

# First to the future

A better regulatory framework  
for increased competitiveness

Teknikföretagen

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# Preface

The effective design of technical regulations is crucial for the competitiveness of Swedish technology companies, both in the EU and globally. Inadequate rules and overly complex regulations are costly for companies and can result in lost growth and fewer jobs. Viewed over a 30-year period, EU regulations have improved, but in recent years, it has become increasingly difficult to balance the objectives of the regulations and the means by which to achieve them.

The EU has repeatedly voiced its ambition to become the most competitive region in the world. Various initiatives have been proposed to achieve this goal, including imposing less administrative burden on businesses.

Although the decision-making process on product regulations in the EU has improved, results have not been the desired one. The regulatory environment in which companies operate has not developed in accordance with political vision and rhetoric. On the contrary, there are several recent examples of regulation deviating from the initial goals set out by the various initiatives.

Efforts must therefore be made to reverse this trend so that regulations contribute to the advancement of companies' competitiveness in response to global societal challenges. When regulations create ideal conditions for companies to invest in tomorrow's solutions, only then do we reach our future goals. This is an important message for politicians and officials responsible for the design of regulations and their compliance both in Sweden and the EU.

Teknikföretagen, the Association of Swedish Engineering Industries, represents more than 4,000 companies that combined have more than 300,000 employees in Sweden alone. This document presents a number of overall goals and principles for conducting regulatory work. The problem is not high regulatory requirements on issues such as health, safety and the environment, but rather that conditions differ across markets – both in the EU and globally – and that these regulations sometimes are both complicated and contradictory.

# A better regulatory framework for increased competitiveness

EU product regulations seek to promote trade and ensure that interests such as health, the environment and safety are all satisfied. It is also important that these regulations are designed in such a way that they as far as possible are in line with the requirements of international organisations.

By basing the rules on international agreements, trade barriers are avoided. Authorities responsible for international trade should therefore be involved in the development of product regulations.

The basic objectives for designing rules are the same for all technology companies. The methods for achieving these goals however differ, depending on the product. For industries such as telecoms and electronics, the EU has for 30 years applied the so-called “New Approach”. Ten years ago, this method was updated and is now called the “Goods Package”, but it still sets out the same basic principles for regulating products.

Teknikföretagen believes that the Goods Package must be applied across the EU in a clear way. Only then can Europe continue the work of setting norms for global product regulation. When new areas are regulated, such as cyber security, the rules of the Goods Package should be the first choice.

In this report, Teknikföretagen will present how we consider regulatory work should be conducted. Following this approach would enhance health, safety and the environment, while also boosting companies’ competitiveness.

## THREE OF THE MAIN FEATURES OF THE GOODS PACKAGE ARE:

1. The essential requirements, i.e., the goals, are decided by politicians and introduced into Directives, while technical requirements are developed through a process of standardization, in which all parties can participate.
2. There is an opportunity for manufacturers to show that their products meet all the necessary requirements, without the involvement of third parties.
3. The use of a harmonized standard leads to presumption of conformity, but the manufacturer can also demonstrate compliance without referring to this standard.



A portrait of Klas Wahlberg, CEO of Teknikföretagen. He is a middle-aged man with glasses, wearing a white shirt and a dark suit jacket. He is standing in front of a stone wall. The text "Teknikföretagen" and "TEKO" is visible on the wall behind him.

Teknikföretagen  
TEKO

*“The starting point for achieving better regulation is having a clear strategy with clear principles at political level, which can be followed through right up to the final text.”*

KLAS WÅHLBERG, CEO, TEKNIKFÖRETAGEN





# Summary

Teknikföretagen has compiled its views on how regulatory work should be conducted, in order to contribute to better health and safety, while protecting the environment and increasing companies' competitiveness.

## Harmonization is key

The main rule of EU regulatory work must be harmonization. A product that has been approved in one EU country should also be accepted in all other Member States. Only then will the conditions for a well-functioning internal market be created.

## No special national requirements

Member States should not impose additional requirements other than those set out by the EU. It is important that Single Market rules are the same across all EU countries. If each country was to add its own additional requirements or rules for a given product, both costs and workload would increase dramatically. For products on the Single Market, additional national requirements should therefore not be permitted.

## Standardization should be more efficient

Standardization is effective for establishing technical specifications that meet technological development, innovation and basic requirements for health and environment, among others. Technical details, which help companies comply with legal requirements, should as far as possible be specified in standards.

## Member States must comply with the rules

EU product legislation also includes obligations for Member States. For fair competition and full confidence in the regulatory system, it is important that Member States properly implement EU rules and perform the required tasks. In case of violations, it should be easy for companies to refer to EU law without time-consuming and costly court judgments. Effective market surveillance is also important here.

## Regulations should promote trade

Besides the competent authority and affected industries, authorities responsible for the development and promotion of trade (both within the EU and internationally) should also be actively involved in developing regulations or revising existing ones. By doing this, barriers to trade in proposed regulations can be identified and minimized from the outset.

## Clear rules are needed

If regulation is necessary, it must meet sound competitive conditions and not hinder companies' development. Such rules must be cost-effective, clear and easy to understand. Technical and other requirements must be based on an evidence-based approach, ensuring that the benefit exceeds the cost. Crucially, the legislative process must be characterized by openness and participation.

### **Decisions should be taken by the right body**

The political decisions and ambitions relating to the environment, health and safety can be problematic as they are often made by the wrong bodies. Politicians should decide on political goals, but decisions on technical requirements and how to achieve these goals, should be entrusted to technical experts from manufacturers, authorities, users and other stakeholders through, among other things, standardization.

### **Impact assessment to come before regulatory decision**

A high-quality impact assessment must always precede a decision on regulation in order to be able to assess the potential of achieving the desired goals. There must be an assessment of the economic effects for companies and society. Consultations with companies are required to gain an insight into the consequences of any proposed regulation and any less expensive options for what one wants to achieve.

At EU level, impact assessments are currently being carried out before the European Commission decides on a proposal for regulation. In order for Sweden to have a greater influence on the negotiation process in the EU, and ensure that Swedish positions are taken based on the potential impact on Swedish companies, a Swedish impact assessment should also be carried out on any EU legislative proposal. An impact assessment on the final text negotiated by the European Council and the European Parliament should also be carried out before a final decision is taken.

Prior to implementing EU rules into Swedish law, impact assessments should also include a clear justification for any over-implementation that is being considered and a summary of its likely effects.

### **The division of responsibility must be adapted for the future**

Teknikföretagen welcomes more straightforward and unified rules for the EU's Digital Single

Market. This legislation would make it easier and safer for individuals, companies and public organisations to operate across the Single Market. Distribution of responsibilities should be adapted for the future and be able to handle new technical solutions, support innovation and be technology-neutral. Only then can new business models benefit. National special requirements or countries legislating on opposing requirements other than those of the EU must be avoided.

### **A holistic approach for the environment**

When defining requirements, a holistic view and full application of the Internal Market rules are needed. Unfavourably formulated requirements run the risk of hampering EU innovation. Requirements must be clearly measurable with internationally agreed measurement methods. A life cycle analysis is a good tool for identifying areas for regulation, but it is very unsuitable for setting measurable regulatory requirements.

Any chemical requirements or obligations related to information on chemical content should be developed as a part of the EU Single Market, not nationally. Similarly, requirements related to waste management should also be taken as "Single Market Acts" in order to enable the recycled material to compete with materials extracted from mines, both in terms of price and quality.

### **Transitional rules should be proportionate and coordinated**

Each product is normally covered by a number of laws and related standards. Therefore, when laws and standards are updated, industry should be given proportionate transition times. In this way, companies can smoothly adapt their products and documentation to new requirements in order to minimize any extra costs.

### **Administration should be minimized and streamlined**

To reduce costs, EU regulations should minimize the administrative burden, be based on the manufacturers' own declarations and avoid mandatory third-party involvement. The same adminis-



trative procedures should be applied to the same risk categories so that companies can implement them in a uniform manner.

Legislation must be characterized by openness and participation, and it is important to avoid conflicts between separate Directives or Regulations. Decision makers should understand the reality of the industry, in which the same product can be covered by a variety of EU Directives and Regulations, each relating to certain characteristics, such as safety or the environment. The industry in question puts products, not "characteristics", on the market. If one single Directive causes major administrative requirements, the entire product can be more costly and delayed.

With regard to information requirements, the current basic principle should be preserved: that technical information is available from the

manufacturer and must be communicated to the authorities in connection with market surveillance. Under no circumstances should sensitive data be required other than when it relates to market surveillance.

### **National over-implementation should be avoided**

Member States should never impose or retain more stringent requirements other than the common minimum requirements adopted in the EU. It is important that the requirements of single market rules are the same in all EU countries. When an EU country retains or adds requirements that go beyond the common minimum requirements, for a given product, both costs and workload increase. For products on the single market, there should therefore be no national over-implementation.



# EU Single Market

Standards play an essential role for Swedish companies as they have a strong dependency on international trade and access to international markets. Global standardization and confidence in international systems is vital so that bigger countries do not control the agenda.

Standardization is an effective tool for establishing technical specifications that meet technological development, innovation and basic requirements for health and the environment, among others. Technical details, which help companies comply with the legal requirements, should as far as possible be specified in standards. The EU system of technical harmonization and presumption of conformity between standards and legislation has played a major role in realising the EU Single Market.

## **An efficient process for harmonized standards is required**

Harmonized standards form a link between political ambitions and the level of protection sought in Regulations, Directives, Decisions and Recommendations. An interest-driven participation, in which technical experts from authorities also participate, is therefore important so that the standards become fit for purpose.



JENNIE CATO, HEAD OF UNIT FOR TRADE AND SUSTAINABILITY, TEKNIKFÖRETAGEN

The EU system of placing goods on the market means that an early revision of a standard can force manufacturers to make an unplanned adaptation of a product family.

It is important that the efficiency of standardization is continuously developed and that various stakeholders with technical expertise are engaged in the development of standards. However the general protective requirements are a political responsibility. It would therefore be inappropriate if standardization became the subject of political influence.

## **No specific national requirements should be permitted**

National rules in addition to rules introduced within the EU often mean that Member States introduce requirements in addition to those under EU regulations. This means that the ambition to create a common EU regulatory framework is effectively countered by Member States establishing different requirements for a given product in different EU countries. This also means that national implementation of EU regulations is extended with requirements that go beyond those jointly decided in the EU. This results in additional costs for companies as they

***“Every adaptation to a revised standard entails costs for companies. The standards therefore need to be formulated so that they are stable over a longer period.”***



need to meet all the technical and administrative requirements. It also makes trade between EU countries more difficult.

An example of a specific national requirement can be seen in the Swedish National Board of Housing, Building and Planning's building regulations, which place higher demands on material content than legally required. Further examples include the Swedish Chemicals Tax, and the WEEE Directive.

### **Controls to be carried out by the manufacturer**

Directives state which requirements are imposed on which product. It is the manufacturer who is responsible for ensuring that a product complies with the Directive. A car, for example, must be type-approved to be sold. This means that a third party or authority has controlled and approved the car in question so that it meets all necessary requirements. Product control prior to going to market should ideally be carried out by the manufacturers themselves without any involvement of third parties. This means that the manufacturer's declaration stating that the product meets all requirements is deemed sufficient.

### **Harmonized standards give businesses a simple tool**

The technical details of a standard specify how a product should be designed to meet all necessary requirements. The Directives drawn up in accordance with the New Approach do not specify the details of these requirements in the Directives themselves. Instead, the Commission sends a request to a standardization body to develop a standard that describes how the essential requirements can be met. If the Commission considers that the standard developed meets all essential requirements, it becomes a so-called harmonized standard. In this case, all products designed in accordance with that standard are deemed to meet the essential requirements. This is known as a presumption of conformity.

Standards are developed with the active collaboration of users, producers, authorities and other

stakeholders, and specify the market's needs and wishes. A harmonized standard gives companies a simple tool to meet the directives' requirements for such issues as safety, health and the environment. A manufacturer who does not test according to standards must otherwise demonstrate that the product meets the requirements. The possibility of referring to the essential requirements rather than referring to a harmonized standard is especially important when developing an innovative product, where a harmonized standard is not yet available.

Standardization makes it possible to adapt the requirements to the development of products, materials and technical development. This possibility of adaptation also reduces the risk of technical and other advances being hampered by detailed rules.

### **Market surveillance – an important building block**

The purpose of market surveillance is to ensure that companies comply with established rules. Market surveillance is important for companies, as it helps them deal with unfair competition. Companies that do not comply with the requirements risk facing sanctions. An intelligent market surveillance is therefore fundamental to a functioning market and for safety, health and the environment.

It is important that governments and parliaments allocate sufficient resources to market surveillance and that the relevant authorities receive clear instructions. It is also important that there is effective national and international coordination. There should be a number of basic requirements that each Member State must meet. The European Commission therefore has the task of strengthening cooperation and information exchange among Member States, as well as evaluating its effectiveness.

For cost-effective market surveillance, authorities must make checks where there is a suspicion that infringements are being committed. Market surveillance should use a proportionate scale in terms of level of infringement.

## TEKNIKFÖRETAGEN'S VIEW:

### 1. The main rule is harmonization

The main rule for EU regulatory work must be harmonization. A product that has been approved in one EU country should also be accepted in other Member States. The EU is a sufficiently large market to make a global impact by designing well thought out rules for health, safety and the environment. At the same time, industry competitiveness is enhanced as is access to global markets.

Swedish companies are hit harder by trade barriers than those in larger countries. This is because countries with larger markets have a relative advantage compared to small countries. They do not need to make as many product adjustments with a larger domestic market.

Thus, it is not primarily the high demands on producers and products that cause corporate problems. However, when conditions differ between markets and actors competition becomes distorted.

### 2. No national special requirements should be allowed

Member States should not impose additional requirements other than those of the EU. Requirements related to Single Market rules should be the same across all EU countries. When an EU country adds requirements on top of the EU's, or adds additional rules for a given product, costs and workload increase. There should be no national special requirements for products in the single market.

### 3. The efficiency of standardization should improve

Standardization helps establish specifications that meet technological development, innovation as well as basic health and environmental requirements. Technical details, which help companies comply with legal requirements, should as far as possible be specified in standards. The EU technical harmonization and presumption of conformity between standards and legislation have played a major role in realising the EU single market. It is important that the efficiency of standardization is developed, and

that the development of standards is driven by companies and not by politics.

Standards play an essential role for Swedish companies as they have a strong dependency on international trade and access to international markets. Global standardization and confidence in international systems is vital so that bigger countries do not control the agenda.

### 4. Member States should comply with the rules

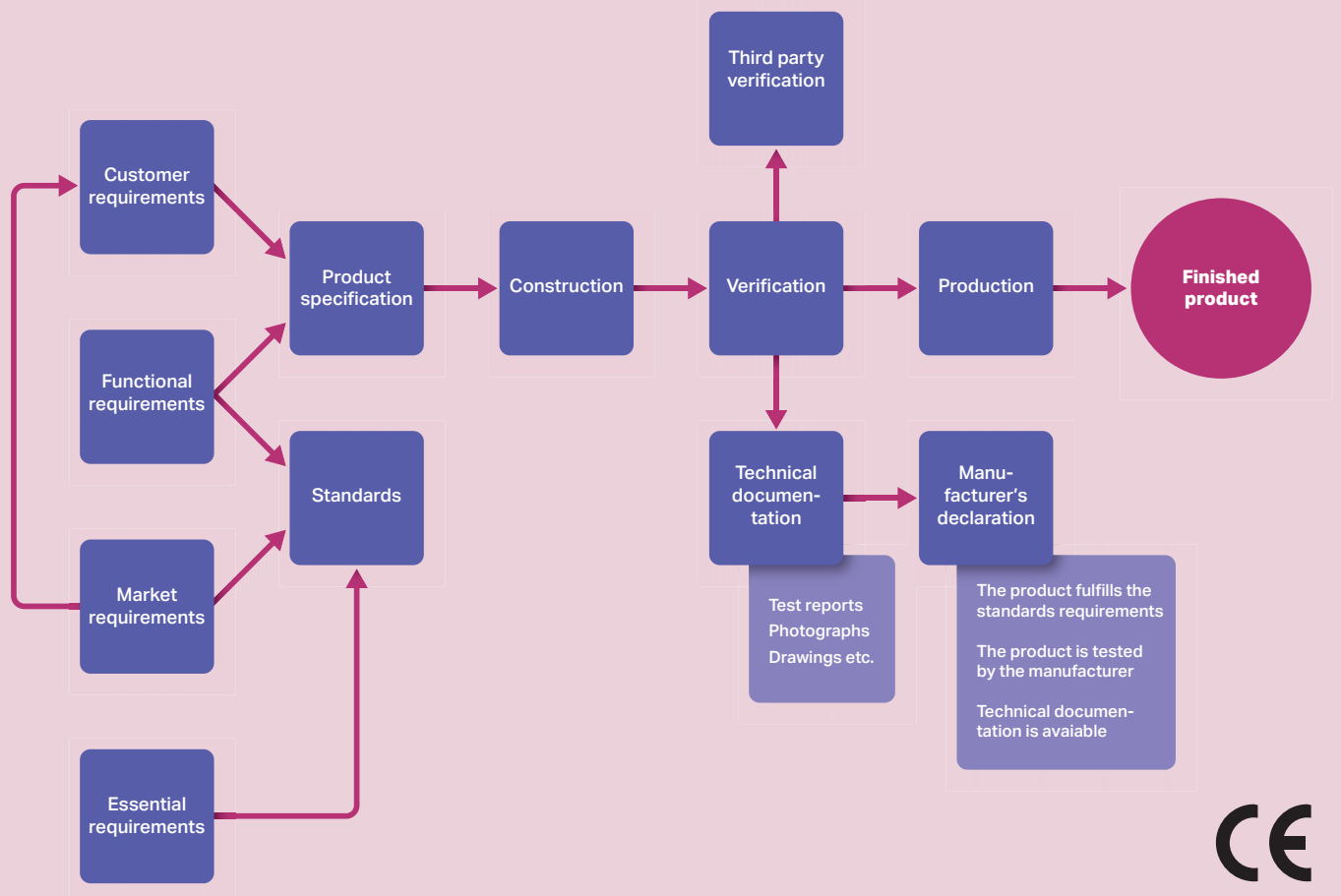
EU product legislation also includes Member State obligations. To have fair competition and full confidence in the regulatory system, it is important that all Member States correctly implement EU rules and perform the required tasks. EU law must become more accessible. It should be easy for companies to apply EU rules nationally without time-consuming and costly legal processes. Cooperation between authorities, both at national and EU levels, is required to agree on the legal requirements, thereby reducing the risk of over (or lack of) implementation at national level.

### 5. Rules must promote trade

If product rules contain a minimal level of administrative requirements, the same law can be introduced in several countries without trade barriers appearing.

These rules should not otherwise hamper export companies wanting to enter new markets. For example, when self-declaration or self-certification is applied, the risk of trade barriers is reduced as the responsibility for testing rests on the manufacturer. A good law should be able to be "exported" without creating trade barriers.

To this end, as well as the authorities and business sector relevant to the product, authorities responsible for the development and promotion of trade (both in the EU and internationally) should also be actively involved in the process from the outset. This would avoid any trade barriers in the proposed rules.





# Product development

Companies developing products must first define the product's characteristics. Here the goal is to meet customer and functional requirements, as well as key obligations set out in Directives. Soft values such as how the product fits with the company's brand and meets market expectations are

also important.

Other than the company's own designers for mechanics, electronics, data etc., purchasing experts are often required during the design stage. Companies have a comprehensive dialogue with several suppliers to find the right materials and components that fit the new product. This process includes defining price, quality and environmental properties. The more components the product consists of, the more complex purchasing dialogue is required in the development work. When the company has found or internally developed all the components, a prototype is designed that needs to be tested. The company must then verify that the product meets all necessary requirements.

All tests are carefully documented, and the results are usually kept for several years and are used for developing other product prototypes. The result is a technical document comprising photographs, drawings, test reports etc.

When all tests have been completed and passed, a declaration that the product meets all the

requirements, is created. In the manufacturer's declaration, the company guarantees that the product meets the relevant standards, that the product has been tested and that the technical documentation is available. Regulations for the new approach require that the technical documentation is saved and is available to the authorities for review during a market surveillance.

Finished products must be CE marked as an acknowledgment that the essential requirements are met. The CE mark symbolises the consistency between the product's properties and current requirements in the Directives. In many cases, these essential requirements are translated into technical requirements in standards.

During serial production, companies must implement additional measures. For example, materials and components that are finally chosen should be ordered in large volumes, while suppliers must be quality assured and reviewed so that they are able to deliver at the right time, with the right price and quality. The product must also be





***“If the EU is to succeed in making a global impression in important areas, such as sustainability, appropriate and effective regulations are required, inspiring others to follow suit.”***

EMANUEL BADEHI KULLANDER, RESPONSIBLE FOR TRADE POLICY AND STANDARDIZATION, TEKNIKFÖRETAGEN





# Decisions must be taken by the right institution

tested before delivery.

The EU has repeatedly voiced its ambition to become the most competitive region in the world. Various initiatives have been proposed to achieve this goal, including imposing less

administrative burden on business.

Although the decision-making process on product regulations in the EU has improved, the results have not always been the desired one. The regulatory environment in which companies operate has not developed in tandem with political vision and rhetoric. On the contrary, there are several recent examples of a marked shift from the initial goals set out by various initiatives.

## Vision vs reality

There is a gap between political vision and the decisions being made. The development of laws and regulations in the EU does not always follow the political vision. Decision-makers need to take the political vision into account when actual decisions are made in order to achieve the best possible conditions for achieving their stated goals.

It is not the political ambitions, nor the will or ability of the officials that fail. The political process, from political ambitions to completed/finished regulations, is so complex that it requires a clear roadmap. Only then can the environmental, health and safety goals be achieved, allowing companies to have cost-effective, simple and clear rules that do not distort competition.

Companies' competitiveness is largely influenced by these regulatory burdens. Too many complex rules have a negative impact on companies' ability to compete in an increasingly global market. Sweden can stimulate its own industry by reducing and simplifying its national rules. The Board of Swedish Industry and Commerce for

Better Regulation's (NNR) 2018 report on Swedish companies' perceived regulatory burden, shows that this burden has been on the rise for quite some time. This negative perception can impair innovation and competitiveness.

## The consequences of multiple, complex rules

The EU has traditionally been seen as a model for other countries in terms of product legislation, due to its simple and predictable rules with a reasonable but relevant level of administrative requirements. The scope of the EU's rules has however increased in recent years. At the same time there are increased administrative requirements that make it difficult for companies to operate on the Single Market. This means that the regulations become more and more complex, eventually weakening the EU's role as a global regulator. It is therefore important that the EU continuously simplifies its regulations to be as coherent as possible among its Member States.

The requirements of Directives, for example, must be designed to be integrated into the existing work flows of companies, from material handling and construction, to product development and production.

The everyday life of companies is characterised by globalisation, tough competition and demanding customers. At the same time, these companies must meet all the requirements imposed on them by the legal system. To survive, they must focus on becoming more efficient, freeing up cap-



ital for investments and resources for their core business. They must also increase their ability to quickly adapt to changes in the environment and ensure that all business support functions are optimal and based on customers' needs.

In order to secure these companies' futures, simplification measures are needed instead of more complicated structures, such as external certification bodies to ensure that companies comply with procedures.

Companies are impacted by a large amount of regulations and every change involves significant work and cost to implement. Improvements are no doubt good, but implementation cost is high. It is therefore important that new and updated regulations are well thought out and quality assured before they are rolled out.

### **Impact assessment at EU and national level**

Impact assessments are carried out in conjunction with regulatory proposals from the European Commission. The quality varies and, unfortunately, is often lacking, despite the fact that impact assessments have been done for many years. A general observation is that the analyses

underestimate the work load for industry. This is often because the knowledge of industry processes is too low. Something that looks easy on paper can be extremely difficult to implement in practice. Contact with the companies is therefore needed to gain an insight into the consequences of proposed regulations and any other less expensive options for what one wants to achieve.

An improvement of these impact assessments is therefore needed, as well as a final impact assessment of the proposal resulting from negotiations between the Commission, Parliament and Council, as the final text sometimes significantly differs from the original one. It is also important to evaluate the effect of the regulation after it has entered into force - did it reach its goal involving the least possible work load for the companies? A Swedish impact assessment of EU legislative proposals also needs to be carried out, to shed light on their effect on the country. This would give Sweden a stronger position regarding these proposals.

Similarly, an impact assessment must clearly set out the effects of over implementation, which can be laborious and costly for Swedish industry, making the country becomes less attractive as a market.

### **EXAMPLE – COMPLEX RULES FOR WASTE MANAGEMENT**

There are enormous costs involved for industry when rules are not harmonized. An example of this can be seen in the current rules for waste.

Today, there are several Directives defining producer responsibility for waste. In the case of the Packaging Directive and for electrical and electronic products (the WEEE directive), there are requirements for the producer to be registered in the markets where they sell. Each Member State is considered as a market. This means that a company must register in 28 different registers if it wants to sell across the entire EU market. Member States all have different requirements as to how many times a producer should report to the registry. In addition, one cannot register in several of the Member States unless they have a business activity in that country or an authorised representative. The requirements for registration and other special national requirements in each individual country prevent many companies from successfully placing products on the Single Market, and this applies, to a large extent, to small, innovative companies that are at the forefront of technology. The costs and additional work are so great that the springboard on to the global arena, which the EU Single Market strives for, disappears. Small and medium-sized companies as a result simply cannot sell their products in other EU countries.

### EXAMPLE – INCREASED REGULATORY BURDEN WITH NATIONAL CHEMICAL TAX IN SWEDEN

The impact assessment carried out in Sweden regarding the introduction of a chemicals tax on a large number of electronic products did not meet the quality standards. This is because the administrative costs for industry were grossly underestimated.

The law means that a special tax is to be imposed on electronics that contain certain chemicals, such as flame retardants. The intent was to impose the tax on consumer products sold in Sweden. However, the products were selected using CN-numbers. This has led to large parts of the Swedish technology industry suffering from extensive new costs and an increased administrative burden. Above all, this significantly impact small and medium-sized companies.

### TEKNIKFÖRETAGEN'S VIEW

#### 1. Clear rules are needed

Technical and other requirements must be based on evidence that ensures that the benefit exceeds the cost. If regulations are necessary, they must be adapted to sound competitive conditions and not hinder the development of companies. Regulations must be cost-effective, clear and easy to understand for companies, which places demands on predictability and clarity. The legislative process must be characterised by openness and participation.

#### 2. Decisions should be made by the right body

Politicians should decide on the political goals, but decisions on the technical requirements should be left to technical experts, such as manufacturers, authorities, users and other stakeholders, for example through standardization. Today political decisions and ambitions relating to the environment, health and safety risk leading to problems, as the decisions are often taken by the wrong body.

#### 3. Impact assessments must always come before a regulatory decision

In order to assess the possibilities of achieving the desired goals of legislation, it is important that high quality impact assessments always precede a decision on regulation.

Impact assessments should be carried out in different phases but should always include an assessment of the economic effects for companies and society. Contact with the relevant companies is required to gain an insight into the consequences of proposed regulations and any less costly alternatives.

- In order for Sweden to have a greater influence in the EU negotiation process, it is important that Swedish positions are based on an analysis of the effects of the proposal on Swedish companies.
- A Swedish impact assessment should be carried out on proposals for EU rules.
- The Commission should perform an impact assessment on the final text negotiated by the European Council and the European Parliament, before a final agreement is sealed.
- An impact assessment should be undertaken before introducing EU rules into Swedish law. In cases of potential over-implementation, the effects of this should be clearly stated





# Digitalization

Digitalization makes it possible to develop new and revolutionary products. The production of goods and services is today increasingly digitised and automated. Goods and services that are digitised means more communication machine-to-machine than human to machine, which opens up even more opportunities.

## A new regulatory landscape for goods and services

Traditionally, it has been easy to define what a product is - a physical good that leaves the loading dock. Compliance with legal requirements has been based on when the goods are physically placed on the market.

However, in today's digital era, more physical products have properties that are defined by software. Products are increasingly connected to the internet and their properties can change over time, not only in terms of different services, but also in terms of the physical behaviour of the product. This means that the regulatory requirements that the product fulfilled when placed on the market do not reflect its function and use over time.

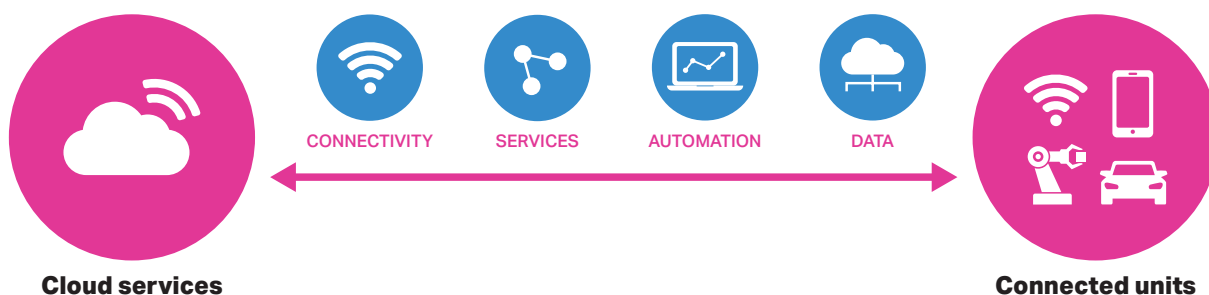
The area of use of the physical product is developed in relation to the requirements it is specified against. An example of this is when the software that controls the product is located outside of the physical hardware, in the so-called cloud. When the software impacts one of the essential requirements relevant to the product, liability as regards product safety becomes unclear. Software updates are often made during the life of a product. Software and hardware can be owned by different companies, which further complicates the situation.

## Responsibility needs to be clarified

The responsibility of using new technologies, such as in additive manufacturing (3D-printing), also needs to be clarified. The quality and properties of the final product are determined

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In the future, connected devices such as dishwasher, stoves, heating systems and process equipment will have to relate to new regulations of the digital single market.





***“Many connected products will likely have to be certified for IT security. This can be costly and time-consuming, therefore it is important to consider how the connection of products is realised in an efficient and secure manner.”***

MARIA ROSENDAHL, HEAD OF UNIT FOR COMPETENCE SUPPLY AND DIGITALIZATION, TEKNIKFÖRETAGEN.

by many factors that normally used to be under the control of a manufacturer, but which are now determined by the user. The company that produces additive manufacturing equipment cannot influence the type of product that the user produces. This also applies to equipment for artificial intelligence.

Electronic commerce involves more actors than what is stated in the current Goods Package, another area where responsibilities need to be clarified.

One way of ensuring a division of responsibility that is compatible with digital principles, is to introduce digital labelling in the areas where there is currently mandatory labelling. Mandatory labelling is, as a rule, something that should only be introduced in exceptional cases as it increases the administrative burden on companies. There may be advantages of introducing digital labelling for products that are already subject to labelling requirements, such as CE marking. With digital labelling, it is possible to update the distribution of responsibilities on products that are already on the market. The label can be updated with little effort and be based on how the product is used, for example if new software has been integrated into the product.

### **An interwoven physical and digital single market**

A well-functioning internal market must seamlessly include both physical and digital commerce. Therefore, regulatory proposals relating to the Digital Single Market should, as a starting point, be dealt with in the same way as other legislative proposals. The Goods Package offers a clear and uniform way of developing proposals in the product area. The Package's principles of essential regulatory requirements, detailed specifications in standards, compliance procedures and market surveillance procedures should also be applied in the digital arena. In this way, the best conditions are created for obtaining a uniform and coherent regulatory system that can be effectively applied.

- Legislation relating to hardware should be adapted so that the responsibility for the product's safety is clear in cases where external software affects the properties of the product.
- Certification based on open global standards should be voluntary also in the field of cyber security.
- Digital CE marks are necessary, also for hardware.

- The Goods Package should be used when regulations are developed for digital processes.
- Separating the Digital Single Market from the Physical Single Market is a regulatory error.
- Uncertainties about geo-blocking should be managed through business contracts and standards.

### Connected products

The EU's work on the Digital Single Market means that products that are connected need to relate to a number of new and future laws. For products that handle personal information, the user of the product needs to consult the Data Protection Regulation or GDPR. Free Flow of non-personal data is another law intended to facilitate the free movement of data that does not fall under this Regulation. This applies to data that, for example, relates to Internet of Things (IoT) devices.

#### EXAMPLE – DISHWASHERS AND COOKERS ARE CLASSIFIED AS RADIO PRODUCTS

As a result of the new Radio Equipment Directive (RED), a large number of products not previously classified as radio products have now been classified as such. The reason for this is that these products use radio communication to connect to the internet.

RED has more administrative requirements than the basic requirements specified under the Goods Package. This creates an increased administrative burden on companies.

It will also be difficult to understand what technical requirements really apply when radio products must meet requirements from different legislative areas that are not properly coordinated.

Connected products, such as dishwashers, stoves, heating systems, and processing equipment, will in the future have to comply with new legislation in the Digital Single Market.

#### TEKNIKFÖRETAGEN'S VIEW:

##### The division of responsibilities must be adapted to the future

Teknikföretagen welcomes the efforts to create simpler and more unified rules for the EU's Digital Single Market. The legislation will make it easier and safer for individuals, companies and public organisations to act in the Single Market. Distribution of responsibilities should be adapted to the future and be able to handle new technical solutions, support innovation and be technology neutral. Only then can new business models benefit. Special national requirements or countries legislating on requirements other than common EU rules, must be avoided.





# Environmental considerations

Resource efficiency has become increasingly important, and much focus is now placed on issues such as material efficiency, reusability, reparability and recycling. It is vital to consider the rapid product development that is taking place today. Requirements that lock in companies to specific detailed obligations risk hampering innovation within the EU, without the long-term environmental benefits exceeding the cost.

## Resource efficiency as ecodesign requirements

Regulatory requirements must be measurable with sufficient accuracy in order to safeguard competition. Therefore, it is important that standardization organisations are involved from an early stage. Since products are comprised by parts from different regions, test methods need to be international.

In ecodesign, requirements are emerging for a guaranteed lifetime, and repairs outside the manufacturer's control. If a service is not provided by authorised organisations, it may compromise the quality and guarantees offered by the producer.

The product's environmental impact needs to precede specific requirements. For example, technical constraints should be considered when ecodesign requirements are tightened for a par-

ticular product group so that functionality is not adversely affected. It would be better to focus on new product groups where greater environmental gains can be achieved, while maintaining functionality.

## Single Market rules also for environmental requirements

The EU principle of free movement of products should also apply to their environmental performance. This is especially important when it comes to requirements for, or information about, their chemical content. Components for the electrical engineering sector are largely manufactured outside the EU, and the ability of companies to influence the components is limited, especially if the market is small. The Restriction of Hazardous Substances Directive (RoHS) is a good example of beneficial Single Market legislation.



***“It is important that the overall picture is not forgotten when environmental requirements are imposed on individual products. Improper use of life cycle analyses leads to sub-optimisation and increased costs without any significant environmental benefit.”***

ELINOR KRUSE, RESPONSIBLE FOR ENVIRONMENTAL ISSUES, TEKNIKFÖRETAGEN.

It is important that the Single Market also includes waste management in the longer term. If waste is to be better converted into a resource, the single market’s mechanisms also need to apply to waste. Recycled material competes with raw material extracted from mines, both in terms of price and quality. In order to use raw materials from recycled electricity waste, administrative costs throughout the recycling chain must be minimized. For the commercial forces to work positively for cleaner waste streams, a larger market is required than individual Member

States – the Single Market should therefore also apply to waste legislation.



A broken product to be repaired should not be classified as waste, as this makes it more difficult to transport these broken products to repair facilities. Repairing complex products can also mean cross-border transport. This is an area where environmental legislation hinders environmental progress, but where the rules of the Single Market favour resource efficiency and the circular economy.

**EXAMPLE – INCREASED REQUIREMENTS FOR ENERGY LABELLING AND ECODESIGN REQUIREMENTS LEAD TO ERRORS**

Energy labelling and ecodesign have long been regulated and achieved significant results in the form of energy and water saving. However, with increased energy labelling and the ecodesign of dishwashers for example, their functionality has suffered, and technology has had to advance in order to compensate. This has seen the cost of dishwashers rising so much that consumers can no longer afford to buy the most energy efficient models.

In 2016, just under one third of all the EU’s dishwashers were classified in the highest energy class, yet these models only accounted for one tenth of sales. So, one can conclude that while industry develops models in accordance with the Commission’s expectations, consumers do not have the means or interest in buying these expensive products.

When dishwasher technology becomes so advanced that consumers lose interest in the product, water and energy savings from these products when compared to hand washing, are also lost. In 2016, the proportion of households in Europe that had access to dishwashers was about 50 percent – an increase in this figure would reduce energy and water consumption.

	Energy (kWh)	Water (l)
1975*	2,64	59,5
2015**	0,96	9,8
		
Decrease	-63,6%	-83,5%

\* University Bonn, Sektion Haushaltstechnik. \*\* JRC Final report, Task 5 Base case BC1

### TEKNIKFÖRETAGEN ´S VIEW:

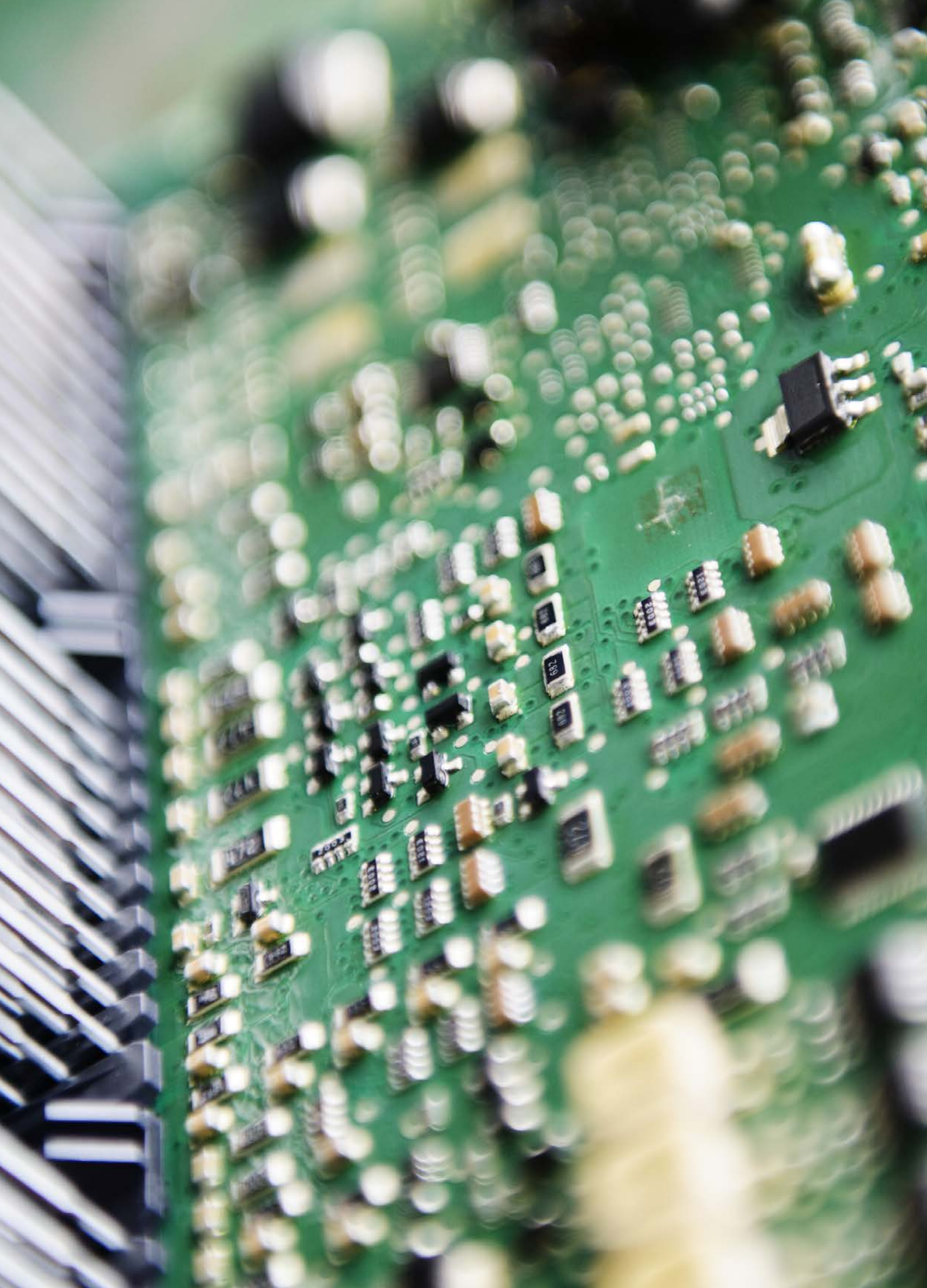
#### **A holistic view shall apply for environmental aspects**

A holistic application of the Single Market rules is an important starting point for new, specific requirements for products to become effective. If this approach is not followed, there are great risks that a regulatory framework that favours one area will have undesirable effects on another. Therefore, it is important that the legislator has a holistic perspective. Life cycle analyses can be an important tool for identifying such areas but is too unprecise to set final requirements.

Any requirements on chemicals or requirements on information on chemical content should be developed for the EU Single Market, not nationally. Similarly, requirements related to waste management should also be taken as Single Market acts in order to enable the recycled material to compete with materials extracted from mines, both in terms of price and quality.









# Designing regulations

Creating a cleaner environment and increasing health and safety do not contradict better and clearer laws and regulations. Swedish technology companies do not seek a lower level of ambition in these areas, but rather better regulations. European legislation must assume that Swedish, as well as European companies, operate in an international environment. The regulations are designed to be applied within the EU primarily but must also take into account that the corporate market is global.

A strategy for increased European competitiveness must have a better functioning of the Single Market and simplified rules as a starting point. . Important principles of such a strategy must be European regulatory harmonization and global regulatory cooperation.

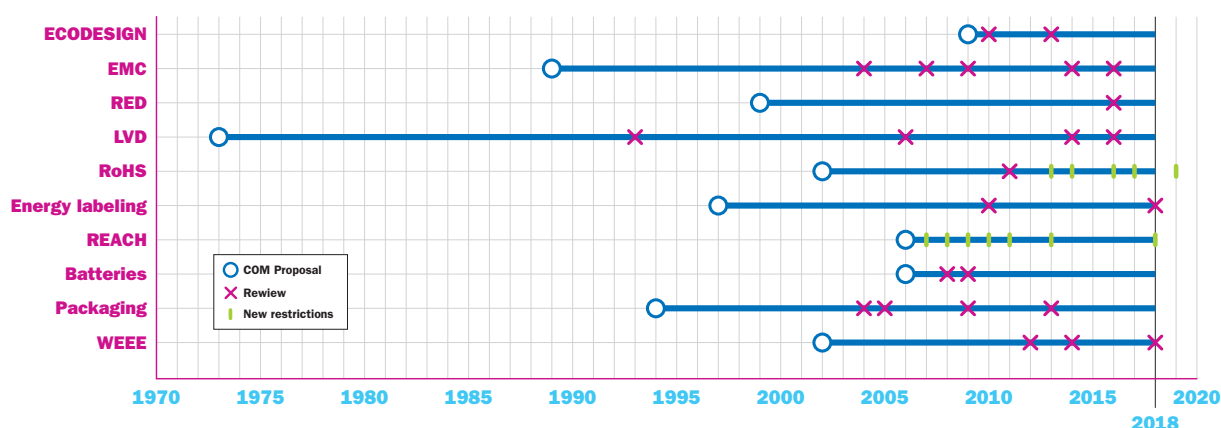
## Avoid legislation if there are other ways

Equally important is that legislation should be avoided if there are alternative ways of achieving the desired goals. If it is clear that the goals cannot be achieved in other ways than through legislation, it is important to review what other laws exist for the product and which could be used before creating new ones.

It is also important that regulatory frameworks are limited to essential aspects and that the administrative requirements only cover necessary information. In many cases, data, or specific formats, are required because they are “good to have” rather than “necessary to have”.

When planning to regulate parts where an individual product does not pose a risk in relation to the policy objective, for example, when it comes to resource efficiency (mainly ecodesign), it is important to regulate product groups where it is most effective rather than in groups where it is easy to regulate. The result may otherwise have the opposite effect - an over-regulated product becomes so expensive that the consumer makes a worse choice from an environmental point of view.

Each harmonized standard need to be revised due to changed requirement in the Directives.



There are major global environmental challenges that need to be addressed through active political measures. This is where EU has the strength to push through changes that have a positive impact.

Unfortunately, Swedish organisations and authorities are impatient which means that there is a wish that Sweden should be a frontrunner and create good examples. Swedish industry is often at the forefront when it comes to taking environmental measures, and it actively participates in dialogue with authorities and politicians. It is important that national measures have the potential to lead to a better environment, while it must not result in less competitiveness. A poor impact assessment that leads to the implementation of laws and regulations where environmental benefits are lacking, and where the cost for industry is high, not only means that Swedish companies are disadvantaged in the market, it also causes the risk of environmental damage when products with a higher environmental impact take market shares.

### **Transitional rules – allow for a structured adaptation**

Industry is increasingly finding it difficult to adapt its products in order to continuously follow current rules due to the short transition times that often occur when legal requirements or standards are updated. Unfortunately, in the case of legislative changes, a large part of the transition period involves adapting national rules. This means that, above all, small companies, who are not able to actively monitor what is happening at EU level, receive information about the changes too late and thus have very little time to adapt to the new requirements.

It is rare that a Directive or standard is revised due to a rapid need for change. It is rather due to modernisation in order to be better suited to

the market's normal product development. There is therefore rarely any need for short transition times. An individual product is covered by several Directives and related harmonized standards, all with their own transition times between revisions. The companies therefore need to continuously update their documentation, including the manufacturer's declaration. It should be noted that the life cycles of products are all different depending on the type of product, from a few years up to 20-30 years. In the latter cases, updates of the product are not made as often as for products with a short life cycle and the consequence of short transition times becomes more noticeable when it comes to costs.

### **Information requirements at proportionate level**

Protecting non-public product information is central to competition. The model prescribed by the Goods Package (and earlier under the New Approach), where information is kept by the manufacturer and communicated to the authorities on request in conjunction with a market surveillance activity, minimizes the risk of undue leakage of secret data. It is worrying that more and more information must be provided in advance as part of the approval process regarding energy labelling.

There are also instances where the legislator wants to gather information on the chemical content of products in public registers. This leads to high administrative costs and no increased protection for the consumer. It is only if products contain substances that are a risk to human health and the external environment that there is a reason for the legislator to require producers to report the contents of these substances. Recycling of products is also not simplified by the fact that authorities keep a database and collect data on chemicals from products.

### EXAMPLE – SHORT TRANSITION TIMES HAMPER SMALL COMPANIES

The Radio Equipment Directive (RED), had only one year of transition, while new essential requirements were introduced from the old directive (R&TTE). This resulted in a significant workload for the standardization bodies, during which the European Telecommunications Standards Institute, ETSI, had to update almost 200 standards. Through the new standardization regulation with its interpretative document, it now takes much longer for the Commission to examine the content than previously. This led to a situation where industry could not use harmonized standards because they did not exist. For radio aspects, RED stipulates that a third-party body should be engaged. For small companies, this became difficult, as access to these bodies was limited. A number of standards are still missing, thereby resulting in increased costs for industry. A longer transition time would have made it easier for all parties.

### TEKNIKFÖRETAGEN'S VIEW:

#### 1. Transitional rules shall be proportionate and coordinated

Each product is covered by several laws and legislation, with a number of different standards. When updated, the industry should be given proportional transition times in order to smoothly adapt its products and documentation to new requirements in order to minimize additional costs for transitioning to new requirements.

Short timeframes risk complicating the effective implementation of these new rules. Coordination of changes such as in Regulations, Directives, Decisions or Recommendations would simplify the implementation of the legal requirements for manufacturers.

#### 2. Administrative routines should be minimized and streamlined

To reduce corporate costs, EU regulations should minimize the administrative burden and this should as far as possible be based on manufacturers' own declarations, while avoiding mandatory third-party involvement. The same administrative procedures should be applied to the same risk categories so that companies can perform them in a uniform manner.

The legislative process must be characterised by openness and participation, and it is important to avoid conflicts between separate Directives or Regulations. It is also crucial that decision makers understand the reality of the industry, where the same product can be covered by a variety of EU Directives and Regulations, each focusing on certain aspects (such as safety and the environment). Industry puts products, not "characteristics" on the market. If one single Directive cause major administrative requirements, the entire product can be more costly and delayed.

As regards information requirements, the current basic principle should be preserved: technical information is available from the manufacturer and communicated to the authorities in connection with market surveillance. Under no circumstances should sensitive data be required other than when it is relevant to market surveillance.

#### 3. National over-implementation should be avoided

National over-implementation often means that Member States keep old or introduce additional requirements in addition to the common minimum requirements of EU regulations. This means that the goal of creating a common regulatory framework within the EU is effectively counteracted by Member States establishing different requirements for an individual product across the EU countries. There will be additional costs for the companies as they need to meet the requirements both technically and administratively. It also becomes more difficult for trade between countries within the EU.



# First to the future

## A BETTER REGULATORY FRAMEWORK FOR INCREASED COMPETITIVENESS

Teknikföretagen's members welcome a set of rules that are cost-effective, functional, clear and accessible to everyone. A uniform EU regulatory framework gives our companies access to the rest of the world. A set of clear rules allows legislators, consumers and companies achieve their health, safety and environmental objectives. We want to help develop this regulatory framework and will do what we can to guide politicians, authorities and other decision makers in their important work. This will help us get to the future first.



## Teknikföretagen

### **In a globalised world, creativity is sweden's strength**

TEKNIKFÖRETAGEN is the employers' organisation for creative, technology companies that make up one third of Sweden's exports. Throughout the country, we help these companies deal with labour law and industry issues, so that they can focus on developing world-class goods and services.