tds exposure

European Commission

TDS Implementation – pilot studies

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Stakeholder´s meeting
Brussels, February 5th 2014

INTRODUCTION

STRATEGIC OBJECTIVES

- **Objective 1**

  To **harmonize** and **implement** basic TDS methodology on national or regional level in different European countries

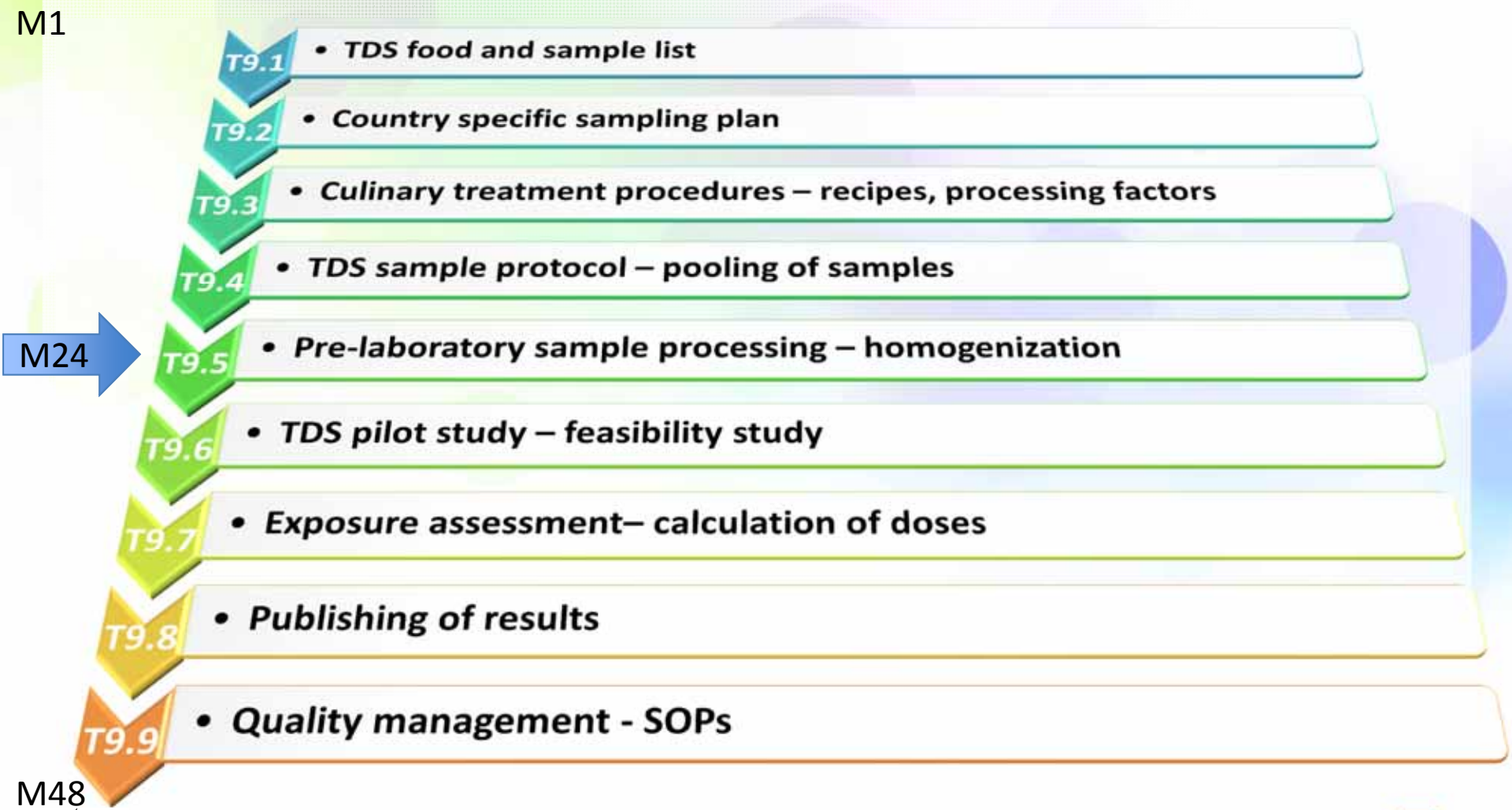
- **Objective 2**

  To **perform** national or regional TDS **pilot studies** to collect practical information on feasibility of harmonized TDS.

PARTNERS: 5+1 BENEFICIARIES

- SZU (CZ), BfR (DE), EVIRA (FI), MATIS (IS) INSA (PT) + RIVM (NL)

WP9 road map – flow of implementation



CAPACITY AND INVOLVEMENT OF PARTNERS IN TASKS

Partner	PMs	T9.1 food list	T9.2 sample protocol	T9.3 kitchen prep	T9.4 pooling	T9.5 sample homogen.	T9.6 pilot study	T9.7 exposure assess.	T9.8 publishing	T.9.9 quality
5 SZU (CZ)	81	**X**	**X**	x	x	x	**X**	x	**X**	x
4 RIVM (NL)	3							**X**		
7 BfR (DE)	76	x	x	x	x	x	x	x	x	
13 EVIRA (FI)	84	x	x	x	x	**X**	x	x	x	
16 INSA (PT)	46	x	x	**X**	x	x	x*	x*	x	**X**
18 MATIS (IS)	43	x	x	x	**X**	x	x	x	x	
TOTAL	**333**									

X* - task is not obligatory

PARTNER MEETINGS

- WP9 kick off meeting, ANSES, Paris, France, 3 March 2012
- WP9 workshop, INRAN, Rome, Italy, 6 September 2012
- WP9 workshop, IFR, Norwich, United Kingdom, 21 March 2013
- WP9 conference call SZU-MATIS, 7 May 2013
- WP9 workshop, INSA, Lisbon, Portugal, 4 September 2013
- WP9 technical consultation, SZU, Brno, Czech Republic, 22-23 January 2014
- WP9 workshop, SZU, Prague, Czech Republic, 21 March, 2014

MAIN RESULTS (M1-24)

Action plan for T9.1 – TDS sample/food list

Data from the national FCD and laboratory results from national systems

Step1: decision about harmonized food description system + decision about chemicals of our interest (Hg, Cu, Mn, Se)

Step2:
selection of foods representing diet

Step3:
Combination of foods into TDS samples

Step4:
corrections, harmonization

TDS sample/food list

Results will be used in T9.2 country specific sampling protocol

Illustration of individual diet (only lunch/dinner) composition during 1 year – how to tackle this complexity?

Reported amount of food consumption in FCDBs - differences

Food	Pork chop 					
Reported amount	raw	Meat processin 	raw, edible portion /part	Culinary treatment 	As consumed, not corrected	As consumed, corrected for all loses
Description	raw meat with bones		raw meat without bones		Cooked meat with bones and possible wastes	cooked meat without bones and wastes

FI

CZ

DE IS PT

STEP1 A HARMONIZED FOOD CLASSIFICATION SYSTEM

TDS sample/food lists – based on the FoodEx2 food groups (20)

1. **Advantages**
   1. Agreed system for RA data collection in EU
   2. Logical grouping into 20 food groups
   3. 7 hierarchic levels covering basic food items

2. **Disadvantages**
   1. System is still under development
   2. Code logic is a bit different in food groups
   3. Not all food groups are well balanced in hierarchic details

1. **Solutions**
   1. To use national sub codes in cases where Foodex2 system is not appropriate (Foodex2 unique code followed by suffix (allowed by the MCRA syntax) e.g. …$CZ123 and own national name
   2. In this case comparison among partners is possible on the nearest upper hierarchic code from Foodex2
   3. Record of situation into „troubleshooting“ table for transparent description in a future

STEP1 B CHEMICALS OF OUR INTEREST

DoW expects only feasibility study with inorganic substances

1. **Discussion about feasibility in partner labs and about cost for the project**
2. **Justification of suggested chemical substances**
3. **Decision about 4 toxic/benefit substances done in M6:**
    1. **total Hg**
    2. **Se (not BfR)**
    3. **Mn**
    4. **Cu (BfR instead of Se but open also for other partners)**

Step 2 TDS food list – new principle suggested

- **Principal question:**

  How to select foods into the TDS food list?

  – **Theoretical solution**

  - *to apply selection criteria (consumption rate and expected concentration, etc.) group by group*

  – **Practice**

  - *selection process has been used for each Foodex 2 core food group (Level 1) individually*

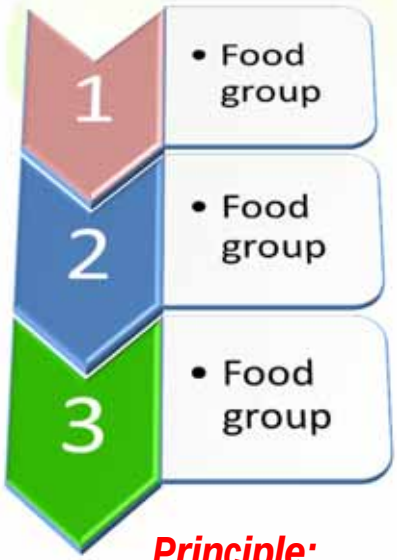
Step 2 TDS food list principle :

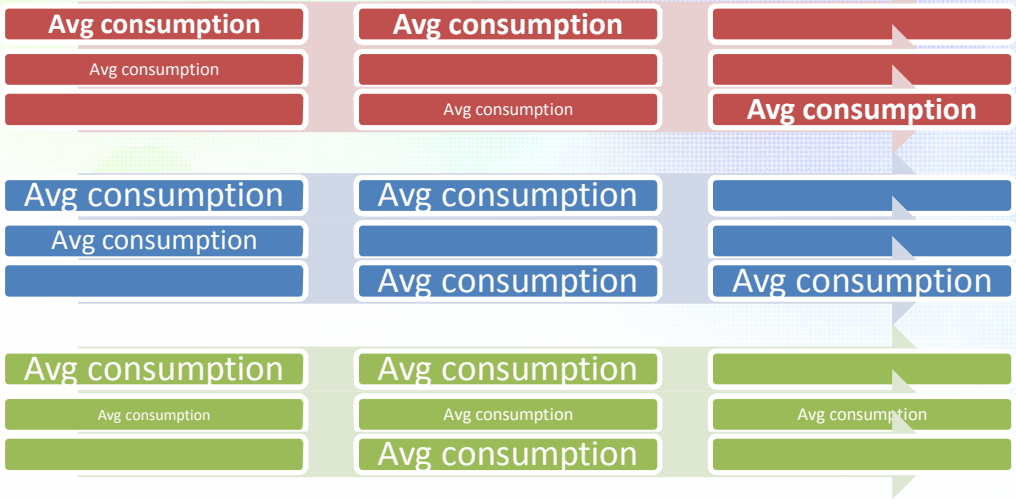
multiple choice for one TDS list – flexible for more TDS exposure scenarios

Food consumption data

Foodex 2 mapping

Population to be studied (grouping according to various criteria)





Combined TDS food list

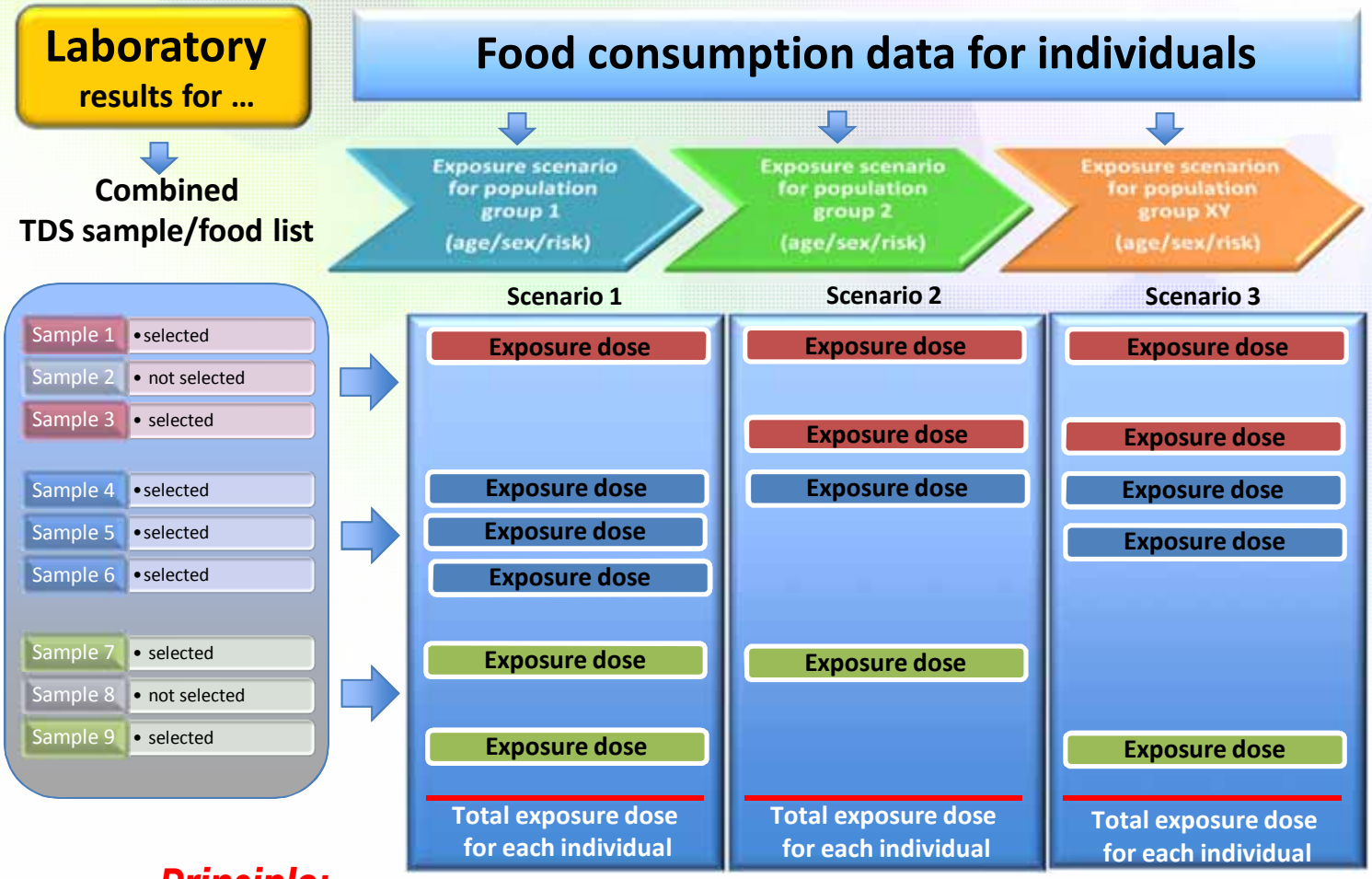
TDS samples

Principle:

A choice is done independently for each combination of population and food group. This approach allows construction of specific TDS exposure scenarios.

Future usage: TDS exposure scenarios

construction of specific TDS exposure scenarios



Principle:

Specific TDS exposure scenarios are used for population groups.

Step 3 Construction of TDS samples

Results available at the http://tds.szu.cz/T9.1%20ref_table2.htm – in >380 files

No	Name of food groups according to the FoodEx 2	Coordin. partner	Version 1						Version 2						Version 3						Compilation of the national TS tables
			CZ	PT	DE	FI	IS	H	CZ	PT	DE	FI	IS	H	CZ	PT	DE	FI	IS	H	
1	Additives, flavors, baking and processing aids	CZ	X	X	X	X	X	H	O	O	O	O	O	H	F	F	F	F	F	H	SOLUTION
2	Alcoholic beverages	FI	X	X	X	X	X	H	O	O	O	O	O	H	F	F	F	F	F	H	SOLUTION
3	Animal and vegetable fats and oils	FI	X	X	X	X	X	H	O	O	O	O	O	H	F	F	F	F	F	H	SOLUTION
4	Coffee, cocoa, tea and infusions	PT	X	X	X	X	X	H	O	O	O	O	O	H	F	F	F	F	F	H	SOLUTION
5	Composite dishes	DE	X	X	X	X	X	H	O	O	O	O	O	H	F	F	F	F	F	H	SOLUTION
6	Eggs and egg products	DE	X	X	X	X	X	H	O	O	O	O	O	H	F	F	F	F	F	H	SOLUTION
7	Fish, seafood, amphibians, reptiles and invertebrates	IS	X	X	X	X	X	H	O	O	O	O	O	H	F	F	F	F	F	H	SOLUTION
8	Food products for young population	CZ	X	X	X	X	X	H	O	O	O	O	O	H	F	F	F	F	F	H	SOLUTION
9	Fruit and fruit products	CZ	X	X	X	X	X	H	O	O	O	O	O	H	F	F	F	F	F	H	SOLUTION
10	Fruit and vegetable juices and nectars	DE	X	X	X	X	X	H	O	O	O	O	O	H	F	F	F	F	F	H	SOLUTION
11	Grains and grain-based products	IS	X	X	X	X	X	H	O	O	O	O	O	H	F	F	F	F	F	H	SOLUTION
12	Legumes, nuts, oilseeds and spices	PT	X	X	X	X	X	H	O	O	O	O	O	H	F	F	F	F	F	H	SOLUTION
13	Meat and meat products	CZ	X	X	X	X	X	H	O	O	O	O	O	H	F	F	F	F	F	H	SOLUTION
14	Milk and dairy products	CZ	X	X	X	X	X	H	O	O	O	O	O	H	F	F	F	F	F	H	SOLUTION
15	Products for non-standard diets, food imitates and food supp	CZ	X	X	X	X	X	H	O	O	O	O	O	H	F	F	F	F	F	H	SOLUTION
16	Seasoning, sauces and condiments	IS	X	X	X	X	X	H	O	O	O	O	O	H	F	F	F	F	F	H	SOLUTION
17	Starchy roots or tubers and products thereof, sugar plants	DE	X	X	X	X	X	H	O	O	O	O	O	H	F	F	F	F	F	H	SOLUTION
18	Sugar, confectionery and water-based sweet desserts	FI	X	X	X	X	X	H	O	O	O	O	O	H	F	F	F	F	F	H	SOLUTION
19	Vegetables and vegetable products	PT	X	X	X	X	X	H	O	O	O	O	O	H	F	F	F	F	F	H	SOLUTION
20	Water and water-based beverages	IS	X	X	X	X	X	H	O	O	O	O	O	H	F	F	F	F	F	H	SOLUTION
	SUMMARY								Summary file						S	S	S	S	S		
	GRAPHICAL EVALUATION								DESCRIPTIVE GRAPHS available before work on the final version 3												

I - TDS sample lists - harmonization snapshot; ; CZ = SZU; PT = INSA; DE = BfR; FI = EVIRA; IS = MATIS; S - summary evaluation of the national version 2 by partners and suggests of chang

Step 4 CORRECTIONS AND HARMONIZATION

Work organized in 3 steps – **versions** of TDS sample/food lists:

- **Version 1**: original national suggestions of TDS sample food lists
- **Version 2**: based on comparison with results of other partners for particular food group – suggests for more similar TDS sample/food lists. This work was based on the national expert judgment. („intra food group harmonization“)
- **Version 3**: based on comparison of whole TDS sample/food lists in the country and among countries - the final iteration/harmonization. This work was based on the national expert judgment. („inter food group harmonization“)

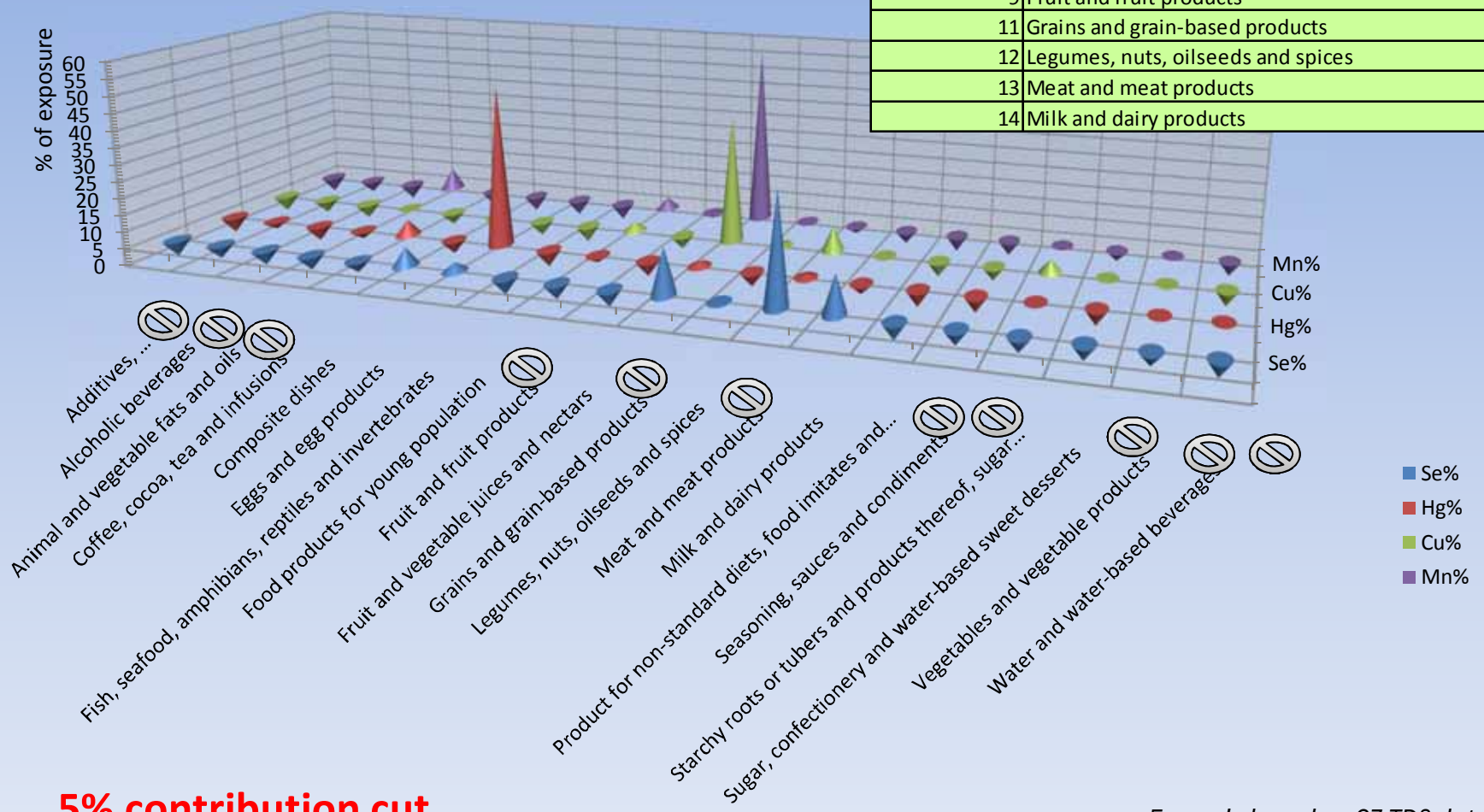
TDS sample list – to be used for sampling plan

Country	TDS samples defined	Food groups with the highest number of samples
CZ 	152	Meat (24), Grains (23), Vegetables (22)
PT 	166	Composite dishes (35), Fish (25), Vegetables (22)
DE 	243	Composite dishes (36), Meat (26), Vegetables (26)
FI 	128	Vegetables (19), Grains (13), Meat (13)
IS 	150	Grains (25), Meat (19), Fish (17)

Remark: number of TDS samples can be changed during the project.
Not all TDS samples will be analyzed during a pilot study.

Which food groups should be involved in the TDS pilot study - exposure sources contributing > 5%?

Foodex2 group	Name
7	Fish, seafood, amphibians, reptiles and invertebrates
9	Fruit and fruit products
11	Grains and grain-based products
12	Legumes, nuts, oilseeds and spices
13	Meat and meat products
14	Milk and dairy products



5% contribution cut

Example based on CZ TDS data.

Action plan for T9.2 – country specific sampling plan

Results from T9.1

TDS sample/food list

Step1:

decision about regionality and seasonality

Step2:

shopping list - application of results from T9.4 (pooling principles)

Step3:

TDS sampling plan

Step4: corrections

TDS sampling plan

Results will be used in T9.6 TDS pilot study

Step 1-2Template of the shopping list – CZ data example (02_CZv3_shop)

This is a desk research before writing practical guideline for sampling officers

Box 1 Sample characterization and number of subsamples (in national languages)

No.	TDS sample name:	Foodex2 code:			Total N subsamples:
	Unsweetened spirits	A03PD			12
	Items from the TDS food list	Characteristics (if needed):		Considered consump.	N of subsamples:
	lihovina ovocná	ovocný destilát nebo jiná lihovina z ovoce, min. 37,5% alk.		0,01	5
	tuzemák			0,01	4
	vodka	neochucená, nearomatizovaná		0,01	3
			Total	0,02	12

Box 2 Food items selection criteria (only in EN)

Nat/Reg:	Seasonal changes in TDS sample composition	National criteria for choosing of subsamples:	Place of purchase (type of store):
N	none	brand	not specified

Box 3 Shopping list (in national languages)

	Food items purchased:	National criteria	Place of purchase	Purchased quantity and other details	
No.	Subsample	Brand		Min. (ml)	Notes
1	lihovina ovocná	Slivovice	nespecifikonáno	500	
2	lihovina ovocná		nespecifikonáno	500	
3	lihovina ovocná		nespecifikonáno	500	
4	lihovina ovocná		nespecifikonáno	500	
5	lihovina ovocná		nespecifikonáno	500	
6	tuzemák	Božkov	nespecifikonáno	500	
7	tuzemák		nespecifikonáno	500	
8	tuzemák		nespecifikonáno	500	
9	tuzemák		nespecifikonáno	500	
10	vodka	Pražská	nespecifikonáno	500	
11	vodka		nespecifikonáno	500	
12	vodka		nespecifikováno	500	

Conclusion: results strongly depend on the quality of TDS sample/food list, especially on the number of proposed TDS samples

Step 3: next step after M18 = tailored „sampling plan“

A detailed time and place plan including all steps required to produce the required sizes and frequencies of food samples for a study. Sampling plan has to be country specific according to the national conditions.

1. Who will collect samples
2. When (date)
3. Where (geographical place) to collect samples
4. What (defined in previous step)
5. How much (sample quantity)
6. Expected kitchen processing

Action plan for T9.3 - kitchen preparations to be used for food cooking

Results from T9.1 / T9.2

available usual kitchen practices

Step1:

detection of usual kitchen procedures for particular foods

Step2:

SOPs for kitchen procedures

Step3:

Testing of standardized kitchen procedures

Step4:

corrections

Results will be used in T9.6 TDS pilot study

Where to start with T9.3/9.5: identification of challenges

No.	Food groups (Foodex 2)	Expected kitchen operations	Feasibility of homogenization	Problematic food samples / notes
1	Additives, …	-	-	
2	Alcoholic beverages	no treatment	1	
3	Animal and vegetable fats and oils	no treatment	1	
4	Coffee, cocoa, tea and infusions	no treatment	1	
5	Composite dishes	culinary treatment	3	mix of different types of food
6	Eggs and egg products	culinary treatment	2	
7	Fish, seafood…	culinary treatment	2	we have no experience with seafood
8	Food products for young population	-	-	
9	Fruit and fruit products	peeling	2	fruit with skins, fruit with small seeds like berries
10	Fruit and vegetable juices and nectars	no treatment	1	
11	Grains and grain-based products	culinary treatment	3	bread, products with whole seeds
12	Legumes, nuts, oilseeds and spices	culinary treatment	2	nuts
13	Meat and meat products	culinary treatment	2	some meat products like fermented salami
14	Milk and dairy products	no treatment	1	some cheese could be problematic
15	Product for non-standard diets…	culinary treatment	1	
16	Seasoning, sauces and condiments	no treatment	1	
17	Starchy roots or tubers…	culinary treatment	2	
18	Sugar, confectionery…	no treatment	3	chocolate, sweets with filling
19	Vegetables and vegetable products	culinary treatment	3	vegetable with seeds
20	Water and water-based beverages	no treatment	1	

Processing: 1 – easy, 2 – medium, 3 – difficult

3 main challenges to be addressed within task 9.3

1. **Approach how to define usage of salt, fat and water**
   - **Important consequences – agreement for this project but not for future TDSs (problem with added contamination, e.g. Na, I, uncertainty)**

2. **How to deal with situation when one TDS sample will involve more culinary treatments (e.g. raw, steamed and grilled)**
   - **Generally addressed in T9.4**

3. **How to calculate factor of loses when consumption of food is in the format "as purchased" and or "as consumed"**
   - **Will be addressed after M18 (differences among beneficiaries)**

Action plan for T9.4 - protocol for composition of TDS laboratory samples

Theoretical work with principles how to pool TDS samples

Step1:

Statistical considerations about number of sub-samples

Step2:

Considerations about combination of food units into pooled samples

Step3:

Examples how to combine foods into pooled TDS sample

Step4:

Considerations about sample quantity and collection process

Pooling of TDS samples

Results immediately used in T9.2

STEP 1+2 Statistical considerations – decided min 12 subsamples in one TDS pooled sample

- Width of half of the 95% confidence intervals for estimates of mean ($\bar{x}$) concentrations obtained by TDS approach, based on given number of sub-samples pooled and given ratio of true standard deviation (σ) and true mean (μ) (low variability, σ:μ=1:3 and high variability, σ:μ=1:1). (MATIS, 2013)

Level of confidence = 95%		
	trueSD (σ):true mean (μ)	
n	1:3	1:1
20	±16%	±48%
15	±19%	±57%
12	±22%	±66%

Expected RSD = 33%

Expected RSD = 100%

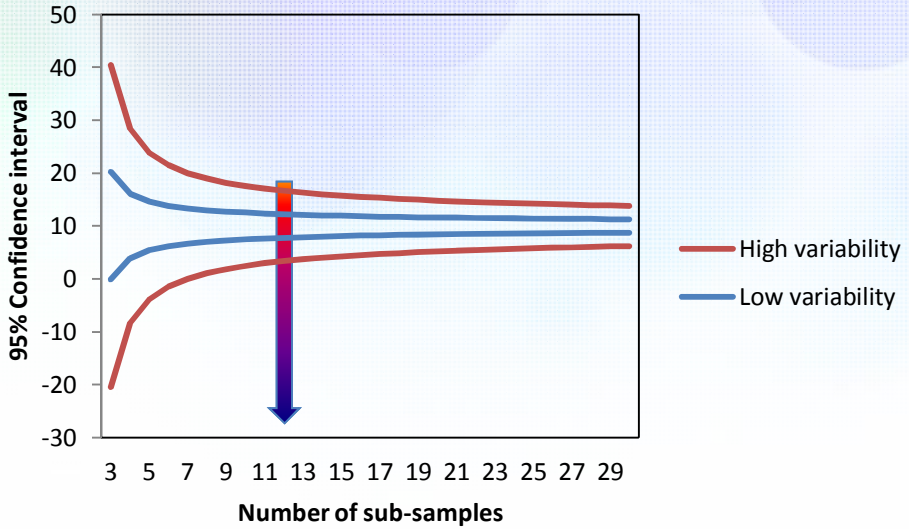


Figure 1. 95% confidence intervals around a sample mean ($\bar{x} = 10$) with high and low variability. (MATIS,2013)

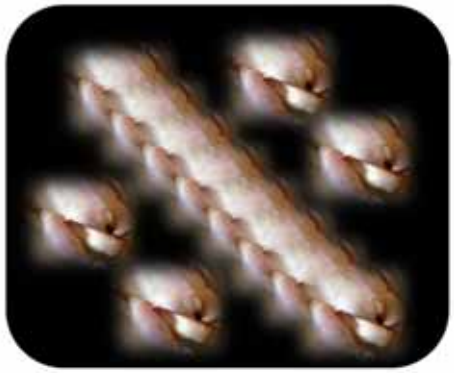
STEP 3 Example: „how to pool TDS sample (mixed food approach)

Sub-sample	TDS sample „Unsweetened spirits“	Consumption rate (g/kg b.w./day)	%	Place of collection	Specific factors for selection	Type of retail	Min. purchased quantity	Remark
No	Food name	weighted average	Ratio	N/R	brand	shop	volume	
1	fruit brandy	0,0093	42	NS	Brand Slivovice	NS	500 ml	
2	fruit brandy			NS	NS	NS	500 ml	
3	fruit brandy			NS	NS	NS	500 ml	
4	fruit brandy			NS	NS	NS	500 ml	
5	fruit brandy			NS	NS	NS	500 ml	
6	tuzemak	0,0063	33	NS	Brand Bozkov	NS	500 ml	
7	tuzemak			NS	NS	NS	500 ml	
8	tuzemak			NS	NS	NS	500 ml	
9	tuzemak			NS	NS	NS	500 ml	
10	vodka	0,0056	25	NS	Brand Prazska	NS	500 ml	
11	vodka			NS	NS	NS	500 ml	
12	vodka			NS	NS	NS	500 ml	
XY								
	Total	0,0212	100					

STEP 4 Considerations about sample quantity and collection process

- **Food sample quantity**
  - The general principle for the TDS pilot study - **a minimum of 100 g** of edible part from each sub-sample prepared as consumed (this may depend on the character of the food).
- **Food sample collection process (12 samples = 1 TDS sample)**
  - **Freezing before kitchen processing** - not recommended if not usual practice
  - Possibility to use „**serial sample collection**“ due to limited kitchen capacity ((e.g. 4 parts with 3 chickens)

All samples in 1 day

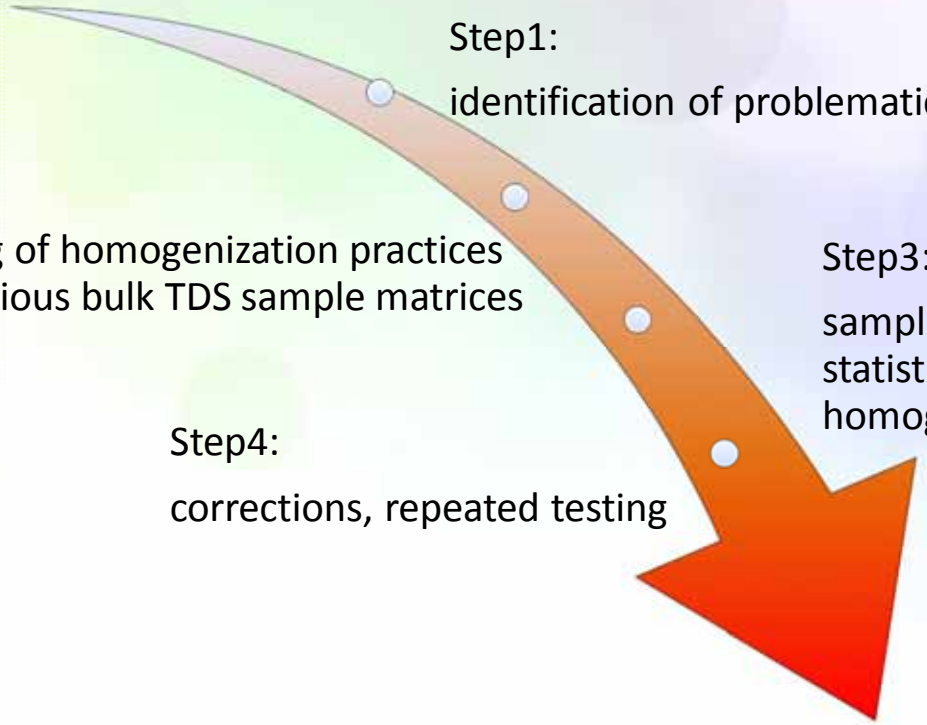


versus

3samples / 1 day per 1 week = **1 month sampling campaign**

Action plan for T9.5 – Pre-laboratory treatment

TDS samples defined in T9.1 and T9.2



Step1:

identification of problematic TDS samples (homogeneity)

Step2:

testing of homogenization practices for various bulk TDS sample matrices

Step3:

sample analyses (12*2) and statistical evaluation of homogeneity

Step4:

corrections, repeated testing

Input to tailored national SOPs for a pilot TDS

Pre-laboratory treatment - expected TDS kitchen processing

- Testing of homogenization practices for various bulk TDS sample matrices
- Practices for each TDS sample described in SOPs

Sample analyses and statistical evaluation of homogeneity

- Testing of homogenization tested according to the FAPAS protocol

Analyte and matrix analysed: **Mercury (Hg) in Table-grapes**

Target LOQ	Declared LOQ	Real Lab LOQ	Unit
0,011900	0,000100	0,000040	mg/kg

Table 1

Sample No.	Insert analytical results: result a (mg/kg)	result b (mg/kg)	D (a-b)	S (a+b)	D^2
1	0,000132	0,000132	0,000000	0,000264	0,000000
2	0,000066	0,000106	-0,000040	0,000172	0,000000
3	0,000079	0,000092	-0,000013	0,000172	0,000000
4	0,000158	0,000172	-0,000013	0,000330	0,000000
5	0,000066	0,000079	-0,000013	0,000145	0,000000
6	0,000145	0,000079	0,000066	0,000224	0,000000
7	0,000092	0,000132	-0,000040	0,000224	0,000000
8	0,000106	0,000040	0,000066	0,000146	0,000000
9	0,000158	0,000092	0,000066	0,000251	0,000000
10	0,000079	0,000119	-0,000040	0,000198	0,000000
11	0,000185	0,000106	0,000079	0,000290	0,000000
12	0,000066	0,000106	-0,000040	0,000172	0,000000
Sum	0,001333	0,001254		0,002588	0,000000
Avg	**0,000108**		variance	0,000000	
			MSB	0,000000	

Table 2

Choose your Target Standard deviation (Target SD)	0,000024	mg/kg

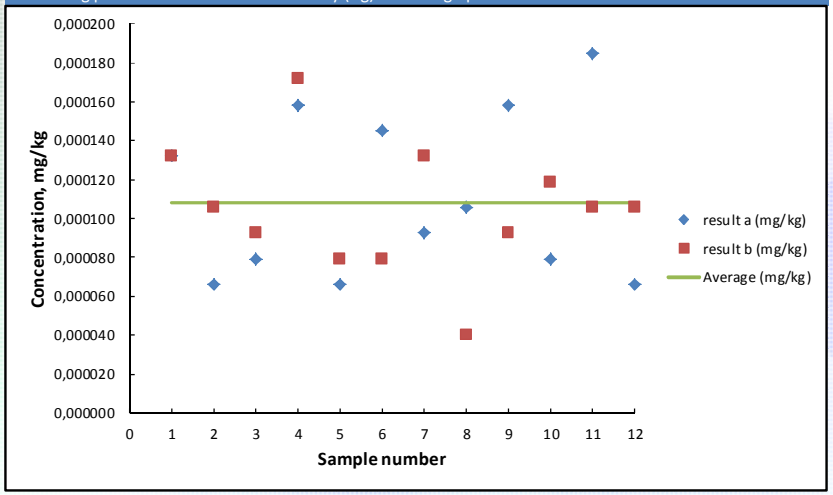
HORWITZ "SD" CALCULATOR

Average concentration of analyte in set of tested samples	0,000108	mg/kg
Calculated Target SD (σ_H)	0,000024	mg/kg

Additional calculations *see ref.1*

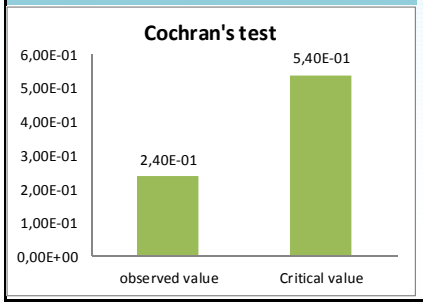
		Cochran´s test	
Cochran's test (ratio)	2,40E-01	observed value	Critical value
Estimate of analytical variance, s^2_{an}	1,09E-09	2,40E-01	5,40E-01
Test for acceptable between-sample variance, (σ^2_{all})	5,06E-11		
Est. of between-sample variance, (s^2_{sam})	3,29E-10		
Critical value	1,03E-09		

Testing procedure visualization: Mercury (Hg) in Table-grapes

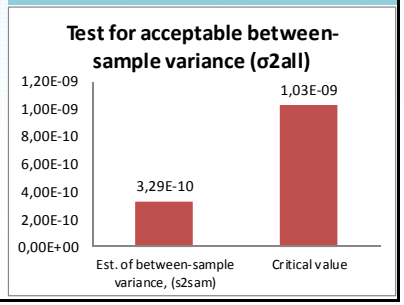


TDS sample homogeniety evaluation:

COCHRAN OK



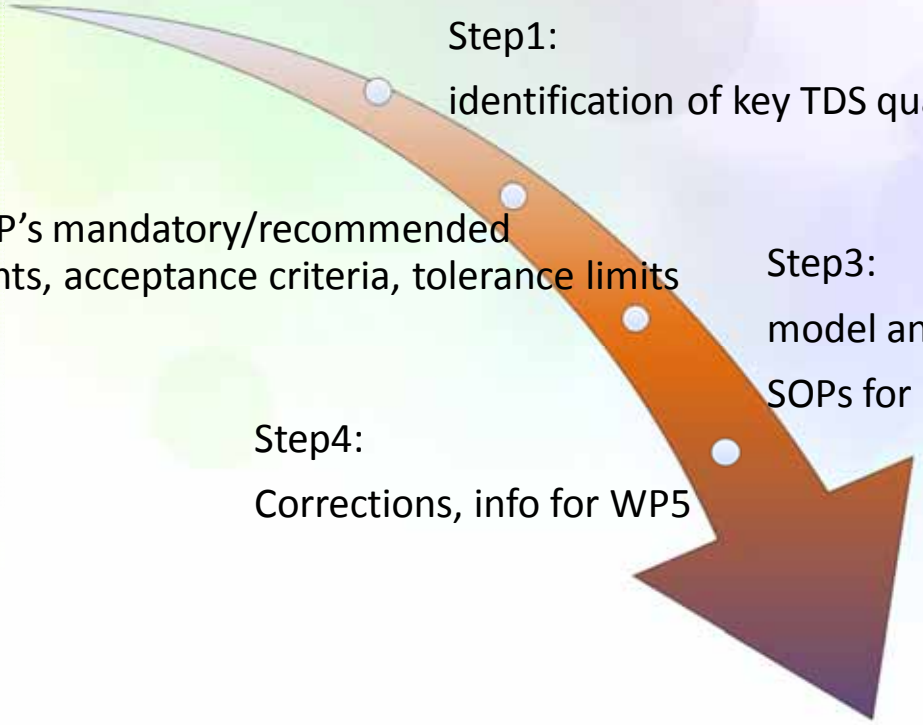
IS HOMOGENEOUS



Remarks:

Action plan for T9.9 - Quality management practices

Experience from TDS countries



TDS quality guide / tailored national SOPs for a pilot TDS

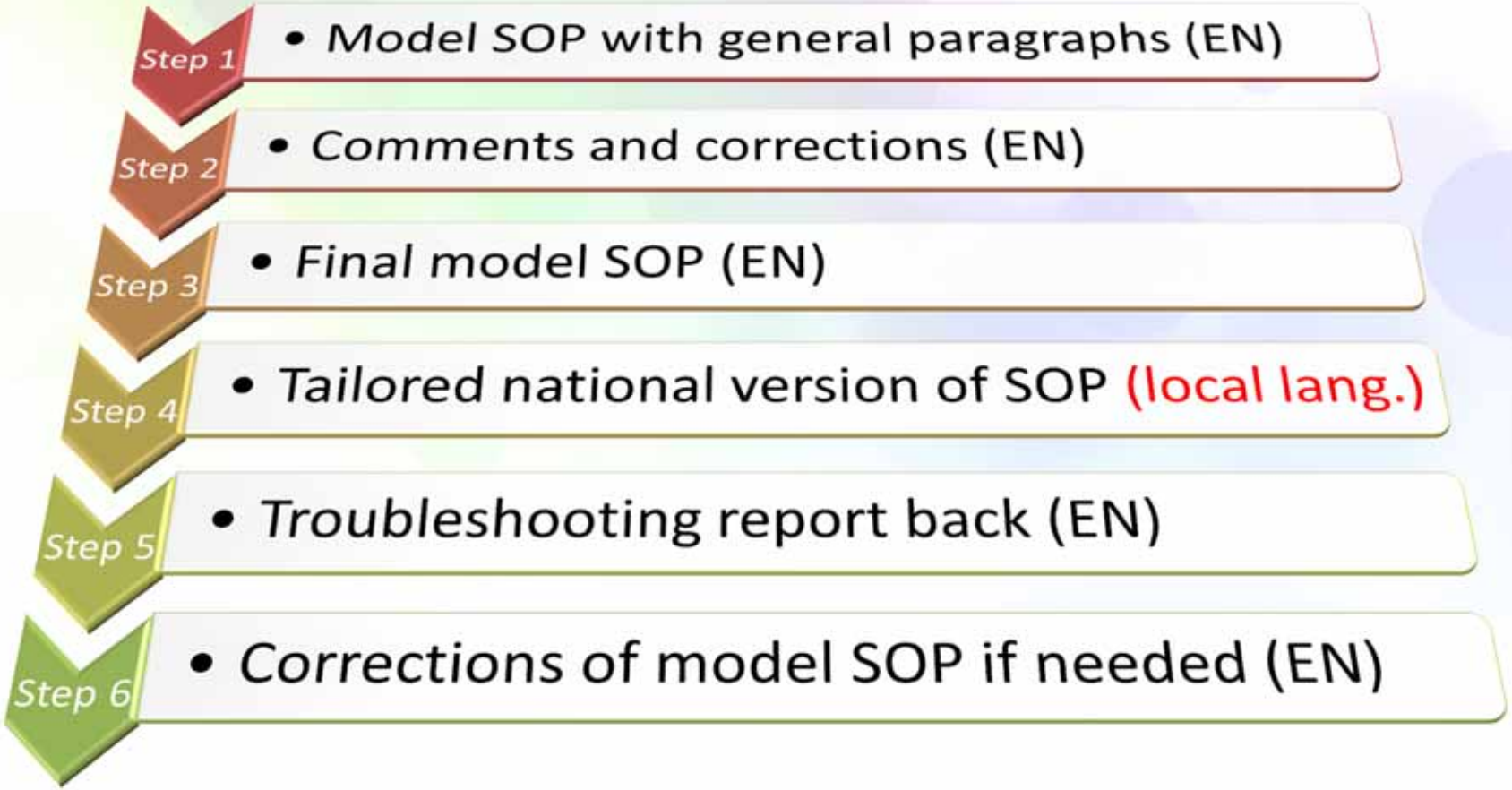
Methodology used for preparation of generic SOP's mandatory/recommended requirements, acceptance criteria, tolerance limits

1. Identification of key link elements
2. Identification and analysis of reference documents (EFSA, NIPH/SZU, INSA, ...)
3. Proposal of draft flowchart and CCP
4. Approval of flowchart and CCP
5. Proposal and Approval of generic SOP list

List of SOPs to be prepared for a pilot TDS

Preparation for food collection, sample preparation and analysis	SOP 01
Food collection	SOP 02
Reception of individual samples (at kitchen laboratory)	SOP 03
Sample preparation (at kitchen / pre-analytical laboratory)	SOP 04
Chemical analysis of laboratory samples	SOP 05

How we work on SOPs - principles



CONCLUSIONS

- **What are principal conditions for harmonization:**
  - Format of food consumption data
  - The same food classification system – FoodEx2
  - The same range for parameters of used approaches (LoQ, etc.)
- **What was successfully tested/implemented:**
  1. Methodology „how to create harmonized TDS sample / food list“
  2. Methodology „how to pool TDS sample“
  3. Methodology „how to construct shopping and sampling plan“
  4. Methodology „how to apply standard (the same) culinary treatment“
  5. Methodology „how to calculate culinary factors“ (3 situations)
  6. Methodology „how to test adequate homogeneity of TDS samples for analyses“
  7. Methodology „how to predict target LoQ for analytical methods“
  8. Methodology „how to create tailored national SOPs“, based on definition of generic SOP’s- mandatory/recommended requirements, acceptance criteria, tolerance limits for a TDS

TDS PILOT STUDY

Plan: April 2014 – April 2015