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Issue 1

WELMEC

European cooperation in legal metrology

Risk Assessment Guide for Market Surveillance: Weigh and Measuring Instruments



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WELMEC

European cooperation in legal metrology

WELMEC is a co-operation between the legal metrology authorities of the Member States of the European Union and EFTA. This document is one of a number of Guides published by WELMEC to provide guidance to manufacturers of measuring instruments and to Notified Bodies responsible for conformity assessment of their products. The Guides are purely advisory and do not themselves impose any restrictions or additional technical requirements beyond those contained in relevant EC Directives. Alternative approaches may be acceptable, but the guidance provided in this document represents the considered view of WELMEC as to the best practice to be followed.

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1 Introduction

The focus of this document is on the risk assessment of weighing and measuring instruments in the context of market surveillance, this is targeted at the point or close to the point instruments are put into the market.

The rationale behind this document is the need for more selective market surveillance, as a result of the increasingly limited resources of the WELMEC Member States. Another reason for such a document is the requirement in *Art. 19, 1 of REGULATION (EC) No 765/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93*. This article runs as follows:

“Market surveillance authorities shall perform appropriate checks on the characteristics of products on an adequate scale, means of documentary checks and, where appropriate, physical and laboratory checks on the basis of adequate samples. When doing so they shall take account of established principles of risk assessment, complaints and other information.”

Risk assessment directly related to weighing and measuring instruments, is one part of market surveillance; this is to understand the impact the instrument will have on the end user/consumer. The other part is using risk assessment as tool for the market surveillance authority to define priorities and to determine the choice of strategies to achieve their goals.

The way market surveillance is performed as with conducting a risk assessment is heavily influenced by a set of underlying assumptions and philosophies about its position, its role and the functions it performs in Member States.

To prevent duplication with “Best practice techniques in market surveillance” published by Prosafe, principles have been used when writing this document but it is not a direct copy.

The following chapters are dedicated to:

- What is risk assessment for weighing and measuring instruments?
- Definition of essential terms
- When starting a risk assessment
- Risk assessment process

2 What is risk assessment for weighing and measuring instruments?

Risk assessment with respect to Market Surveillance activities is concerned with the likelihood that a piece of weighing and measuring equipment maybe incorrectly placed on the market as a result of a failure to meet the essential requirements of the MID and NAWI Directives; and the effect that a non-compliance has on the end user.

If the authority finds non-conformity in an instrument, then the authority may wish to use the methods from this guide to conduct their own risk assessment to decide on the risk level associated with the specific non-conformity. However non-conformity does not necessarily imply a high level risk is posed.

Example

The CE-marking on a measuring instrument is 3 mm high. The NAWI Directive requires a minimum height of 5 mm. Therefore the product does not comply with the Directive and it must not be placed on the market. However, the authority may, on the basis of a risk assessment, decide that minimal corrective action is necessary as the effect on the consumer protection is small.

3 Definition of essential terms

In order to be sure that different organisations and Member States understand each other's risk assessment, all parties should use the same terminology with the same definitions. For this document risk is defined as the probability something may occur versus its impact.

The following definitions are assumed:

Risk = Probability x Impact

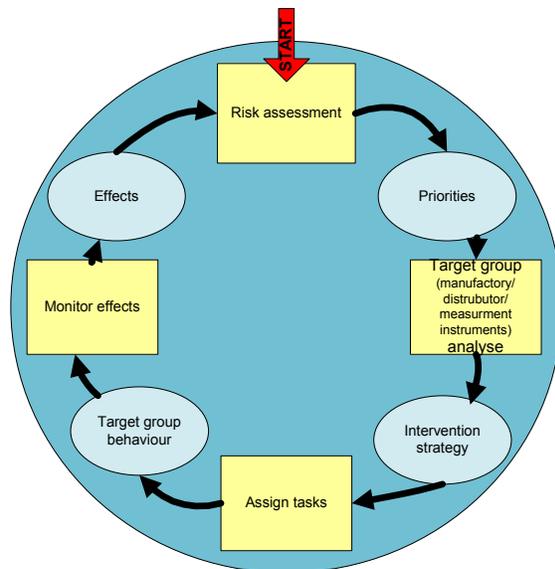
Risk:	Combination of the probability of unwanted occurrence and the severity of that unwanted occurrence.
Probability:	Degree to which the unwanted occurrence has happened.
Impact:	Impact of the unwanted occurrence on the legal interest.
Legal interest:	Protection of the consumer, fair play for the manufacturer, confidence in the CE mark indirect confidence of the consumer, producer (manufacturer of the product, the manufacturer's representative, the importer into the EU or other professionals in the supply chain whose activities may select the safety properties of the product).
Tolerable risk:	Risk, which is accepted in a given context, based on the current values of society. In general the level of risks that society accepts is determined amongst others by culture, risk perception and technical development.

4 When starting risk assessment?

4.1 Risk assessment as part of plan do check

Risk assessment can be seen as a starting point of the plan, do, check, and act cycle.

Diagram 1. Risk assessment as starting point of plan, do, check, act cycle



Risk assessment is of importance to provide insight into the degree to which the desired policy effects run the risk of not being realised. How great is the chance that the desired behaviours will not occur and what is the effect of that on the realisation of the policy objectives and the interests that are to be protected?

With consideration for the limited available capacity for market surveillance, it is good to know which behaviours by which target groups pose the greatest risks and therefore should have priority for market surveillance. In the market surveillance programme, the initial focus is on the issues that have the highest priority, and the risk analysis serves to establish this focus. In annex 1 there is given some questions to analyse the behaviour of the target group.

Substantiating the market surveillance choices and providing transparency in this regard is of importance both internally and externally. It is important internally in order to deploy the enforcement capacity in an effective, targeted manner to combat the behaviours associated with the highest risk, and externally in order to provide transparency concerning what can be expected of the government in terms of market surveillance efforts. In addition, clarity is obtained concerning that intended policy effects are or are not likely to be achieved.

You analyse, assess and prioritise risks relating to (compliance) behaviour. In doing so, you examine the behaviours of target groups (Instruments or companies/manufacturers/distributors). You estimate the chance that that behaviour is not in accordance with the behaviour desired by the government or European Commission and the impact thereof on the legal interests.

4.2 Risk assessment for priority setting

Market surveillance authorities must make a choice on where to allocate their resources to obtain maximum results. This prioritisation is necessary, because the available resources cannot cover every product and all parts of the market at the same time. Therefore one part of the planning process involves choosing areas of priority and where the share of resources will be spent.

The main objective of (market) surveillance in Europe is consumer protection and ascertaining fair and free circulation of goods in the common market. For most of the (market) surveillance authorities in Europe, consumer protection is a more important objective and priorities are chosen with this in mind.

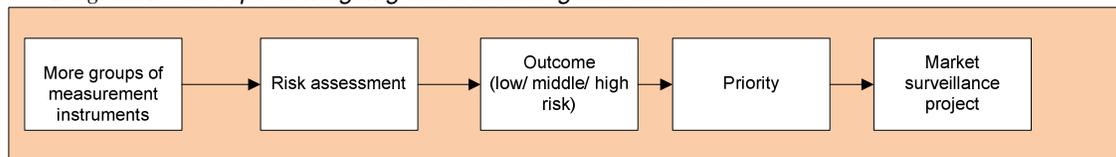
There are good reasons for this. All activities performed to promote fair trade by the use of legal measuring instrument by market surveillance automatically contribute to establishing the 'level playing field' and fair competition. Nevertheless, it should be kept in mind that a level playing field for business competition is also an important corner stone for the proper functioning of the internal market and therefore deserves due attention.

Risk assessment for setting priorities between:

- Manufacturers/suppliers of measuring instruments
- Specific types of Weighing and Measuring instruments

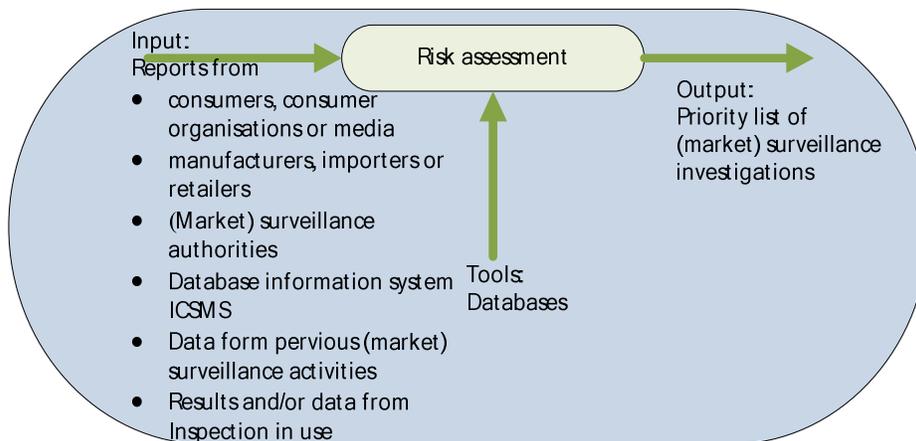
The diagram below demonstrates the process.

Diagram 1. Groups of weighing and measuring instruments



The diagram below summarizes the input, tools and output of a risk assessment process:

Diagram 2. Risk assessment for setting priorities between manufacturers/suppliers of measuring instruments or specific measuring instruments



4.3 The target group: manufacturers/suppliers of measuring instruments

The results of a risk analysis gives a list of priorities that the market surveillance authority might use to analyse the target group who are bringing the instruments into the marketplace or who are using the instruments in the marketplace and find out which intervention strategy would be most effective for the specific measurement instrument or target group.

The material collected during the preparation phase concerning the policy objectives, interests that are to be protected, target groups and compliance levels can serve as input. In this manner, with an eye towards the (most relevant) legal interests and/or intended policy effects, you arrive at behaviours of certain target groups (or subgroups) that require enforcement priority, that is to say, those that should be the primary focus of the intervention strategy within your enforcement policy. To know what the behaviours of the target group in Annex I will support you in this process.

For setting priorities between weighing and measuring instruments this might be done by dividing resources over the variety of product categories covered by the authority (e.g. which category deserves the most attention: non automatic weighing instruments (NAWI), electricity meters or water meters and how much resource should be allocated to the priorities).

Having made these choices for the top-level categories, similar decisions might be taken for the sub-categories (e.g. is consumer protection best served with the surveillance of NAWI class II or NAWI class III). Further in detail: who are the manufacturers/suppliers who are putting the instrument in the market? What is their behavior? (See also the questions in Annex I)

The process is complicated by numerous constraints such as available human resources, technical capacities and funding. In practice, the number of different kinds of instruments or surveillance to be made, each requiring different planning and/or test programs and therefore differing in the resources need, is so high that this is impracticable. Ultimately, these choices result in a surveillance program. The surveillance program preferably contributes maximally to consumer protection and fair competition.

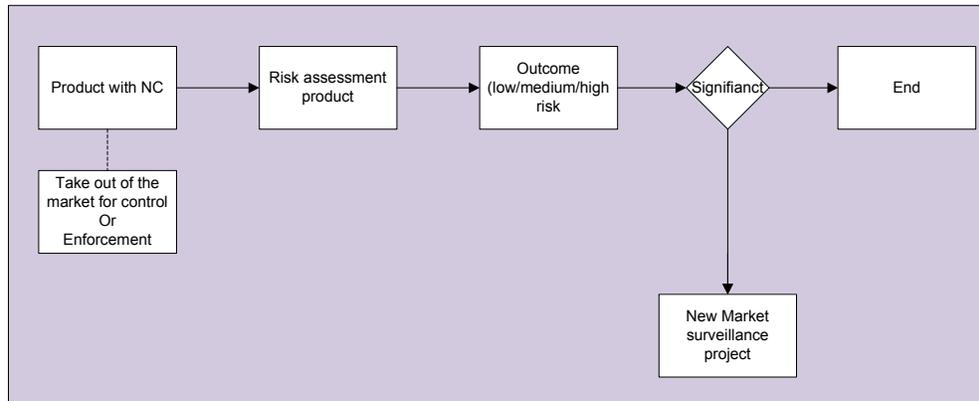
- One characteristic of all measurement instruments
- One group of measurement instruments
- More groups of measurement instruments

4.4 Part of investigations on one measuring instrument

Risk assessment also may be started after Non Conformity has been found in relation to one specific product. Based on the outcome of the risk assessment a decision about the appropriate action will be taken.

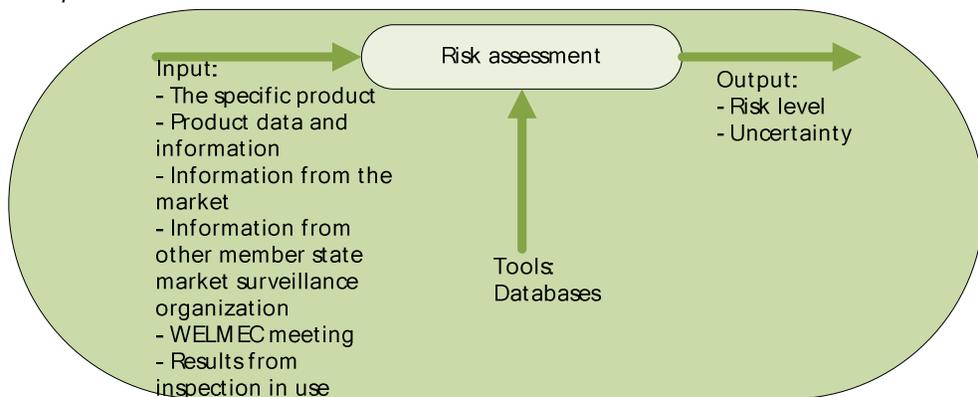
The diagram below demonstrates what action might be taken.

Diagram 3. Flowchart NC



The diagram below summarises the input, tools and output of a risk assessment process:

Diagram 4. One product



5 Risk assessment process

The focus of this chapter is on the risk assessment process to set priorities for market surveillance activity or to determine the risk of specific weighing or measuring instruments. Risk assessment always focuses on three basic questions:

- 1) What can go wrong?
- 2) If it does happen what are the consequences? (Impact)
- 3) How likely is this to happen? (Probability)

When establishing the risk the same steps can be taken to set priorities for market surveillance activity or to determine the risk of specific weighing or measuring instrument. In the matrix below there are given numbers, which correspond with the steps to be taken.

Tabel 1. *The risk matrix*

	Legal interest (2)	Legal interest (2)	Legal interest (2)	Average Impact (4) e.g. = (2)+(2)+(2)/3	Probability (5)	Risk (6)
Groups (1)	Score 1-5 Impact (3)	Score 1-5 Impact (3)	Score 1-5 Impact (3)	E.g. average score is 2 Score 1-5	Score 1-5	Total Impact (4) X (multiply) Probability (5) Score 1-25

The numbers in brackets () will be explained in greater detail below, they are used to provide examples of each step of the process in the matrix above.

Steps to be taken (number in the matrix correspondent with the numbers below)

Step (1) Groups: decide the area of focus

A stock of

- Behaviour of manufacturer/suppliers of measuring instruments
- One characteristic of different type of measuring instruments
- One type of measuring instrument
- One group of measuring instruments
- More groups of measuring instruments
- One type of measuring instrument used in different fields

Step (2): Legal interest

If the risk is based on the effect and the chance of non-compliance, we need to establish a pretext to be able to estimate the effect. That effect can take many forms. Non-compliance can for instance lead to financial losses. The following categories of legal interests for the horizontal axis of the matrix might be:

- Economic implications
- Public health
- Consumer confidence
- Legal issues
- This section can be tailored to meet the need of specific member states

Step (3): Assessment of impact

An estimate of the impact (effect) of non-compliance for each legal interest against the area of focus.

Tabel 2. *Level of Impact*

Level of Impact	Score
Minimal	1
Limited	2
Moderate	3
Increased	4
Significant	5

In practice it is not always clear which legal interest is impacted by non-compliance or how great the impact is. Often the effect is an indirect result of non-compliance. The impact estimate is based on the maximum plausible impact – the maximum effect that the non-compliance incident can have in a realistic scenario.

Step (4): Average impact

Summarise all the impacts and determine the average impact score i.e. $(3+5+2)/3$. The Average Impact will be then multiplied by the probability to ascertain the risk score.

Step (5): Assess the probability of non-compliance

Next you estimate the probability of non-compliance behaviour. This concerns the chance that a rule will be violated or how often a violation has or will occur. Issues to consider for probability include, but are not limited to: known factors, historical data and statistics from other market authorities, stakeholders, etc.

Questions might be asked:

- How many times does it occur that a measuring instrument doesn't fulfil this requirement as mentioned under group?
- How many times the manufacturer doesn't fulfil the requirements not only for this instrument but also for the whole range of products?
- Does the manufacturer/supplier have a quality system?
- Does the manufacturer/supplier have a large or small market share?
- Is the measuring instrument a mass produce or individually assembled and checked?
- Is it easy to check the instrument during inspection?
- Is there any motivation to change a critical aspect of the measurement instrument?
- Is there any possibility or tradition for the end-user to check the measurement instrument?
- Etc.

Tabel 3. *Level of Probability*

Level of Probability	Score
Very unlikely: Highly improbable that it will occur during duration or the lifetime of the project or activity	1
Unlikely: Not probably that it will occur during duration or the lifetime of the project or activity	2
Possible: Doubtful that it will occur during duration or the lifetime of the project or activity	3
Likely: Probably that it will occur during duration or the lifetime of the project or activity	4
Very likely: High expectation that it will occur during duration or the lifetime of the project or activity	5

Step (6): Risk

The matrix calculates the risk by multiplying the total impact by the probability. This provides insight into the risk as a number that can then be plotted on the risk diagram below.

Diagram 5. Risk diagram



6 Beyond the risk assessment

The final risk score can be further evolved to provide an overall score by taking into account the perceptions e.g. political impact (image), media effect and the cost to address the risk. Sometimes there is a low risk however other perceptions/factors can elevate the group to action. The risk matrix mentioned before could be extended with the criteria: perception and costs, as shown below in the multi criteria analyses matrix.

Tabel 4. *The multi criteria analyses*

	Impact				Probability (5)	Risk (6)	Criteria			Final Score (10)
	Legal interest (2)	Legal interest (2)	Legal interest (2)	Total Impact (4) = (2)+(2)+(2)/3			Risk conversion (7)	Perception (8)	Cost (9)	
Groups (1)	Impact (3) Score 1-5	Score 1-5	Score 1-5	Score 1-5	Score 1-5	Total Impact (4) X (multiply) Probability (5)	Score 1 - 5	Score 1-5	Score 1-5	=(7)+(8)+(9)

Step (7) Risk conversion score

Once the final risk score has been decided the score can then be converted and used forward to overall score.

Tabel 1. *Risk Conversion*

Risk (6)	Conversion
1-5	1
6-10	2
11-15	3
16-20	4
21-25	5

Step (8): Perception

The risk acceptance matrix provides an estimate of the priority given by society to the risks associated with the products. Risk acceptance comprised:

- Political and media attention regarding the product category
- Risk perception of the public with respect to the product
- Frequency of consumer complaints

Tabel 2. *Level of perception*

Level of Perception	Score
Minimal	1
Limited	2
Moderate	3
Increased	4
High	5

Step (9): Cost

The costs are also important when deciding your priorities and they can be defined into the following:

- Presence of useful legal and standard requirements
- Observance level (from historical data)
- Resources required to address the risk

Tabel 3. *Level of cost*

Level of Cost	Score
Minimal	5
Limited	4
Moderate	3
Increased	2
High	1

Step (10): Final score

The final score comprises of adding together the risk conversion score, the level of perception and the level of cost the maximum score is 15. This might be divided in low up to high score to take action.

Tabel 4. *Level of Final score for prioritising*

Level of final score	Score
Minimal	0-5
Moderate	6-10
High	11-15

The results will allow for the products to be categorized and actioned dependant on the Overall risk however if a product already has a high-risk score then the extra steps may not be necessary or needed to be used.

7 Example

Step (1): Groups

A stock of manufacturers and suppliers of class III NAWI for the consumer market. Eexample question for each manufacturer/supplier: Is the measuring instruments in accordance with the TAC?

Groups
The manufacturer/suppliers of NAWI class III for the consumer market with the focus on the measuring instrument are in accordance with TAC

Step (2): Legal interest

For market surveillance on measuring instruments and in this example the following legal interest has been taken into account:

- Economic implications
- Consumer confidence

Groups	Economic	Consumer confidence
The manufacturer/suppliers of class III NAWI for the consumer market with the focus on the measuring instrument are in accordance with TAC		

Step (3): Assessment of impact

The impact for each question for each manufacture has to be determined.

Groups	Impact	
	Economic	Consumer confidence
The manufactory/suppliers of NAWI class III for the consumer market with the focus on the measuring instrument are in accordance with TAC	2	4

Step (4): Average impact

Summarise all the impacts. The total Impact will be multiplied by the probability to get the risk.

Group	Impact		
	Economic	Consumer confidence	Average Impact
The manufacturer/suppliers of class III NAWI for the consumer market with the focus on the measuring instrument are in accordance with TAC	2	4	$(2+4)/2=3$

Step (5): Assess the probability of non-compliance

Next you estimate the probability of non-compliance behaviour.

Group	Impact			Probability
	Economic	Consumer confidence	Average Impact	
The manufacturer/suppliers of class III NAWI or the consumer market with the focus on the measuring instrument are in accordance with TAC	2	4	$(2+4)/2=3$	4

Step (6): Risk

The outcome of step 4 Impact is 3 and for step 5 it is 4 (x). The risk is the impact times the probability is 12.

Group	Impact			Probability	Risk
	Economic	Consumer confidence	Average Impact		
The manufacturer/suppliers of class III NAWI for the consumer market with the focus on the measuring instrument are in accordance with TAC	2	4	$(2+4)/2=3$	4	$3*4=12$

Diagram 6. Risk diagram

Probability	Very likely	5					
	Likely	4					
	Possible	3					
	Unlikely	2					
	Very unlikely	1					
			1	2	3	4	5
			Minimal	Limited	Moderate	Increased	Significant
			Impact				

Step (7) Risk conversion

Conversion of risk 12 becomes is 3.

Group	Impact			Probability	Risk	Risk Conversion
	Economic	Consumer confidence	Average Impact			
The manufacturer/suppliers of class III NAWI for the consumer market with the focus on the measuring instrument are in accordance with TAC	2	4	$(2+4)/2=3$	4	$3*4=12$	3

Step (8): Perception

Group	Impact			Probability	Risk	Criteria	
	Economic	Consumer confidence	Average Impact			Risk Conversion	Perception
The manufacturer/suppliers of class III NAWI for the consumer market with the focus on the measuring instrument are in accordance with TAC	2	4	$(2+4)/2=3$	4	$3*4=12$	3	3

Step (9): Cost

Group	Impact			Probability	Risk	Criteria		
	Economic	Consumer confidence	Average Impact			Risk Conversion	Perception	Cost
The manufacturer/suppliers of class III NAWI for the consumer market with the focus on the measuring instrument are in accordance with TAC	2	4	$(2+4)/2=3$	4	$3*4=12$	3	3	5

Step (10): Final score

The final score is 11, that means high and actions is expected to be taken.

Group	Impact			Probability	Risk	Criteria			Finale score
	Economic	Consumer confidence	Average Impact			Risk Conversion	Perception	Cost	
The manufacturer/suppliers of class III NAWI for the consumer market with the focus on the measuring instrument are in accordance with TAC	2	4	$(2+4)/2=3$	4	$3*4=12$	3	3	5	11

Annex I: Questions for analysing target group

For learning more about the behavior of the target group (manufacturer/supplier of measuring instruments) below you will find some questions that is adopted from the 'Table of Eleven'. The 'Table of Eleven' is a behavior-analysis model allowing legislators, policy makers and enforcers to get a picture of the motives for compliance or non-compliance of a specific rule in a specific target group. The 'Table of Eleven' consists of eleven dimensions that together are decisive for the extent to which rules are complied with. The dimensions give criteria for assessing the extent to which draft legislation can be enforced, but can also be used for assessing whether it is possible to enforce and comply with existing legislation. The iT11 is the Internet version of the 'Table of Eleven' (<http://www.it11.nl/it11/login.jsp>). This iT11 consists of 4 modules:

- Data Management
- The Checklist for the Legislator
- The Motives-for-Compliance Test
- The Compliance Estimate

1. Knowledge of the rules

Familiarity and clarity of legislation among the target group

a. Familiarity

- Does the target group know the rules?
- Do they only need to make limited efforts to find out about the rules?
- Is the legislation too elaborate?

b. Clarity

- Are the rules formulated in such a way that the target group can understand them easily?
- Is the target group actually capable of understanding the rules?
- Is it sufficiently clear to the target group what the rules apply to?
- Is it clear to the target group what rules apply?

2. Cost/ Benefits

The tangible/intangible advantages and disadvantages of breaking or complying with the rule, expressed in time, money and effort

a. Financial/economic

- According to the target group, does complying with the rules cost relatively little time, money or effort?
- Do they think that breaking the rules will yield little or no advantage in terms of time, money or effort?
- Do they think that breaking the rules could yield any disadvantages?
- Do they think that complying with the rules could yield any advantages?

b. Intangible

- Does the target group believe that complying with the rules yield emotional or social advantages?
- Does the target group believe that breaking the rules yield emotional or social disadvantages?

3. Degree of acceptance

The degree to which the target group regards the policy and the rules as acceptable

a. Acceptance of policy objective

- Does the target group regard the policy (and the principles it is based on) as reasonable?
- Does the target group feel it shares responsibility for putting this policy into practice?

b. Acceptance of effects of policy

- Does the target group regard the way the policy objective is being put into practice as acceptable?
- Do they regard the resulting rules that follow from this policy as acceptable?

4. Target group's respect for authority

The extent to which the target group is willing to respect governmental authority

a. Official authority

- Does the target group generally abide by the rules?
- Does the target group generally have respect for authority?
- Does the target group respect the judgement of those responsible for law enforcement?

b. Competing authority

- Are the target group's own values in line with legislation?

5. Non-governmental control (social control)

The risk, as estimated by the target group, of positive or negative sanctions on their behaviour other than by the authorities

a. Social control

- Does the target group feel that its community would soon notice any violation?
- Does the target group community generally disapprove of such violations?
- If so, does the community try to correct this behaviour in some way or other?
- Does this social sanction have an impact on the target group?

b. Horizontal supervision

- Is there any horizontal supervision, e.g. financial auditing, disciplinary codes, auditing for certification?
- Does this horizontal supervision contribute to better compliance with the standard in question?
- Does the target group see this horizontal supervision as an additional form of control?
- Does this horizontal supervision have an impact on the target group?

6 Risk of reporting

The risk, as estimated by the target group, of a violation detected by others than the authorities being reported to the authorities

- According to the target group, is its community generally inclined to report detected violations to the authorities?
- According to the target group, are those exercising horizontal supervision generally inclined to report detected violations to the authorities?
- Does the target group think that people generally know which government department to report detected violations to?

7. Risk of inspection

The risk, as estimated by the target group, of being inspected by the authorities for possible violations

a. Records inspections

- Is there a major objective risk of records inspections?
- Does the target group think that there is a major risk of records inspections?

b. Physical inspections

- Is there a major objective risk of a physical inspection?
- Does the target group think that there is a major risk of a physical inspection?

8. Risk of detection

The risk, as estimated by the target group, of a violation being detected if the authorities inspect

a. In records inspections

- Is all the data being checked in a records inspection?
- Is it easy for the inspectors to detect violations?

- Is it difficult to falsify records?
- Is there a major objective risk of detection in a records inspection?
- Does the target group think that there is a major risk of detection in a records inspection?

b. Physical inspections

- Is everything being checked in a physical inspection?
- Is it easy for the inspectors to detect violations?
- Are violations restricted to a particular place and/or time?
- Is the inspection technology used sophisticated enough?
- Is there a major objective risk of detection in a physical inspection?
- Is the objective risk in a physical inspection large?

9. Selectivity

The perceived increased risk of inspection and detection of a contravention resulting from selecting the businesses, persons, actions or areas to be inspected

- Do offenders have the impression that they are always inspected more frequently than those who comply with the rules?
- Do selective inspections find more offenders, relatively speaking, than non-selective inspections?
- Does the target group believe that the enforcement agency is capable of ‘separating the chaff from the wheat’?

10. Risk of sanction

The risk, as estimated by the target group, of a sanction if a violation is detected in an inspection

- Is there a major objective risk of a sanction being imposed once a violation is detected?
- According to the target group, is it easy to prove a violation?
- Does the target group estimate the risk of a sanction as a result of a detected violation as being high?

11. Severity of sanction

The severity and type of sanction associated with the violation and additional disadvantages of being sanctioned

a. Severity of sanction

- Does the target group know what sanction they face in the event of a violation?
- Do they regard it as severe?
- Is the sanction imposed quickly (tit-for-tat)?
- Does the enforcement of the sanction have any additional tangible or intangible disadvantages for the person concerned?

b. Damage to reputation as a result of sanction

- Does the target group mind that it becomes known that have been sanctioned?