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Directorate-General for
Health & Consumers

Ensuring safety of food as regards chemical contaminants through regulation and control

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Health and Consumers

Principles for regulating contaminants in food in the EU

* Principles and requirements apply to all stages of the production, processing and distribution of food and also of feed produced for, or fed to, food producing animals **"farm to fork" approach**

→ Food and feed → e.g. feed: analytical interferences to be taken into account

* a **high level of protection of human and animal health** has to be pursued

→ Contaminants: low level of presence / strict regulatory levels

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Principles for regulating contaminants in food in the EU

*** free movement within the European Union of food compliant with EU legislation**

→ Need to ensure comparable control results across the EU

* **international standards** to be taken into account.
→ Need to ensure comparable control results across the world

*** feed and food placed on the market shall be safe**

*** contaminant levels shall be kept as low as can reasonably be achieved following good practices at all stages (ALARA)**

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Principles for regulating contaminants in feed and food in the EU

* In order to achieve the general objective of a high level of protection of human health, **EU feed/food legislation shall be based on risk analysis** (process consisting of three interconnected components: risk assessment-risk management-risk communication)

* Risk assessment shall be based on the **available scientific evidence** and undertaken in an **independent, objective and transparent manner**

* **Risk management shall take into account the results of risk assessment**, **other factors legitimate** to the matter under consideration and the precautionary principle where appropriate

Risk management
Prevention and Regulation

"prevention is better than cure" to protect the consumer (humans and animals) from the toxic effect of contaminants → need for encouraging preventive actions such as good agricultural practice, good storage conditions, use of improved sorting procedures, good manufacturing practice …

Fixing maximum limits is not contrary to prevention. Fixing maximum levels at a reasonably achievable level, stimulates preventive actions at all stages to avoid contamination of the feed/food chain.

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Risk management
Prevention and Regulation

Regulatory standards provide a benchmark against the effectiveness of the successful implementation of prevention programmes and provide a tool for control authorities to control the correct application of prevention measures by each actor in the chain

If regulatory standards are fixed, these should be fixed at a level reasonably achievable but stimulating a preventive approach.

Trends and challenges in EU policy on contaminants in feed and food

Cost – benefit considerations (impact assessment)

Balance risks of contaminants – benefits of consumption of certain foods (feed) (health risk – health benefit considerations)

New risk assessment approaches: The Margin of Exposure (MOE) approach, threshold of toxicological concern (TTC), …

Maximum levels → other appropriate risk management tools

Risk management tools used – to be used – consequences for control

Maximum levels: aflatoxins, ochratoxin A, lead, cadmium, 3-MCPD, inorganic tin, citrinin

Maximum levels with regional derogations: dioxins

Maximum levels combined with code of practice for prevention and reduction: patulin, Fusarium-toxins

Comprehensive strategy (feed and food) comprising of a combination of maximum levels, action levels and source-directed measures: dioxins and PCBs

Risk management options used – to be used → consequences for control

Maximum levels with data collection: PAH

Maximum levels combined with dietary advice: mercury

Code of practice: ethylcarbamate

Dietary advice only: …

Data collection: acrylamide, furan, PFOS/PFOA, …

Tools for reduction of presence: acrylamide combined with monitoring to monitor effective implementation of tools – indicator values

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Driving forces for initiating new EU-legislation on contaminants

*** Contamination incidents with "new" (not yet regulated) contaminants:** melamine, mineral oil, …

*** New (at EU level) risk assessments:** non-dioxin like PCBs, arsenic, …

*** Updated risk assessments:** cadmium, PAH, mercury, ochratoxin A, lead, …

*** Developments in risk assessment approaches**

- **Risk-benefit assessment**: nitrates in vegetables
- **Margin of Exposure (MOE):** genotoxic carcinogens such as aflatoxins, PAH

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Driving forces for initiating new EU-legislation on contaminants

* **Emerging contaminants:** Brominated flame retardants (BFR), PFOS/PFOA, Alternaria toxins, 3-MCPD esters, enniatins, …

* **Changing production conditions/ climate change:** Mycotoxins, phytotoxins (?)

* **International developments within the Codex Alimentarius :** lead in fish, aflatoxins, melamine, …

* **Identified problems with current legislation:** Fusarium toxins **…**

Challenges for enforcement of mycotoxins in feed and food - general

Development of adequate sampling procedures: representative and feasible – heterogeneity –large size batches – estimation of sampling uncertainty

Methods of analysis + measurement uncertainty

- **Confirmatory**
- **Screening**

Screening approach (not only analysis but also sampling): sampling and analysis – very low rate of false negatives – acceptable rate of false positives → **growing importance for the enforcement**

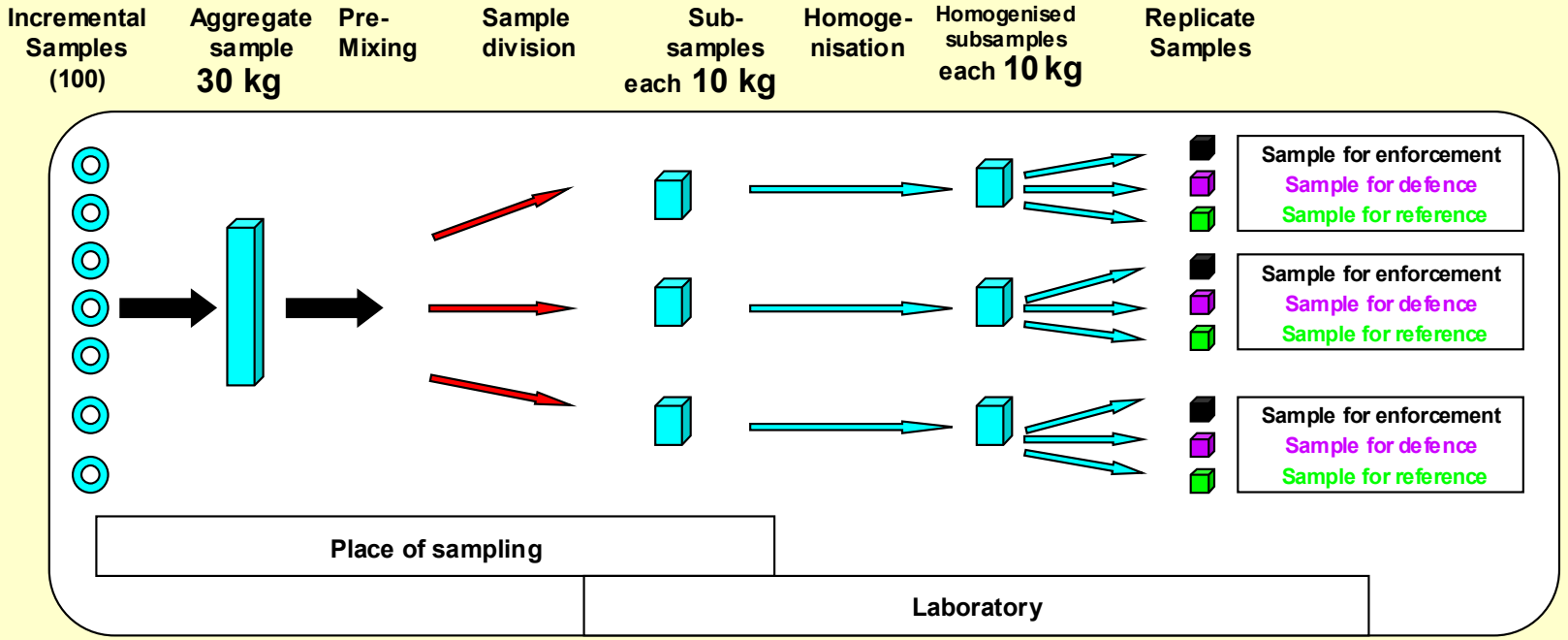
Importance of sampling

Adequate sampling procedure is of crucial importance for estimating lot average levels in case contaminants are heterogeneously distributed throughout a lot (as is the case for aflatoxins, ochratoxin A,…) and is therefore in these cases an essential component in the development of any maximum level

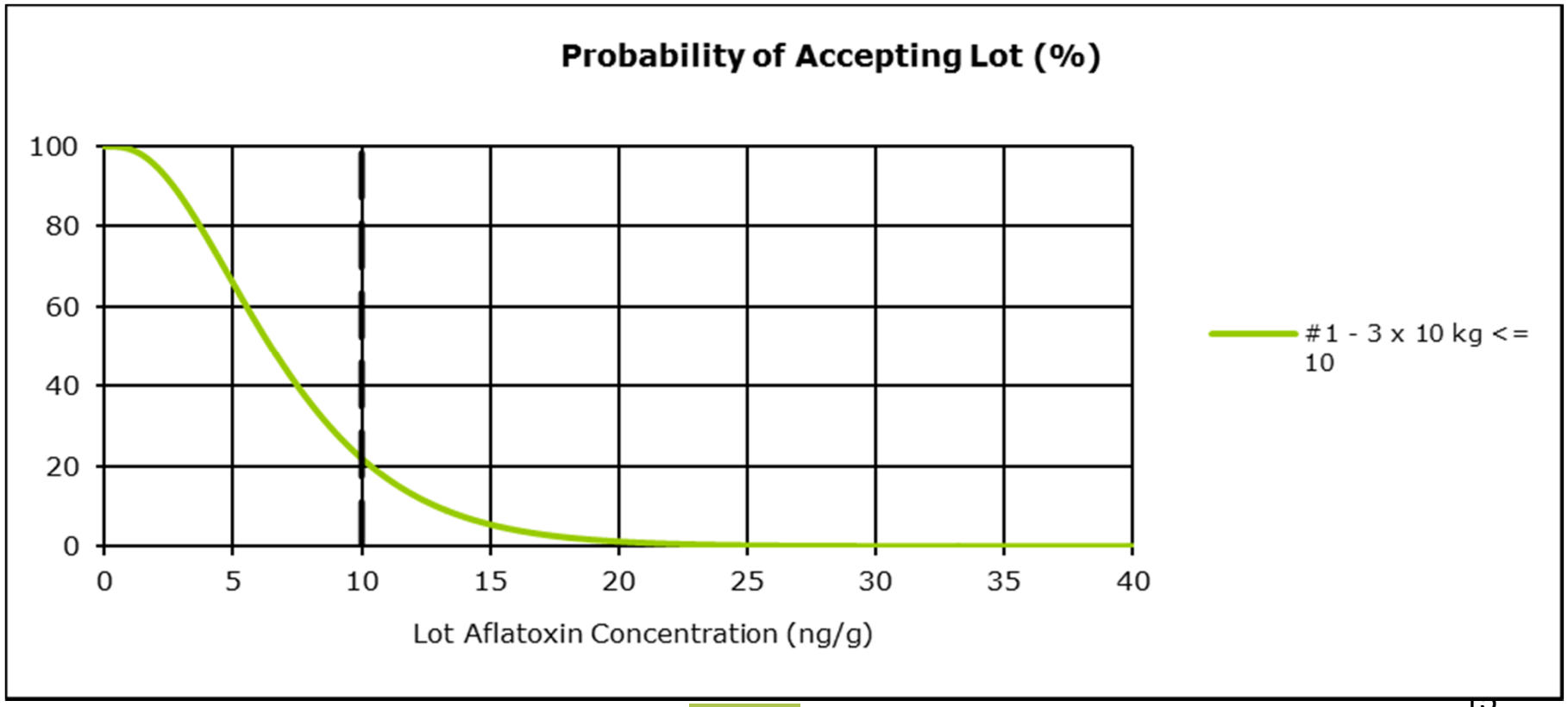
exporter's risk/producer's risk against importer's risk/consumer's risk: EU policy is that a sampling procedure must be practicable and must minimise the consumer's risk without rendering trade impossible

Samples for defence and reference –figs

Samples for enforcement, defence and reference taken from homogenised laboratory or subsamples



OC Curves - FAO mycotoxisn sampling tools - http://www.fstools.org/mycotoxins/



Legislation on official controls Reg. 882/2004

General obligations

- Member States shall ensure that controls are carried out on a regular basis, on a risk basis and with an appropriate frequency to achieve the objectives taking account of:
  * identified risks
  * experience and knowledge gained from previous controls
  * reliability of controls already carried out by food and feed business operators (own-controls)
  * suspicion of possible non-compliance

Legislation on official controls Reg. 882/2004

General obligations (cont'd)

- the official controls are carried out without prior warning (as a general rule) and
- at any stage of production, processing and distribution
- official controls must be applied with the same care to exports, to the placing on the market within the Union and on the import

Regulation 882/2004
Competent authorities

Competent authorities shall ensure

- the effectiveness and appropriateness of official controls
- to have access to adequate laboratory capacity and sufficient suitably qualified staff
- that staff carrying out the control is free from any conflict of interest

Regulation 882/2004
Import controls

Controls on the import of feed and food

- Regular official controls at an appropriate place (point of entry / point of release for free circulation/ premises of food business / other points of the chain)
- controls include documentary check (always), an random identity check and, as appropriate, a physical check

Regulation 882/2004
Import controls

Controls on the import of feed and food (cont'd)

- **frequency of physical checks function of**
  - * possible risks associated with food commodities
  - * history of compliance (product, establishment of operator, importing operator, exporting operator, third country)
  - * controls carried out by the importer
  - * guarantees provided by competent authorities of third country

Regulation 882/2004
Sampling and analysis

Sampling and analysis methods used in the context of official controls shall comply with relevant Union rules or

- if none exist, internationally recognised rules or protocols, for example those that the European Committee for standardisation (CEN) has accepted or those agreed in national legislation
- if none exist, other methods fit for the intended purpose or developed in accordance with scientific protocols

Regulation 882/2004
Sampling and analysis

In case the above mentioned does not apply, validation of methods of analysis may take place within a single laboratory according to an internationally accepted protocol

Regulation 882/2004 Sampling and analysis

The Commission may lay down

- methods of sampling and analysis, including the confirmatory or reference methods to be used in the event of a dispute
- the performance criteria, analysis parameters, measurement uncertainty and procedures for the validation of such methods
- rules on the interpretation of the results

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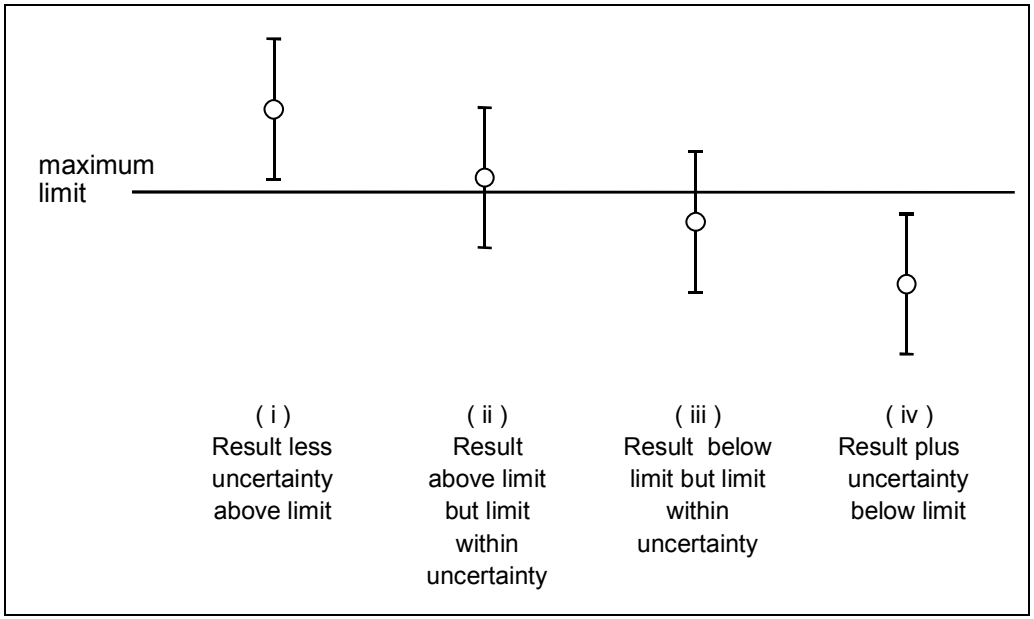
INTERPRETATION OF ANALYTICAL RESULTS

A consignment is considered as non-compliant if analytical result, corrected for recovery exceeds the maximum level beyond reasonable doubt taking into account the measurement uncertainty

INTERPRETATION OF ANALYTICAL RESULTS

Interpretation of the measurement of uncertainty when considering compliance with a statutory limit, where the circle is the analytical result.



Action: reject accept accept accept

Accreditation requirement Regulation 882/2004

Laboratories (Article 12)

- Competent authority shall designate laboratories that may carry out the analysis of samples taken during official control
- Competent authorities may only designate laboratories that operate and are assessed and accredited following EN ISO/IEC/17025 on "General requirements for the competence of testing and calibration laboratories"
- The accreditation and assessment of laboratories relate to individual tests or groups of tests

EURL – NRL network : objectives

* Regulation (EC) No 882/2004 provides for the establishment of an European Union Reference Laboratory (EURL) / National Reference Laboratory (NRL) network in different areas of food safety

* EURL/NRL network should contribute to a high quality and uniformity of analytical tasks

* the tasks and duties of the EURL/NRL provided for in the Regulation aim to achieve this objective.

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Regulation 882/2004 - Tasks and duties of the EURL

The EURL shall be responsible for

- Providing NRLs with details of analytical methods, including reference methods
- Co-ordinating application by NRLs of the methods, in particular by organising comparative testing and by ensuring an appropriate follow-up of such comparative testing in accordance with internationally accepted protocols
- Co-ordinating practical arrangements needed to apply new analytical methods and informing national reference laboratories of advances in this field

Regulation 882/2004 - Tasks and duties of the EURL

The EURL shall be responsible for (cont'd)

- Conducting initial and further training courses for the benefit of staff from national reference laboratories and of experts from developing countries
- Providing scientific and technical assistance to the Commission, especially in cases where Member States contest the results of analysis
- Collaborating with laboratories responsible for analysing feed and food in third countries

Regulation 882/2004 –Tasks and duties of the NRL

* Member States designate one or more reference laboratories (NRLs) for each European Union laboratory (may be a laboratory in another Member State or EFTA Member, one lab can be NRL for more than one Member State.

* In case Member States gave more than one NRL for one EURL, they must ensure that these laboratories work closely together to ensure efficient co-ordination between them, with other national laboratories and with the European Union reference laboratory.

Regulation 882/2004 – Tasks and duties of the NRL

These NRLs shall

- Collaborate with EURL
- Co-ordinate for their area of competence the activities of official laboratories
- Organise where appropriate comparative tests between the official national laboratories and ensure follow-up of such comparative testing
- Ensure the dissemination to the competent authority and official national laboratories of information that the EURL supplies
- Provide scientific and technical assistance to the competent authority for the implementation of co-ordinated control plans

Standardisation of methods

* Standardised methods of analysis are of importance to guarantee the safety of feed and food and to ensure the free circulation of feed and food within the EU

* DG Health and Food Safety intends to establish methods of analysis only in very specific cases as regards safety of feed and food.

* Standardisation of methods is largely entrusted to CEN (European Standardisation Committee)

* European Commission addresses mandates for standardisation to CEN to provide standards of methods of analysis and sampling within a certain time period

Effective Enforcement

Importance of representativeness of sampling and reliability of analysis: to guarantee that once controlled at an early step in the feed and food production chain that feed and food is safe and is found compliant also at later stages: no need for recalls etc

Importance of quick/rapid sampling analysis (but reliable)

- Industry HACCP/autocontrol: need for quick and reliable results to ensure “fluent” ongoing production process and to avoid unreasonable production costs
- Control authorities (see next slide)

Effective Enforcement –Importance of quick, but reliable sampling and analysis

Official controls have to be carried out regularly on a risk basis and with the appropriate frequency

- at random (non-suspicion) – in these cases sampled lot as a rule not detained

  → late analysis can have large consequences

  - On the safety of the consumer
  - Economic cost: large recalls

Effective Enforcement-Importance of quick, but reliable sampling and analysis

- in case of suspicion – in these cases sampled lot as a rule detained
  → late analysis can have large consequences
  - Deterioration of the quality and safety of the sampled lot pending analysis
  - Economic cost of blocking the goods pending analysis: time is money! Seasonal products / delivery just in time

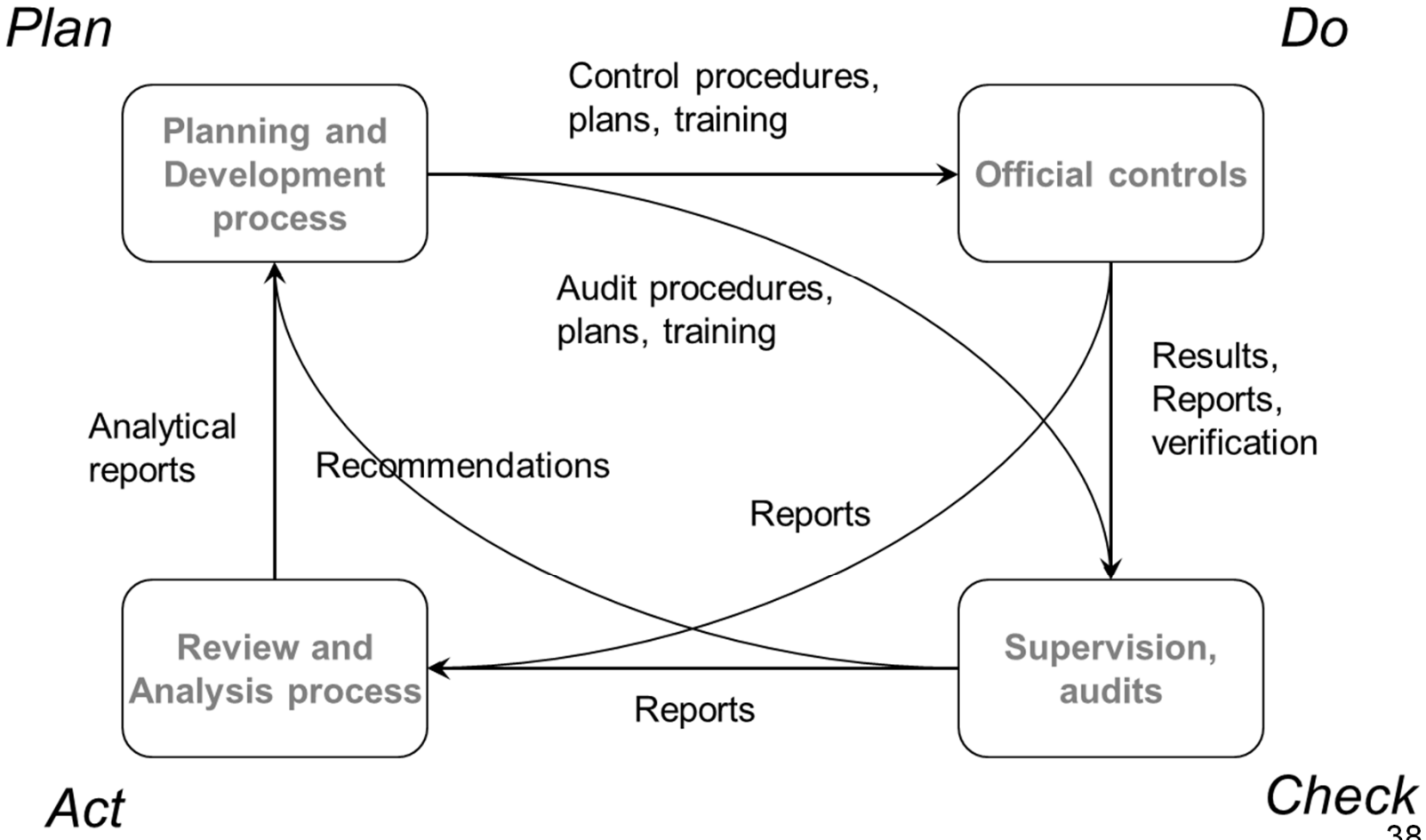
Effective Enforcement
not only reliable and quick analysis

* Keep period of time between arrival lot and sampling as short as possible
* Ensure representative feasible sampling
* Keep period of time between sampling and arrival of sample at laboratory as short as possible
* Ensure Reliable and quick sampling analysis
* Ensure that reporting of the result to the responsible inspector is done as soon as possible after analysis

Setting enforcement in context
Building blocks of control system

- Risk-based controls and prioritisation of activities, including enforcement activities (Resource allocation/Databases/ results of previous controls)
- Legislation in place, including, where necessary, enforcement legislation
- Clearly defined competent authorities and responsibilities, including for enforcement activities
- Co-ordination between bodies responsible for controls and bodies responsible for enforcement.
- Effective enforcement is a necessary element of effective compliance

PDCA cycle-applies also to enforcement



KEY POINTS

- **Enforcement strategy**
  - Risk-based controls
  - Dialogue with industry/operators
  - Incentives/dissuasive measures
  - Measurement of effectiveness of enforcement activities
  - Reporting: Links between
    Controls → Non-compliances → Enforcement activities
  - Reports should analyse overall trends in enforcement
  - Review mechanism

THANK YOU FOR YOUR ATTENTION !

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