Quality Framework and European TDS Centres

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Isabel Castanheira (INSA), Hannah Pinchen (IFR) and Mark Roe (IFR)

A Harmonised Approach to European Total Diet Studies
8 October 2015, Brussels

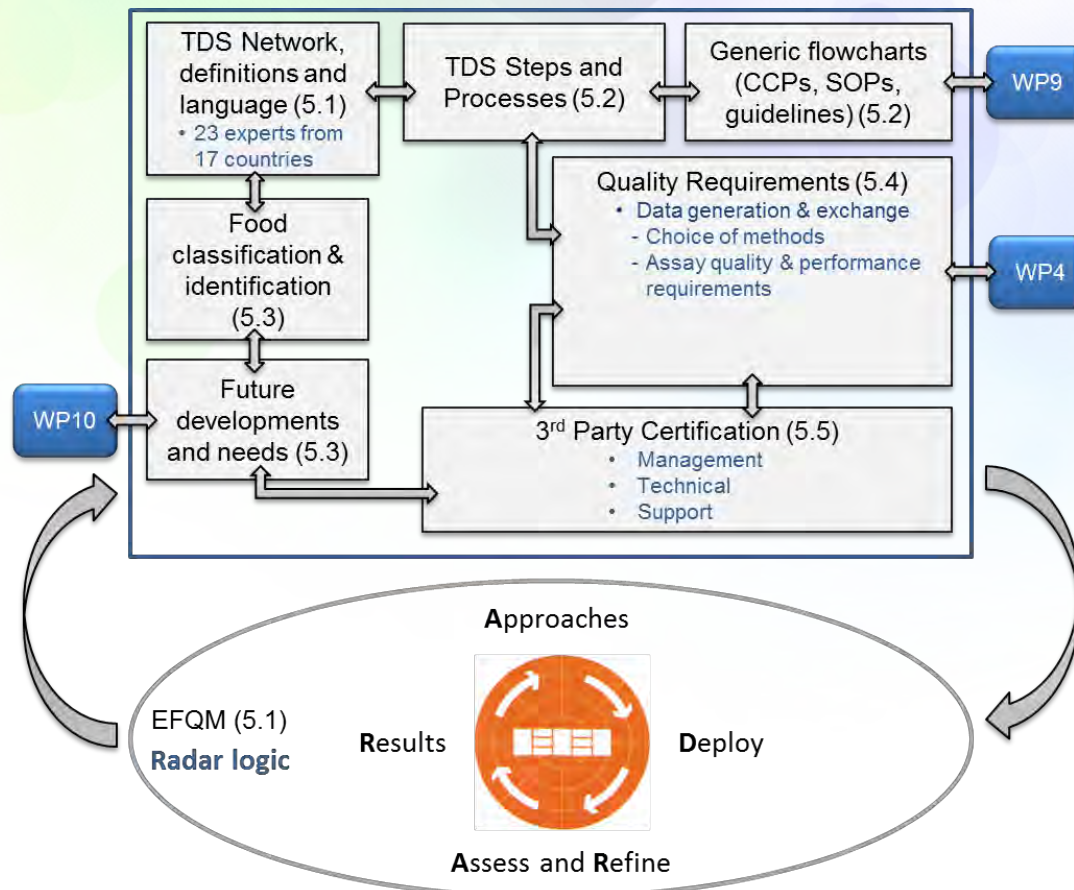www.tds-exposure.eu

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Outline

- Objectives: Total Quality Management System
  - EFQM approach
  - EuroFIR approach

- Guidance Documentation
  - Key processes and Standard Operating Procedures
  - Guidance Documents
  - TDS Vocabulary

- Tools
  - Classification and description tools
  - TDS Centre Network
  - Quality requirements for data generation, collation and interchange

- Future plans

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Objectives

To develop, test and implement a Total Quality Management System for TDS in Europe: Improve the quality of the data and comparability between countries for use by risk assessors and managers

TDS Network & Vocabulary

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TDS Network

22 experts from 16 MS and 7 from 4 additional European countries

+

17 experts from 14 countries outside of Europe

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Uniform Vocabulary

TDS Vocabulary

▶ **209 terms**

Examples

Exposure

The concentration or amount of a particular agent that reaches a target organism, system or (sub) population in a specific frequency for a defined duration, via a specific or several routes (adapted from FAO/WHO, 2009)

Sampling food list

A list of foods made up with aggregations of items from the TDS food list (from the food consumption survey) that corresponds to samples analysed in a TDS. This list includes, as appropriate, region or season/date.

EFQM Vocabulary

▶ **29 terms**

Examples

Process

A set of activities that interact with one another because the output from one activity becomes the input for another activity. Processes add value by transforming inputs into outputs, using resources

Radar logic

A dynamic assessment framework and powerful management tool that provides a structured approach to questioning the performance of an organisation

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European Foundation of Quality Management (EFQM) approach

Luisa Oliveira

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EFQM Excellence Model

To support organisations performing Total Diet Studies (TDS Centers) in their journey towards Excellence, through a Total Quality Management (TQM) approach

▶ Comparison of different organisations with a common assessment language

▶ Not used to score organisations – provides a Benchmark for organisations to improve

▶ Opportunity to jointly define common indicators specific to TDS activities

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EFQM Excellence Model structure

Enablers			Results	
Leadership	People	Processes, Products & Services	People Results	Key Results
	Strategy		Customer Results	
	Partnerships & Resources		Society Results	

Learning, Creativity and Innovation
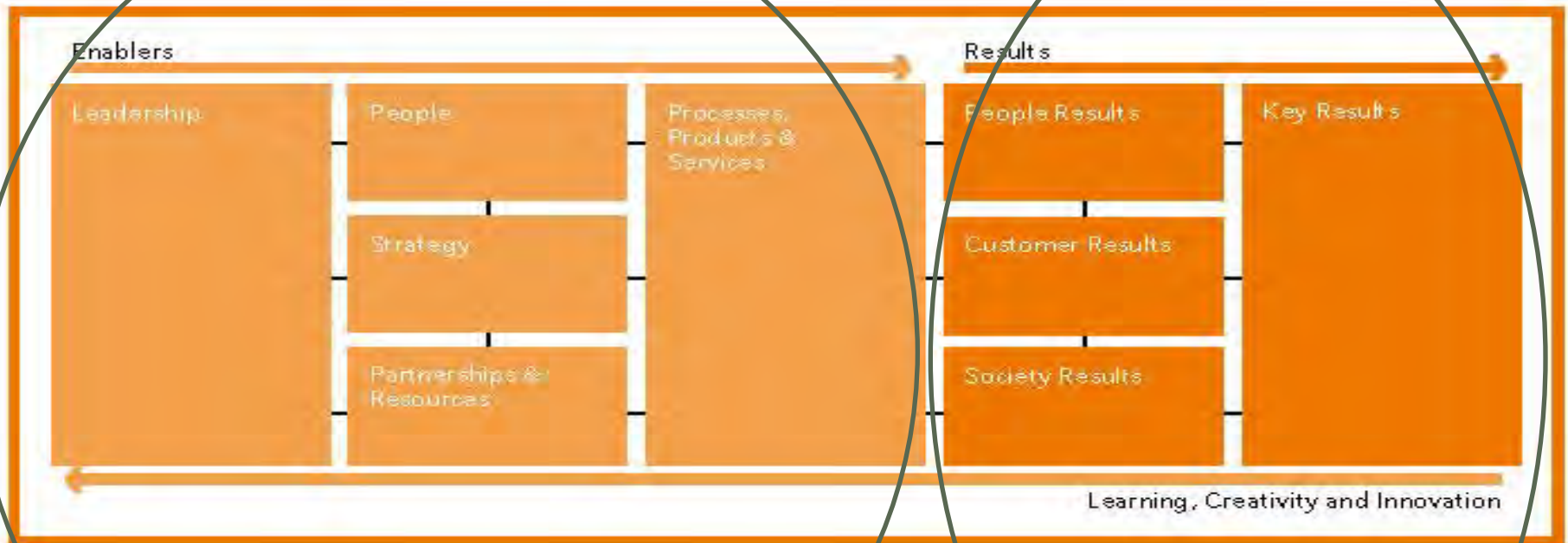
What the organisation does and how it does it

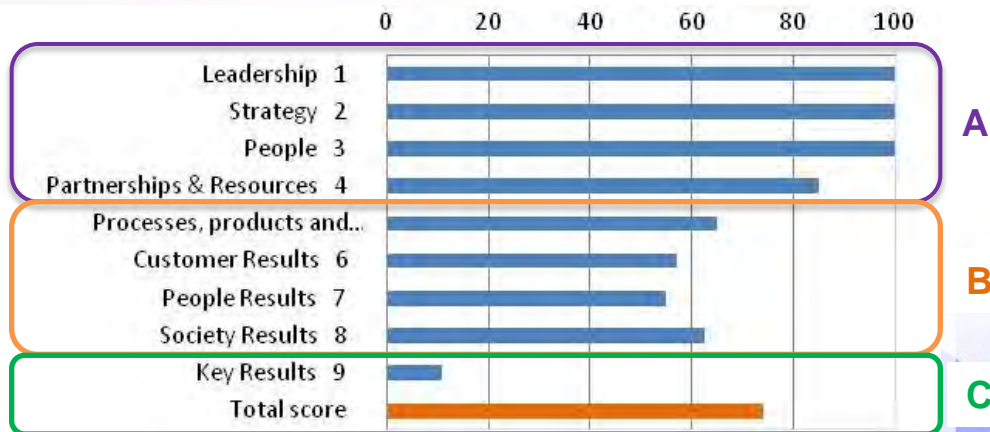What the organisation achieves

"footprint"

Use of the EFQM model

▶ Self-assessment questionnaire

- Identify strengths and areas for improvement

- Define priorities for future action

- Encourages monitoring

✓ Adapted to give possible synonyms

- E.g. customers/stakeholder, chief executive/TDS general manager

- 'Key products' correspond to TDS reports; 'Service Delivery' corresponds to stakeholders' questions

✓ Questionnaire tested by TDS-Exposure participants

- Benchmarking processes identified

- Model can be used for TDS, however training is needed

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Example results of self-assessment

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Overall achievement of organisation **74** %

Organisation's profile   SZU

	E	D	C	B	A	% Achivement (from previous sheets)
1 Leadership 1	0	0	0	0	5	100
2 Strategy 2	0	0	0	0	5	100
3 People 3	0	0	0	0	5	100
4 Partnerships & Resources 4	0	1	0	0	4	85
5 Processes, products and services 5	1	0	1	1	2	65
6 Customer Results 6	0	1	4	1	1	57
7 People Results 7	0	1	2	2	0	55
8 Society Results 8	0	1	0	3	0	63
9 Key Results 9	0	3	0	0	0	11
Total score						74
Total number of ticks (a)	1	7	7	7	22	
Factor (b)	0	25	50	75	100	
Value (a x b)	0	175	350	525	2200	
Total / 49 (44)=	74	% Achivement of the Organisation				
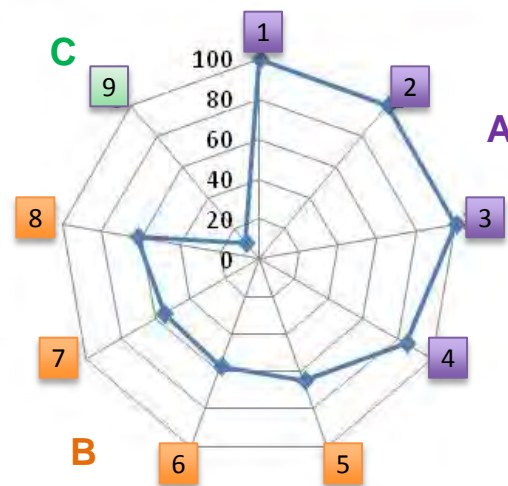
Guidance document on implementation of a TQM System to TDS

Based on
EFQM excellence model

Table of Contents

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EuroFIR approach

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How was it designed?

Previous work in the EuroFIR Nexus project e.g. "Report on framework for certification scheme"

Features identified of EuroFIR Nexus framework that apply to TDS

EuroFIR NEXUS framework modified to fit current TDS practices - identification of the standards TDS Centres are working towards

Four TDS Centres were involved in an audit visit to test the framework. Framework modified

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TDS-Exposure quality standard framework

Identify strengths and weaknesses of each organisation and improve quality systems through identification and dissemination of 'best practice' processes

Policies	Description of work
Organisation structure	

Organisation processes

Analysis	Equipment	Publication processes
Project planning	Data analysis	Sampling procedures

TDS processes

Contracts	Document control	Decision making processes
Personnel	Quality management system	

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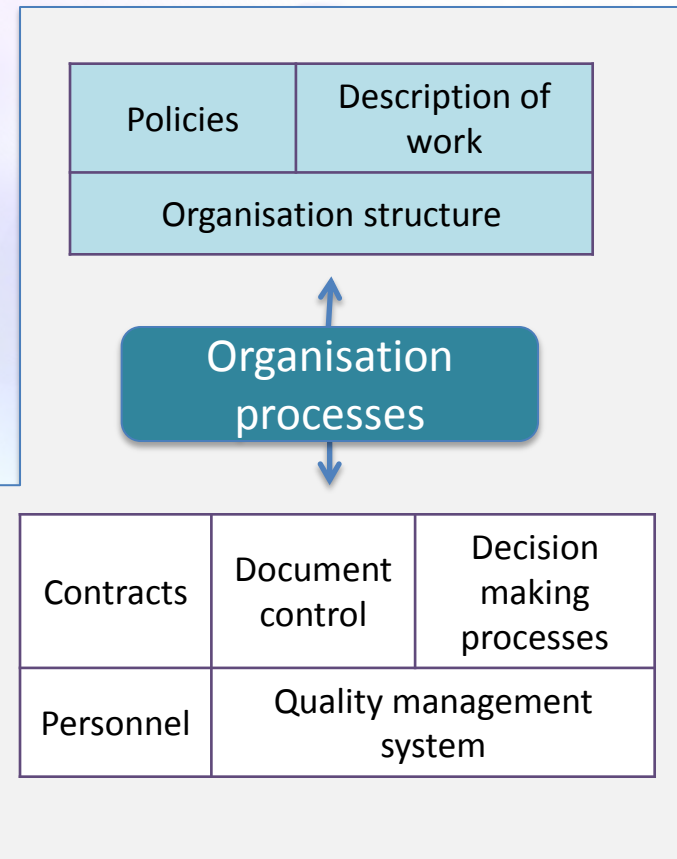
TDS Reviews
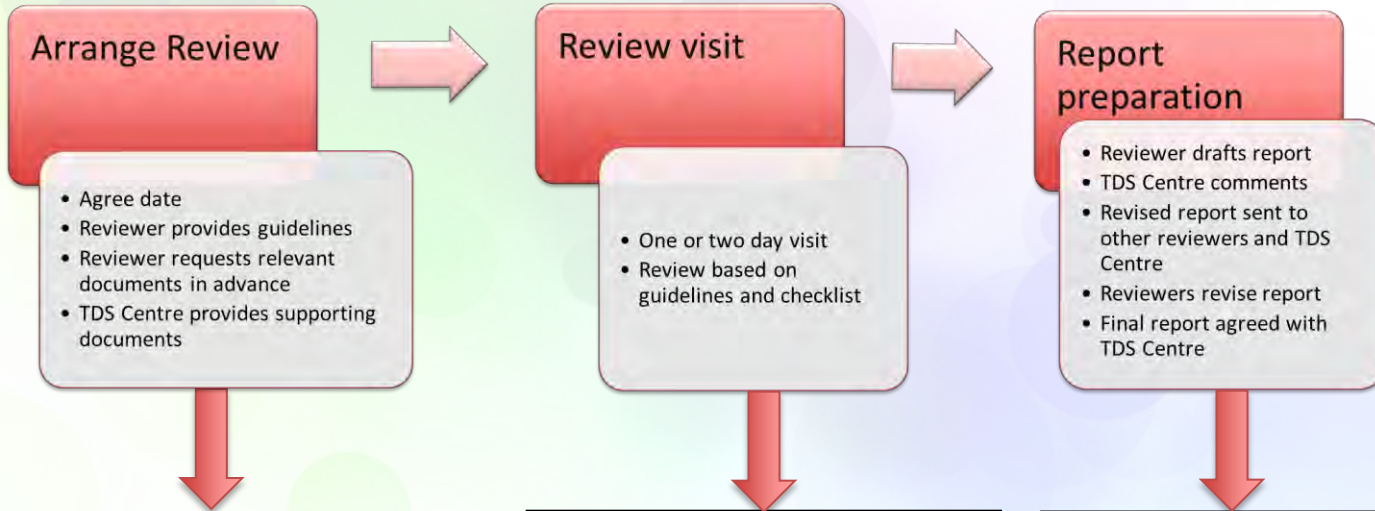
Arrange Review
- Agree date
- Reviewer provides guidelines
- Reviewer requests relevant documents in advance
- TDS Centre provides supporting documents

Review visit
- One or two day visit
- Review based on guidelines and checklist

Report preparation
- Reviewer drafts report
- TDS Centre comments
- Revised report sent to other reviewers and TDS Centre
- Reviewers revise report
- Final report agreed with TDS Centre

Outcomes and recommendations

Date	TDS Centre	Reviewer (s)
22-23 October 2014	ANSES (FR)	Mark Roe (IFR) Paul Finglas (IFR), Isabel Castenheira (INSA), Hannah Pinchen (IFR)
13-14 November 2014	NIPH/SZU (CZ)	Mark Roe (IFR), Hannah Pinchen (IFR)
10-11 December 2014	EVIRA (FI)	Luisa Oliviera (INSA), Isabel Castenheira (INSA)
14-15 January 2015	MATIS (IS)	Luisa Oliviera (INSA), Paul Finglas (IFR), Hannah Pinchen (IFR)

Annex 1 Checklist for TDS review

Topic	Content	Reviewed Yes/No	Comments
Organisation structure	Structure of organisation		
	Who is responsible for TDS processes		
	Other responsible staff		
	Mission statement		
	Links with other departments		
	Links to other organisations		
	Policy descriptions related to TDS		
	Decision making processes		
	Links to other TDS organisations		
Description of work	Work plans, project descriptions and objectives		
	Customer requirements		
	Outputs		
	Personnel descriptions (related to work plans)		
	Progress review/work plan		

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TDS Review outcomes

▸ Framework proved to fit well to most organisations

 – Approach used for pilot reviews (Matis, Anses, BFR & SZU/NIPH) should be applicable to any TDS organisation

▸ Organisations without an overall quality framework still followed the general principles

 – Reviews demonstrated that TDS organisations can meet requirements of an informal standard and possibly a formal standard

▸ Restrictions such as budget and available methods/equipment suggest it may not be possible to implement the ideal procedures for all aspects of TDS work

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- Having two reviewers present over two days was beneficial
  - TDS process contains several different procedures, e.g. analysis, risk exposure etc. so wide ranging experience necessary
  - Day one was discussed at the end of the day, any missing information included in day two
- Organisations work in different ways and are subject to constraints dependant on funding, staff, previous experience and infrastructure but all should be able to meet basic requirements for quality assurance

Consider possibility of Certification Standards

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Guidance & Best Practice Documentation

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TDS Flowchart – developed with WP9

Annex 1- TDS process flowchart
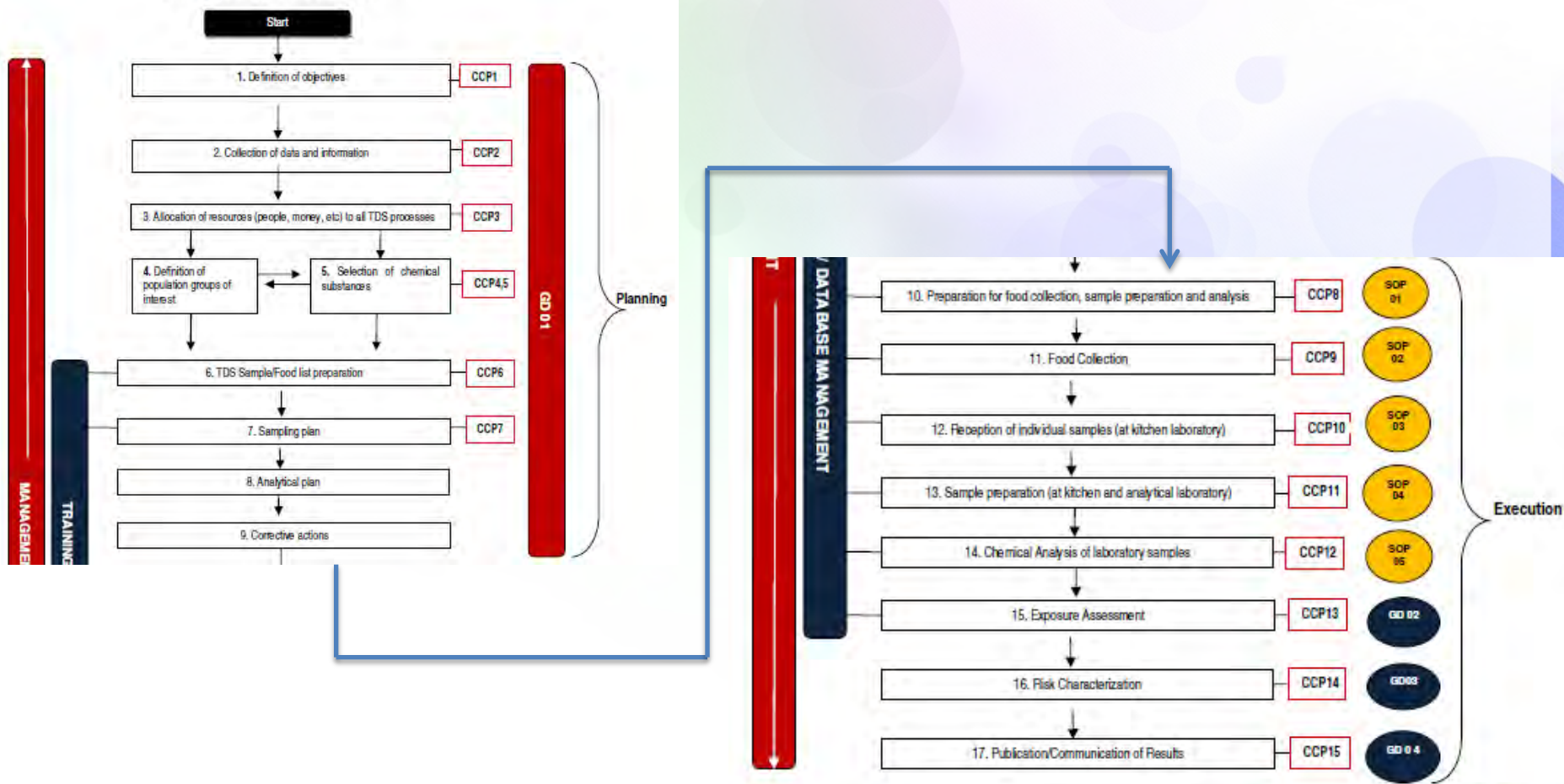
SOPs (according to flow chart)

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Guidance DOCs

Description of General Principles, Rules & Requirements for:

- Planning a TDS Study
- Exposure Assessment
- Risk Characterisation
- Publication & Communications

Three types of activity:
- Management
- Technical
- Support

Generic SOPs

SOP 01: Preparation for food collection, sample preparation and analysis

SOP 02: Food Collection

SOP 03: Reception of individual samples (at kitchen laboratory)

SOP 04: Sample preparation (at kitchen laboratory)

SOP 05: Sample chemical analysis (at analytical laboratory)

Specific SOPS

Country Specific

Method Specific

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SOP1: Preparation for food collection, sample preparation and analysis

▶ **Scope**

– This procedure is a generic SOP applicable for the preparation for collection, kitchen processing and analysis of food samples for TDS (step 8 of flowchart). It should be applied before starting the collection of food samples. It is intended to be used by TDS Centres as basis for preparing their country specific documents.

▶ **Objective**

– To describe a generic procedure for the preparation of materials, kitchen and laboratory environment, within the 2014 pilot TDS.

▶ **Definitions**

– This document follows the terminology adopted in TDS Vocabulary

▶ **Responsibilities**

– According to job descriptions and /or competence matrices

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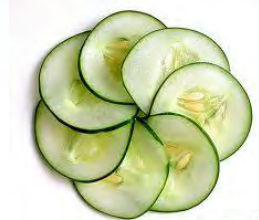
Guidance documents

▶ GD01 (Planning a TDS)

▶ GD02 (Exposure assessment)

▶ GD03 (Risk characterisation)

▶ GD04 (Communication of results)

Main Structure for Guidance Documents:

- Title
- Scope - Mandatory
- Objectives - Mandatory
- References - Optional
- Acronyms - Optional
- Definitions - Optional
- Responsibilities - Mandatory
- Procedure (general principles) - Mandatory
- Bibliography - Optional
- Annexes - Optional

Tools

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Why do we need them in TDS?

▸ Foods are grouped or described in a common way

▸ Prevents misinterpretation

▸ Allows harmonised data analysis between countries

Food composition- occurrence/ consumption data

Classification and description System | **Description System**

EFSA FoodEx2 ⟷ LanguaL

Food list with additional facet descriptors e.g. cooking methods

Developed for use with consumption data

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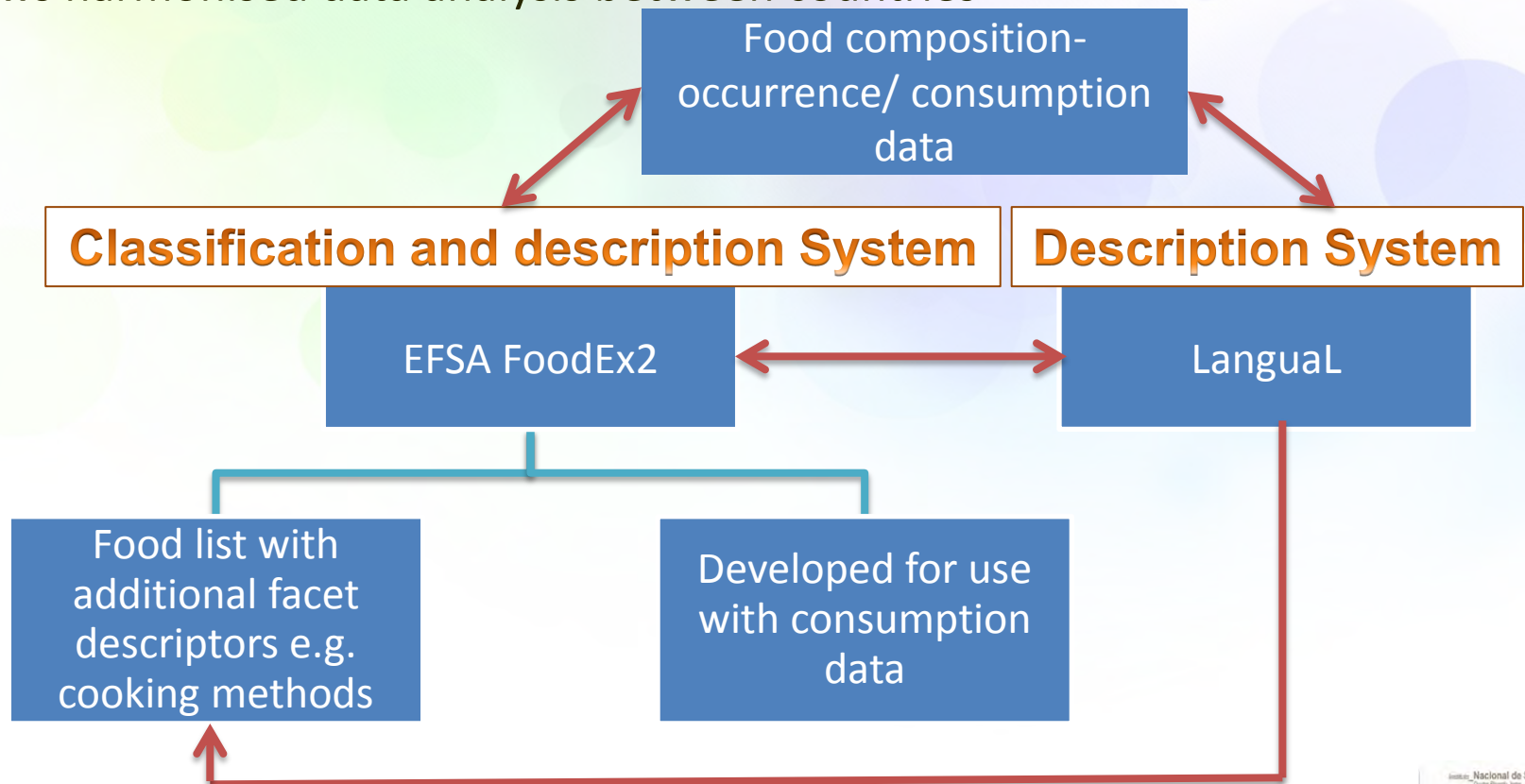
Example of FoodEx2 codes – parent/child relationship

Type	Code	Food Group	flag
H	A04KY	**Single grain bread and rolls**	s
C	A004Y	**Wheat bread and rolls, white (refined flour)**	s
E	A004Z	Wheat bread and rolls, white with maize	s
E	A005A	Wheat bread and rolls, white with potato	s
E	A005B	Wheat bread and rolls, white with rice	s
E	A005C	Wheat bread and rolls, white with soya	s
C	A005E	**Wheat bread and rolls, brown or wholemeal**	s
C	A005G	**Rye bread, refined flour**	s
C	A005H	**Rye bread, wholemeal**	s
E	A005J	Pumpernickel	s
C	A005K	**Bread and rolls with special ingredients added**	s

(Back to the core and extended list index)

Type	Code	Food Group	flag
H	A005L	**Multigrain bread and rolls**	s
C	A005N	**Rye-wheat bread, refined flour**	s
C	A005P	**Rye-wheat bread, wholemeal**	s
C	A005Q	**Multigrain (not only rye-wheat) bread and rolls**	s

(Back to the core and extended list index)

Type	Code	Food Group	flag
H	A04KZ	**Unleavened bread and similar**	s
C	A006T	**Matzo**	s
C	A006S	**Pita bread**	s

FoodEx2 – Advantages and Problems

- Results from the pilot studies and food composition work (EFSA project)

Advantages

▶ FoodEx2 has been designed for exposure studies in Europe

▶ Allows a basic classification of foods, linking different food group levels were required

▶ Contains different facets

▶ Easy to use – scope notes available

Problems

▶ Some country specific foods cannot be mapped

▶ Contains some 'unspecified' food codes

▶ Some language may be confusing e.g. laminated doughs

▶ Level of detail inconsistent e.g. no distinguishment between peeled/unpeeled potatoes, mashed potatoes and the prepared product 'mashed potato'

Roe, M. et al. (2013) Updated food composition database for nutrient intake. EFSA supporting publication 2013:EN-355, 21 pp

Available online: www.efsa.europa.eu/publications

Definition of assay quality and performance requirements

Objectives

Objectives
Identification of assay parameters and performance criteria (LoD and LoQ)
Definition of requirements for acceptance of Proficiency Testing results
Establishment of target uncertainties

Results

Results
Eight performance criteria identified
Literature review showed that the best criteria were those based on z or En-scores
Questionnaire launched to identify which substance groups each participant works with

Links to WP4

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Definition of quality profiles for TDS laboratories

Identify:

- Accreditation
- Method validation
- Participation in proficiency schemes (PTs)

TDS laboratory questionnaire

Questions	**Substances**
General	Five trace elements
Method Performance	Dioxins-PCDDs
Internal Quality	PCBs
External Quality	Acrylamide
	Mycotoxins

Example of method performance results

Analyte	Validation level of the method?		Reference for validation study	Limit of Detection (LoD)	Limit of Quantification (LoQ)	Working range	Selectivity/ specificity	TRUENESS (Recovery%)			PRECISION			
											RSDr		RSDR	
	% Lab	Level						Conc. Level	Rec.%	RM/CRM	Conc. Level	%	Conc. Level	%
Acryamide	100	Fully validated	- EUROCHEM - Eerola, Hollebekkers, hallikainen & Peltonen. Mol. Nutr. Food Res. 2007, 51, 239-247.	1-20 µg/kg	2,5-50 µg/kg	2,5-7500 µg/kg	No interference	10-1000 µg/kg	74-125	ERM, FAPAS (Crispbread, rusk, toasted bread)	10-350 µg/kg	0,9-14	10-350 µg/kg	2-11
PCBs	75	Fully validated	- EUROCHEM - EC 2002/657 - EC 252/2012	0,003-2,5 pg/g fat	0,01-8,2 pg/g fat	0,01 – 12500 pg/g fat	No interference	-	65-110	ERM (Pork Fat), In house (fish oil)	-	3-12	-	7,2-30
	25	In-house validated												

Methods of Analysis

Preservatives
Colours

HPLC-UV

Food
Additives

Acrylamide

LC-MS/MS

Food
Processing

Cadmium
Lead
Arsenic in water

ICP-MS

Trace
elements

Gentamicin

LC-MS/MS

Veterinary
drugs

Dioxins

LC-MS/MS

Persistent
Organic
Pollutants

Bisphenol A

GC-MS

Food Contact
Materials

TDS Wiki

Information of target compounds

➤ Details of the appropriate analytical methods for each contaminant:
  - Reference methods
  - Other available validated methods

➤ Key steps in each method

➤ Available Certified Reference Materials (CRMs)

➤ Appropriate Proficiency Testing Schemes

➤ Legislative requirements (both national and EC Directives)

Dashboard › EuroFIRGAMA - TDS-EXPOSURE › … › Summary - As

Search

- ⊞ Nutrients
- ⊟ Contaminants (TDS-EXPOSURE)
  - ⊟ Inorganic contaminants
    - ☐ Aluminium (Al)
    - ⊟ Arsenic (As)
      - ☐ Summary - As
      - ☐ Analytical methods - As
      - ☐ Reference materials - As
      - ☐ Proficiency testing - As
      - ☐ References - As
    - ⊞ Cadmium (Cd)
    - ⊞ Copper (Cu)
    - ⊞ Lead (Pb)
    - ⊞ Manganese (Mn)
    - ⊞ Mercury (Hg)
    - ☐ Nitrites (E249-250)
    - ⊞ Radionuclides
    - ⊞ Selenium (Se)
    - ☐ Sulfites (E220-228)
  - ⊞ Organic contaminants
  - ⊞ Contaminants - additional information
- ☐ Meeting minutes
- ☐ Contact information
- ⊞ FAQs

EuroFIR — European Food Information Resource **tds▶exposure** **Summary - As**

Added by Stefan Voorspoels, last edited by Stefan Voorspoels on 2013-07-18

Arsenic is described as a metalloid because it displays properties intermediate of those typical for metals and non-metals [1-Link]. The chemistry of arsenic is similar in many respects to that of nitrogen and phosphorus, two essential elements. These chemical similarities may be the reason that arsenic occurs at high levels in many marine organisms, and hence in many seafoods (Francesconi and Edmonds, 1997)[2-Link]. For example, the inorganic ion arsenate occurs in seawater together with the structurally similar phosphate. Marine algae appear unable to distinguish between these two oxoanions; in their efforts to take up essential phosphate they inadvertently take up the potentially toxic arsenate. The process of detoxification begins by methylation leading to methylated organoarsenic compounds. Arsenobetaine is structurally similar to glycine betaine, which is used by aquatic organisms to maintain osmotic balance under conditions of changing salinity, *i.e.* when ambient salinity is high, an organism's glycine betaine level is high. The coincidental structural similarity between arsenobetaine and glycine betaine might explain why arsenobetaine levels are much higher in marine animals than they are in freshwater animals.

Although arsenic forms species under reducing conditions with the arsenic atom in oxidation state -3 and +3, the most stable arsenic species found under normal environmental conditions contain the arsenic atom in oxidation state +5. Consequently, the vast majority of arsenic species found in

organisms and in foods also contain arsenic in oxidation state +5 (e.g. arsenate, dimethylarsinate, arsenobetaine, arsenosugars). The table below summarises some arsenic species found in foods, and some relevant human metabolites.

Names, abbreviations, and chemical structures for some relevant arsenic species in food.

Name	Abbreviation	Chemical structure[a]	Relevance/comment
Inorganic arsenic	iAs		Sum of As(III) and As(V).
Arsenite	As(III)	$As(O^-)_3$	Trace to low levels in most foods; highly toxic.
Arsenate	As(V)	$O=As(O^-)_3$	Trace to low levels in most foods; a major form in water; h

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Main Achievements

- A comprehensive TDS network established in Europe and internationally

- Consensus achieved on terms, concepts and approaches for QMS for TDS studies

- Best practice guidance developed for TDS steps including food description and classification systems, analytical performance criteria & uncertainty estimates, and Wiki for methods information (with WP4 & 9)

- EFQM developed for TDS centres and 4 TDS centres evaluated as basis of future 3rd party recognition

- Two papers under preparation

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Any questions?

With thanks to the TDS-Exposure partners

Anses	UGR	FERA	URV
IFR	NUID UCD	INSA	VITO
EuroFIR AISBL	UGENT	NIPH/FHI	NFA
RIVM	HAH	Matis	ETHZ
NIPH/SZU	PVD	NFNI/IZZ	ILSI Europe AISBL
INRAN	EVIRA	ISS	
BfR	CNA/AESAN	TUBITAK	

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What are Total Quality Management (TQM) systems?

Main work objective

TQM

Culture
Processes
Products
Services

Customer satisfaction

Success
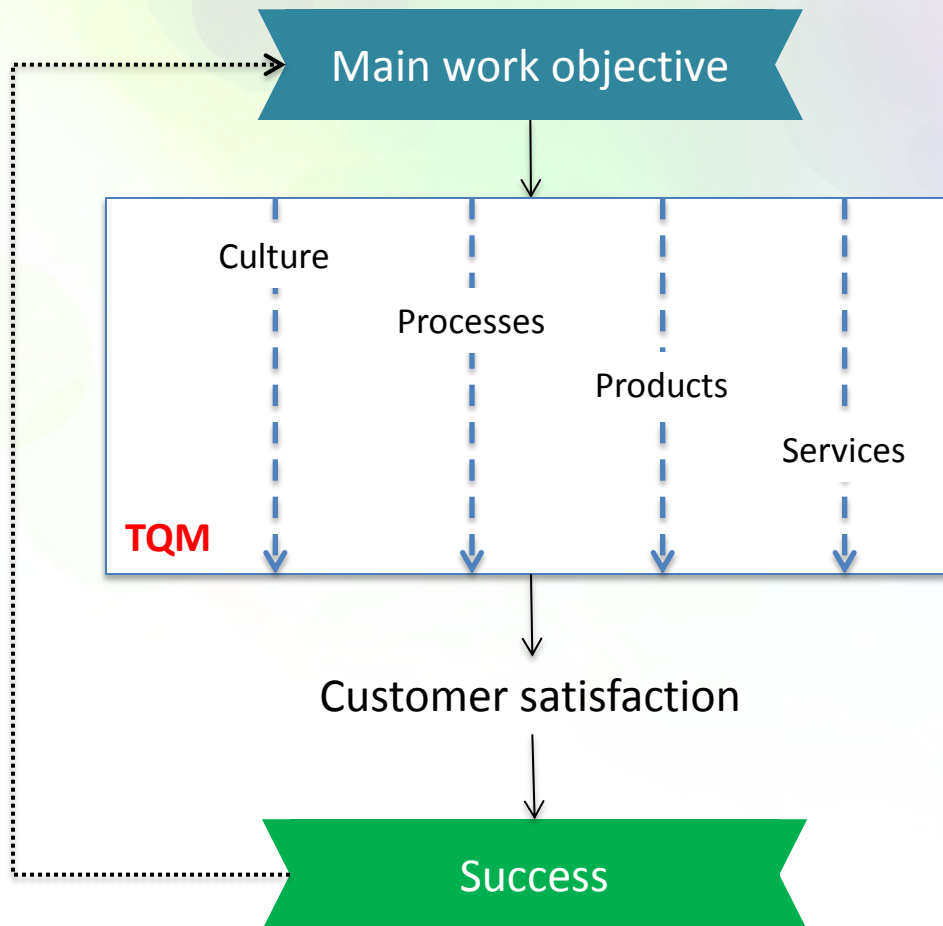
- European Foundation of Quality Management (EFQM) System

- TDS-Exposure third party recognition framework (EuroFIR approach)

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▶ Quality an important element of the sustainability plan and real benefit to TDS centres

▶ Maintain and develop TDS Centre network to:

- Refine & enhance tools and methods to meet requirements

- Define common indicators to access TDS centres key results and data sharing/evaluation

- Training and benchmarking

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Process Design for Analytical Performance Criteria

Reporting Results
(EFSA)

Performance Parameters

(LOD/LOQ etc…)

Methods of analysis (wiki)

References

Acronyms

Definitions

Substances

(Prioritized +pilot studies)

Quality System   Written Documents