What analysis concepts do we need to ensure the safety and quality of our food?

Franz Ulberth

The European Commission's science and knowledge service

Joint Research Centre

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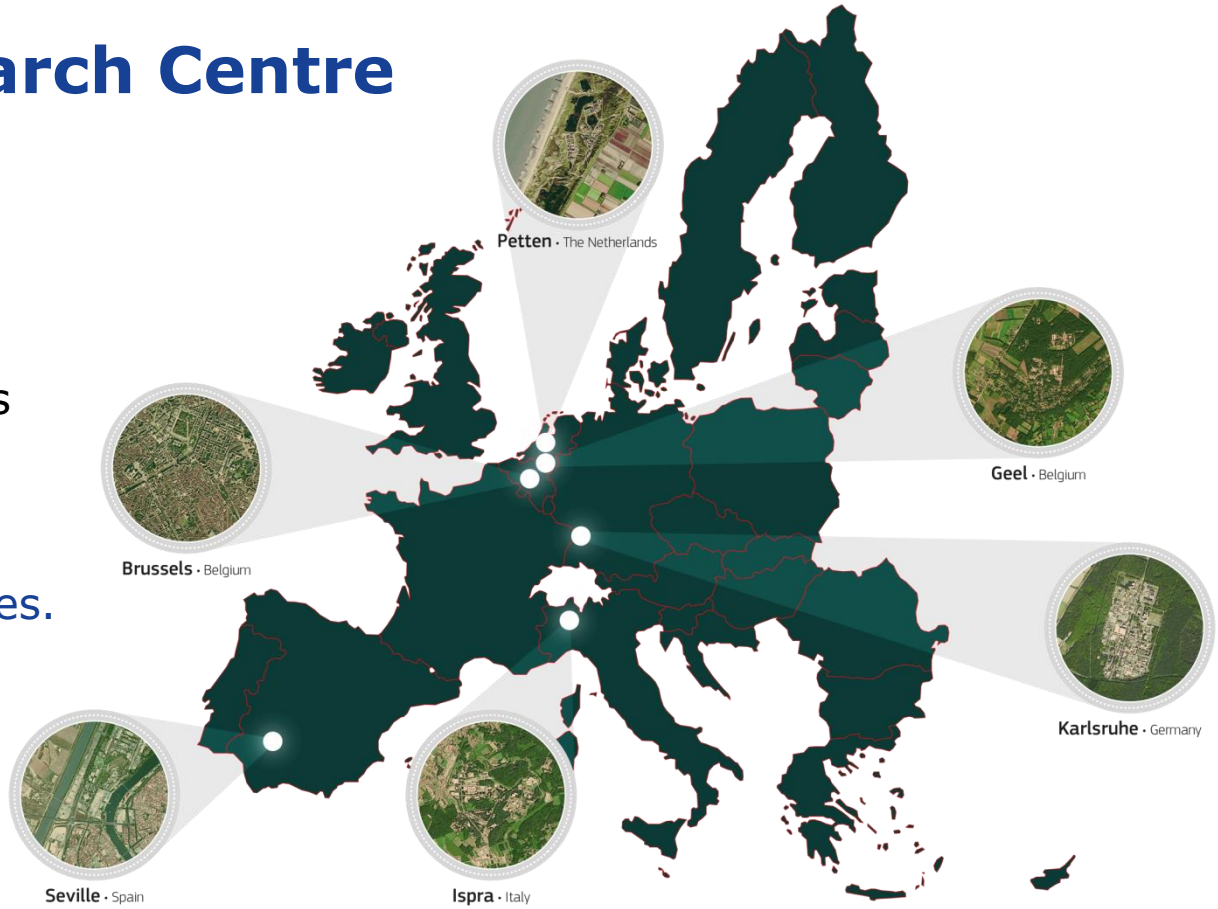
The Joint Research Centre at a glance

3000 staff
Almost 75% are scientists and researchers.
Headquarters in Brussels and research facilities located in 5 Member States.



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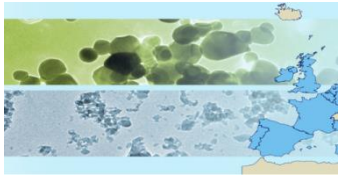
The Policy context

7th Environment Action Programme

Strategic plan 2016-2020 Health and Food Safety

EP Resolution on regulatory aspects of nanomaterials



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JRC response to global challenges

- Economy, finance and markets
- Energy (including nuclear activities) and transport
- Educations, skills and employment
- Food, nutrition and health
- Environment, Resource scarcity, climate change and sustainability
- People, governance in multicultural and networked societies
- Civil security
- Migration and territorial development
- Data and digital transformation
- Innovation systems and processes


A TREATISE
ON
ADULTERATIONS OF FOOD,
AND
Culinary Poisons,
EXHIBITING
THE FRAUDULENT SOPHISTICATIONS
OF
BREAD, BEER, WINE, SPIRITUOUS LIQUORS, TEA, COFFEE,
Cocoa, Confectionery, Vinegar, Mustard, Pepper, Cheese, Olive Oil, Pickles,
AND OTHER ARTICLES EMPLOYED IN DOMESTIC ECONOMY.
AND
Methods of detecting them.
THE SECOND EDITION.
BY FREDRICK ACCUM,
London:
SOLD BY LONGMAN, HURST, REES, ORME, AND BROWN,
PATERNOSTER ROW.
1820.

BAYER Pharmaceutical Products

HEROIN—HYDROCHLORIDE

is pre-eminently adapted for the manufacture of cough elixirs, cough balsams, cough drops, cough lozenges, and cough medicines of any kind. Price in 1 oz. packages, $4.85 per ounce; less in larger quantities. The efficient dose being very small (1-48 to 1-24 gr.), it is

The Cheapest Specific for the Relief of Coughs

(In bronchitis, phthisis, whooping cough, etc., etc.)

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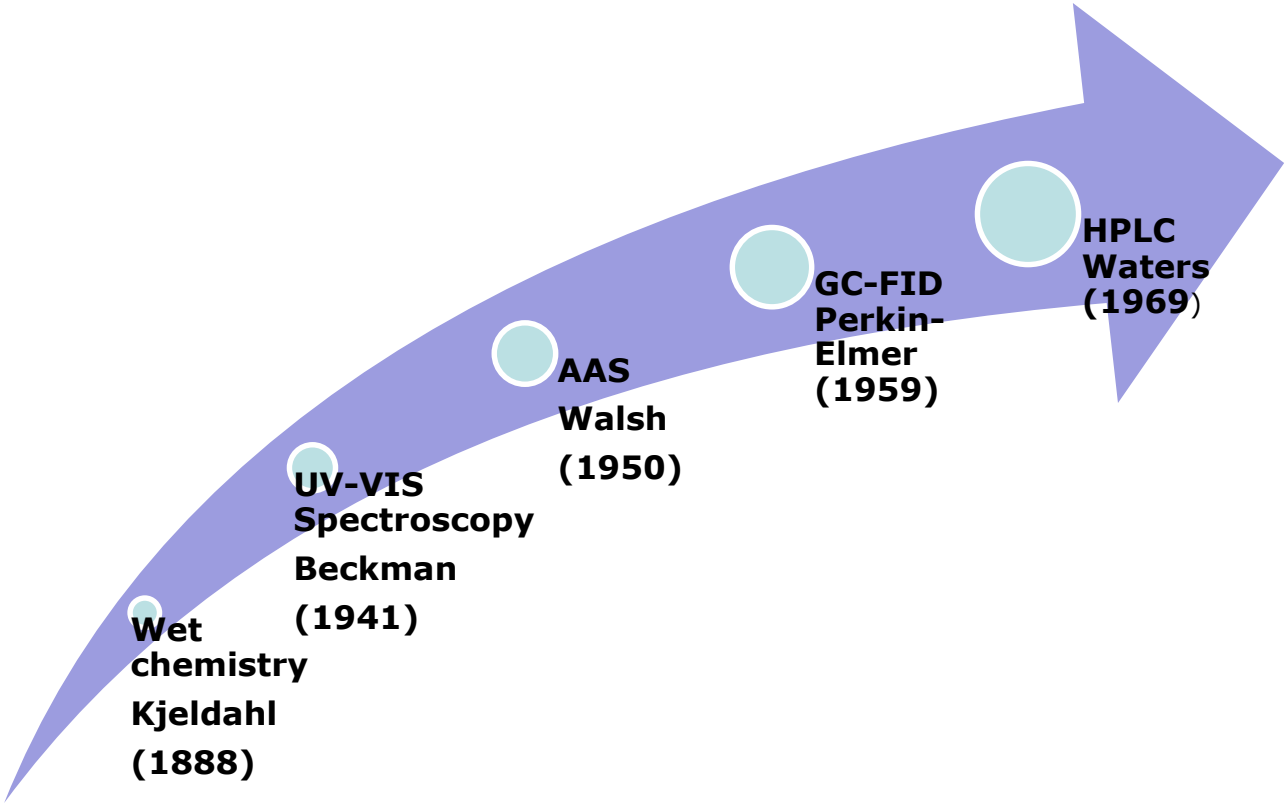

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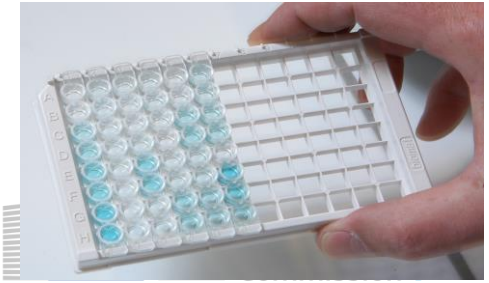
Typology of methods

Open methods

- do not describe any particular and/or exclusive trademark names of reagents or equipment
- describe in detail the composition and nature of chemicals and consumables
- may contain specifications and requirements related to instrumentation, chemicals and consumables
-

Proprietary methods

- require specific reagents and/or instrumentation
- mostly available from only one supplier
- do not disclose composition and nature of chemicals
- protected by intellectual property rights



Open methods

AOCS Official Method Cd 5-40
Reapproved 1997

Reichert-Meissl, Polenske and Kirschner Values, Modified AOAC Methods

APPARATUS

1. Graduated cylinder—25 mL.
2. Glass distillation apparatus of the dimensions and assembly shown in Figure 1.

REAGENTS

1. Sodium hydroxide (NaOH) solution—50% NaOH by weight (see Notes, *Caution*). This solution must be free from carbonates and kept protected from carbon dioxide. It is advisable to allow the solution to settle and use only the clear liquid.
2. Sulfuric acid (H_2SO_4) solution—prepared by adding 200 mL of concentrated H_2SO_4, sp. gr. 1.84, to distilled water and diluting to 1 L (see Notes, *Caution*).
3. Phenolphthalein indicator solution—1% in 95% alcohol.
4. Barium hydroxide [$Ba(OH)_2$] solution, 0.1 N—accurately standardized.
5. Glycerol-soda solution—add 20 mL of the 50% sodium hydroxide solution to 180 mL either USP grade or reagent grade glycerol.
6. Boiling chips that have been cleaned in distilled water. Store in distilled water until used.
7. Sodium hydroxide (NaOH) solution, 0.1 N—accurately standardized. See AOCS Specification H 12-52.
8. Aluminum wire.
9. Ethyl alcohol—95%, SDA Formulas 30 and 3A are permitted (see Notes, *Caution*).
10. Silver sulfate—reagent grade.

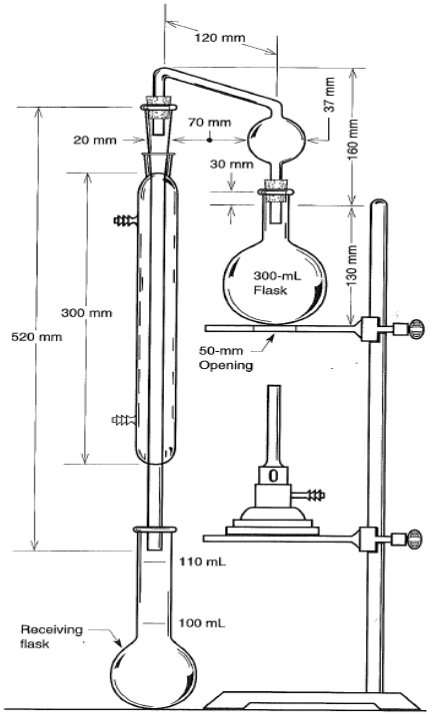


Figure 1. Reichert-Meissl distillation apparatus.

Convenience

QuEChERS
Protein assays (Bradford, BCA)
Enzymatic test kits for acids, sugars, ethanol, etc
Dietary fibre
Culture media and diluents for microbiology

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Consumables and reagents

Clean-up

- Sorption materials
- Solid phase extraction
- Immuno affinity columns
- UF membranes

Chromatography

- Columns / stationary phases

Reagents

- Chromogenic / fluorogenic substrates

Performance specification

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Alternative (rapid) methods

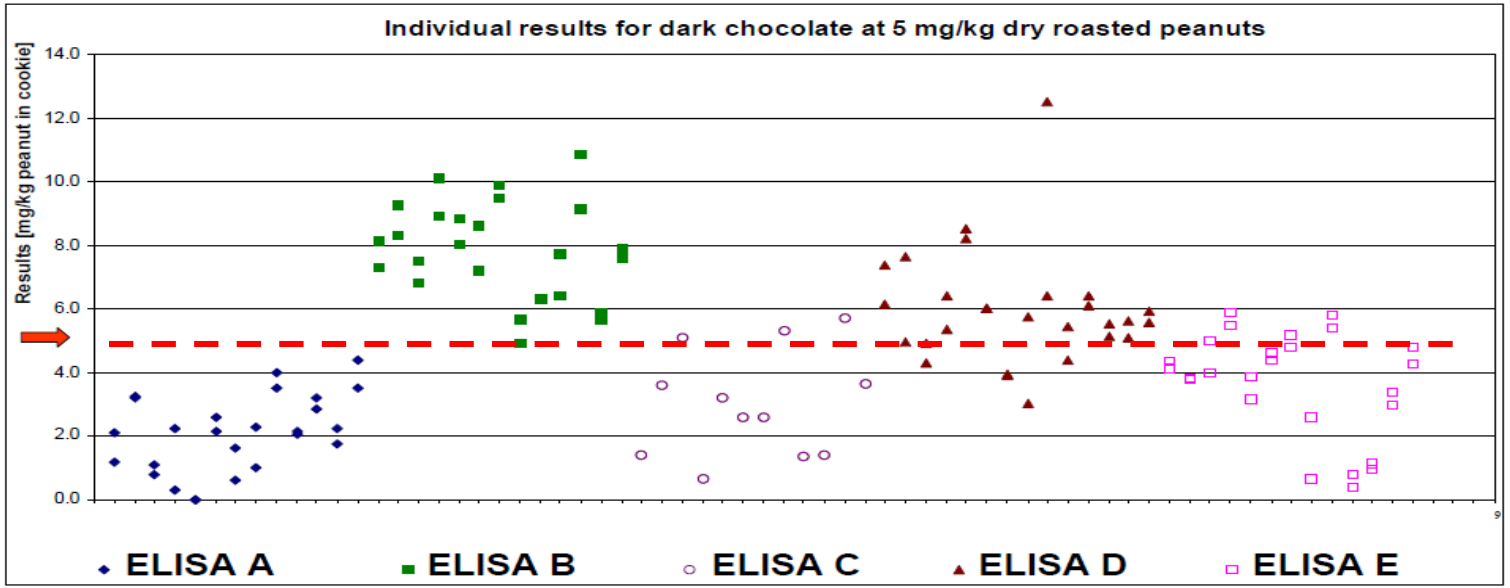
Microbiology

- Food pathogen detection by PCR
- Food pathogen detection by immunochemistry
- Culture media
- Membrane filtration
- Flow cytometry

Chemistry

- ELISA (toxins, drug residues, vitamins, etc)
- Reporter gene assay (Calux)
- Sensors

Reliability of test results



Poms *et al.* (2005)

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Future of testing?

https://www.youtube.com/watch?v=YKv9ESLMOEE

https://www.youtube.com/watch?v=6EXDQLMRq7Y

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Article 34
Methods used for sampling, analyses, tests and diagnoses

- *shall comply with Union rules establishing those methods or the performance criteria for those methods*
- *in the absence of the Union rules:*
  (a) available methods complying with relevant internationally recognised rules or protocols;
  or relevant methods developed or recommended by the European Union reference laboratories

(b)in the absence of the suitable rules or protocols, as referred to in point (a), methods which comply with relevant rules established at national level; or

relevant methods developed and validated with inter or intra-laboratory methods validation studies

Criteria approach

Mandating a certain analytical method in regulations

- **denies the analyst to choose the most appropriate method for a given task**
- **discourages development of alternative approaches and the use of automation**
- **complicates administrative procedures if the prescribed method needs to be replaced by a more suitable one**

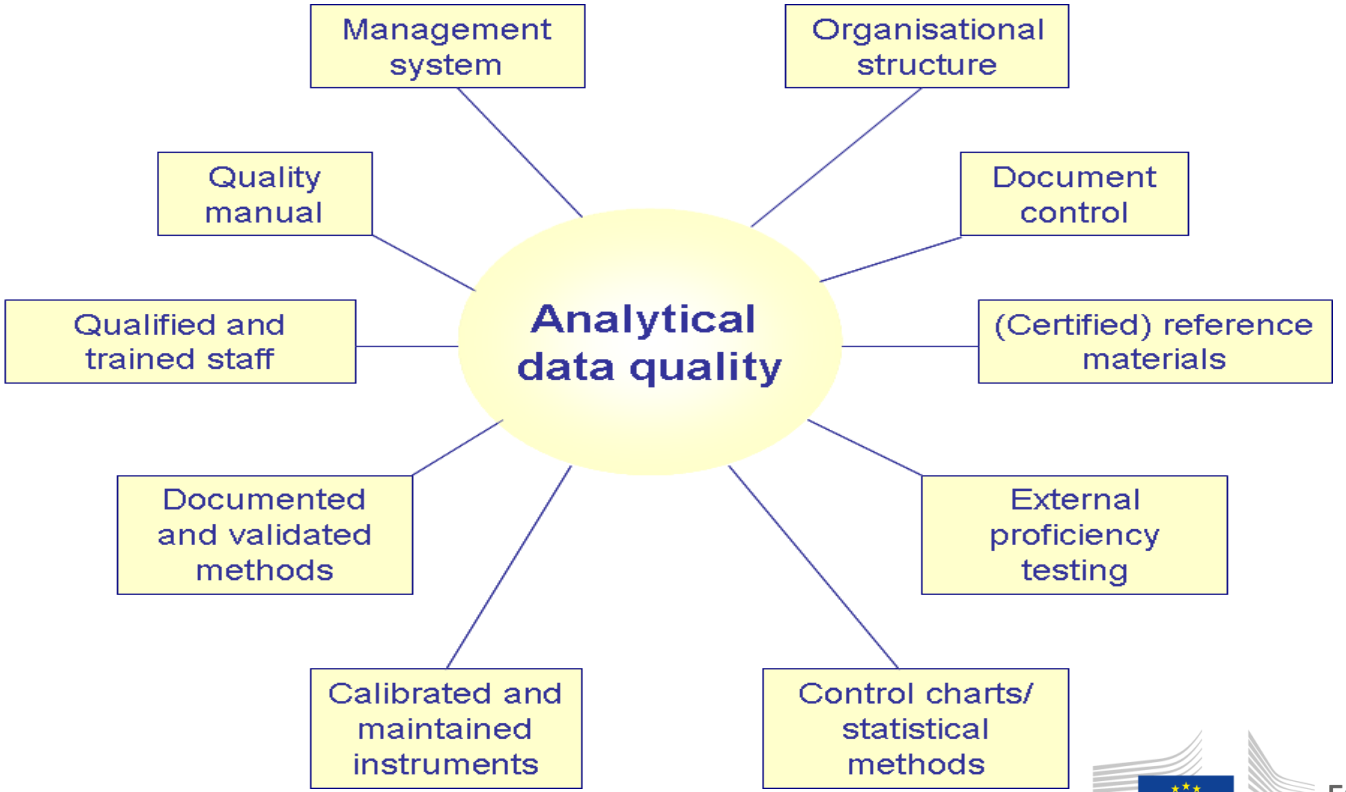
Paradigm shift

Method selection based on procedure

Method selection based on performance

Fit-for-purpose

Integrated system for analytical data quality



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Quality by Design (QbD)

"a systematic approach to development that begins with predefined objectives and emphasizes … understanding and … control, based on sound science and quality risk management"

The outcome of using QbD concepts is a well-understood product and process that consistently delivers its intended performance.

ICH Q8 and Q11

20

Analytical Quality by Design (AQbD)

- **Analytical Target Profile**
  - Performance requirements of analytical method
- **Risk Management**
  - Identifying variables that may affect data quality
- **Design of Experiments**
  - Confirm and optimize critical method variables
- **Method Operable Design Region**
  - Operating range for the critical method variables
- **Method Performance Control Strategy**
  - System suitability criteria
- **Method validation**

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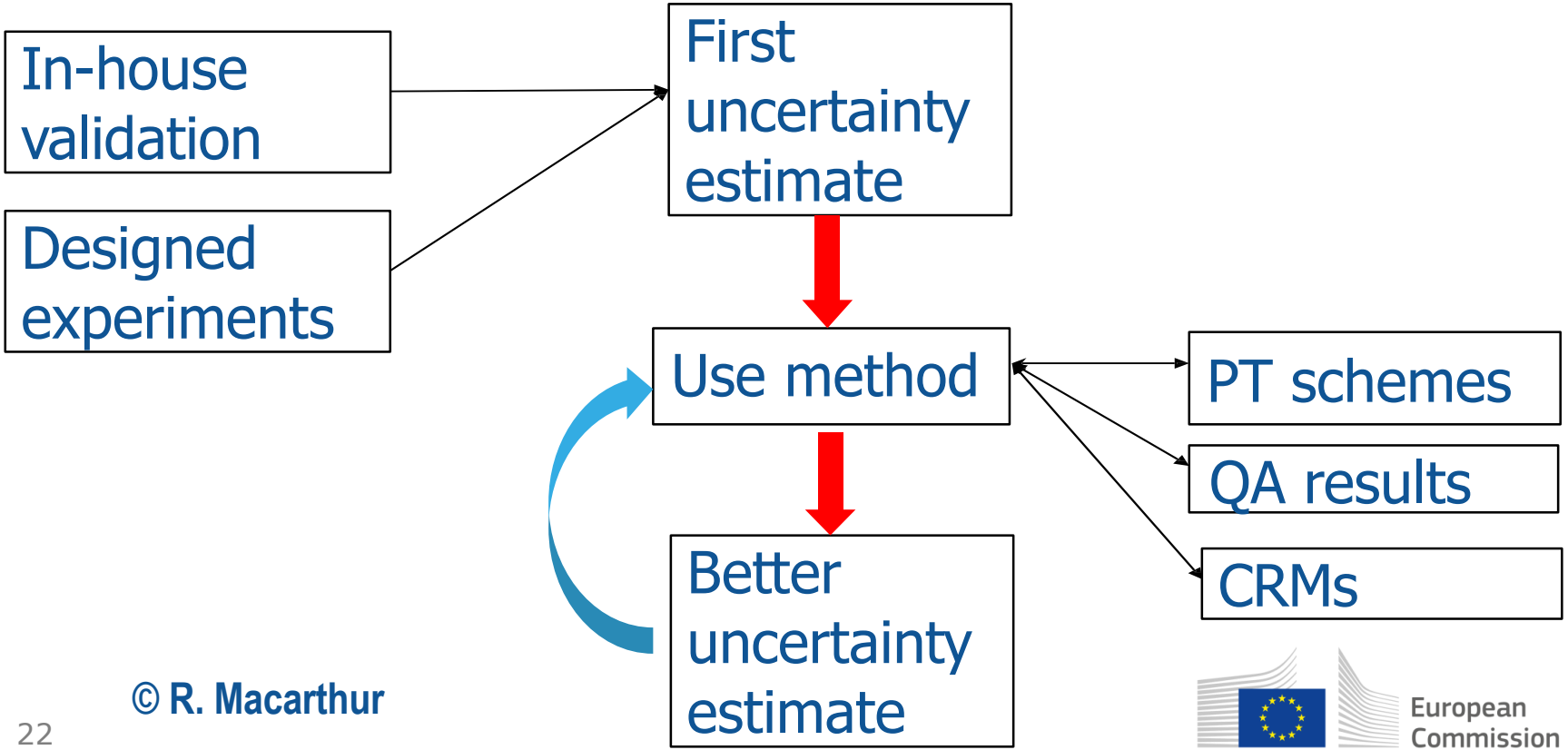
Practical approach



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EUR 230 MILLION WORT
FOOD AND BEVERAGES
GLOBAL OPSON OPERA
TARGETING FOOD FRA

25 April 2017

Press Release

Maandag 1 mei 2017 - 18u06:43
Aanmelden | 0 bewaard

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Lezersservice | Digikrant | Abonnement

Vind ik leuk 841K | Volgen

NIEUWS | REGIO | SPORT | SHOWBIZZ | NINA | TERUG NAAR HLN

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Voor 230 miljoen aan voedselfraude opgespoord

Aanbevelen 0 | Delen | Tweet | G+1 0 | 1 REACTIES

Bewerkt door: LB
25/04/17 - 14u04 Bron: ANP

BEWAAR ARTIKEL

OPSON (ὄψον) means food in ancient Greek

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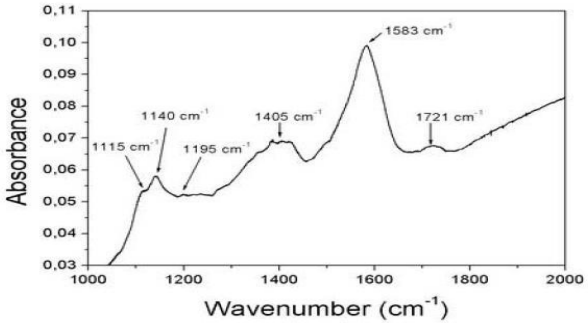
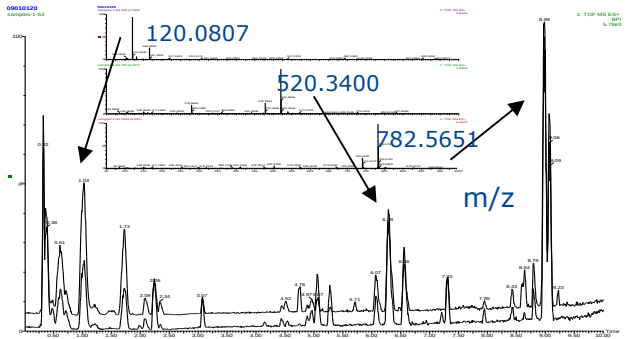
Targeted – untargeted analysis





	Primary ID	2	3	4	5	6
1	Concentratio	?M				
2	Export Date	Fri May 1				
Primar		4 Aminob	ADP	AMP	ATP	Acetate
4	fcx_02.cnx	0.052799	0.000769	0.001136	0.003712	0.00334
5	fcx_03.cnx	0.044776	0.001106	0.001869	0.007100	0.00452
6	fcx_04.cnx	0.054721	0.000934	0.000328	0.002636	0.00411
7	fcx_05.cnx	0.059619	0.000584	0.000454	0.002342	0.01121
8	fcx_06.cnx	0.063699	0.000937	0.000871	0.002003	0.00804
9	fcx_07.cnx	0.051731	0.000412	0.000249	0.001831	0.00847
10	fcx_08.cnx	0.046755	0.001264	0.000383	0.005650	0.00755
11	fcx_09.cnx	0.061909	0.000312	0.000382	0.001327	0.01222
12	fcx_11.cnx	0.059761	0.000314	0.000253	0.001152	0.00805
13	fcx_12.cnx	0.064242	0.000758	0.000457	0.001613	0.00747
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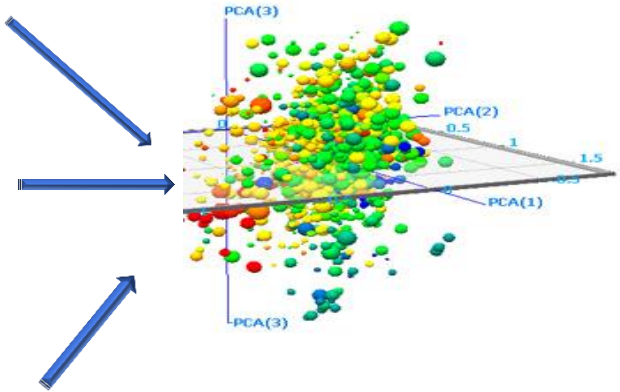

genuine

adulterated

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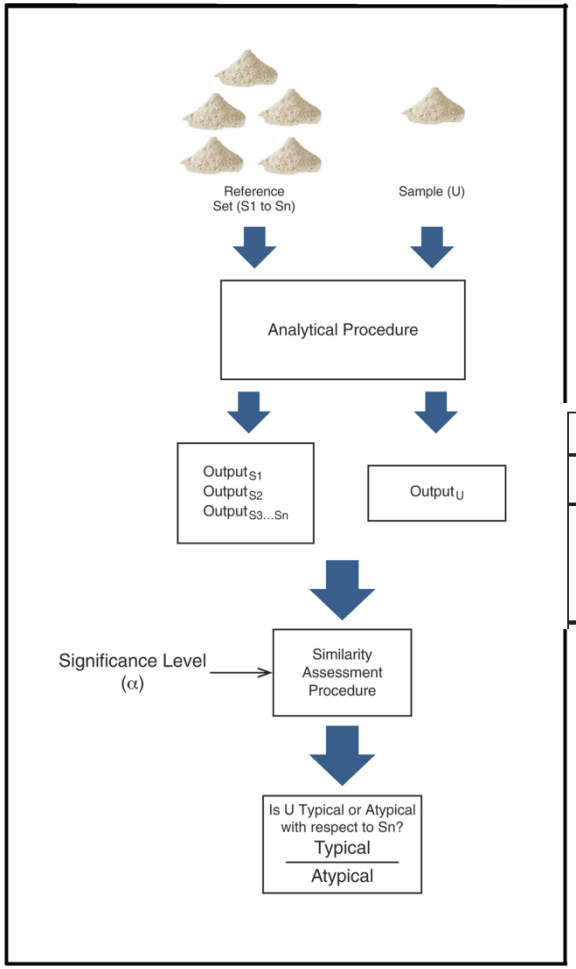

USP Guidance on Developing and Validating Non-Targeted Methods for Adulteration Detection

		Actual Sample State	
		Typical	Atypical
Method Prediction[a]	Typical	Correct Typical	Incorrect Typical
	Atypical	Incorrect Atypical	Correct Atypical

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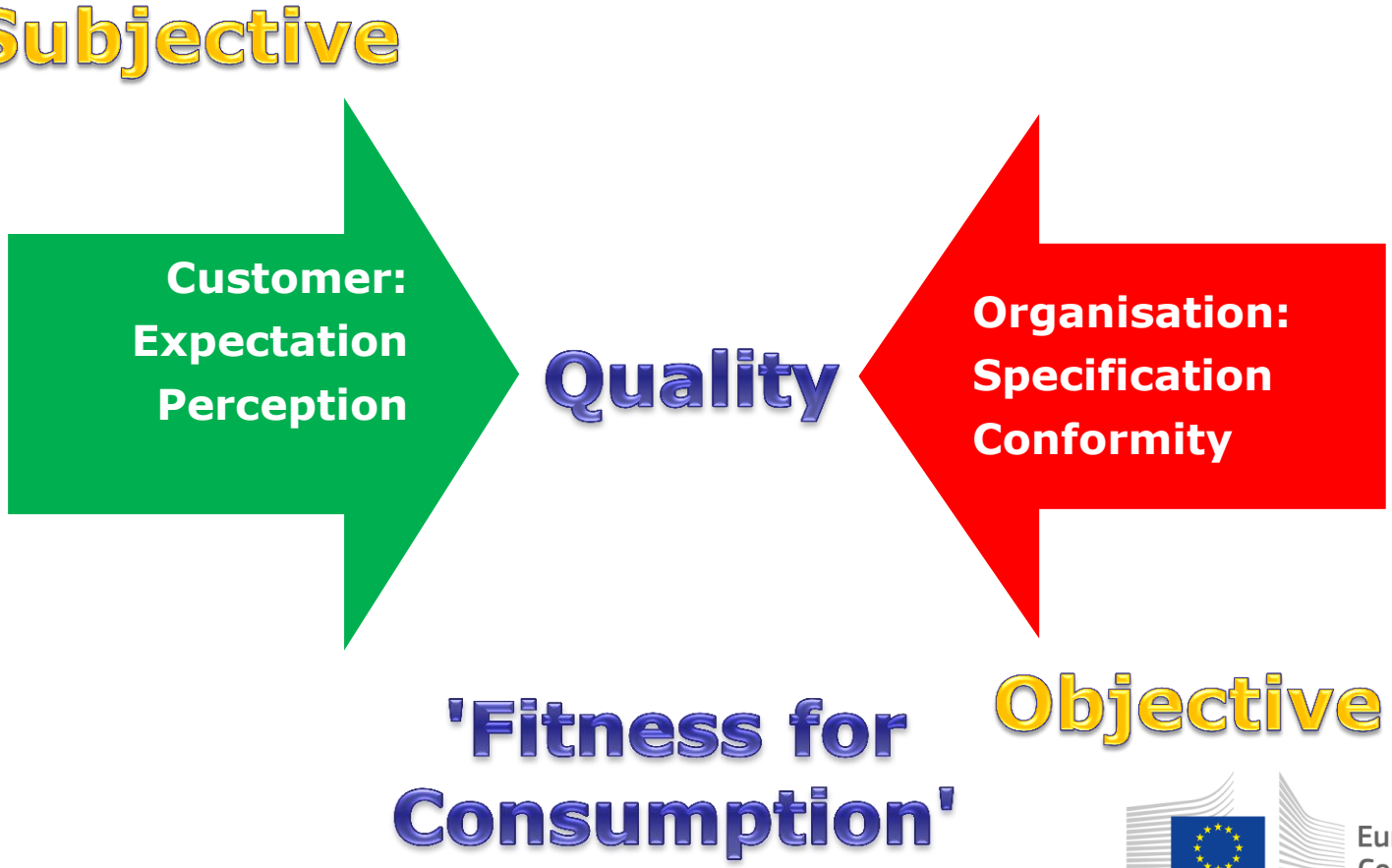
Food quality

1. Historically, quality has been primarily understood as the absence of defect, fraud and adulteration.

2. More recently, quality rests on expected properties such as organoleptic and nutritional characteristics or resulting benefits. This introduces the need to take the legitimate expectations of users into account and to require that operators do likewise.

3. Finally, quality designates desirable characteristics likely to justify added value; for example, forms of production (organic farming, environmental consideration, animal welfare), production areas (designation of origin) and their associated traditions.



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