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# Risk-based Sampling: Perspective from Hungarian National Food Chain Safety Office

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# The food-chain

- The system of food supply is fairly complicated, complex activity, with a number of stakeholders and with many sources of hazards.
- The average consumer usually meets only the final product and at the point of buying the consumer is in a defenceless and confidential situation.
- The consumer trusts the FBOs but **there is a deeper trust in the official control** of the operators.
- These feelings has been strengthened in the past decades:
  - effects of more and more food compounds on the human organism recognized
  - usage of food additives increased
  - new technologies evolved
  - new hazards identified
  - better and more sensitive analytical methods developed

# Specialties in food-chain

- The food market is **not a perfect market** (in an economical meaning)
  - The market control power of the consumer itself is not enough for an appropriate risk level food supply
  - **Strong informational asymmetry** between FBOs, the control authorities and consumers
- The average consumer becomes uncertain, and this means a remarkable political and economical risk
- Role of the authorities?

# Role of the authorities: operate the cycle of food safety control



# Reg. 882/2004/EC on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules

## Article 3

### General obligations with regard to the organisation of official controls

*“1. Member States shall ensure that official controls are carried out regularly, on a risk basis and with appropriate frequency, so as to achieve the objectives of this Regulation taking account of:*

*(a) identified risks associated with animals, feed or food, feed or food businesses, the use of feed or food or any process, material, substance, activity or operation that may influence feed or food safety, animal health or animal welfare;*

*(b) feed or food business operators' past record as regards compliance with feed or food law or with animal health and animal welfare rules;*

*(c) the reliability of any own checks that have already been carried out; and*

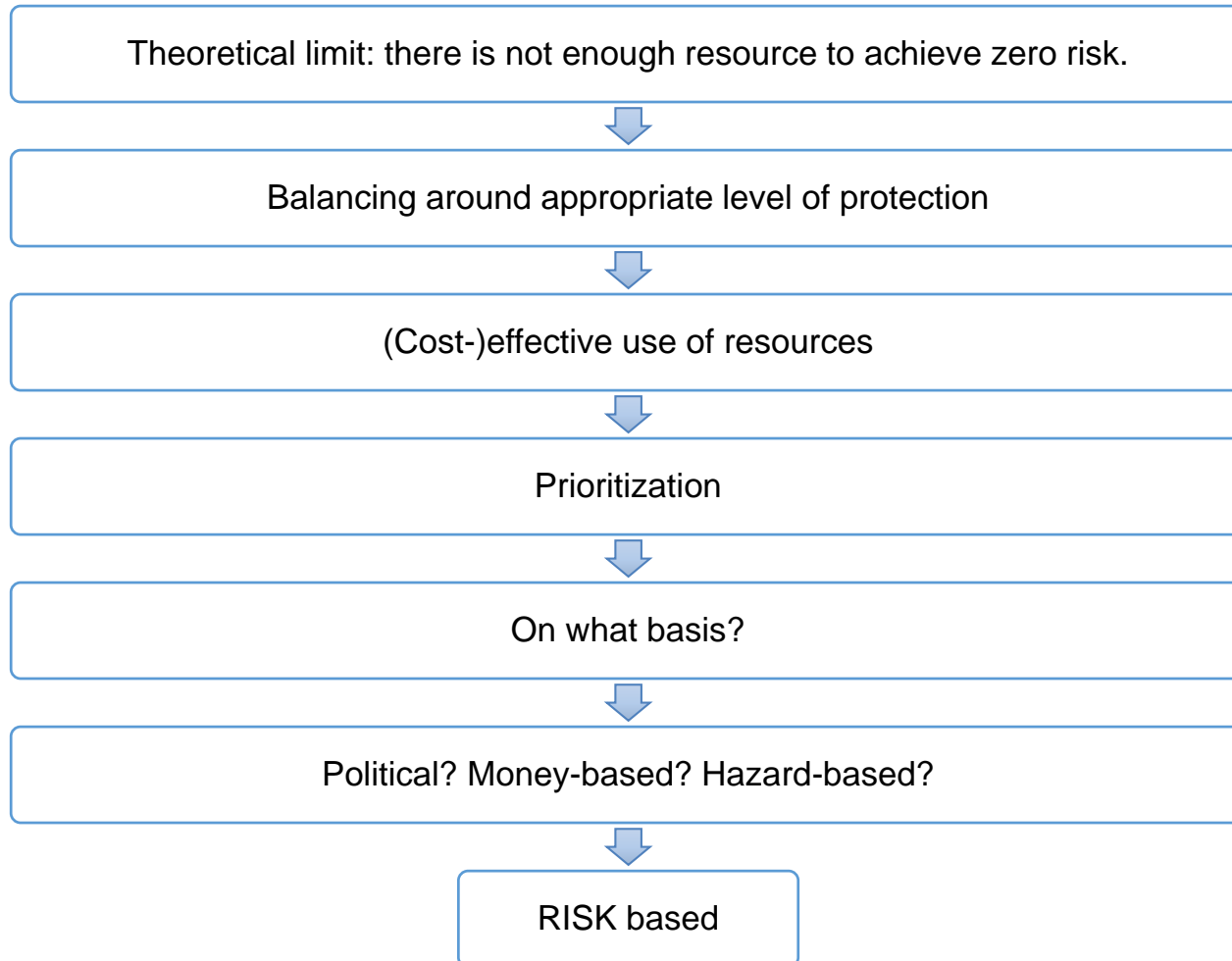
*(d) any information that might indicate non-compliance.”*



# Risk based?

What does it mean?

# Why risk based?

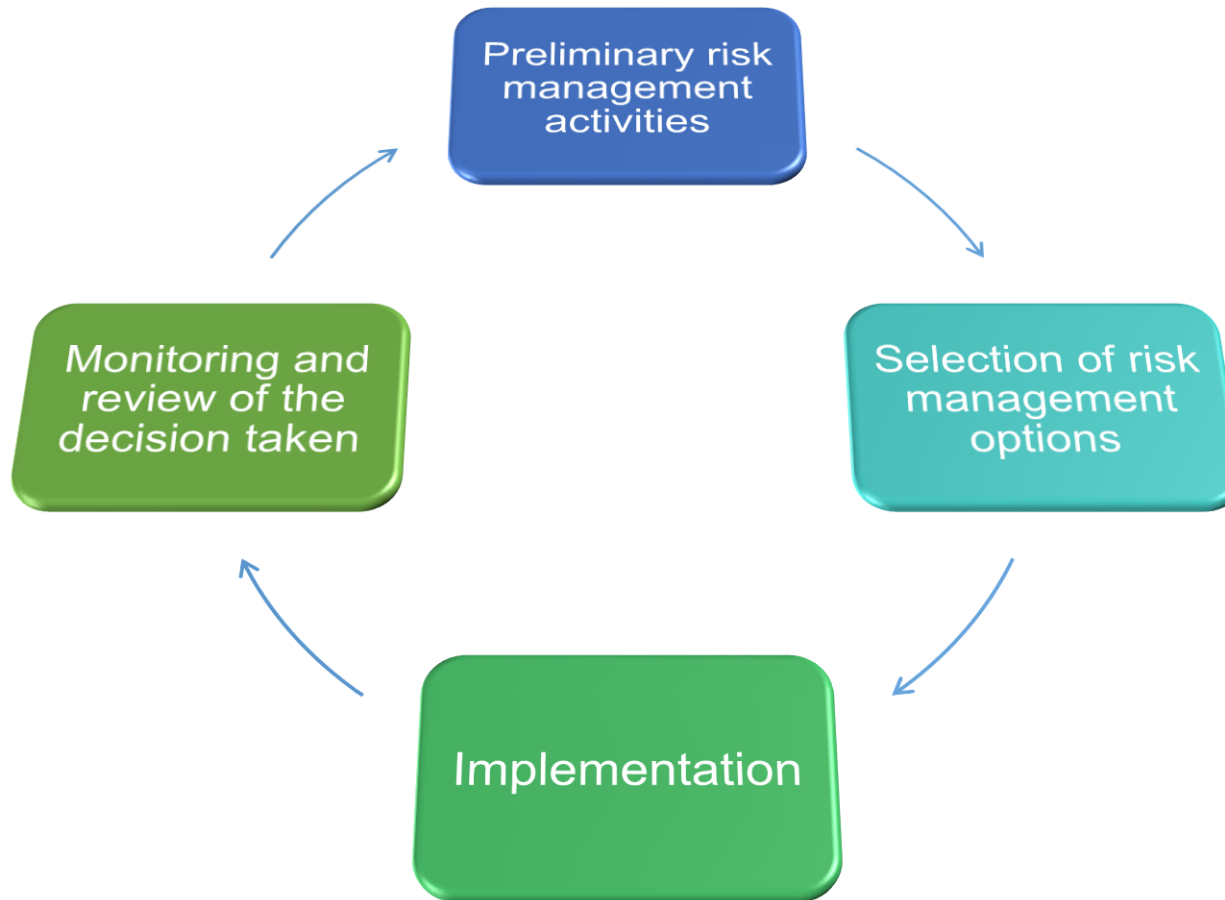


# Risk: definiton

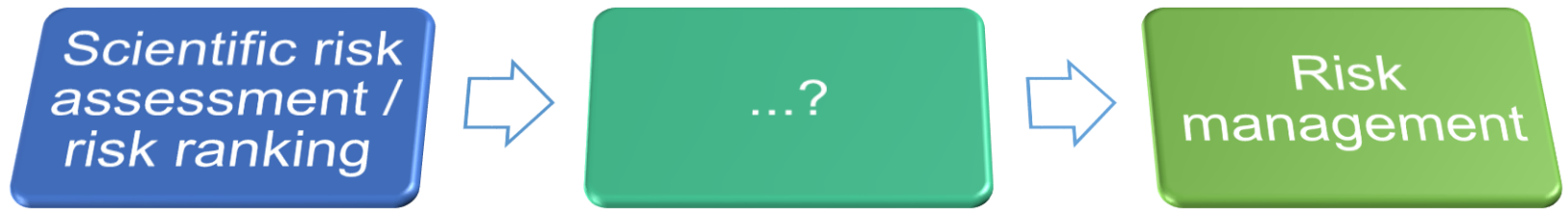
$$\text{Risk} = \text{Hazard} \times \text{Likelihood}$$

- Different risks:
  - 178/2002/EC and 882/2002/EC refers to risk as human health risk
  - economical risk
  - political risk
  - social risk
  - etc.

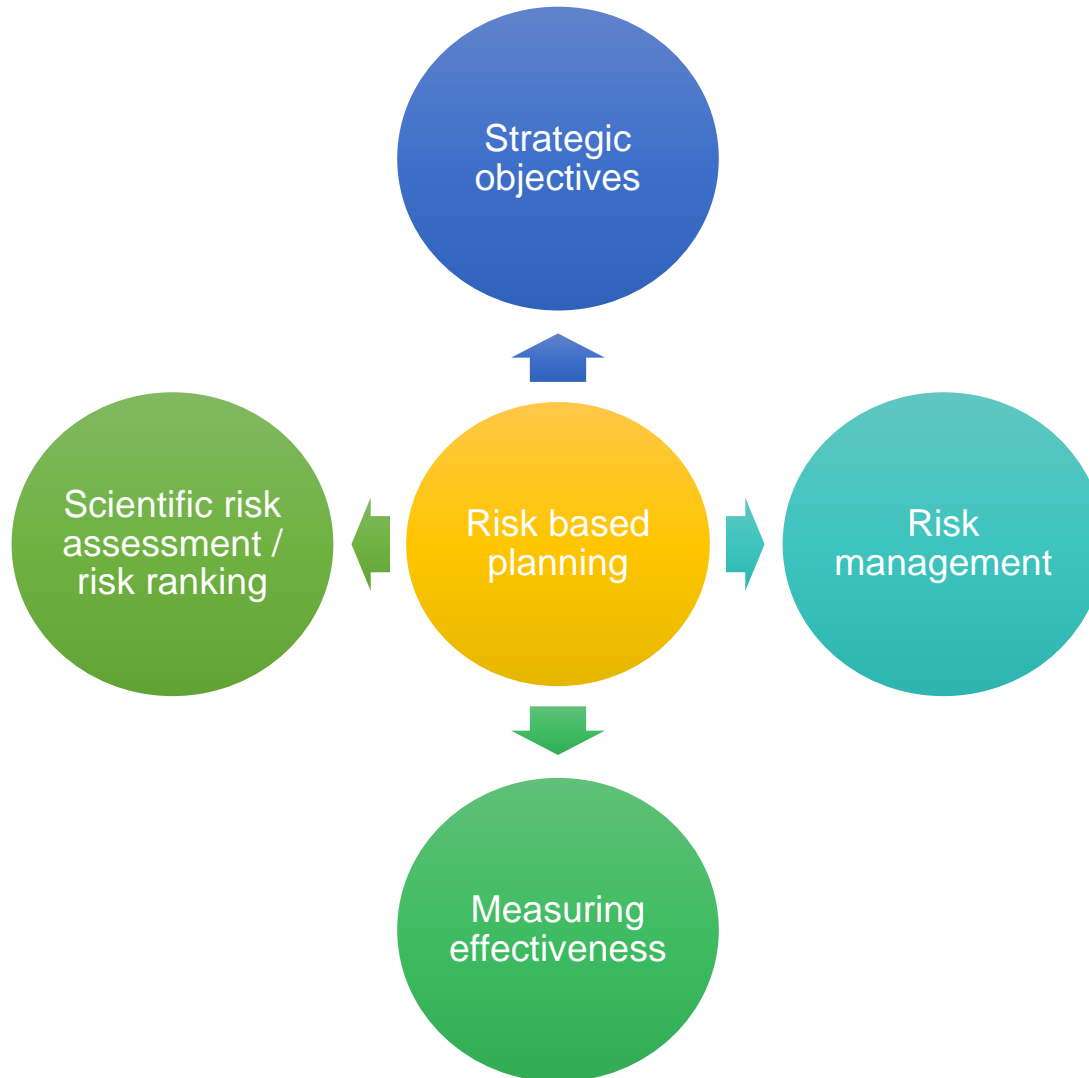
# Risk Management cycle



# Risk based planning



# Risk based planning



# Benefits of a risk based system

- Ensures effective controls with limited resources/staff
  - Resource allocation in areas which indicate high risk and where maximum impact can be expected
- Provides reasonable assurances as to the level of compliance with feed and food law (animal health and welfare, plant health, etc.) and effectiveness of official controls (in other words: safety of food)
- Improves public confidence and justifies the allocation of resources
  - Consumers have a legitimate expectation to have relatively high assurances on high risk areas and get good value for public spending
- Contributes to the management of legislative risk
  - i.e. where legislation is in some respect ineffective, to indicate those deficiencies to the legislative process

# Challenges of a risk based system

- Balance between consumer, political and economical risks
- Need to have sufficient knowledge of activities to be controlled
- Hard to ensure adequate level of controls in low risk FBO/activities
  - Need to keep low risk operations under review to ensure no significant changes missed
- Sensitive relationship between central and local authorities
- Hard to ensure flexibility
  - Determining the frequency of controls (other parameters as well)
  - Adjustment (long term, short term)
  - Suitability for all types of planning at all levels
- Distortion of risk categorisation by media/political/interest group intervention
  - Pressure to relax or to increase control activity on certain sectors or commodities in response to media coverage of issues or lobbying
- Certification requirements are sometimes not compatible with risk-based approach
  - International acceptance of risk-based controls

# Desirable features of a risk-based system

- Not too complex a system nor too costly, in terms of resources
  - It is important that the system/processes are practicable and easily adaptable.
  - They should not detract from the overall aim of MS to perform effective official controls.
- Documented system
  - Evidence of decision-making process
- Relatively easy to understand for all stakeholders
  - especially those involved in risk-based planning and those who must assess these processes.
  - Ensure transparency.
- Continuous improvement process
- Flexible and modular process



# Implementation of a risk based planning system

How to be risk based in practice?

How to connect strategic (public health) objectives with risk management?

# PDCA

- Plan – Do – Check – Act
- Planning: P from the PDCA-cycle
- It is important to emphasise, that the PDCA-cycle is different at different points of planning process
  - (i.e. strategic/multi-annual vs. operative/annual planning).



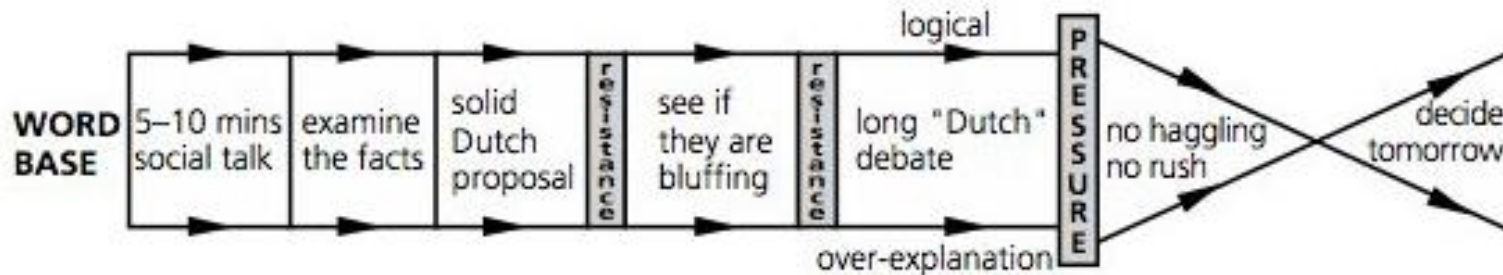


# No 'one size fits all' solution

Different MS approaches co-exist

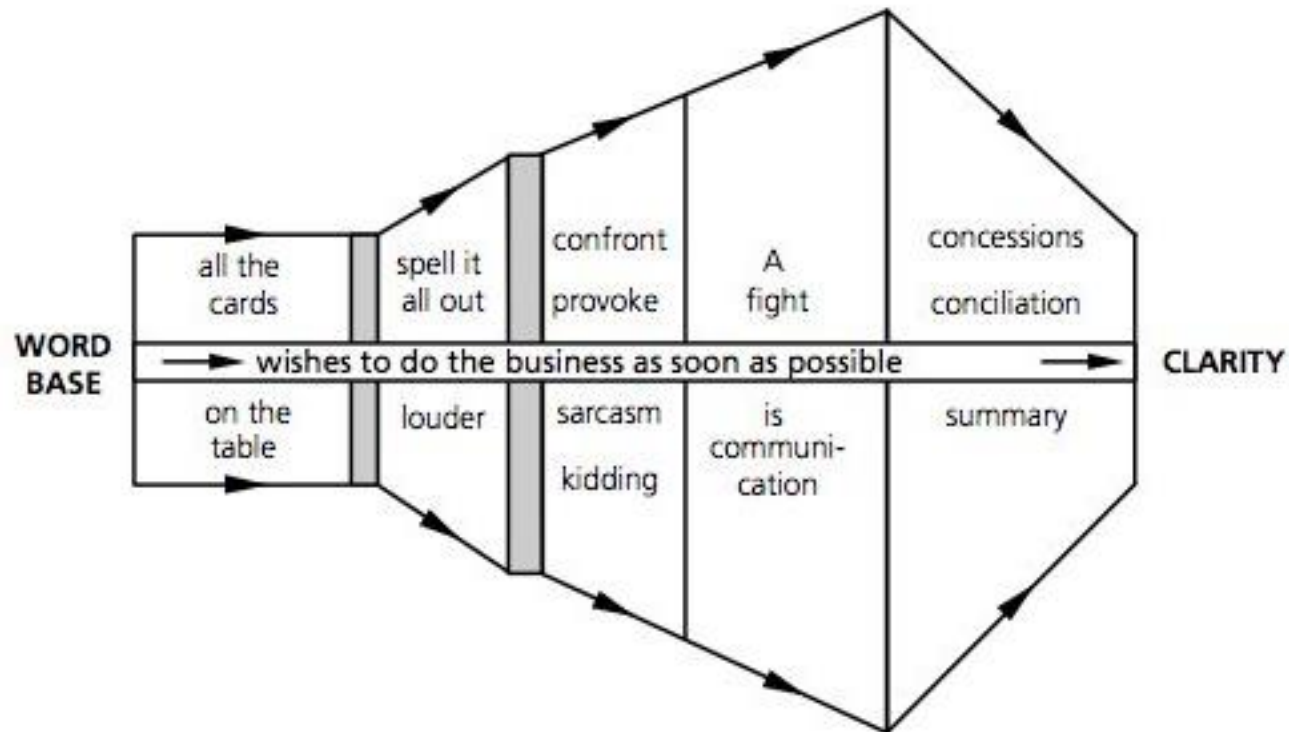
# Communication patterns

## DUTCH



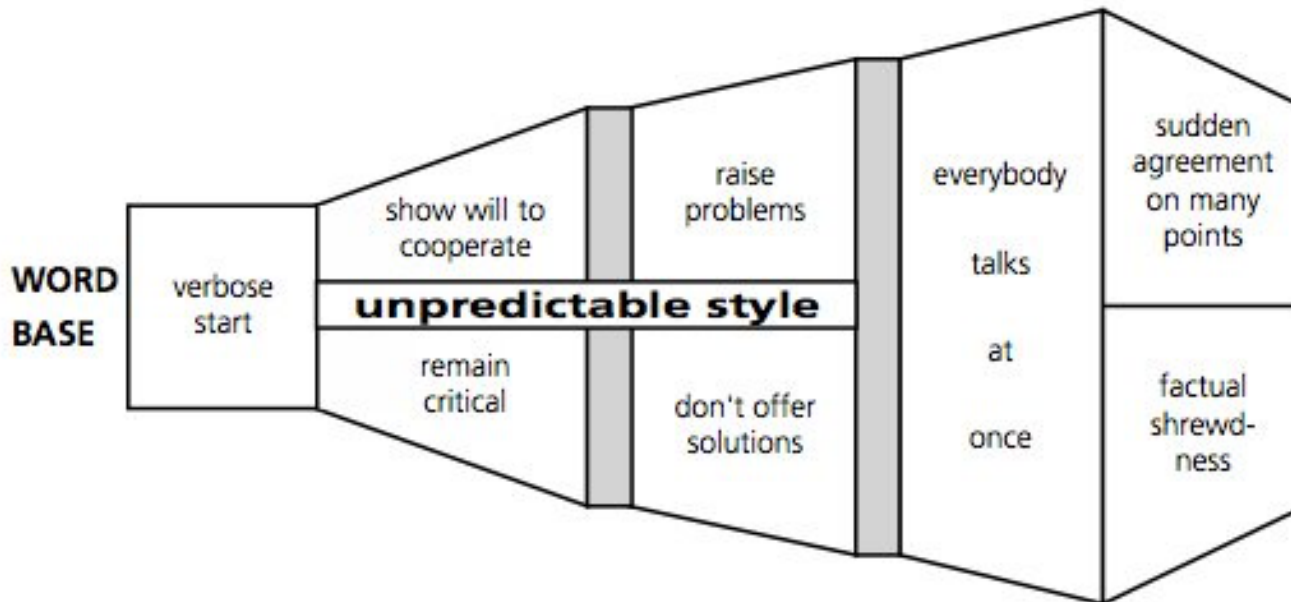
# Communication patterns

## AMERICAN



# Communication patterns

## HUNGARIAN



# Risk based planning

- Single organisation responsible for the whole food chain safety
- The risk based approach helps us in setting priorities between different fields of tasks, and makes possible to maintain a risk based resource allocation.
- During the central and local risk based planning the product control (**sampling plans**) and the process control (establishment **control plans**) is linked, letting an effective data utilisation.
- It is important to emphasise that there is a 2 level risk based planning: central and local.
  - The task of the **central level** is to elaborate, operate and review the planning process, and the supervision of different risk factors, their weighting system and the algorithms behind the process.
  - The task of the **local level** is to optimise controls system performance with expertise and local control knowledge.

# Organizational background

- Coordinating WG
  - delegates from every directorate
- Scientific Panels
  - High risk soils, soil conservation and crop enhancing substances
  - Plant health, seeds and propagating materials
  - Plant protection, pesticides and pesticide-residues
  - Feed safety and quality
  - Animal health and animal welfare
  - Microbiological (biological) hazards
  - GMO
  - Veterinary medicines and their residues
  - Chemical contaminants and FCM
  - Radioisotopes
  - Additives and food quality
  - Data management and reports

# Risk based planning

- The planning starts with risk assessment together with the risk assessors.
- The risk assessment targets matrix (product) - parameter (hazard) pairs.
- The result is a 'risk assessor priority list' (**risk ranking**) with relative risk scores within every hazard group (grouping based on Eurostat description).

# Risk based planning

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- We use 'risk assessor priority list' (risk ranking) as an input for 'risk management priority list', which differs from the previous risk ranking
- Other than health risk factors are considered:
  - political risks
  - economical risks
  - consumer risk perception
  - available risk management tools
  - etc.
- The 'risk management priority list' is used as a core list for product sampling and establishment control planning process

# Objective vs selective strategies

- The risk assessment needs objective (random) data, but for increasing effectiveness and introducing risk based approach, selective (risk based) strategies should be used.

- Objective (random) samplings vs. Selective (risk based) sampling
  - random
  - makes the statistical evaluation possible
  - suitable for risk assessment, trend analysis or comparison between countries
- not random (risk based)
- no statistical evaluation possible
- not suitable for risk assessment or trend analysis or comparison between countries
- more effective in finding non-compliances

# Plans run: High priority projects

- Decreasing risk posed by *Salmonella* spp. in *Gallus gallus* breeding flocks
- Decreasing human health risk posed by *Campylobacter* spp.
- *Trichinella* and *Echinococcus* monitoring program
- Fusarium control plan
- GMO control plan
- Honey fraud control plan
- Monitoring the occurrence and the dynamics of pesticide residues in wine production
- Increasing preparedness posed by radioanalytical hazards
- Control plan of wood packaging materials and monitoring of emerging plant health risks
- Control plan of crop enhancing materials and EC fertilizers

# Plans run: Sampling plans

- Soil protection plan
- Plant health plan
- Plant protection products plan
- Pesticide residues plan
- Fruits and vegetables quality control plan
- Feed plan
- Animal health plans
- Veterinary drug residues plan
- Parasites plan
- Microbiological risks plan
- Antibiotic resistance monitoring plan
- Chemical risks plan
- Food additives plan
- Food Contact Materials plan
- Entomological and mushroom plan
- Cleaning and disinfectant materials plan
- Potable water plan
- Food quality plan
- Geographical indication plan
- Organic products plan
- Fraud plan

# Plans run: PR products tests





# Measuring the effectiveness

Are we doing the right things?

Are we doing the things right?

# Cycle of food safety control



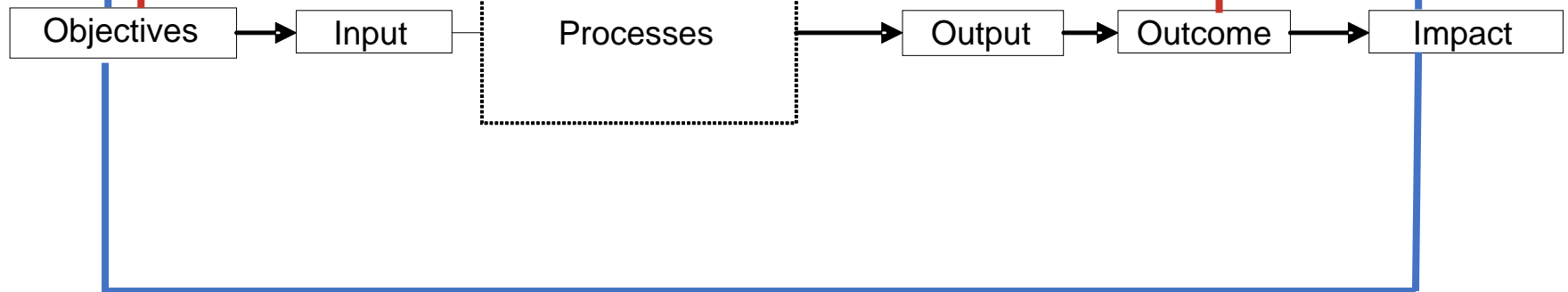
# Input – Process – Output

Environment

Business operators

Competent Authorities

Effectiveness



# How?

- Going back to PDCA
- Measuring at different levels: system of indicators
- Performance indicators
  - reflecting program performance
  - typically inputs, activities, outputs, immediate outcomes and intermediate outcomes
  - over which the authority has some reasonable degree of control
  - and which have a logical connection to the ultimate results
- High level objective indicators
  - typically intermediate and ultimate outcomes
  - measure things over which we have no, or virtually no control
  - however we have to monitor them, because they have profound relevance to the design and the implementation of our program
  - These are the results that we are managing for even if we can't control them.

# How to compare different areas?

- High level (strategic) outcome/impact indicators
- Economic burden of foodborne diseases
- Comparing intervention strategies/tools/programs by their impact on strategic indicators (e.g. QALYs)

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Future

Plans

# Future in sampling plans

- Uniform (modular) model for risk assessment/risk ranking
- Single integrated data system
- IT support for planning process:
  - automatic sample distribution based on several factors (e.g. seasonality in matrices and parameters, production data, changes in available matrices, laboratory capacity, etc.)
  - documented and transparent workflow for planning process
- Exploring sophisticated methods:
  - Data mining
  - Network science
  - Burden of disease
  - MCDA
  - Using companies' data for analysis (?)
- Towards full risk based prioritization and resource allocation

The logo for NEBIH (National Institute for Research and Innovation in Food Safety) is displayed on a dark blue background. The text 'nébih' is written in a lowercase, sans-serif font. The 'n' and 'i' are white, while the 'é' and 'b' are green. The 'é' has a small green dot above it, and the 'i' has a small green dot below it.

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**THANK YOU FOR YOUR ATTENTION!**

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