UNECE WP6 panel session

Advanced Market SUrveillance Model

project proposal

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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)**
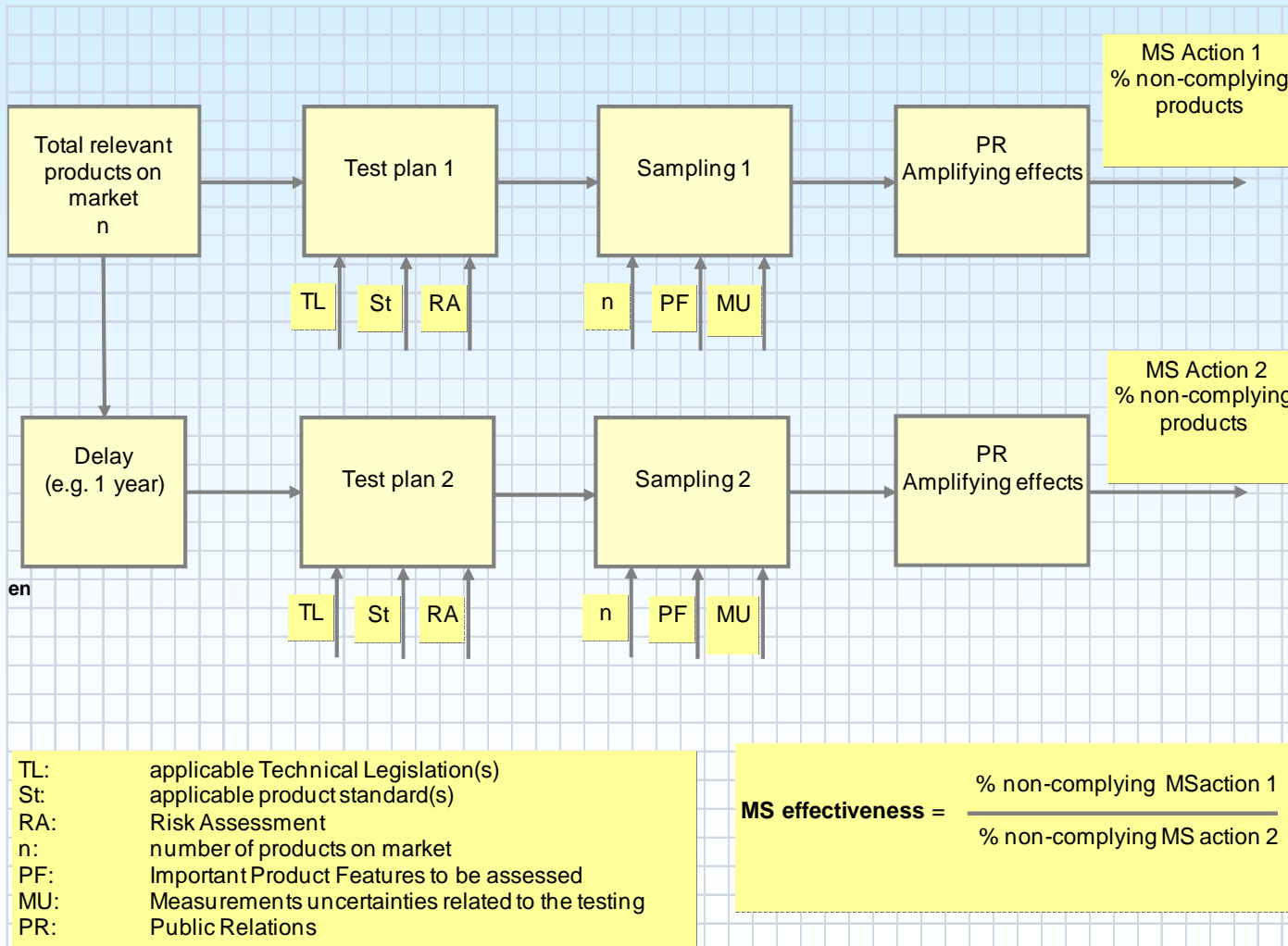
2. AMSUM research proposal

- ✓ **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**

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
PR: Public Relations

$$\text{MS effectiveness} = \frac{\% \text{ non-complying MSaction 1}}{\% \text{ non-complying MS action 2}}$$

2. AMSUM research proposal

✓ **Outline of the project**

1. **User requirements**
2. **Development of the advanced MS model**
3. **Dissemination**

2. AMSUM research proposal

✓ **Consortum 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