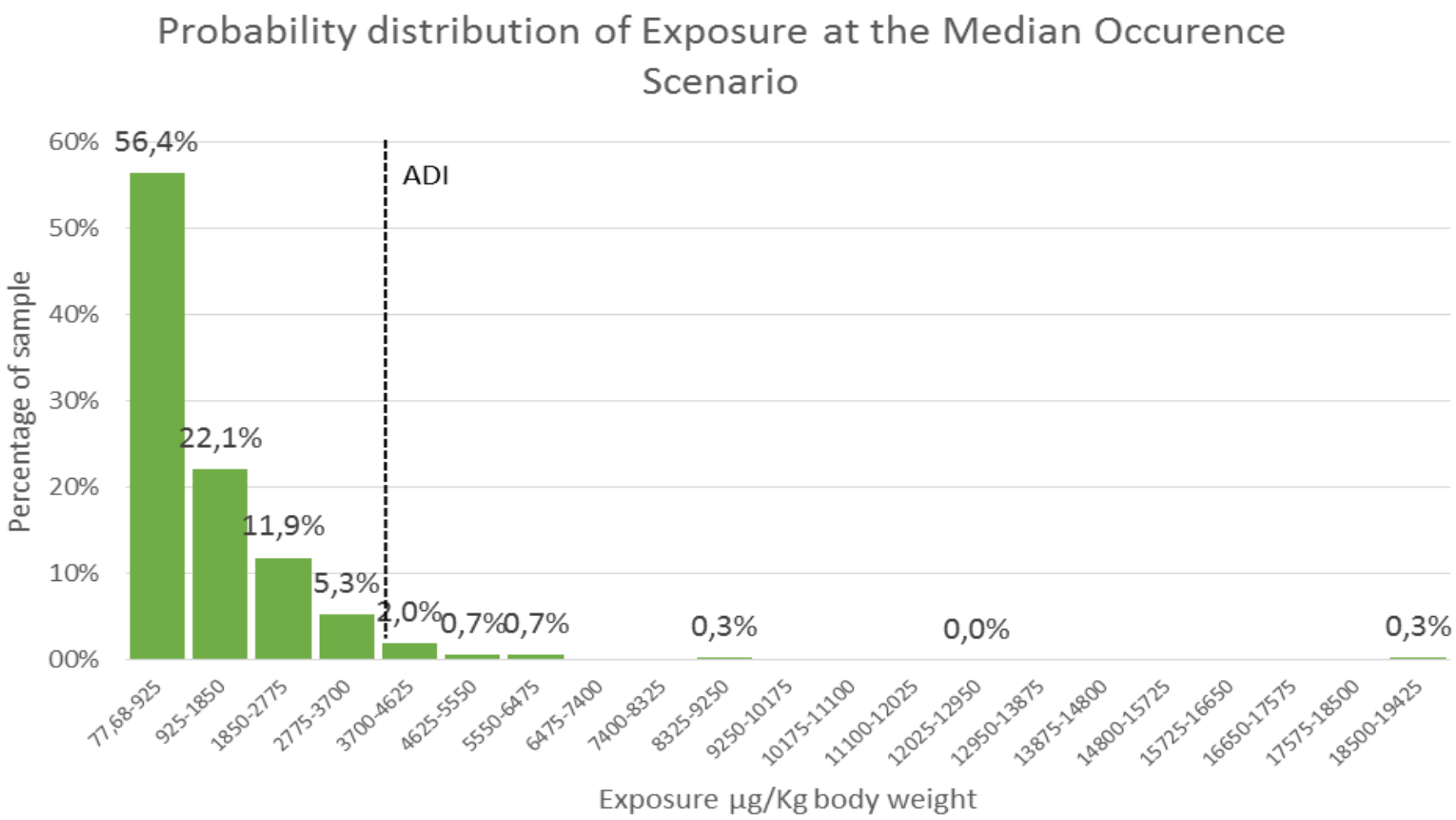
Dietary exposure (mg/kg b.w./day)	Mean	95th percentile
Cyprus adolescents	1.25	3.31
EFSA calculations for European adolescents*	0.77	2.41

* EFSA Journal 2010;8(12):1935.

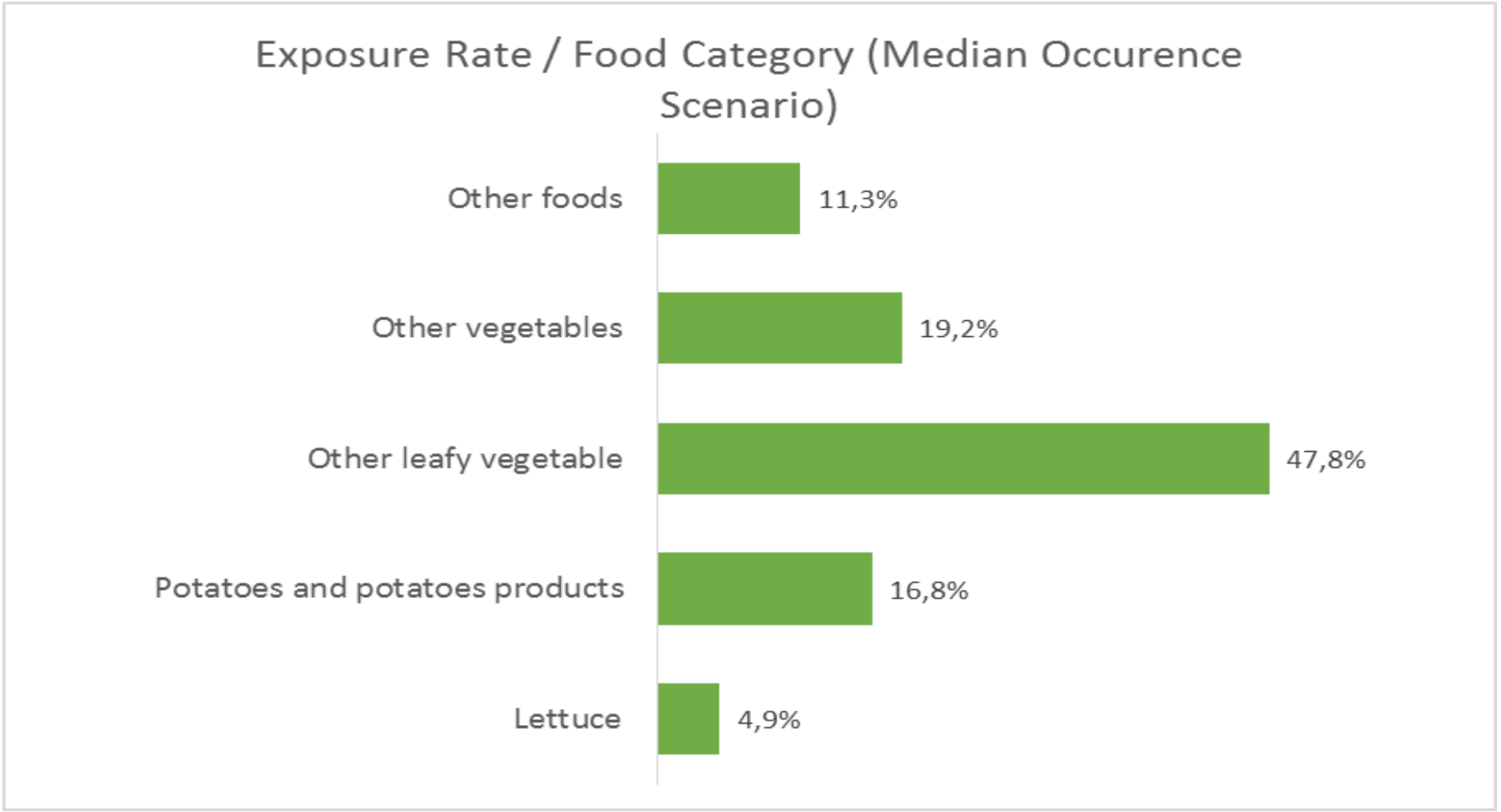
B) Risk characterisation

- Mean & 95th percentile exposure represented 33.8 & 89.5 of ADI, respectively
- Only a small percentage of the population (~4%) exceeds the ADI.

Distribution of exposure in the Cypriot population



% Contribution of each food group to the exposure to nitrates



Definition of Uncertainty

"Uncertainty is a general term referring to all types of limitations in available knowledge that affect the range and probability of possible answers to an assessment question. Available knowledge refers here to the knowledge (evidence, data, etc.) available to assessors at the time the assessment is conducted and within the time and resources agreed for the assessment."

Guidance on Uncertainty in EFSA Scientific Assessment, 2016

Sources of uncertainties (EFSA, 2006)

The EFSA Journal (2006) 438, 1-54

- **Exposure model/ scenario**
- **Model parameters:**
  - **Food consumption**
  - **Body weight**
  - **Concentration of chemicals**

Guidance of the Scientific Committee on a request from EFSA related to

Uncertainties in Dietary Exposure Assessment

Request No EFSA-Q-2004-019

Adopted on 14 December 2006

❖ **In this study the uncertainties related to the use of the deterministic model ImproRisk, the Child Health Database and the concentrations of nitrates, were identified and assessed.**

Uncertainties related to the use of the exposure model ImproRisk

- **The exposure scenario used in this study is based in raw products (same as in EFSA opinion (2010))**
- **ImproRisk does not take into account the possible changes of the nitrate content due to processing of food commodities, such as washing, peeling and/or cooking**
- **It seems that processing is likely to reduce nitrate levels**
- **Thus the non-consideration of the quantitative impact of food processing on nitrate levels may lead to an overestimation of the exposure.**

Uncertainties related to the selection of parameters - Food Consumption and Body weight

- **Extrapolation uncertainties arise since an individual survey of food consumption is used to estimate dietary exposure over a timescale longer than the survey duration.**

- **In general, averaging individual daily exposures over a survey of several days is likely to over-estimate the between-individual variation in long-term exposure**

- **Recording food types and measurement error in amounts of consumed foodstuffs**

- **Measurement error in individual body weights.**

- **Should we wish to generalise exposure to the Cyprus population, additional uncertainty due to the lack of consumption data for other population groups (e.g. adults).**

Uncertainties related to the nitrate concentration in foodstuffs

- Concentration data for specific types of vegetables (coriander, taro etc.) were not taken into account, due to the absence of the respective food names in the FoodEx, which leads to under-estimation of the exposure

- Owing to lack of analytical data, a default value (provided by EFSA) was assigned to certain vegetable groups at FoodEx level 2

- Uncertainty related to the representativeness of the samples, as nitrate concentration levels are affected by season and type of vegetable

- No uncertainty due to the use of the UB approach considering the low number of sample results below LOD.

Summary of qualitative evaluation of the impact of uncertainties on the dietary exposure to nitrates

Sources of uncertainty	Direction[1]
Uncertainties regarding the influence of food processing and/or cooking on the nitrate levels in the processed food – ImproRisk limitation	+
Different time frame between concentration data and consumption data	+/-
Uncertainty of the analytical measurements	+/-
Uncertainty about the representativeness of samples concerning, country of origin, size, seasonal differences, specific type of vegetable	+/-
Exclusion of concentration data for some vegetables, due to the absence of a corresponding food name in FoodEx	-
Use of 225 mg/kg default value for nitrate concentrations of some food groups under “Other vegetables”	+/-
Use of 2 L default value for chronic daily total liquid intake	+/-
Extrapolation uncertainties affecting the estimation of food consumption	+
Available consumption data in Cyprus only for adolescents, which are partly covered in the survey	+/-
Uncertainty in recording food types	+/-
Measurement error in amounts of food consumed	+/-
Measurement error in individual body weights	+/-

[1] (+)= uncertainty with potential to cause over-estimation of exposure; (-) = uncertainty with potential to cause under-estimation of exposure

Conclusions and final remarks

- **Median dietary nitrate exposure of the Cypriot adolescent population was calculated as 1.25 and 3.31 mg/kg b.w./day for mean and high consumers, respectively**

- **Nitrate intake was estimated to be lower than the ADI (3.7 mg/kg b.w/day), for 96% of the Cypriot adolescents**

- **Lettuce & other leafy vegetables showed the highest contribution (53%) to nitrate exposure**

- **ImproRisk, a model that allows calculating individual exposure, resulted in accurate exposure estimations for nitrate, comparable to EFSA calculations**

- **Uncertainties related to the use of ImproRisk and the model parameters (food consumption, body weight, nitrate levels) were assessed**

- **More accurate and detailed food consumption data with larger sample size in order to reduce uncertainties in the exposure assessment**
- **Data obtained when the National Dietary Survey in Cyprus under EU MENU project will finish (in 2018).**

Acknowledgements

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  - Environmental and Other Food Contamination & Natural Toxins
  - Food Additives & Special Analyses of Food
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