

ANALYTICAL PROCESS

(Requests on realization of analysis and related issues)

Analytical process - complex of relations among customer demands, costs and analytical procedure (commonly characterized by Quality Assurance/Quality Control System)

Reason of realization - acquisition of validated data for investigated combination analyte / matrix

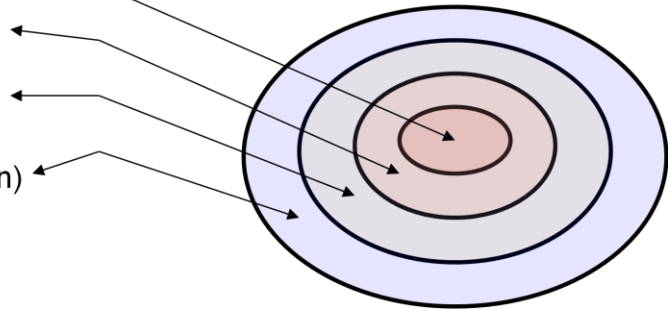
Validated data - analytical results including interpretative information (Report of Analysis)

Primary data (detector response)

Secondary data (results calculation)

Results/Outcomes (including method performance characteristics)

Validated data (including interpretation)



CONTRACTOR AND OBJECTIVE OF ANALYSIS

Contracting authority / customer - enterprisers, corporations, individuals

inspectories

arbitration commissions

ministries

agencies of government etc.

Purpose - **monitoring**: all concentration levels

limits inspection: levels defined in legislation

research: levels depend on experimental setup

produce: levels in expected interval

Role of Institutions, Organizations and Other Bodies

CR:

Ministry of Environment – monitoring, inspection of environment

Ministry of Agriculture – inspection of food materials and food products,
based on corresponding legislation

CAFIA (Czech Agriculture and Food Inspection Authority)

SPA (State Phytosanitary Administration)

SVA (State Veterinary Administration)

Ministry of Health - inspection of food contact materials etc. (migration)

National Institute of Public Health (NIPH)

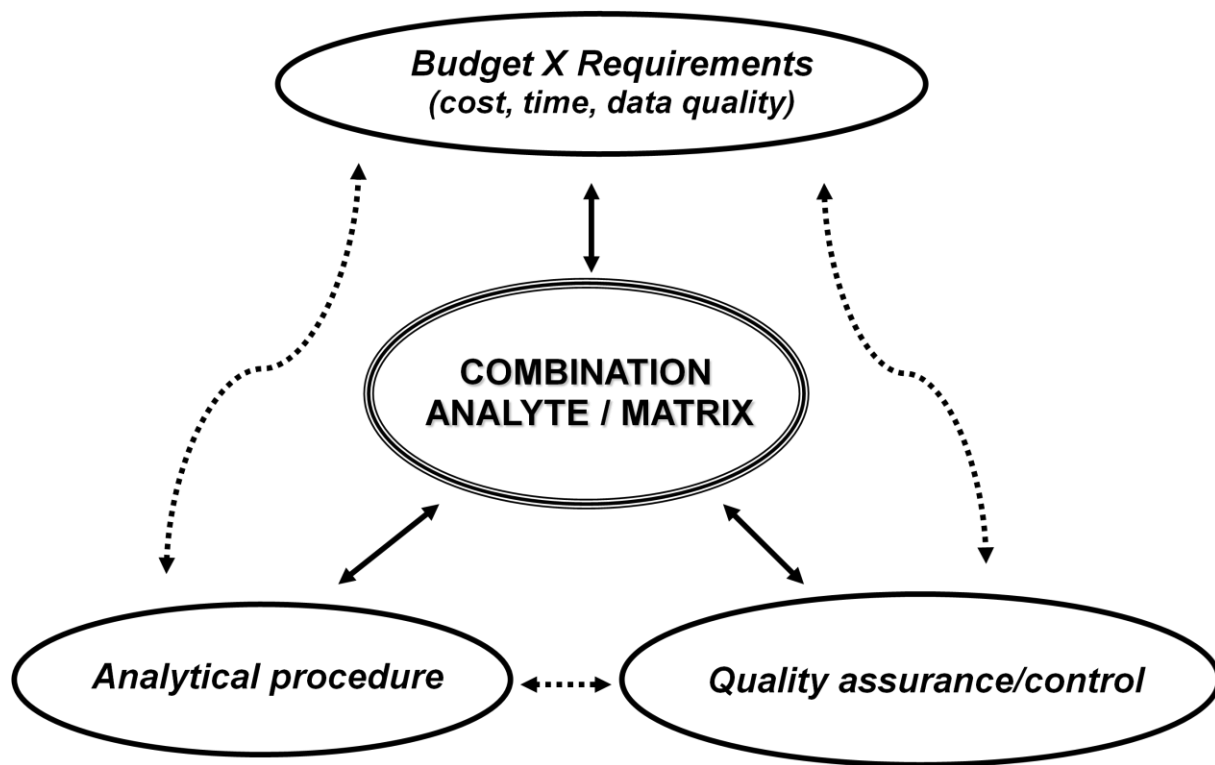
Universities, Research institution, Government departments, Agencies etc.

EU and world:

Standard organizations, more transparent system, priorities and competences: WHO, FAO, FDA, USDA, EPA, NFA

Eur-Lex: European Legislation - <http://europa.eu/documents/eur-lex>

PARAMETERS OF ANALYTICAL PROCESS



BUDGET X REQUIREMENTS

Cost: objectives, frame and extent, parameters of analytical procedure

Time: decision on health risk or commercial aspects

Quality assurance/control: representative sampling, repeatability,
LOD, LOQ, accreditation

ANALYTICAL PROCEDURE

Sampling: representative sample

Sample handling: analytical sample

Analyte(s) isolation: form (phase) suitable for analysis

Analyte(s) determination: qualitative and quantitative analysis
(primary data measurement, results calculation)

Data validation: analytical report including method parameters, interpretation

QUALITY ASSURANCE/CONTROL

(parameters of analytical procedure)

Mathematico-statistical parameters:

- accuracy (precision + trueness)
- repeatability, LOD, LOQ

Suitability/applicability:

- Matrix type, analyte(s) characteristics, concentration level, time, method principle

Intra laboratory (in house) validation and tests:

- model experiments, reference materials usage

Inter laboratory (national and international) validation and test:

- method validation: unified system (the same method application – AOAC,USA)
- proficiency testing (various methods to achieve the same results - EU)
National reference laboratory, Community reference laboratory
- testing and certification of new reference materials

Accreditation:

- standard operation procedures (SOP), system of quality assurance/control, audits...
- registration, reporting, data protection...

AQUISITION OF NECESSARY INFORMATION

Legislative aspects: solving of new born problems

Analytical aspects: optimization of new procedures

Interpretation aspects: complying with legislation/customer requirements

Information sources:

Scientific papers, books

Laws, norms, regulations, directives – CR, EU, USA (EFSA, FDA, EPA)

Internet: official servers, public sources, Wikipedia...

Personal communication, consultations, projects