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Report:

Risk assessment. Market surveillance, construction products.

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Contents

1 Abstract

The purpose of the risk assessment is to develop a method for prioritizing construction products, or groups of products, to be surveyed by a member state, in order to check for correct implementation of the CE-marking.

The method is based on a method called FMEA: Failure Mode and Effect Analysis, which is often applied in manufacturing industries to estimate the risk of failure of products and processes. In this report, the term "failure" in a product is therefore used in a broad perspective, meaning:

- A product failing to comply with the relevant technical document, under here its declaration, possibly leading to the product not enabling that the construction works satisfies the basic requirements *and/or*
- A failure in the CE-marking of a product, under here inadequacies in the required documentation for CE-marking

To perform the FMEA risk analysis in the normal way, one would need statistics covering the failures mentioned. These data are not available. Instead, a number of factors are applied, which are assumed to have an effect on the risk of failure. Part of this report explains why these factors must be regarded as relevant. The actual weighing of the factors, which is expressed in a point score for each factor, is tested through a number of cases. In these cases a number of construction products are chosen, for which the industry, Norwegian Building Authority (NBA) and The Danish Technological Institute (DTI) have discussed an intuitive risk level. It must be emphasised, that the point score should be revised, as more experience with the method is obtained.

The method is as far as possible developed to be useful and meaningful in any member state, using international statistic standards.

2 Project description

The Danish Technological Institute (DTI) has carried out the project "Risk assessment. Market surveillance, construction products" according to Norwegian Building Authority (NBA) offer dated 28.02.2011 and the following project description.

Any changes from the original project description must be agreed with NBA, and will be noted in this section.

The projects deliveries will be submitted in the form of a final report, which will be transferred to NBA before 01.11.2011.

Methods for Risk Assessment

The method of risk assessment applied has been FMEA: Failure Mode and Effect Analysis.

The FMEA method analyses and ranks various risks from:

- Severity of a failure in the product
- Occurrence (frequency of failure)
- Probability of detection

The severity was assessed by the effect of a failure in the product, with respect to the essential properties of the CPD.

The frequency was assessed based on the market analysis as was the probability of detection, since any surveillance of the production and / or at the building site played a role in the probability of detection of failing products.

By applying this approach a set points system can be reversed to calculate the so-called "RPN" figure (Risk Priority Number), which ranks the risks for each construction product or group of products, which then can be used for a systematic prioritization of the market surveillance.

The essential requirements of the CPD/CPR

The drafting of harmonized standards is based on the so called essential requirements of the CPD, which forms the basis for an assessment of the level of attestation of conformity (AoC levels) of each construction product. The influence of this principle on the risk analysis is discussed in detail in section 3.

A scoring system was developed where each construction product was assigned points according to the relevant essential requirement. This defined the severity of a failure in the product, and is further described in section 4.1. NBA has requested that all 7 requirements was to be treated equal.

The AoC levels was used as an indicator of the risk degree associated with the product in relation to meet those requirements. AoC levels was therefore included in the risk analysis for each construction product, affecting the probability of detection, and is one of the key elements of the risk assessment, described in section 4.2

Product list

A list of all the products, which are subject to requirements for CE marking was drawn up based on the EU-commission standards' mandates. The list contains information on the harmonized standard and ETAGs (CPD) /TABS (CPR) and the AoC level, using input from the Commissions web portal http://ec.europa.eu/enterprise/newapproach/nando/ and http://www.eota.be/ (endorsed ETAGs)

The list is grouped by mandates and product areas respectively. The groups are subdivided by similar products where relevant. The list of products is found in annex A (supplied as a separate excel file).

Details on the collection of data are found in section 5.

Factors relevant to the risk evaluation

A number of factors have been evaluated for relevance and availability of data.

An overview of the construction products market and use in Norway was created by using data from Statistics Norway as well as data from the relevant industry associations, taking into account the proportion ex-

ported to other countries, and how large a quantity of products imported from other countries. Also the Norwegian building tradition and the proportion of housing, industrial building etc. have been taken into consideration. These data, however useful, are unfortunately not complete for every industry, so the use of such data has been limited in the present version of the risk assessment method.

The above mentioned methods and the qualitative descriptions were used as a basis to rank the main groups of products.

Against this background the 10 most relevant product areas were identified, from which cases were selected.

Case studies
Once the method for risk assessment was developed, 10 case studies were carried out to demonstrate the method and show how, the risk assessment turned out for the selected products.

The construction products for the case studies were selected based on the assessments described in Section 4 and based on input supplied by the NBA, to represent construction products in the following groups:

- Products with different AoC levels: at least 1 construction product in each of the groups AoC level 1+ to 2+ (continuous NB monitoring), 2 and 3 (no on-going NB monitoring) and 4 (no requirement for the involvement of third party).
- Products with a high, respectively, a low score in relation to the 7 essential requirements.

The proposed method of risk analysis was conducted for these products to serve as an example.

Statistics and data
Based on the information that was sought out and in view of the method described in section 6, the data that can form the basis for a system for continuous assessment of construction products are defined.

Also relevant statistical methods for the continuous risk assessment were described.

Since it may not be relevant to use raw statistics based on number of products, economics etc., other ways of using the available statistics and gathering data is suggested and discussed in this part of the project.

Risk of wrongful use
Finally, the risk of wrongful use was briefly discussed. This was not a part of the original project description, but is supplied as a means of further discussion on the subject of risk assessment.

3 The essential requirements of the CPD/CPR

In this section the meaning of the so-called essential (or basic) requirements and the AoC level is discussed, and how they influence the risk evaluation.

The drafting of technical specifications (harmonised product standards or ETAGs/TABs) is based on the so called essential requirements of the CPD/CPR.

The construction product should enable that "subject to normal maintenance construction works must satisfy these basic requirements for construction works for an economically reasonable working life. "

The basic requirements are (see also annex B):

1. Mechanical resistance and stability
2. Safety in case of fire
3. Hygiene, health and the environment
4. Safety and accessibility in use
5. Protection against noise
6. Energy economy and heat retention
7. Sustainable use of natural resources (new requirement in CPR)

For each of the requirements, except no. 7, a so called interpretative document has been elaborated, describing how the requirement relates to the construction products.

A construction product failing may lead to a non-conformity with these requirements. The committee drafting a technical specification has for each construction product evaluated the effect of a product failing with respect to the essential requirements, and set the level of attestation of conformity (AoC levels) accordingly.

This means that the AoC levels can be used as an indicator of the severity of a product failing. When the AoC level is set in the area of level 1, 1+ or 2+ it indicates that the product is so significant for one or more of the essential characteristics that a third party, a notified body (NB), should be involved at some level in the ongoing attestation of conformity with the relevant harmonised standards. Conversely, when the AoC levels are determined in the area of level 2, 3 or 4, it is not required for a NB to be involved in the ongoing attestation of conformity for the product. See table 1. One could infer that the product is then assessed as having less impact on the essential properties of the CPD/CPR. In a sense, a risk evaluation has already been performed when assigning the AoC levels.

Procedures for CE-marking	AoC					
	1+	1	2+	2	3	4
Manufacturer						
Initial Type Testing (ITT)			X	X		X
Factory Production Control (FPC)	X	X	X	X	X	X
EC declaration of conformity and technical documentation	X	X	X	X	X	X
CE-marking	X	X	X	X	X	X
Notified Body – initial inspection						
Initial Type Testing, ITT	X	X			X	
Product and Factory Production Control certification	X	X				
Factory Production Control certification			X	X		
EC certificate	X	X	X	X		
Notified Body – continuous inspection						
Inspection	X	X	X			
Sampling for external testing and audit testing	X					

Table 1. Short description of AoC systems and levels.

In other words:

Serious effect → AoC level 1+ → High degree of surveillance →low risk of product failing

and:

Mild or no effect → AoC level 4 → no surveillance →high risk of product failing

The AoC level would then apparently "score" every construction product equally on the "medium" axis, with respects to the risk analysis method:

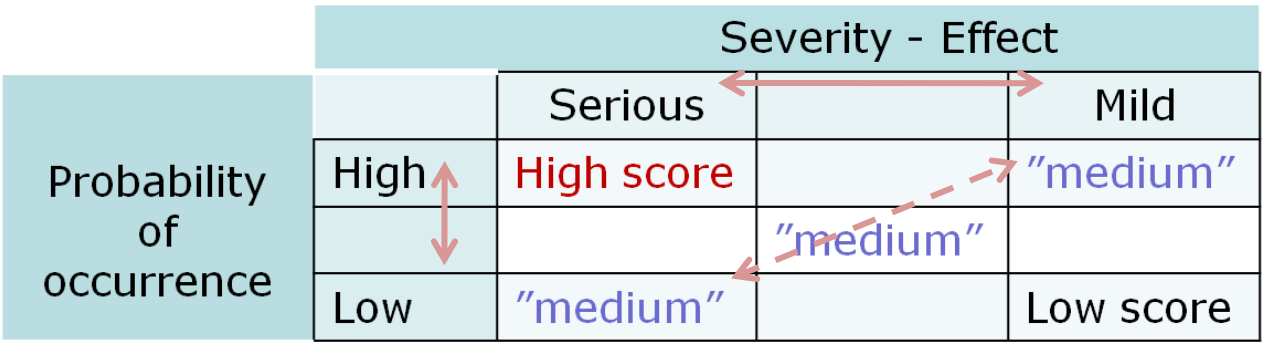

Figure 1. Diagram showing correlations between severity and probability of occurrence

What is of interest with respect to prioritize and select products for market surveillance, is then to identify those products falling above the "medium risk" axis, that is, either scoring a high probability or scoring a more severe effect (or both).

To reveal this, two questions must then be asked;

1. What is the risk of a "high" AoC level (1+, 1 & 2+) product failing, in spite of the NB surveillance?

2. Can the effect of a “low” AoC level (2, 3 & 4) product failing be more severe than appears from the AoC level?

Ref. 1: As a starting point, one must place trust in the NB system of surveillance. However, fraud can occur, and therefore there must be a procedure to handle the “high” AoC level products as well.

Ref. 2: To estimate the severity of the construction products failing, the number of essential requirements that are likely to be affected by a failure in the product is evaluated in section 4.1.

Handling of the AoC level is further discussed in section 4.2.

4 Factors relevant to the risk evaluation

In this section an overview of the elements forming the basis of the FMEA method is given, and their relevance is discussed.

4.1 Essential requirements

As described in section 5 Data a list of harmonized standards and ETAGs are compiled in annex A.

The reference point of each construction product is the technical document forming the basis of the CE-marking, either a harmonized standard (hEN) or ETA-guideline (ETAG).

The technical documents are listed, grouped by mandates (hEN's) or corresponding product areas (ETAGs) and further subdivided by similar construction products and end use where relevant.

Mandate or product group
These are the official mandates, created by the commission, to ensure the necessary knowledge was involved in creating the standards. The mandates and product groups mainly focus on the end use of the product. For example, Mandate 116 is "Masonry and related products" and Mandate 101 is "Doors, windows and related products".

Subdivision, subgroups
In order to estimate in more detail the end use of the construction products, a subdivision were necessary.

This is most easily explained by some examples:

Example 1: Mandate 116, Masonry and related products, could be subdivided into:

- masonry units
- masonry mortars
- rendering mortars
- masonry ancillaries (masonry lintels, ties, straps etc.)

These are very different products, but all come together in the end use as part of masonry walls.

Example 2: Mandate 101 Doors, windows and related products, could be subdivided into:

- Doors and windows (elements forming part of the building envelope)
- Shutters, gates (exterior elements to the building)
- Related hardware (hinges, locks etc.)

Again, these are different products both with respects to manufacture and with respects to the impact on the building.

The evaluation of which essential requirements are relevant is done by each subgroup of products, since the product in a subgroup has similar end use, and therefore similar effect.

For every sub-group the influence of a possible failure in the product needs to be assessed with respect to each of the 7 requirements.

To make this evaluation, it is necessary to have a broad insight in the building industry and the various possible uses of the products in the finished construction as well as the environmental aspects regarding production and reuse/dismantling.

When assessing the product with respect to e.g. the first requirement “Mechanical resistance and stability” the risks, if the product fails, could be: collapse, major deformations, consequential damage on other parts of the construction due to deformations, damages to the product disproportional to the cause etc. A failure in a masonry lintel could include all the risks mentioned above, but a failure in a concrete paving block would not likely include any of the risks.

For each of the requirements, Annex B gives examples of issues to consider from the different interpretive documents. Annex B was used as a guideline and checklist when evaluating the product subgroups of the product list with respect to the requirements.

The evaluation result can be found in Annex A. Each subgroup was assigned with a number of requirements. Then, the number of requirements was transferred to the individual technical documents of the product list. Some individual adjustments were made for a few technical documents.

The essential requirements form part of the risk evaluation as a way to evaluate the effect of a failure.

It should be emphasized, that the evaluation of the essential requirements has already been performed by the technical committees drawing up the technical documents when assigning the AoC levels. Therefore, the present evaluation only assigns the most significant requirements for each subgroup of products. It could be argued, that all 7 requirements are always relevant in some perspective. Here, a conservative evaluation was made, and the number of requirements kept at a minimum.

4.2 AoC levels

The AoC level/levels are given in each technical document and noted in the products list.

Several products are assigned with more levels of AoC. As an example, see EN 13984:2004 “Flexible sheets for waterproofing - Plastic and rubber vapour control layers - Definitions and characteristics”, where the AoC level is noted in table ZA.3 as 1, 3 or 4 :

Table ZA.2 — Systems of attestation of conformity

Product	Intended use	Level(s) or class(es)	Attestation of conformity system[1)]
Water vapour control layers	Water vapour control layers subject to reaction to fire regulations	(A1, A2, B, C)*	1
		(A1, A2, B, C)**, D, E	3
		F	4
	Water vapour control layers	–	3

[1)] System 1: See Directive 89/106/EEC (CPD) Annex III.2(i) without audit-testing of samples

System 3: See CPD Annex III.2(ii) second possibility without a continuous surveillance, assessment and approval of the factory production control by the approved body

System 4: See CPD Annex III.2(ii) third possibility

* Products/materials for which a clearly identifiable stage in the production process results in an improvement of the reaction to fire classification (e.g. an addition of fire retardants or a limiting of organic materials)

** Products/materials not covered by footnote (*)

NOTE Because all products require initial type testing of water vapour permeability, the only systems which apply are 1 or 3. The inclusion of system 4 here indicates that no testing is required for products in reaction to fire Class F

For products under attestation of conformity system 3, the characteristics reaction to fire, watertightness and water vapour permeability shall be subject to initial type testing by a notified test laboratory under the responsibility of the manufacturer.

Initial type testing of the relevant characteristics of Table ZA.1, carried out by the manufacturer, or by a notified test laboratory in the case of reaction to fire, watertightness and water vapour permeability, shall be in accordance with the provisions of 6.2. The manufacturer shall operate a factory production control system in accordance with the provisions of 6.3. The systems of attestation of conformity are shown in Tables ZA.3.1 and ZA.3.2.

Figure 2: Table ZA.2 from EN 13984:2004

This example shows how one product may have different levels of attestation, based on the intended use.

In this case, products subject to reaction to fire regulation, for which a clearly identified stage in the production process results in an improvement of the reaction to fire classification are subject to AoC system 1, all others to system 3 or 4, i.e. no continuous surveillance.

The risk here is that both the manufacturer and the end user may choose the wrong level of AoC for the application or product.

The ranking must be performed by the lowest AoC level for each product. That is, when a standard has assigned levels of 1, 3 and 4, the ranking must be given according to AoC level 4. This is because, when there is a "choice" of level, there is also a risk that the manufacturer and/or the purchaser may choose a level not suited for the application or product.

The principle is illustrated in table 2. Note that "no NB surveillance" scores high because of the probability of a failing product not being detected and reaching the market.

AoC level of attestation	Main risks	Score by AoC level
1+, 1	(Certificates are adulterated)*	Low score
2+	(Certificates are adulterated)* Initial type testing is not performed correctly	-
2	FPC system is certified by a NB and therefore known to be established, but with no surveillance there is a risk of "decay"	-
3 and/or 4	No involvement of NB surveillance. Manufacturer may be unaware of demands etc.	High score

*Table 2: Principle of scoring by AoC level. *) this risk is discussed in section 4*

The AoC level form part of the risk evaluation as a way to evaluate the possibility of detection of a failure, since failure in the less surveyed products are less likely to be detected.

4.3 Manufacturers; size of manufacturing companies

It is assumed that a larger company has more resources to keep updated with the standards, rules and regulations. Therefore, it is also assumed that "small" companies are more likely to overlook, misunderstand or not have the skilled manpower to perform some or all of the tasks that are necessary to perform CE-marking. Therefore, the size of the manufacturing company is likely to affect the frequency of failure.
For products or product groups it is possible to obtain data from the official statistics databank regarding:

- Amount of products manufactured in the country
- Size of companies manufacturing

To give an example of the distribution of sizes of companies, table 3 below shows the distribution of wood industries in Norway:

Industry (SN 2007)	I alt	Number of employees:						
		0-4	5-9	10-19	20-49	50-99	100-199	200 and more
16 Timber and wood industry								
Companies[2]	**1 930**	1 361	228	165	122	40	10	4
Employees[2]	**14 248**	1 595	1 549	2 209	3 673	2 804	1 352	1 066
Labour costs[3]	**5 266**	297	529	795	1 456	1 172	547	470
Production value[3]	**21 557**	1 798	2 001	2 776	6 067	5 415	2 035	1 465
[2]	Number							
[3]	Mio. crowns							
2011 © Statistisk Sentralbyrå								

Table 3: Distribution of company size in Norway

It is clear that this part of the industry is very much characterized by small companies (70 % of the companies have 0-4 employees). But again, they only represent 8% of the manufactured goods.

There are no scientific studies showing the exact correlation between "number of employees" and the company's ability to implement rules and regulation. Based on a general experience of the smaller companies manufacturing building products (in Denmark) it is estimated that companies with less than 20 employees are unlikely to have a person dedicated to implement CE-marking rules and regulations. Therefore, it is estimated that companies with up to 19 employees have a higher risk of not having implemented the CE-marking correctly. Please note that this may have nothing to do with "product quality" cf. the definition of failure in section 1.

In the case of wood industries, this means that (1798 + 2001 + 2776)/21557 % = 30% of the national production of these products are made by companies having 0-19 employees and are regarded as having a relatively higher risk of failure to comply with the CE-marking rules.

The level of detail for this information varies for each category of industry, and for some, statistic data may not be available. There is a general tendency that nationally important industries will be considered in more detail in the national statistical data. This is certainly the case of the wood industry in Norway. However, for some industries it may be possible to estimate the type of company manufacturing the products based on the nature of the product (by level of technology involved, for instance) and general knowledge of the industry or similar industries.

The size of the manufacturing company form part of the risk evaluation as a way to evaluate the frequency, that is occurrence of a failure, since the smaller companies are supposed to have less resources for establishing the required documentation.

4.4 Voluntary surveillance

For some products in AoC levels 2, 3 and 4, a voluntary surveillance scheme may have been organized.

When a voluntary surveillance is organized and effective, it is logical to assume that the probability of detection of any failure in products is higher.

Therefore, information about such voluntary surveillance schemes being in effect forms part of the risk evaluation as a way to evaluate the frequency of detection.

4.5 Product type

Regardless of the end use or other classifications of product, construction products can be divided into three types of products:

A: "Bulk" or basic material that must be fitted on site

B: "Component" which is installed at the building site

C: "System" which is either a system product that must be assembled or installed in a certain way at the site, or which is a larger part of a building, i.e. room size modules or similar.

Examples of product type A are: cement, aggregates, bricks, timber, sheets, adhesives etc. These products are often made of a single material (for example metal, wood, glass, rubber etc.), and though it is not possible to judge the production process or frequency of failures from this product typecasting, it is possible to

estimate that compared to type B and C, these products are relatively less complex, and failure or lack of correct documentation therefore less likely to occur.

Examples of product type B are: windows, precast concrete elements, whirlpool baths, heating appliances, smoke detection alarms. These products need no fitting, as they are installed as a component in the building. They represent a higher level of complexity and, in general, more different materials are used for the manufacture. Often, the component is assembled using other CE-marked products. For example glass is used to manufacture windows. Therefor type B products represent a higher frequency of failure.

Examples of product type C are: bathroom modules, wastewater treatment systems, system chimneys, wet room systems (liquid). These products represent the highest risk of failure or incomplete documentation, as they certainly represent a complex compilation of other construction products.

The product type form part of the risk evaluation as a way to evaluate the frequency, that is occurrence, of a failure, since the simpler product are supposed to have a lower frequency, while more complex systems are supposed to have a higher frequency of failure.

4.6 Total market

The total market of any given construction product (or subgroup) in a member state can be defined as:

Total market = “nationally manufactured products” minus “export” plus “import”

The frequency of failure would then be affected according to the proportion: (Total market of product) / (total market of all building products), assuming that a large market would mean a higher frequency of failure.

However, the necessary data cannot be readily found for every product group or even industry. A further discussion of the data available can be found in section 8.

4.7 Other information

The above mentioned factors represent the sort of information, which can be systematically gathered or generated. Other sources of information must not be ignored, for example information about fraud and even suspicion of fraud. Such information may rise from the market, where the competition situation will urge manufacturers to report on any suspicion of fraud or lack of compliance with the CE-marking coming to their knowledge.

A number of industrial organizations for manufacturers of construction products are active in Norway. The different associations have a different level of actions and information directed at the manufacturer regarding CE-marking. They will also be expected to have a good overview of the market and the competitive situation.

Therefore, a good cooperation with the industrial association is recommended to supply informal information for the prioritization of products to be surveyed. It must be in the interest of the associations to cooperate in order to ensure a fair competition both nationally and internationally.

An overview of the active industrial associations in Norway is listed in annex C.

A brief discussion on how to collect data can be found in section 8.

5 Data

In this section the data that must be collected to perform the risk analysis is described. The availability and reliability of data is discussed.

For each construction product, which must be CE-marked, there exists either a product standard based on a mandate issued by the committee, or an ETA normally based on an ETAG divided into product groups.

A list (database) of all the products, which are subject to requirements for CE-marking is found in annex A. The list is drawn up based on the EU-commission standards' mandates and product groups as defined in the CPR. The list/database is drawn up using input from the Commission's web portal http://ec.europa.eu/enterprise/newapproach/nando/ and http://www.eota.be/ (endorsed ETAGs)

The reference point for data is then the unique technical document (standard or ETA/ETAG).

The list is grouped by mandates and product areas, and subdivided by similar products/similar end use where relevant as explained in more detail in section 3.

The list/database contains for each standard or ETAG the following information:

- Mandate or product group
- Subgroup, i.e. "Subdivision" of mandate or product area
- Date of end of coexistence period
- AoC level(s)
- Industrial classification (where relevant)
- Number of essential requirements that are deemed relevant for the subdivision group
- Product type

Each of these characteristics is used to form the risk analysis by establishing a point score system.

AoC level and end of co-existence period
The AoC levels are noted in each technical document.

The dates for the beginning and the end of the co-existence period are listed in the web portal mentioned above. Where possible, it is the original dates from the first issue of the standard that are registered. Whenever a new version of a standard is launched, the dates change, but it is more interesting to know the original date of co-existence. This tells how long the standard has been implemented. It is estimated that the longer a standard has been implemented, the more likely it is that the rules are known and followed by the manufacturers. (Minor changes in the standards are discarded for this purpose).

For ETAG's there is not always defined a date for end of co-existence. Therefore the date of endorsement is adopted in the product list.

Industrial classification
The industrial classification is based on "D 383 Standard Industrial Classification", which is used by Statistics Norway. "Norsk standard for næringsgruppering" (SN2007) is based on the European standard NACE (Rev.2) (Statistical Classification of Economic Activities in the European Community). The standard is primarily intended for use in official Norwegian statistics. The main purpose is to provide rules and guidelines

for the classification and unambiguous definitions of statistical unities. The industrial classification becomes the uniform, which is necessary to compare and analyze statistics for specific industries over time and across sources and type of investigations. Each product is classified accordingly. A construction product may be connected to one or more classes. For instance, a window (EN 14351-1) may be manufactured from wood, metal frame or plastic, which corresponds to 3 different industrial classes. But typically 1 or 2 classes will cover the majority of the production.

In this report 3 classes is the maximum assigned to any product.

For some products it may not be possible to identify a relevant industrial classification owing to the complexity of the products.

Based on the industrial classification it is possible from the Official Statistics of Norway to draw information about the market for the product in question. As the classification is based on an international standard, the same procedure can be used internationally.

For any products it is then possible to obtain data from the official statistics databank regarding:

- Amount of products manufactured nationally
- Import/export figures
- Size of companies manufacturing

Information may not be available for every single (sub)classification of the classification system, so the analysis must rely on less detailed information.

Industrial associations
From the industrial classification the products are connected to the possible industrial associations, since for each association the relevant industrial classes are assigned. Please note that some associations cover almost any and every construction product, whilst others are more focused on one industry but may cover more than just construction products. One example is “Norske Trevarefabrikkers Landsforbund” (a wood industry association) which also covers the manufacture of furniture.

In annex A, product list, a list of the industrial associations are linked to the industrial classification, i.e. the association “Norske trævarefabrikker” is linked to industrial classification, classes:

- 16.1 Saging, Høvling og impregnering av tre
- 16.23 Produktion av andre bygningsartikler
- Etc.

Number of essential requirements
From the evaluation of the product subgroups (see section 3) the number of relevant essential requirements 0-7 is noted for the product in question.

Product type
The product type: A: Bulk, B: Component or C: System is noted for each technical document. Where one document covers more than one product type, the more complex type is noted. For example, a standard covering “tubes and fittings” the product type is “B”, because fittings are regarded as components.

Mandate	P-group	Subdivision	tech. Document	Title	end date	AoC	Es. Req.	Type	I-class A	I-cla
M100	1	Prefabricated reinforced components	EN 13978-1	Precast concrete products - Precast concrete garages - Part 1: Requirements for reinforced garages monolithic or consisting of single sections with room dimensions	01.03.2008	2+	2	C	23.610	
M105	6	Chimneys, flues	EN 13063-3	Chimneys - System chimneys with clay/ceramic flue liners - Part 3: Requirements and test methods for air flue system chimneys	01.05.2009	4,2+	4	C	23.320	
M105	6	Chimneys, flues	EN 1856-1	Chimneys - Requirements for metal chimneys - Part 1: System chimney products	01.03.2011	4,2+	4	C	25.110	
M105	6	Chimneys, flues	EN 14471	Chimneys - System chimneys with plastic flue liners - Requirements and test methods	01.06.2007	4,3,2+,1	4	C	?	
M111	12	Signaling device	EN 12352	Traffic control equipment - Warning and safety light devices	01.02.2008	1	2	C	27.900	
M111	12	Road restraint systems	EN 1317-5	Road restraint systems - Part 5: Product requirements and evaluation of conformity for vehicle restraint systems	01.01.2011	1	2	C		
M112	13	Construction elements	prEN 14732-1	Timber structures - Prefabricated wall, floor and roof elements - Requirements	-	2+,1	2	C	16.230	
M118	18	Treatment systems	EN 12566-4	Small wastewater treatment systems for up to 50 PT - Part 4: Septic tanks assembled in situ from prefabricated kits	01.01.2010	3	2	C	22.230	
M118	18	Treatment systems	EN 12566-3	Small wastewater treatment systems for up to 50 PT - Part 3: Packaged and/or site assembled	01.07.2010	3	2	C	22.230	

Figure 3. Example "snapshot" from the product list

Mandate	Title	Product area	Corresponding product areas	Subdivisions (end use)	1	2	3	4	5	6	7	Sum: number of req.
M/100	Precast concrete products	1	Precast normal/lightweight/autoclaved aerated concrete products.	Prefabricated reinforced components	1						7	2
				Secondary purposes							7	1
				Hollow blocks							7	1
M/101	Doors, windows and related products	2	Doors, windows, shutters, gates and related building hardware.	Hardware				4			7	2
				Windows & doors etc.		2		4	5	6	7	5
				Shutters & blinds				4			7	2
M/102	Membranes	3	Membranes, including liquid applied and kits (for water and/or water vapour control).	Waterproofing, roofs			3				7	2
				waterproofing, other			3				7	2
				Vapour control			3				7	2
M/103	Thermal insulating products	4	Thermal insulation products. Composite insulating kits/systems.	Inorganic						6	7	2
				Organic		2				6	7	3
											7	1
M/104	Structural bearings	5	Structural bearings. Pins for structural joints.	Structural bearings	1						7	2
M/105	Chimneys, flues and specific products	6	Chimneys, flues and specific products.	Chimneys, flues		2		4		6	7	4
				Heaters		2		4		6	7	4
											7	1
M/106	Gypsum products	7	Gypsum products.	boards, components					5		7	2
				Fixings, adhesives				4			7	2
				Mortars, plasters							7	1
				Metal lath and beads, profiles				4			7	2

Table 4: Example from Annex A: Subgroups and essential requirements

6 Method for risk assessment

The method of risk assessment applied is the FMEA: Failure Mode and Effect Analysis, which is a systematic procedure for the analysis of a system to identify the potential failure modes. The method used is based on EN 60812 “Analysis techniques for system reliability - Procedure for failure mode and effects analysis (FMEA)”.

FMEA generally deals with individual failure modes and effects on these failure modes on the system. Each failure mode is treated as independent. The procedure is therefore unsuitable for consideration of dependent failures or failures resulting from a sequence of events.

The FMEA will be used as a method to identify the severity of potential failure modes and estimate the probability of occurrence of the failure modes. Further, the level of failure detection will be taken into consideration. Thereby a ranking of the severity of the failure modes is possible to allow prioritization of countermeasures. With this combination of criticality and severity priority for action can be set. This analysis is often called a Failure mode, effects and criticality analysis (FMECA).

One method of quantitative determination of criticality is the Risk Priority Number, RPN. The Risk Priority Number is evaluated by a subjective measure of the severity of the effect (S), an estimate of the expected probability of occurrence (O) and an estimate of the chance to identify and eliminate the failure before the system or customer is affected (D).

$$RPN = S \times O \times D$$

Purpose and objectives of the analysis
The reason for undertaking the Failure Modes and Effects Analysis is to identify those failures, which have an unwanted effect on constructions, e.g. affect the safety of the user, mechanical stability or other essential requirements.

The objectives of the FMEA are therefore to:

- Classify the identity of failure modes according to relevant characteristics including their ease of detection.
- Determination of priority for selection products for inspection by the market surveillance authorities.

Failure modes and effects analysis
The FMEA procedure consists of the following stages:

- Establishment of the basic ground rules for the FMEA
- Executing FMEA using the developed worksheet/database
- Summarize and report the analysis – risk evaluation
- Updating the FMEA

The method analyses and ranks various risks. In the product list certain characteristics (se section 5) are assigned to each product and form the basis for a part of the risk analysis as described in sections 3 and 4.

The reference point for the risk analysis is the technical document (standard or ETA/ETAG).

- Severity of a failure in the product
  - Evaluation of severity is based on the number of essential requirements that the product affects
- Frequency of failure
  - Size of manufacturing companies
  - Date of the end of the coexistence period: tells for how long the technical document has been valid
  - Type of product: “bulk”, “component” or “system” (type A, B or C)
- Probability of detection
  - AoC level: level of surveillance by notified bodies
  - Whether or not there exists a voluntary surveillance system

Each of these characteristics is used to form the risk analysis by establishing a point score system.

6.1 Severity of a failure in the product(S)

Severity is an assessment of the significance of the failure mode’s effect on product operation. Severity classification is based on the essential requirements of the CPD/CPR for the construction products.

The evaluation procedure is described in more detail in section 3 and annex B.

For every product (subgroup) the influence of a possible failure in the product has been assessed with respect to each of the 7 requirements.

The rating of severity (S)

A severity rank is allocated to the failure effect from each failure mode based on the severity on the effect on the overall system performance and safety. Each product (subgroup) will have to fulfill one or more of the essential requirements (Yes=1, No=0). The rating of the severity will therefore be the sum of requirements, which are evaluated to be of relevance, that is, each subdivision is rated 0 – 7.

Essential requirement	Risk (examples)	Professional evaluation	
		M105 Sub: Chimneys, flues	M101 Sub: Windows, doors etc.
1. Mechanical resistance and stability	Collapse in product	0	0
2. Safety in case of fire	Spread of fire and smoke	1	1
3. Hygiene, health and the environment	Mould growth	0	0
4. Safety and accessibility in use	Falling down, Objects falling on persons, explosions	1	1
5. Protection against noise	Noise that threaten health, concentration and sleep	0	1
6. Energy economy and heat retention	Too high energy consumption	1	1
7. Sustainable use of natural resources (new requirement in CPR)	Use of natural resources in manufacturing	1	1
Number of essential requirements		**4**	**5**
Severity (S)	Total number of req.'s +1	**5**	**6**

Table 5. Example of evaluation of requirements

For the sake of calculation of the RPN the point score is given as : Sum of essential requirements +1, since it is not possible to have severity point score = 0.

6.2 Frequency, probability of occurrence (O)

The best practice is applied, when the probability of occurrence is calculated for the products and their failure modes based on their own specific failure rates. The more often a product is used, the more likely it is to encounter a failure. This could be calculated by looking at one year of consumption for each product related to the total consumption for all products. The problem is that information of the total consumption is difficult to get especially on short term. When that information is not available an estimate probability of occurrence has to be assigned. The estimate will be based on three parameters:

- Age of the technical standard
- Size of company
- Product type

"Age" of the technical standard

Assuming that the longer a certain set of regulations has been in effect the more likely it is that the regulations are implemented. Therefore, the older the date of the "end of coexistence period", the more likely it is that the CE-marking is well-established.

Class	Age of the "end of" date	Score points
A	More than 3 years	1
B	1 to 3 years	2
C	Less than 1 year	3

Table 6. Point system for age of standard

Size of company

It is assumed that a larger company has more resources to keep updated with the standards, rules and regulations. Therefore, it is also assumed that "small" companies are more likely to overlook, misunderstand or not have the skilled manpower to perform some or all of the tasks that are necessary to perform CE-marking. Therefore, high points are given to smaller manufacturers and low points to larger manufacturers. This cannot be done individually, but statistics can give information on a given industrial classification, on the weighting of sizes of companies. Examples below show the distribution of wood industries in Norway.

Size of company	Point
0-19 employees	2
20-50 employees	1
50+ employees	0
No info, "neutral"	1

Table 7. Point score by size of company

Calculated example: For subgroup "16 Timber and wood industry", see table 8:

Industry (SN 2007) *16 Timber and wood industry*	***Total***	***Number of employees***		
		0-19	***20-49***	***50+***
Companies, number of	*1930*	1754	122	54
Production, mio. crowns	*21.557*	6.575	6.067	8.915
Percentage of total production	100	31	28	41
Point score	0,9	2	1	0

Table 8. Calculation of point score, number of employees

The total point score, number of employees, is calculated as:

Total point score = (0,31 x 2) + (0,28 x 1) + (0,41 x 0) = 0,9

Product type

Type	Description	Point score
A Bulk	"Bulk" or basic material, that must be fitted on site	1
B Component	"Component" which is installed at the building site	2
C System	"System" which is either a system product that must be assembled or installed in a certain way at the site or, which is a larger part of a building, i.e. room size modules or similar.	4

Table 9: Point score by product type.

Type C is regarded as having a significantly higher risk than type A and B owing to complexity, therefore scoring 4 points.

A window would be regarded as a "component", thus scoring 2 points

Total rating

The rating for "Probability of Occurrence (O)" is calculated as the sum of the three parameters:

O= age + size + type

Factor	Points
Age of technical standard	2
Size of company	0,9
Product type	2
Probability of Occurrence (O), sum	4,9

Table 10: Calculated example "window"

6.3 Probability of detection (D)

The probability of detection is estimated based on:

- AoC Level
- Voluntary surveillance

AoC level

There is six levels of AoC. When the AoC level is set in the area of level 1, 1+ or 2+ it indicates that the product is so significant for one or more of the essential characteristics that a third party, a notified body (NB), should be involved at some level in the on-going attestation of conformity with the relevant harmonized standard. Conversely, when the AoC levels are determined in the area of level 2, 3 or 4, it is not required for a NB to be involved in the on-going attestation of conformity for the product. Generally, a low AoC level means that a failure has a high chance of being detected, before the product goes on the market due to inspection by a NB.

Ranking of AoC Level	AoC					
	1+	1	2+	2	3	4
Ranking (point scores)	1	2	2	4	4	5

Table 11: Point score AoC level

Voluntary surveillance system

If a voluntary surveillance of the manufactured goods is established, it is assumed that it is more likely that the probability of detection is higher. There is inspection by a NB for some AoC levels therefore this ranking is only relevant for AoC level 2, 3, and 4. Notice that the point score is negative, since a voluntary surveillance system subtracts from the overall risk of failure.

Voluntary system	Rating
No voluntary surveillance system	0
A voluntary surveillance system is established (100%)	-2

Table 12. Point score voluntary surveillance

If the voluntary system must be regarded as only partly implemented, the degree of implementation must be estimated as a percentage, and the point score adjusted accordingly.

The rating for "Probability of Detection (D)" is calculated as the sum of the two parameters:

D = AoC level + voluntary surveillance x percentage

Example: A product has levels of AoC 1, 3 and 4, rating by the lowest is 4. A voluntary surveillance system is established in the market and is estimated to cover 80 % of the products.

	Rating
AoC level 4	5
+ 80 % of the goods to be submitted to the voluntary surveillance = 0,8 x (-2)	-1,6
Probability of Detection (D)	3,4

Table 13. Point score by probability of detection

6.4 Risk analysis

Risk Priority Number (RPN)

One of the methods of quantitative determination of criticality and aid to prioritize is the Risk Priority Number RPN. Risk is here evaluated by a subjective measure of the severity (S) of the effects of a failure and an estimate of the expected probability of occurrence (O) plus the additional category for failure detection (D).

RPN = S x O x D

A product within the window industry has been evaluated to be subject to four of the essential requirements (S = 5+1=6). The probability of occurrence, which consist of age of technical standards, size of companies and voluntary surveillance is calculated to 4,9. Probability of detection (D) calculated to 4 (AoC level 3=4 – 0=4).

RPN = 6 x 4,9 x 4 = 118

More examples are given in the section "case studies".

Risk evaluation

Rating all the products with RPN shall be followed by a ranking of priority of actions to be performed to assure the best safety to the customer. For example, a failure mode with high severity, low rate of occurrence and very high detection (say 6, 2 and 2) may have a lower RPN (24) than one with average parameters (say 3, 9 and 4 = 108). Thus additional procedures are often defined to ensure that failure modes with high severity ranking are given priority. The decision about which product to be inspected should be guided

by both severity ranking and RPN. A way to do this is using the double ABC analysis, described in section 8, Statistic.

As a supplement that cannot be integrated in the RPN calculation, any other information about the market and the competition situation can affect prioritizing construction product for surveillance.

6.5 Updating the FMEA

When starting the risk analysis, the point score system is determined based on the case studies. The calculation of RPN for the selected cases forms a starting point, from which experience is gathered. The FMEA should be updated as more experience is gathered. That is, for each performed market surveillance, the calculated RPN for the product groups in question should be critically scrutinized: Does the RPN reflect the actual risk of the products? If not, either the point score system should be adjusted to reflect the actual risk, or the specific circumstances of that product or product subgroup should be noted for future reference.

7 Case studies

From NBA and the industry associations of Norway, some input for the case studies were received:

[A]. Factory made building elements for walls, maybe also flooring and roof elements
[B]. Complex sanitary products, such as bathroom modules, steam douche, spa/jacuzzi
[C]. Insulation products based on polystyrene (EPS)
[D]. Aggregates

Firstly, the relevant standards must be found in the database. Seek out the likely mandates/product groups and subgroups, from annex A:

Mandate	Group	Title	Subgroups	Products
M/122	22	Roof coverings, roof lights, roof windows, and ancillary products. Roof kits.	Roof coverings	
			Lights & windows	
			Roof kits	[A]
			Access and safety	
			Joint fillers and sealants	
M/112	13	Structural timber products/elements and ancillaries.	Fasteners, connectors	
			Construction elements	[A]
M/110	11	Sanitary appliances.	Pipes and fittings	
			Appliances	[B]
-	34	Building kits, units, and prefabricated elements.	Building kits	
			Units and elements	[A], [B]
M/103	4	Thermal insulation products. Composite insulating kits/systems.	Inorganic	
			Organic	[C]
M/125	24	Aggregates.	Aggregates	[D]
			Fibres	

Table 14. The mandates corresponding with the suggested products A - D

Next, from the product list, choose the relevant technical documents from the subgroups:

[A:] Factory made building elements for walls, maybe also flooring and roof elements. Products following ETAG 10 are not made from wood, so prEN 14732-1 is chosen for the case studies.

Mandate	P-group	Subdivision	Doc	Title	End date	AoC	Es. Req.	Product class	I-class A
M112	13	Construction elements	prEN 14732-1	Timber structures - Prefabricated wall, floor and roof elements - Requirements	-	2+,1	2	C	16.230
M122	22	Roof kits	ETAG 10	Self-supporting translucent roof kits	14.12.2010*	4,3,1	5	C	22.230

*Table 15. * There are no "end dates" to this document. The date given is the date of endorsement.*

[B:] Complex sanitary products, such as bathroom modules, steam douche, spa/jacuzzi

Mandate	P-group	Subdivision	Doc	Title	End date	AoC	Es. Req.	Product class	I-class A
	34	Units and elements	ETAG 023	Prefabricated building units	unknown	1	7	C	-
M110	11	Appliances	EN 12764 + A1	Sanitary appliances - Specification for whirlpool baths	01.01.2010	4	2	B	22.230
M110	11	Appliances	EN 14428 + A1	Shower enclosures - Functional requirements and test methods	01.01.2010	4	2	B	22.230

Table 16: As the products differ substantially, 2 products are chosen, namely ETAG 023 and EN 12764.

[C:] Insulation products based on polystyrene (EPS)

Mandate	P-group	Subdivision	Doc	Title	End date	AoC	Es. Req.	Product class	I-class A
M103	4	Organic	EN 14933	Thermal insulation and light weight fill products for civil engineering applications - Factory made products of expanded poly-styrene (EPS) - Specification	01.07.2009	4,3,1	3	A	22.210
M103	4	Organic	EN 14309	Thermal insulation products for building equipment and industrial installations - Factory made products of expanded poly-styrene (EPS) - Specification	01.08.2012	4,3,1	3	A	22.210
M103	4	Organic	EN 13163	Thermal insulation products for buildings - Factory made products of expanded poly-styrene (EPS) - Specification	13.05.2003	4,3,1	3	A	22.210

Table 17. The most recent is chosen, EN 14309

[D:] Aggregates

Mandate	P-group	Subdivision	Doc	Title	End date	AoC	Es. Req.	Product class	I-class A
M125	24	Aggregates	EN 12620 + A1	Aggregates for concrete	01.01.2010	4,2+	2	A	8.100
M125	24	Aggregates	EN 13242 + A1	Aggregates for unbound and hydraulically bound materials for use in civil engineering work and road construction	01.01.2010	4,2+	2	A	8.100
M125	24	Aggregates	EN 13043	Aggregates for bituminous mixtures and surface treatments for roads, airfields and other trafficked areas	01.05.2004	4,2+	2	A	8.100
M125	24	Aggregates	EN 13139	Aggregates for mortar	01.06.2004	4,2+	2	A	8.100
M125	24	Aggregates	EN 13383-1	Armourstone - Part 1: Specification	01.06.2004	4,2+	2	A	8.100
M125	24	Aggregates	EN 13450	Aggregates for railway ballast	01.06.2004	4,2+	2	A	8.100

Table 18. Since the products have similar data, one is chosen at random.

A few more products are chosen to make the cases complete, and to fulfill the criteria in section 2:

Mandate	P-group	Subdivision	Doc	Title	End date	AoC	Es. Req.	Product class	I-class A
M112	13	Construction elements	prEN 14732-1	Timber structures - Prefabricated wall, floor and roof elements - Requirements	-	2+,1	2	C	16.230
	34	Units and elements	ETAG 023	Prefabricated building units	unknown	1	7	C	-
M110	11	Appliances	EN 12764 + A1	Sanitary appliances - Specification for whirlpool baths	01.01.2010	4	2	B	22.230
M103	4	Organic	EN 14309	Thermal insulation products for building equipment and industrial installations - Factory made products of expanded polystyrene (EPS) - Specification	01.08.2012	4,3,1	3	A	22.210
M125	24	Aggregates	EN 13043	Aggregates for bituminous mixtures and surface treatments for roads, airfields and other trafficked areas	01.05.2004	4,2+	2	A	8.100
M127	25	Structural assembly	EN 15275	Structural adhesives - Characterisation of anaerobic adhesives for co-axial metallic assembly in building and civil engineering structures	01.04.2011	2+	3	A	20.520
M102	3	Vapour control	EN 14909	Flexible sheets for waterproofing - Plastic and rubber damp proof courses - Definitions and characteristics	01.02.2008	4,3,1	2	A	22.230
M118	18	Treatment systems	EN 12566-1	Small wastewater treatment systems for up to 50 PT - Part 1: Prefabricated septic tanks	01.12.2005	3	2	C	22.230
M131	28	safety devices	EN 13160-1	Leak detection systems - Part 1: General principles	01.03.2005	4,3	4	C	
M100	1	Prefabricated reinforced components	EN 14992	Precast concrete products - Wall elements	01.05.2010	4,2+	2	B	23.610

Table 19. Technical documents selected for the 10 case studies

The RPN number is calculated in an excel spreadsheet, to make it easier to adjust the points score.

The first run uses point scores as given below:

Point system:	Points
Product class A "bulk"	1
Product class B "component"	2
Product class C "system	4
Age:	Points
A more than 3 years	1
B 1 to 3 years	2
C less than 1 year	3
Size of company	1 (default)

AoC level	1+	1	2+	2	3	4
points	1	2	2	6	6	8

Table 20: Point score system 1

First run RPN calculation:	1	2	3	4	5	6	7	8	9	10
Standard:	prEN 14732-1	ETAG 023	EN 12764	EN 13163	EN 13043	EN 15275	EN 14909	EN 12 566-1	EN 13160-1	EN 14992
Product:	Factory made building elements for walls	Bathroom modules	Whirlpool baths	Thermal insulation, EPS	Aggregates	Structural adhesives (metal)	Flexible sheets for water-proofing	Small wastewater treatment systems	Leak detec-tion systems	Precast con-crete ele-ments (wall elements)
Severity (no. Of requirements)	**3**	**8**	**5**	**4**	**3**	**4**	**3**	**4**	**5**	**3**
Age of standard	c	a	b	a	b	c	a	a	a	b
Product class, ABC	c	c	b	a	a	a	a	c	c	b
Size of company	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
Occurrence, total	**8**	**6**	**5**	**3**	**4**	**5**	**3**	**6**	**6**	**5**
AoC level (lowest level)	4	1	4	4	4	2+	4	3	4	4
Voluntary surveillance	No	No	No	No	No	No	No	No	No	No
Detection, total	**8**	**2**	**8**	**8**	**8**	**2**	**8**	**6**	**8**	**8**
Points score from age of standard:	3	1	2	1	2	3	1	1	1	2
Points score from product class:	4	4	2	1	1	1	1	4	4	2
Points score from size of co.	1	1	1	1	1	1	1	1	1	1
Points score from AoC level	8	2	8	8	8	2	8	6	8	8
Points score from voluntary surv.	0	0	0	0	0	0	0	0	0	0
RPN number:	**192**	**96**	**200**	**96**	**96**	**40**	**72**	**144**	**240**	**120**

Table 21. Calculation of RPN, based on the point score system in table 20.

With this combination of scores, factory made elements, whirlpool baths, wastewater treatment systems and leak detection systems are high scorers, while flexible sheets for waterproofing and structural adhesives are low scorers.

The combination of a complex product and low AoC level gives the ultimate high score. Products with a high severity more often scores relatively low (see for example bathroom modules) because the AoC level is high.

In the second run the point score of AoC level is altered to give less significance to the AoC level.

AoC level	1+	1	2+	2	3	4
Points	1	2	2	4	4	5

Table 22: Point score system 2

Second run RPN calculation:	1	2	3	4	5	6	7	8	9	10
Standard:	prEN 14732-1	ETAG 023	EN 12764	EN 13163	EN 13043	EN 15275	EN 14909	EN 12 566-1	EN 13160-1	EN 14992
Product:	Factory made building elements for walls	Bathroom modules	Whirlpool baths	Thermal insulation, EPS	Aggregates	Structural adhesives (metal)	Flexible sheets for water-proofing	Small wastewater treatment systems	Leak detec-tion systems	Precast con-crete ele-ments (wall elements)
Severity (no. Of requirements)	**3**	**8**	**5**	**4**	**3**	**4**	**3**	**4**	**5**	**3**
Age of standard	c	a	b	a	b	c	a	a	a	b
Product class, ABC	c	c	b	a	a	a	a	c	c	b
Size of company	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
Occurrence, total	**8**	**6**	**5**	**3**	**4**	**5**	**3**	**6**	**6**	**5**
AoC level (lowest level)	4	1	4	4	4	2+	4	3	4	4
Voluntary surveillance	No	No	No	No	No	No	No	No	No	No
Detection, total	**5**	**2**	**5**	**5**	**5**	**2**	**5**	**4**	**5**	**5**
Points score from age of standard:	3	1	2	1	2	3	1	1	1	2
Points score from product class:	4	4	2	1	1	1	1	4	4	2
Points score from size of co.	1	1	1	1	1	1	1	1	1	1
Points score from AoC level	5	2	5	5	5	2	5	4	5	5
Points score from voluntary surv.	0	0	0	0	0	0	0	0	0	0
RPN number	**120**	**96**	**125**	**60**	**60**	**40**	**45**	**96**	**150**	**75**

Table 23. Calculation of RPN, based on the point score system in table 22.

However, this does not significantly alter the prioritization of the products. But bathroom modules closes in.

Finally, in the third run, the point score system of product type is altered as shown: (all other points are kept as in the second run)

Point system:	Points
Product class A "bulk"	1
Product class B "component"	3
Product class C "system	6

Third run RPN calculation:	1	2	3	4	5	6	7	8	9	10
Standard:	prEN 14732-1	ETAG 023	EN 12764	EN 13163	EN 13043	EN 15275	EN 14909	EN 12 566-1	EN 13160-1	EN 14992
Product:	Factory made building elements for walls	Bathroom modules	Whirlpool baths	Thermal insulation, EPS	Aggregates	Structural adhesives (metal)	Flexible sheets for water-proofing	Small wastewater treatment systems	Leak detection systems	Precast concrete elements (wall elements)
Severity (no. Of requirements)	**3**	**8**	**5**	**4**	**3**	**4**	**3**	**4**	**5**	**3**
Age of standard	c	a	b	a	b	c	a	a	a	b
Product class, ABC	c	c	b	a	a	a	a	c	c	b
Size of company	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
Occurrence, total	**10**	**8**	**6**	**3**	**4**	**5**	**3**	**8**	**8**	**6**
AoC level (lowest level)	4	1	4	4	4	2+	4	3	4	4
Voluntary surveillance	No	No	No	No	No	No	No	No	No	No
Detection, total	**5**	**2**	**5**	**5**	**5**	**2**	**5**	**4**	**5**	**5**
Points score from age of standard:	3	1	2	1	2	3	1	1	1	2
Points score from product class:	6	6	3	1	1	1	1	6	6	3
Points score from size of co.	1	1	1	1	1	1	1	1	1	1
Points score from AoC level	5	2	5	5	5	2	5	4	5	5
Points score from voluntary surv.	0	0	0	0	0	0	0	0	0	0
RPN number	**150**	**128**	**150**	**60**	**60**	**40**	**45**	**128**	**200**	**90**

Table 24. Calculation of RPN, based on variation of the point score of product type.

As would be expected, this rises the RPN for products of type C, thus placing building elements, bathroom modules and treatment systems at the top of the list.

8 Statistics and data

8.1 Prioritization. A brief introduction to the ABC classification method

The term covers a standard classification technique and has become one of the most commonly used methods for identifying different groups of items. Once identified different management control can be applied to each group.

When an ABC categorization is carried out, the method separates important items from less important ones, A's being most important and C's being least important. Items are ranked upon a categorization criterion.

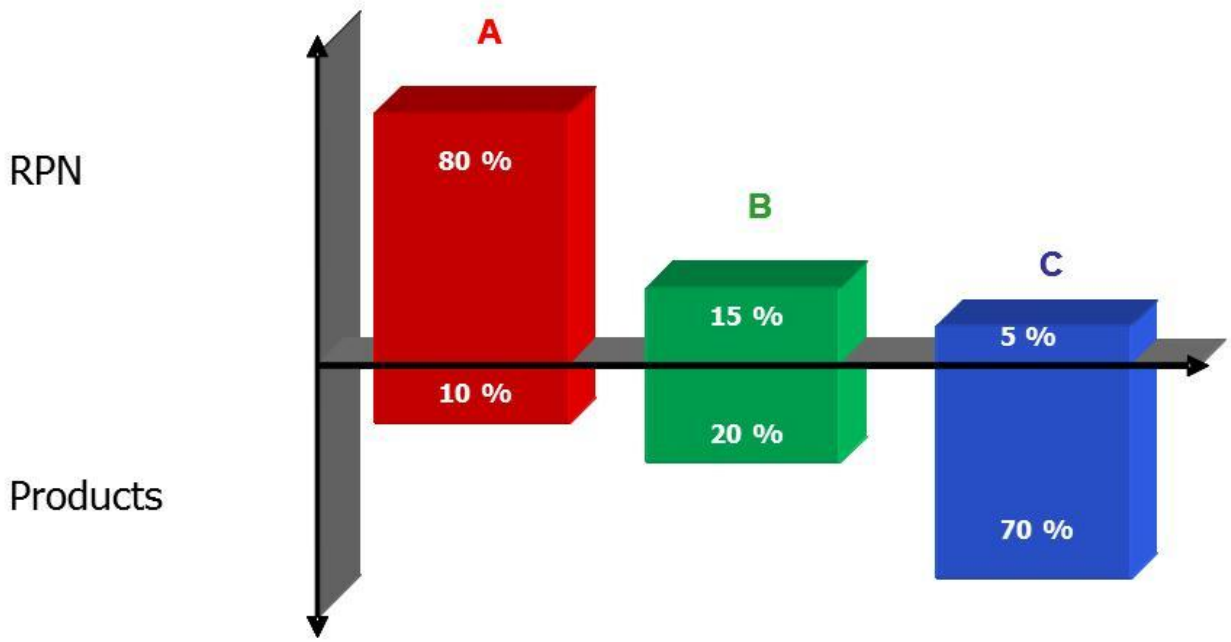

Figure 4: Illustration of the principle of ABC categorization

Managing A, B and C items

The classic ABC method is based on a single−criteria method.

- A class items are critically important and require close monitoring and tight control
- B class items are normal items requiring standard control
- C class items require the least control

Introducing double ABC categorization

The classic ABC approach has left some practitioners with a struggle, the ability to incorporate two, or more dimensions in the analysis. An item with high RPN and low severity may contribute the same level of risk as an item with high severity and lower RPN. While the Classic ABC categorization provided only three categories: A, B and C, two variables allow for nine and more importantly, distinct strategies for each category.

Figure 5. Illustration of the principle of double ABC

The double ABC consists of nine boxes, each with more homogenous and unique item characteristics. Based on the parameters used in the analysis, a company's most important items (AA items) can easily be identified. This group of items is significant and unparalleled, thus management resources applied to AA items are crucial. On the opposite, CC items have almost no significance and require little attention.

Managing AA and CC items

The larger number of categories, each requiring different management policies, deviates from the simplistic theme of ABC. However, standardized policies can be applied to multiple classes, resulting in nine classes with e.g., three different policies.

- AA class items are of the most critically important and require close monitoring and tight control. These are items with a high RPN and high severity of failures.
- BA class items have high severity and lower RPN which also require attention and control.
- AB class items have lower severity and high RPN which also might require attention and control but less than the other.
- The remaining categories do not need attention and control in the first place.

Example of analysis of the RPN number, which shows the items divided into 9 groups. AA represents those items with highest RPN number and highest severity of failures.

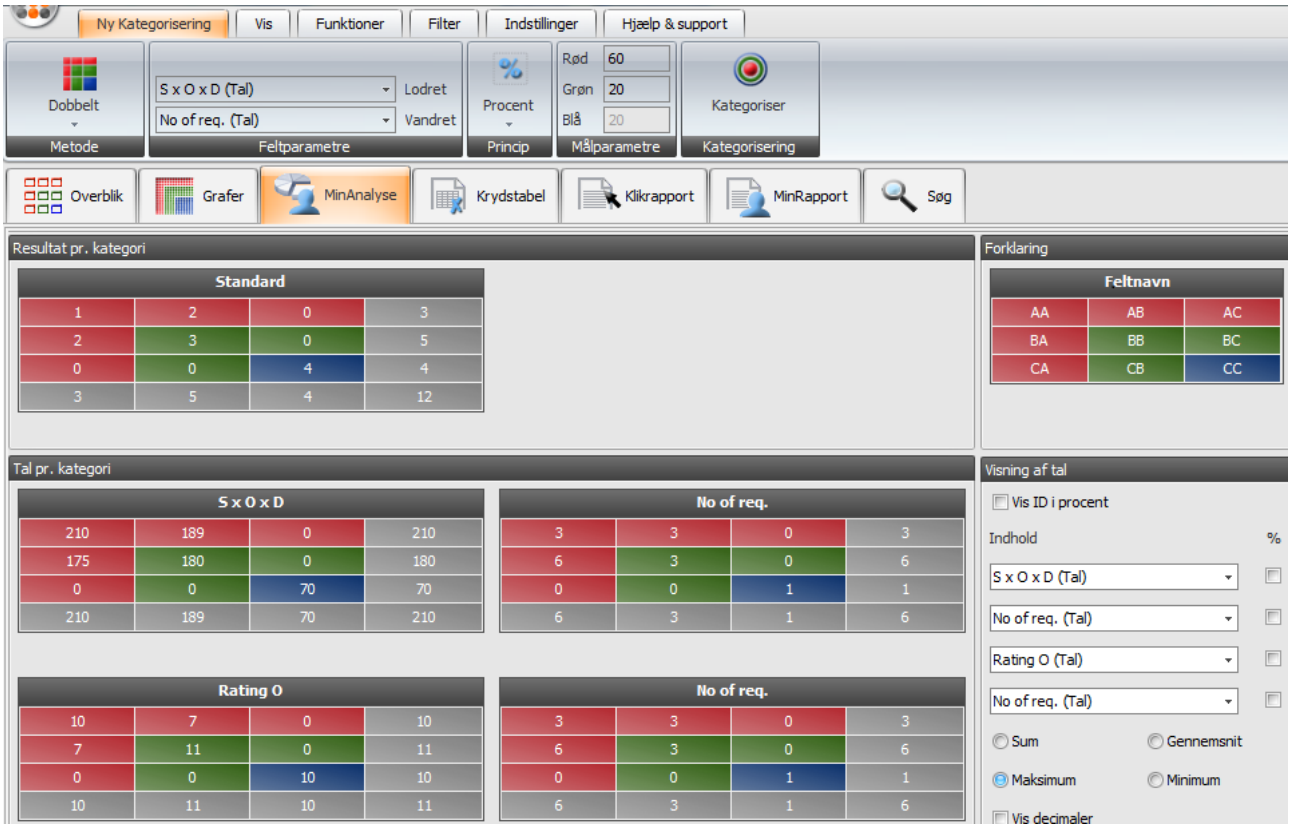

Figure 6. "snapshot" of the ABC software(abcsoftwork)

There can be made a report showing, which item there is included in category: AA, BA and AB.

In table 25 below, a fictive example of a classification report is shown, based on the calculations of the 10 cases (from the second calculation run):

Case no.	Technical document	Product	Rating S	Rating O	Rating D	RPN number (SxOxSD)	ABC
			High:			High:	
9	EN 13160-1	Leak detection systems	5	6	5	150	AA
3	EN 12764	Whirlpool baths	5	5	5	125	AA
			High:			Low:	
2	ETAG 023	Bathroom modules	8	6	2	96	BA
8	EN 12 566-1	Small wastewater treatment systems	4	6	4	96	BA
4	EN 13163	Thermal insulation, EPS	4	3	5	60	BA
			Low:			High:	
1	prEN 14732-1	Factory made building elements for walls	3	8	5	120	AB
10	EN 14992	Precast concrete elements (wall elements)	3	5	5	75	AB
			Low:			Low:	
5	EN 13043	Aggregates	3	4	5	60	-
7	EN 14909	Flexible sheets for waterproofing	3	3	5	45	-
6	EN 15275	Structural adhesives (metal)	4	5	2	40	-

Table 25. Prioritization by ABC double classification.

Based on this analysis it will be possible to prioritize and select product which need to be inspected.

The tool used for making the ABC analysis is from ABC Softwork (http://abcsoftwork.com/).

8.2 Collecting data and experience

In section 6.2 is was argued, that since specific failure rates are not available for the construction products, then the various factors (age of standard, size of company, product type) substitutes the specific failure rates to form a basis for the point score system.

When products are selected and the actual market surveillance is performed, then the specific failure rates for the products become known for a limited period of time.

This information can be used for two purposes:

1. Adjust the point score system accordingly (se section 6.4)
2. For the product(s) in question, replace the point score for “occurrence” with the actual failure rate

To do the latter, and keep the product in the RPN calculation system, a transformation from the point score to the failure rate is needed.

Point score "occurrence"	minimum	maximum
Age of standard	1	3
Size of co.	0	2
Product type	1	4
Total point score occurrence "O"	**2**	**9**

Table 26: Point score min. and max. "occurrence

In table 26 the point score for occurrence is summarized. (These point scores may be altered in the final model chosen by the market surveillance authorities.) To utilize the actual failure rates, in order to be able to calculate the RPN number, one must translate the minimum point score to the minimum failure rate of all construction products, and the maximum point score to the maximum failure rate of all construction products. It is estimated that at least 5 different product subgroups should be surveyed and the failure data collected, before such a translation can be made.

A simpler way would be to replace the point score of occurrence "O" with the percentage of failure, but this would mean that RPN number calculated for the surveyed construction products can no longer be directly compared with the RPN of the products, calculated solely by the point score system.

8.3 Market data

In an earlier section the need for establishing the market size for a construction product or group of products, relative to the total market of construction products, has been discussed, with the purpose of establishing the frequency of failure.

Several sources of data have been investigated, but it is not readily possible to obtain sufficient and reliable data for all industries in Norway.

From the report "Endrede strukturer I byggevarehandlen: 1996-2011", by Marius Nordkvelde, information about the total turnover for the largest DIY centers and wholesalers of building materials for 2010 can be found. This equals 33.205 million NOK. But it is well known that these companies sell other products than construction products, i.e. Garden furniture etc. And it is unclear, what smaller and other businesses may bring to market, which makes the figure unreliable.

From Statistics Norway, information about "sold production of industrial goods, larger companies" can be found. Selecting only the relevant industrial classes (cf. section 5), the total turnover for 2010 can be found to 36.935 million NOK. But again, these industrial classes are not selective enough to rule out non-construction products, and numbers from smaller companies are missing.

From the industry association "Byggevareindustriens Forening", some information regarding import and export of various building materials has been received, but the data is organized differently than the data from Statistics Norway, and cannot readily be compared for the individual products or groups of products.

However, the total figures for 2010 are:

- Import, total: 23.582 million NOK
- Export, total: 22.412 million NOK.

Even though these data are not precise, there are two points to be learned: firstly, import and export play a substantial role in the total market, equaling roughly 2/3 of the sold construction products per year. Secondly that import more or less balances the export.
From these numbers it may be safe to estimate that the total market of construction products lies in the vicinity of 3,5 billion NOK, yearly.

To be able to judge the market of individual groups of products, it is necessary to gather more precise data, either from Statistisk sentrabyrå or the industry itself. The combination of subgroups and industrial classification could form a new basis for gathering this information.

8.4 Other information

In section 4.7 the usefulness of information from the industrial associations about the market, unfair competition or even fraud is discussed. It is recommended that such information must be gathered systematically in the future to give a stronger basis for the prioritization of construction products.

9 End use of products. Risk of wrongful use

The purpose of the risk assessment is narrowed to prioritize the market of construction products with regards to CE-marking. However, a large risk of failures in the final construction works certainly lies in the construction industry and the building in of construction products.

There are two relevant perspectives:

- The type of construction
- The type of product

The annual amount of constructions initiated will normally be available in statistics, divided as for instance:

Percentage per year	Type of construction works
30?	Housing, individual
15?	Housing, block of flats
40?	"Public"(offices, industry, arenas etc.) (business)
10?	Civil engineering (roads, bridges, rail)
5?	Other (low risk *)) e.g. stables, cowsheds, stocks
100 %	Total

Table 27. Example of typecasting of construction works

It must be considered that it is difficult to find a common yardstick. Buildings are often registered by volume of m^2, but it may be difficult to compare with civil engineering such as railways, bridges and roads. Price seems then to be the best yardstick.

The type of construction can be used to assess the risk, by assessing who builds them. Mainly two types of construction, namely "housing, individual" and "other low risk" can be identified as types of construction, where the less skilled (or even amateur) personnel may be working, and therefore there exists a higher risk of wrongful use.

It can also be assessed for a given product or subgroup of product, in which type of construction the product is typically found.

From the subdivision of the products it is possible to score the products relation to the end use:

For example:

- Windows and doors are used in all types except civil engineering
- Road materials are only used in civil engineering
- Fixed fire fighting equipment is rarely used in individual housing
- Clay bricks are used in a certain percentage of detached housing, depending on local tradition and preferences.

This method could be refined and used as a basis to develop a point score system.

The other issue of ”complexity” of product has been discussed in section 4.5 Product type, where 3 product types have been identified:

A: “Bulk” or basic material that must be fitted on site

B: “Component” which is installed at the building site

C: “System” which is either a system product that must be assembled or installed in a certain way at the site, or which is a larger part of a building, i.e. room size modules or similar.

There is no simple way to decide, which type gives the higher risk of wrongful use. Type A could be said to need more skill, since there are no information built-in the product. How to produce masonry from bricks and mortar? You have to be a skilled mason.

However, type B products are more complicated and may also need specific training to install. But here one could infer that the manufacturer must supply some installation guide, and this might ensure a more correct installation. Or, one could infer, that since the necessary knowledge comes with the product, and is not a part of the education of the builder, there exists the risk that the builder “does it as usual” and does not take into consideration the information supplied.

Much the same could be said for type C, but to a more extreme extend, since even more information is “built” into the product.

It is therefore not immediately apparent, which type A, B or C yields the higher risk of wrongful use. The various possible risks as described above must be evaluated and ranked, in order to decide which – if any – of the product types are more at risk of being wrongfully used.

A closer study of the failures involving wrongful use might reveal a relation between product types as defined here – bulk, component or system – and the knowledge can then be used to develop some sort of scoring system.

A study of the reports that have been made to investigate quality problems in the building industry could reveal a connection between types of constructions or types of products. If so, the classifications made in this report could prove useful for the assessment of risk of wrongful use.

Aarhus, November 1st 2011
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Annex A – List of construction products

Annex A is found in a separate file product list: GG 11 1651 Annex A.xlsx

Annex A consists of:

- Product list: List of technical documents with the criteria as described in section 5.
- Subgroups and essential requirements
- Industrial classification with an industrial associations overview
- Cases, calculation. It is possible to vary the point score system and see the effect on the calculation of RPN

Annex B – Basic requirements

Construction works as a whole and in their separate parts must be fit for their intended use, taking into account in particular the health and safety of persons involved throughout the life cycle of the works. Subject to normal maintenance, construction works must satisfy these basic requirements for construction works for an economically reasonable working life.

1. Mechanical resistance and stability

The construction works must be designed and built in such a way that the loadings, which are liable to act on them during their constructions and use will not lead to any of the following:

(a) collapse of the whole or part of the work;

(b) major deformations to an inadmissible degree;

(c) damage to other parts of the construction works or to fittings or installed equipment as a result of major deformation of the load-bearing construction;

(d) damage by an event to an extent disproportionate to the original cause.

2. Safety in case of fire

The construction works must be designed and built in such a way that in the event of an outbreak of fire:

(a) the load-bearing capacity of the construction can be assumed for a specific period of time;

(b) the generation and spread of fire and smoke within the construction works are limited;

(c) the spread of fire to neighbouring construction works is limited;

(d) occupants can leave the construction works or be rescued by other means;

(e) the safety of rescue teams is taken into consideration.

3. Hygiene, health and the environment
The construction works must be designed and built in such a way that they will, throughout their life cycle, not be a threat to the hygiene or health and safety of workers, occupants or neighbours, nor have an exceedingly high impact over their entire life cycle, on the environmental quality or on the climate during their construction, use and demolition, in particular as a result of any of the following:

(a) the giving-off of toxic gas;

(b) the emissions of dangerous substances, volatile organic compounds (VOC), greenhouse gases or dangerous particles into indoor or outdoor air;

(c) the emission of dangerous radiation;

(d) the release of dangerous substances into ground water, marine waters, surface waters or soil;

(e) the release of dangerous substances into drinking water or substances, which have an otherwise negative impact on drinking water;

(f) faulty discharge of waste water, emission of flue gases or faulty disposal of solid or liquid waste;

(g) dampness in parts of the construction works or on surfaces within the construction works.EN 4.4.2011 Official Journal of the European Union L 88/33.

4. Safety and accessibility in use
The construction works must be designed and built in such a way that they do not present unacceptable risks of accidents or damage in service or in operation such as slipping, falling, collision, burns, electrocution, injury from explosion and burglaries. In particular, construction works must be designed and built taking into consideration accessibility and use for disabled persons.

5. Protection against noise
The construction works must be designed and built in such a way that noise perceived by the occupants or people nearby is kept to a level that will not threaten their health and will allow them to sleep, rest and work in satisfactory conditions.

6. Energy economy and heat retention
The construction works and their heating, cooling, lighting and ventilation installations must be designed and built in such a way that the amount of energy they require in use shall be low, when account is taken of the occupants and of the climatic conditions of the location. Construction works must also be energy-efficient, using as little energy as possible during their construction and dismantling.

7. Sustainable use of natural resources
The construction works must be designed, built and demolished in such a way that the use of natural resources is sustainable and in particular ensure the following:

(a) reuse or recyclability of the construction works, their materials and parts after demolition;

(b) durability of the construction works;

(c) use of environmentally compatible raw and secondary materials in the construction works.

Using table B1 and the above as a guideline, a number of essential requirements have been assigned to each subgroup of construction products.

As starting point, essential requirement no. 7 Sustainable use of natural resources has been assigned to all, but for a few subgroups or products based essentially on renewable resources like wood, the requirement no. 7 has been omitted.

For some individual products the number of requirements differs for that of the corresponding subgroup, where it is relevant.

Table B1. Overview of the relation between products and essential characteristics (only to be used with products with AoC levels 2, 3 or 4 as the lowest level).

Essential requirement	Risks (examples)	Indications of relevant products (examples)
1. Mechanical resistance and stability	Collapse in product Deformation of product, leading to increased stress in another loadbearing element Deterioration of product	Loadbearing Construction repair products Connecting/jointing products Stabilizing products
2. Safety in case of fire	Spread of fire and smoke The time of loadbearing capacity lower than expected	Loadbearing and not fire resistant Partitions Spreading of fire Fire alarms
3. Hygiene, health and the environment	Mould growth Release of dangerous substances, gas or radiation	Damp or moisture barriers Containers, barriers and pipes for gas, sewage etc. Products in contact with drinking water
4. Safety and accessibility in use	Falling down, slipping Objects falling on persons Explosions Non-accessibility for disabled persons	Floorings, surfaces Stairs Security products (roof ancillaries) Glues
5. Protection against noise	Noise that threaten health, concentration and sleep	Wall and roof covering Road traffic noise reducing devices Joints and sealants Insulation
6. Energy economy and heat retention	To high energy consumption for heating, cooling, lightning and ventilation Construction work and dismantling uses to much energy	Products that form part of the building envelope: façade, roof etc. as well as joints Ovens and heaters (efficiency) Insulation
7. Sustainable use of natural resources (new requirements in	Use of too much energy in manufacturing Use of scarce raw materials Leakage of drinking water or other resources Limited possibility for reuse Short lifespan	Production method Raw materials Reuse: a ”complex” product, i.e. with more parts connected, is more complicated to reuse… Aspects regarding LCA

Annex C - Industrial associations in Norway

Number:	1
Name:	Byggevareindustrien
Remarks/description	Covering products widely, nearly all industries. Missing, however, glass and electrical products
Homepage	www.byggevareindustrien.no
Number of members	213

Number:	2
Name:	Bygg Uten Grenser
Remarks/description	Covers a wide range of products, concrete and concrete elements, cements, mortars etc. Members are both manufacturers and others.
Homepage	www.byggutengrenser.no
Number of members	70 approximately (manufacturers)

Number:	3
Name:	Treindustrien
Remarks/description	Covers roughly 90 % of the wood industry in Norway
Homepage	www.treindustrien.no
Number of members	92

Number:	4
Name:	Norske Trevarefabrikkers Landsforbund
Remarks/description	80% of the furniture and wood products manufacturers are members.
Homepage	www.trevare.no
Number of members	364

Number:	5
Name:	Norsk Asfaltforening
Remarks/description	Has recently been associated with no. 6
Homepage	www.norskasfaltforening.no
Number of members	Totally no. 5 and 6: 386, but not all are manufacturers

Number:	6
Name:	Norsk Bergindustri
Remarks/description	Has recently been associated with no. 5
Homepage	www.norskbergindustri.no
Number of members	Totally no. 5 and 6: 386, but not all are manufacturers

Number:	7
Name:	Norsk stålforbund
Remarks/description	
Homepage	
Number of members	

Number:	8
Name:	Norsk Betongforening
Remarks/description	Association for both manufacturers of concrete products and other parties
Homepage	www.betong.net
Number of members	902

Number:	9
Name:	Betongelementforeningen
Remarks/description	For manufacturers of concrete elements for the construction industry
Homepage	www.bnl.no
Number of members	37