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1. Introduction

✓ The current business environment
  ✓ Global manufacturing, sourcing of components/materials
  ✓ Short time to market implying lean regulatory system

✓ hence
  ✓ Fast regulatory track requires effective market surveillance
1. Introduction

✓ An effective market surveillance system requires:
  ✓ Optimal assessment techniques
  ✓ Maximizing the use of resources: person-power and budget
  ✓ A harmonized approach for the market procedure
1. Introduction

✓ Most product standards:

✓ Do not provide a sampling scheme

✓ Do not provide a classification of critical features
1. Introduction

✓ Use of ISO 2859-x for market surveillance sampling

✓ ISO 2859-x has been designed for the relation manufacturer-client in a homogenous production lot

✓ Sample sizes are large (especially for safety critical product features)
1. Introduction

- Other statistical techniques for obtaining the size of the sample
  - Sampling procedures based on the binominal distribution
  - Sampling procedures based on Bayesian statistics
1. Introduction

✓ Sampling procedures based on the binominal distribution

✓ Uses “traditional” statistical techniques

✓ In comparison with ISO 2859-1, it is expected to obtain smaller sample sizes, especially for large lots.
1. Introduction

- Sampling procedures based on Bayesian statistics
  - Uses “modern” statistical techniques
  - Takes into account prior knowledge (data from prior inspections)
- It is expected that sampling procedures developed by this approach will be more complicated than the one from ISO 2859-1. Development of special computer software is necessary to make them applicable.
2. AMSUM research proposal

✓ Research question 1

If a heterogeneous mass of products on the market \((x)\) is considered, and if a limited sampling plan is used, how sure are we that these MS actions are appropriate?

Possible deliverables:
- Studying \(x\) as a function of independent random variables
- Definition of the type of distribution for \(x\)
- Characteristics of the distribution (mean, standard deviation, ...)
- Probability curves
2. AMSUM research proposal

✓ Research question 2

Considering the same distribution as described in research question 1, how can we integrate into the model:

- Classification of critical product features
- Measurement uncertainty
- Sampling schemes
- Visibility and its effect on MS effectiveness

the above supported by appropriate risk assessment

Possible deliverables:

– Numeric model: possible to simulate what-if scenarios (cost of MS actions)
2. AMSUM research proposal

☐ Objectives

- To analyse existing non-food MS systems at regional and international level and to provide a basic specification for a new numeric MS model (AMSUM)
- To develop this new model based on the outputs of above
- To validate this model for selected MS cases.
2. AMSUM research proposal

✓ Basic model

- To develop a numeric MS model integrating critical product features with measurement uncertainty, sampling schemes, supported by risk assessment.
2. AMSUM research proposal

✓ Basic model

- **Total relevant products on market**
  - Delay (e.g. 1 year)
  - Test plan 1
  - Sampling 1
  - PR Amplifying effects
- **Test plan 2**
  - Sampling 2
  - PR Amplifying effects

**TL**: applicable Technical Legislation(s)
**St**: applicable product standard(s)
**RA**: Risk Assessment
**n**: number of products on market
**PF**: Important Product Features to be assessed
**MU**: Measurements uncertainties related to the testing

**MS effectiveness** = \( \frac{\%\ non\-complying\ MS\ action\ 1}{\%\ non\-complying\ MS\ action\ 2} \)
2. AMSUM research proposal

✓ Outline of the project

1. User requirements
2. Development of the advanced MS model
3. Dissemination
2. AMSUM research proposal

✓ Consortium partners

- Market Surveillance Authorities (MSAs)
- Technical Regulations Authorities (TRAs)
- Economic Operators (EOs)
- Conformity Assessment Bodies (CABs)
- Scientific/academic institutes (ACs)
- Standardization & Accreditation Bodies (SABs)

The direct users of the results of this project are the MSAs
2. AMSUM research proposal

9 workpackages

0 Project management
1 User Requirements
2 Analysing/classifying of essential requirements among non-food technical regulations
3 Interrelation between classified ERs and existing product standards and other requirements
4 Study of existing risk assessment methods related to classified ERs
5 Measurement uncertainty to be used in selected priority sectors
6 Existing and new statistical methods in technical regulations/standards/MS procedures
7 Existing and new MS models; development of a new, integrated MS model using above defined parameters
8 Dissemination
2. AMSUM research proposal

✓ Role of WP6 in this project

- User requirements:
  Input of UNECE members to the needs of MS systems

- Dissemination
  Results of the project to be used as training for national/regional administrations
2. AMSUM research proposal

✓ Resources, budget and duration

- resources
  - person-power: 81 months

- budget
  - person-power: 800,000 EUR
  - other: 200,000 EUR

- duration
  - 36 months
THANK YOU

СПАСИБО