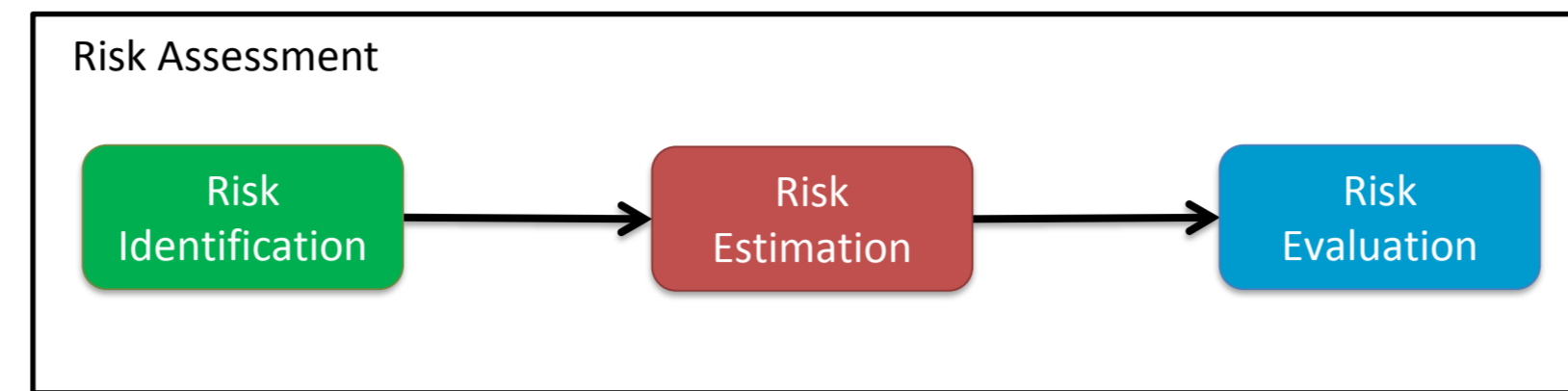


# Exemplary data-based metrological support service: Risk Assessment

## Motivation

- MID requires risk assessment to be part of the documentation submitted for modules B, H1 etc.
- Investigated method has been adopted by WELMEC WG7
- Approach uses structure of ISO/IEC 27005 for the analysis
- Methods from ISO/IEC 15408 and 18045 employed to provide reproducible numerical risk scores.

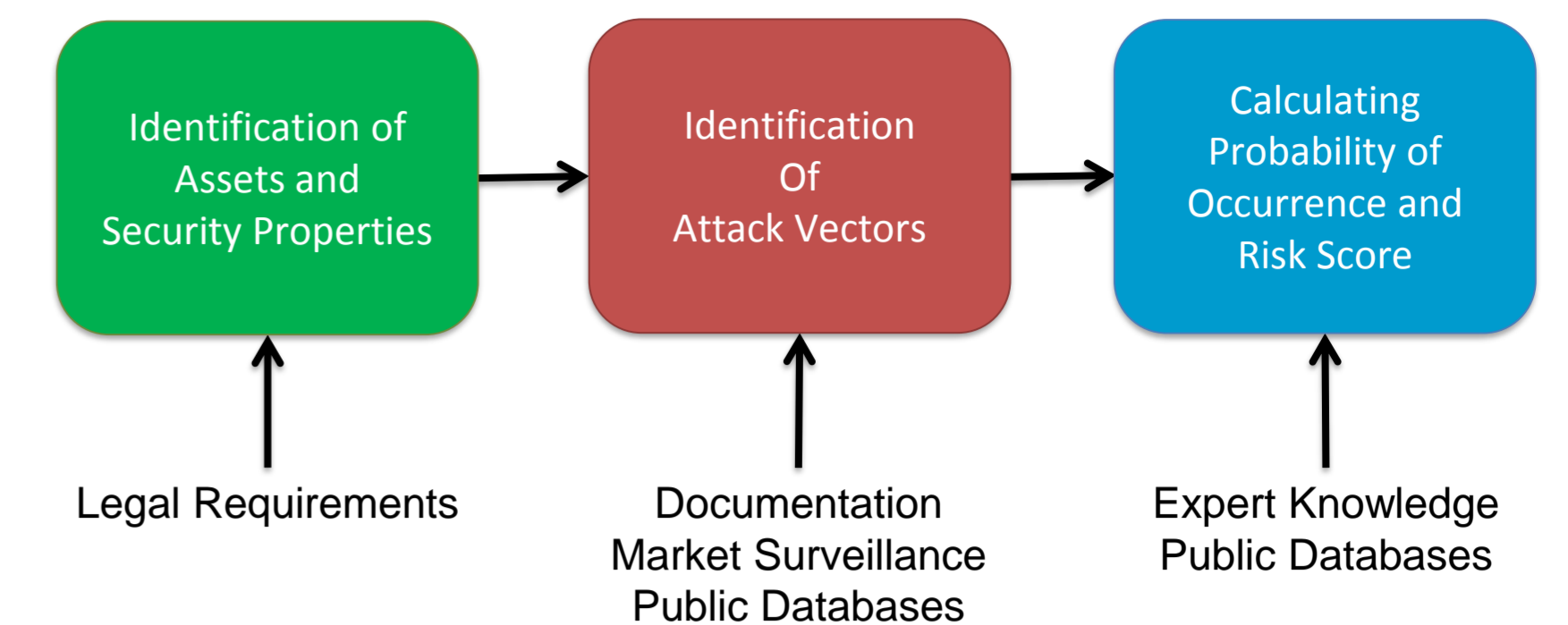
## Procedure according to ISO/IEC 27005



Components needed to calculate risk:

- list of unwanted events (**threats to assets**)
- consequences resulting from such events (**impact/hazard/consequence**)
- Probability of occurrence (**probability/likelihood**)

## Current Risk Assessment Workflow



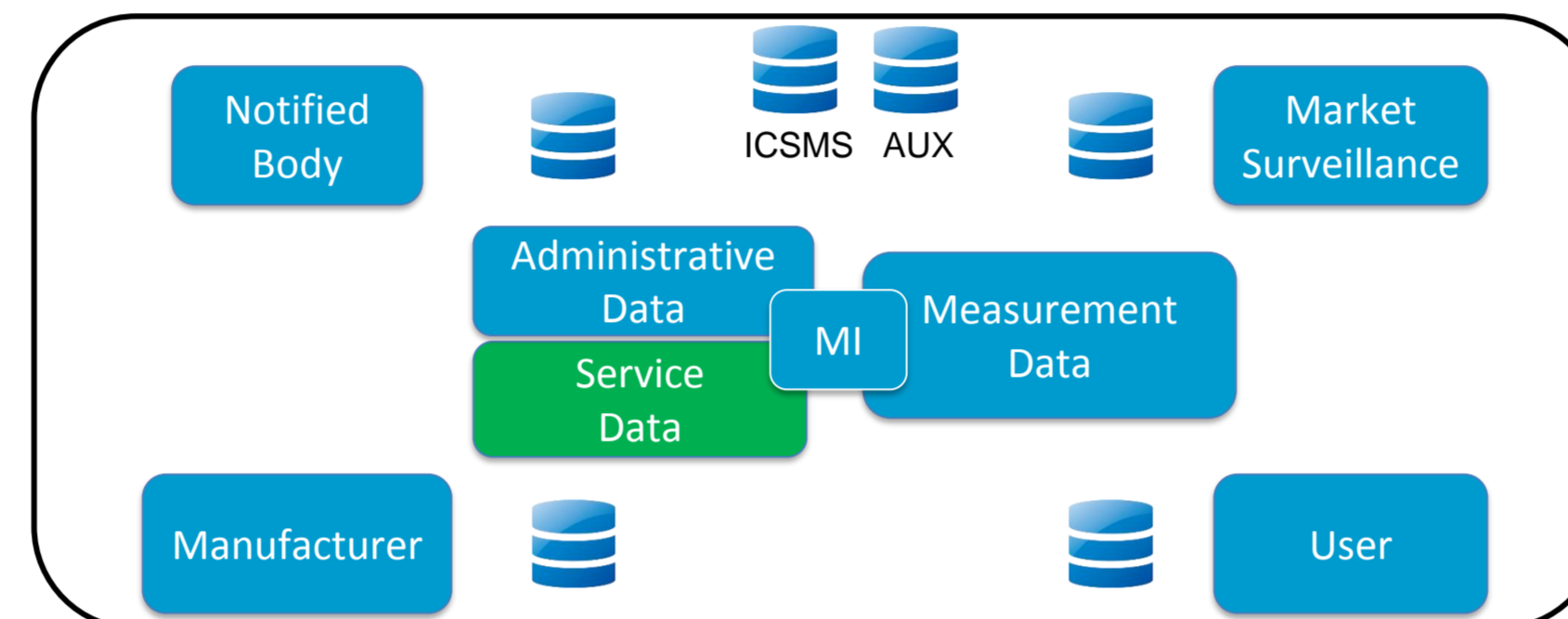
- Risk assessment is performed by the manufacturer.
- Results are evaluated by Module B Notified Body.

## Challenges and Opportunities

### Limits of the Current Method

- No objective way to reflect attacker motivation
- No link between probability of occurrence and incident information from the field
- Accuracy depends on the evaluator's skill and knowledge about the measuring instrument.
- Parties involved consider the calculated risk a theoretical value
- **Possible solution: inclusion of incident information**

### Possible Sources of Information



- Number and location of instruments in use
- Information on realized threats
- Evaluation and corrective actions determined by MSA

### Validation by Means of a Ring Comparison

- Show that the WG7 provides reproducible objective scores
- Abstract measuring instruments to be used as a benchmark
- By circulating abstract instruments among Notified Bodies, risk assessment results could be compared objectively.
- **Deviations among assessment results will be used to further improve and correct the used method.**

### Manufacturers:

- ✓ Easier to convince Notified Bodies
- ✓ Suggestions for new attack vectors can be formed based on incidents from other instruments.

### Market Surveillance:

- ✓ Module B acts as risk-based hurdle to market access.
- ✓ Assessment results mirror MSA database entries.

### Notified Bodies:

- ✓ Easy validation of submitted risk assessments
- ✓ Up-to-date information on state of the art

## Tasks and Activities

### Task 4.1: EU ring comparison

- Activity 1: Practical training on the risk assessment method
- Activity 2: Revision of available abstract devices
- Activity 3: Assessment of abstract instruments By different Notified Bodies
- Activity 4: Collection of results and evaluation

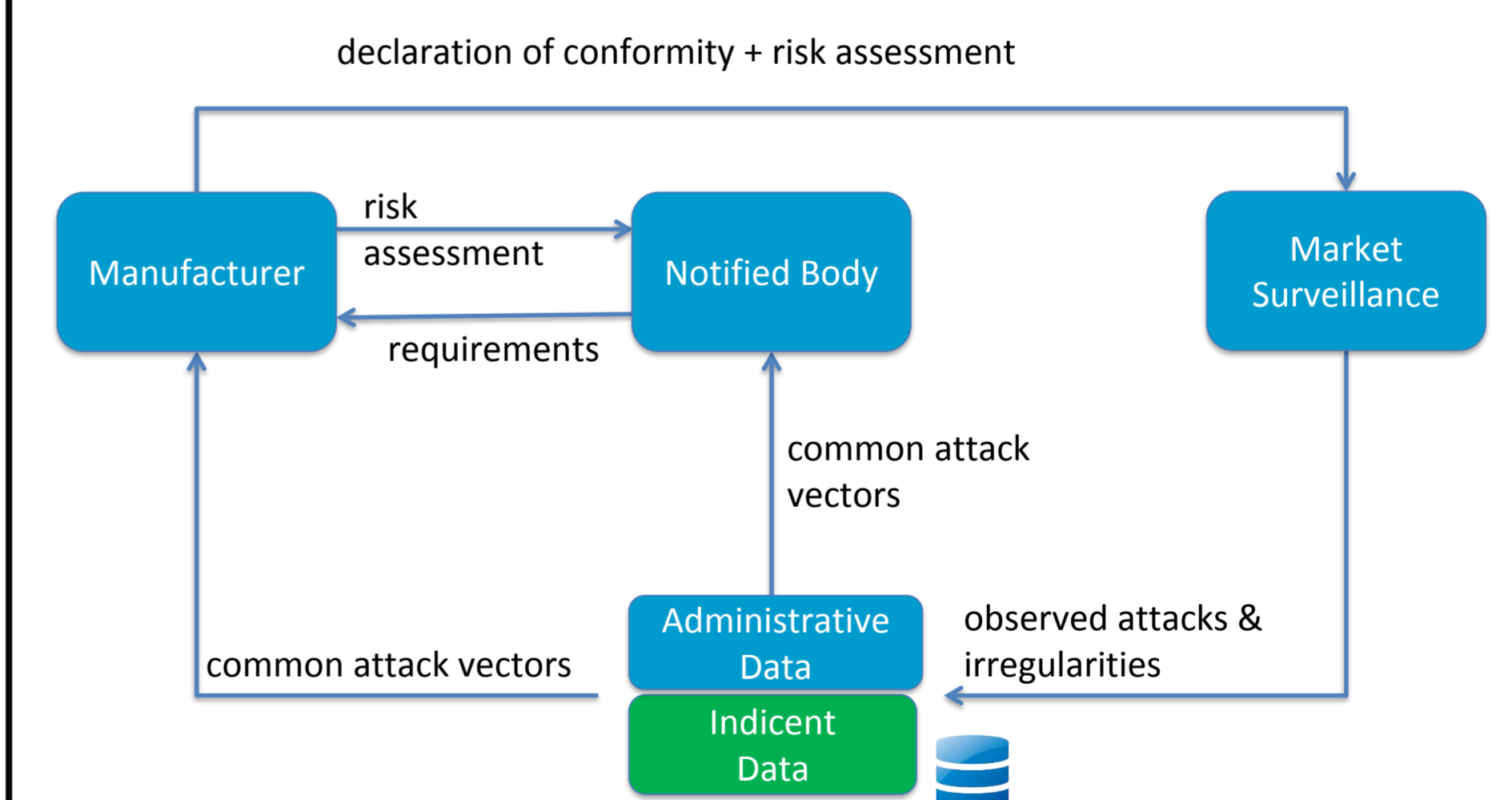
### Task 4.2: Closing the risk assessment loop

- Activity 1: Survey of strategies for including empirical data in risk assessment
- Activity 2: Survey of existing incident databases
- Activity 3: Draft concept of the feedback loop
- Activity 4: Practical Tests

### Target Results

- Validate risk assessment method
- Extend current method with incident information
- Improve acceptance of risk assessment results
- Faster digital workflow for all parties involved

### Target Workflow



### Links to other Work Packages

WP1: Trustworthy Metrological Core Platform

WP2: Reference Architecture

WP3: Technology based Metrological Support Services

WP4: Data based Metrological Support Services

- Trustworthy core platform provides access to existing databases.
- Digital representation acts as data template for incident information.