

EU LEGISLATION WITH POTENTIALLY NEGATIVE EFFECTS ON THE ECONOMY AND CONSUMERS

ORDER REPRESENTS ROUGHLY RELEVANCE AND/OR NUMBER OF AFFECTED SECTORS

1. Taxonomy Regulation

- from 2022, limited reporting obligations (qualitative information obligations)
- from 2023, full reporting obligations for non-financial companies
- from 2024, full reporting obligations for companies on the financial market (incl. KPIs)
- from 2026, adjustment of the performance indicators of credit institutions
- regulation in force, delegated act partly in force (climate), partly in preparation (biodiversity)
- ecological criteria for the evaluation of economic activities for the control of financial flows
- considerable bureaucratic effort; small-scale management requirements; restrictive access to financing; conflicts of objectives for the production of nutritional substances and raw materials
- jungle of new reporting obligations for companies, which - especially according to the will of the European Parliament - also directly affects SMEs
- due to the numerous "delegated acts" with the concrete implementing regulations (like German statutory order), there is a threat of an extremely volatile and constantly changing regulatory environment, which, besides additional bureaucracy, also continually results in conversion costs for companies
- This is aggravated by the fact that a legal link would also automatically extend the scope of the Taxonomy Regulation to SMEs. The rigid classification scheme of the Taxonomy Regulation, according to which economic activities are to be divided administratively and arbitrarily into "green" and "non-green", has a serious impact on the attractiveness of companies on the financial markets and thus a considerable influence on their access to investment capital
- There are plans to introduce social taxonomy in the future.
 - If the ecological taxonomy is extended with a social taxonomy, this problem will increase. In contrast to the ecological taxonomy, reference values for the "social performance" of companies cannot be determined on a scientific basis – these would be purely political guidelines.

- De facto, new and even higher social standards would be created outside the parliamentary legislative process by delegated act.
- Economic impact:
 - Besides companies on the financial market, all sectors are directly affected: Disclosure obligations
 - Additional indirect effect by an increase in the cost of access to capital (transparency requirements & reporting obligations for capital products)
 - Additional bureaucratic obligations. No implementation possible without third-party service provider. Large effort (LCA, third-party certification) with question of concrete benefits.
 - Examples:
 - Companies in the field of data processing & hosting must carry out extensive audits according to the environmental objectives which were defined
 - The taxonomy does not clearly regulate whether the manufacture of supplier parts for taxonomy-eligible vehicles (essentially electric vehicles) is considered taxonomy-eligible itself.
 - If a car manufacturer produces the seat for an electric car by himself, then it is taxonomy-eligible. However, if the seat is manufactured by a supplier, taxonomy eligibility is questionable.
 - Drastic consequences: Distortion of competition between manufacturers and suppliers; no fair access to capital markets, which severely disrupts the transformation towards climate-neutral incentives.
 - Policy recommendation: Production of supplier parts must be taxonomy-eligible and the financing requirements must be open to technology and globally standardized
 - The non-listing of most technologies from mechanical engineering may result in a disadvantage in access to sustainable financing in the future. This is the case even though mechanical engineering is the enabler for climate protection. The same situation arises when funding programs are taken into account.
 - Additional sustainability reporting obligations will create a new competition for taxonomy conformity between European companies in addition to the common competitive criteria, which will be decoupled from the global competitive success factors.
 - Increased need for information on taxonomy-specific data with regard to the real economy due to mandatory disclosure of taxonomy key performance indicators.
 - Partially higher due diligence costs expected in financing (see Third Party Verification requirement also with regard to the auditors).

2. European regulation of supply chains

- Current state: The Commission presented the proposal for a directive in February 2022; the first consultations in the Council and Parliament are currently beginning.
- Content: The proposal contains regulations on due diligence obligations (environmental and human rights) of companies across the value chain and on obligations of members of the executive board; civil liability is also planned.
- civil liability across the entire supply chain
- Documentation and storage bureaucracy for decades
- Shift from regulated larger companies to medium-sized companies
- Withdrawal from supplier markets
- Relocation of production outside Europe
- The directive is to apply to all companies with more than 500 employees and in "risk sectors" (including textiles, food, and metal extraction/processing) from 250 employees. The Directive applies within and outside Europe.
- The audit should cover the entire value chain (not only the supply chain, but upstream and downstream as well) and not be limited to direct contracting partners. In case of violations against the obligations to audit or prevention of violations of human/environmental rights, civil liability of the companies is also foreseen - in addition to official sanctions.
- Any natural or legal person can report companies to authorities in case of a "substantiated assumption" of breaches of duty. Management is also to be liable in the case of a breach of duty (equation audit obligations with the "interest of the company").
- The Directive will lead to legal uncertainty and possibly long-term legal disputes when it comes to the question of whether obligations have been violated or whether damage has been caused as a result. The requirement that a breach of duty must be causal for damage is not specifically regulated in the Directive.
- It is practically impossible - especially for SMEs - to comply with these obligations if raw materials are imported from third countries. Due to lower threshold values (250 employees, 40 million euros turnover or 20 million euros balance sheet) in the food sector, craft businesses will also be affected directly (or at the latest indirectly). Indirectly, all companies will be affected by the requirements of the upstream and downstream stages.
- The even longer catalogue of 31 international agreements / conventions (compared to the "Act on Corporate Due Diligence Obligations for Prevention of Human Rights violations in Supply Chains") completely fails to reflect the reality in the areas of human rights and the environment that should be monitored.
- Problem: The Commission's proposal goes far beyond the very ambitious German Supply Chain Act.
- BDA assessment: Due diligence obligations across the entire value chain are not feasible in practice; due diligence obligations exceeding the first supplier level are illusory. The

thresholds for the exception of SMEs are set much too low. Overall, the Commission's proposal goes far beyond the German Supply Chain Due Diligence Act.

- Examples:
 - Companies in the automotive industry (and SMEs in particular) are faced with the mammoth task of managing the transformation. Additional burdens weaken global competitiveness or a medium-sized mechanical engineering company manufactures complex products and often has several hundred suppliers from all over the world. Controlling the second or third stage of the supply chain is completely illusory.
 - Supply problems with raw materials such as lithium or palladium
- Policy recommendation: Protection of human rights is a joint task of politics and economy. Responsibility lies on both sides. Practicability must be noticed. Companies may only be held liable for those parts of the value chain over which they have direct influence.

3. EU regulatory project on Basel III

- Law and state of affairs
 - Legislative proposal of the EU Commission from the 27th of October 2021 regarding Regulation (EU) 575/2013 Capital Requirements Regulation (CRR) with the aim of an EU-wide implementation of Basel III
 - Legislative proposal of the EU Commission was presented on the 27th of October 2021
 - Negotiations between Commission and Council since the end of February 2022. Next Council meetings on the 10th/31st of March 2022. Results are expected for autumn 2022.
 - BMF in charge of national position (support by BaFin and Bundesbank)
 - Start of application of stricter EC requirements is scheduled for the 1st of January 2025; incremental transitional provisions have been announced for parts of the package
- Subject
 - Because of the financial crisis in 2008, capital requirements for banks are being revised with the aim of promoting financial market stability.
 - At the core are planned changes to the credit risk standardized approach (in particular art. 121 CRR), which foresees a tightening of the so-called risk weighting for receivables from companies, concerning the lending of banks, and removes special features of the country of domicile.
 - BaFin already certified many years ago that leasing companies have a robustness comparable to that of CRR institutions due to their risk situation and the fact that they are subject to the German Banking Act (KWG). Therefore, leasing receivables could previously be weighted at 20% in the same way as receivables from banks.
- Effects on the leasing industry
 - Due to a regulatory gap in the current CRR draft, leasing receivables may in future no longer have to be risk-weighted at 20% but at 100-150%.
 - The consequence is that leasing refinancing by banks will no longer be offered at all or will become considerably more expensive.
 - Leasing companies will therefore have to restrict their business activities or risk being forced out of the market completely because their leasing offers can no longer be offered to customers (businesses and consumers) at competitive prices.
 - This reduces investment-financing overall, as either government or private or bank financing cannot compensate it.
 - This affects the business volume of the approximately 150 leasing companies in Germany, which in 2021 will amount to approximately 72

billion euros with a portfolio of approximately 200 billion euros (equivalent to approx. the government's investment volume in equipment).

- The 72 billion euros refer to the annual new business in 2021 of the leasing companies in Germany only.
- Almost 90% of this volume represents the medium-sized enterprise sector, since leasing is an interesting investment alternative to credit in the area of external financing, especially for medium-sized enterprises. The public sector accounts for only about 2% and the private (consumer) sector for about 11%.

- Effects on medium-sized enterprises

- As a result, the financing of operating equipment such as machinery, production equipment, commercial vehicles, passenger cars or IT of the entire German economy is affected (companies of BDI, VDMA, DIHK, ZDH etc. are affected).
- Since leasing companies often combine their financing offers with service and consulting services due to their special object competence, not only the financing of SMEs suffers, but also the transfer of know-how.
- In order to remain competitive and to promote the willingness to innovate and invest, medium-sized enterprises in Germany depend on an active leasing industry.

- Concrete example

- Introduction of an "output floor" will significantly increase the capital burden at banks with internal risk measurement procedures for all types of financing.
- Receivables from companies and commercial real estate financing would be particularly strongly affected.
- The financing conditions of the public sector could also be deteriorated by Basel III (especially for federal states and municipalities)

4. CBAM

- Carbon Border Adjustment Mechanism (CBAM) would be highly problematic for the German economy, especially in the version proposed by the Commission. The Commission wants to phase out free allocation simultaneously with the introduction of the CBAM.
 - Free allocation means that there is currently the possibility for certain industries to apply for the free allocation of emission certificates for e.g. energy-intensive production or manufacturing processes
- Serious impact on companies importing inputs (more expensive) and most likely on exporters, as products are no longer competitive
 - Rising prices of raw materials, which are imported. Competitiveness at risk, both for production in the EU and for exports.
 - Competitiveness/production within the EU could be threatened by increased imports of complex goods not covered by the CBAM. Thus, third country companies would be able to avoid the CO2 price. The products would be cheaper than EU products.
 - Export: no price compensation at the border when exporting (for WTO reasons) means more expensive EU products.
- Carbon leakage treasure completely open due to the regulation.
- A withdrawal of the regulation concerning the free allocation of emission certificates could be connected with considerable additional costs for the affected industries and place an additional burden on those industries that are very energy-intensive and already suffer from rising energy prices.
- The EU Commission's model does not foresee protecting the competitiveness of the export industry as well. A level playing field is to be created only within the Single European Market.
 - This would be dangerous for the German economy, which is a strong exporter, as market shares would be lost in third-country markets.
 - This last point is also critical, as the CBAM is to be successively extended to more products from additional economic sectors.
 - Therefore, it cannot be assumed that a limited number of sectors will be affected.
- Possible trade wars by disadvantaged states
- The plan will also have higher costs for consumers in any case, as both domestically produced goods and imported goods will become more expensive. This should also boost inflation further.

5. NIS-II Directive

- The Directive on measures for a high common level of cybersecurity 2016/1148/EU (NIS Directive) is currently under revision. The informal trilogue negotiations between the Council, the European Parliament and the EU Commission have started.
- Trilogue negotiations (expected to be concluded by April 2022)
- The Commission's proposal expands the scope of the current NIS Directive to include new sectors due to their criticality to the economy and society. This would cover all companies in certain sectors (including the food industry) with more than 50 employees whose annual turnover or annual balance sheet exceeds 10 million euros.
- Increasing cybersecurity through compulsory measures for institutions/companies in specific sectors (health, energy, transport, digital services, etc.), among others.
 - Compulsory risk management with minimum security standards
 - Tight requirements for incident recording
 - Disclosure obligations
- Economic Impact:
 - Incident recording cannot be implemented within 24 hours, at least 72 hours period is required
 - Legal uncertainties with imprecise definitions of terms & cybersecurity measures, e.g., "cloud computing services providers" (Scope)
 - Increasing reporting obligations also to customers on threats without added value
- Additionally:
 - no application to public administration; From a business perspective, local and state administrations that process highly sensitive data from citizens and companies and are responsible for planning as well as approval procedures must meet the same IT security requirements. The administration is in the crosshairs of cybercriminals. Uninterrupted administrative processes are of utmost relevance, especially in times of crisis.
 - Legal harmonization difficult
 - Penalties for non-compliance with the measures: The proposed amount (10 million euros / 2% global annual turnover) is far too high. The amount of the penalty should be limited to two million euros and a reference to turnover should be removed completely. Differentiation of the amount of the penalty according to the facts of the case.
- The companies affected would probably have to invest high five-digit amounts in their cybersecurity if the proposal would be implemented.
- SMEs as a whole are irreplaceable for the supply of e.g. food, but the failure of a few companies would not be decisive for the supply of the population. The extension of the

scope will financially burden SMEs to the point of threatening their existence and is not necessary.

- General assessment: Given the current geopolitical background and the 223 billion euros in damage caused by cybercrime to the German economy only last year, strengthening the cyber resilience of operators of critical infrastructures, public administration as well as companies is right and important
- The problem in a nutshell: Europe lacks sufficient cyber specialists to implement the requirements & some of the measures are far too extensive - especially for medium-sized companies. We are in favor of strengthening cyber resilience but under consideration of risk-based sales.
- The problem is not the factual content, but the lack of consideration of feasibility in small businesses. There is a lack of exceptions for medium-sized enterprises, transition periods and support measures. Exemptions for SMEs are missing.

6. Corporate Sustainability Reporting Directive

- COM proposal published (April 2021), discussion in EP committees and Council working group ongoing
- The CSRD has already been adopted by the Council. Adoption by the European Parliament is still pending. Further tightening is to be expected in the scope of application, scope of reporting and obligation to audit.
- Member states must pass laws by December 2022, first financial year affected is 2023
- Extension of sustainability reporting obligations incl. the circle of affected companies, publication together with financial reports
- Economic consequences:
 - Extension of the scope = further reporting requirements for more companies
 - More extensive reporting requirements ==> higher expenditure
 - Joint publication with financial report sometimes difficult ,because sustainability data is often not as easily available as own financial data
 - Cost increase (one-time as well as annually recurring, such as for audits)
 - In addition to the financial report, SMEs will thus also have to prepare sustainability reporting in the future. The availability and accessibility of data is a key challenge here, Additional bureaucratic burdens, especially for SMEs. Great need for advice for SMEs
- Significant changes to the existing reporting obligations according to the NFRD (nonfinancial Reporting Directive)
 - Extension of the scope of application in Germany from 500 to 15,000 companies by including all large corporations according to the German Commercial Code (HGB), which also includes limited liability commercial partnerships.
 - Extension of the scope of reporting through
 - Softening of materiality considerations according to the existing accounting principles (providing decision-useful information to investors),
 - Establishment of double materiality with the obligation to also report on the impact of business activities on the environment and society,
 - Inclusion of reporting obligations according to the taxonomy without consideration of materiality,
 - Development of a European sustainability standard that will be mandatory until October 2022 without synchronization with the development of international standards,
 - Development of a European sustainability standard which, in its granularity and complexity, can neither meet the quality requirements nor the compliance requirements,

- Development of a KMW standard with the risk of an indirect application obligation, without any significant relief
 - Extension of the requirements for those obliged to report through
 - Introduction of an immediate audit obligation, even if initially limited (limited assurance) with the prospect of a full audit obligation,
 - Introduction of an immediate publication obligation in the digital format ESEF (European Single Electronic Format)
- The new requirements place a massive burden on companies already subject to reporting obligations (capital market-oriented with >500 employees), since new reporting processes and systems must be established to fulfill the new reporting obligations, if they can be implemented at all. In relation to the newly introduced audit obligation, implementation within one year (as foreseen) is not possible. For companies that have not been subject to reporting obligations so far, are not on the capital market and often have fewer than 250 employees, it is not feasible to implement the planned reporting obligations within two years. Overall, the requirements raise significant compliance questions.
- Core requirements:
 - Postponement of the scope of application by at least one year for financial years beginning on the 1st of January 2025,
 - Reduction of the scope of application to capital market-oriented companies,
 - International compatibility of the CSRD with the international standards of the ISSB (International Sustainability Standards Board),
 - Waiver of immediate audit obligation and reporting obligation in electronic format.

7. Revision of the REACH Regulation

- Within the framework of the EU Chemicals Strategy (published in October 2020 as part of the Green Deal), the EU Commission has started the revision of the REACH Regulation. The foreseen adjustments are very ambitious and numerous tightening measures are foreseen.
- In particular, the following adjustments will lead to far-reaching consequences for the industry:
 - increased data requirements for the registration of chemicals
 - inclusion of new hazard classes
 - extensive restrictions on use and extended regulation of groups of substances with specific characteristics;
 - Exemptions from broad restrictions only for uses that are "essential" for safety, health and the functioning of society.
- Overall, the planned measures are intended to make EU chemicals legislation much more hazard-based than before. Regardless of the actual risk involved in the manufacture or use of the substances, many chemicals will no longer be able to be manufactured or used in the EU in the future due to their characteristics only.
- This will lead to a limited availability of materials and substances and hinder the further development of innovative technologies. This will also limit the implementation of innovative future technologies, so that the achievement of climate and environmental goals of the Green Deal could be impaired by a reduced material base.
- In the future, it must still be possible to produce and use hazardous chemicals if there is no risk to humans or the environment. Only then will the production of sustainable products and added value continue to take place in Europe.

8. Revision of the EU Industrial Emissions Directive (IED)

- In the context of the Green Deal, on the environmental side we are particularly concerned about the planned amendment to the EU's Industrial Emissions Directive (IED). The Commission plans to tighten the directive considerably. The proposals are threatening the "license to operate" for companies. Without a license for industrial plants, no production will take place in companies anymore. Every additional requirement in the IED prolongs and complicates the approval procedures.
 - It must be prevented that the directive is tightened: No further industry segments should be included in the directive (e.g. mining industry). Smaller plants should not be included in the IED (these are regulated in the EU Medium Combustion Plant Directive).
 - Other policies should not be regulated in the IED and thus become a requirement for a permit for the industrial plant. Duplication of regulations must be avoided - for example decarbonisation, circular economy and energy efficiency. There is a functioning ETS system; regulations for non-ETS installations at European level are planned.

9. Revision of the EU's air quality directives

- The EU Commission also plans to revise the air quality directives (2008/50/EC and 2004/107/EC) as part of the Green Deal. One of the most important elements of the proposal is the alignment of EU air quality standards with the recommendations of the World Health Organization.
- The new WHO guidelines recommend air quality guideline values for six pollutants. The EU wants to turn the reference values into threshold values; the particulate matter value, for example, is to be lowered from 20 to 5 $\mu\text{g}/\text{m}^3$ and the nitrogen dioxide value from 40 to 10 $\mu\text{g}/\text{m}^3$ - a considerable tightening.
- Berlin has published that the new particulate matter values could not be met on 291 days of the year. The air quality at measuring points "in nature" (e.g. Eifel) would also not comply with the new values.
- If the values are adopted into European law, for example, considerable effects are to be expected, such as on traffic in cities, but also on industrial production. The problem of compliance with the current EU values had recently led to the numerous lawsuits against cities (e.g. by DUH) and driving bans.
- A revision of the EU's air quality directives is not necessary at present. First of all, an impact assessment is required with regard to the feasibility and costs of the new values.

10. Revision of the Environmental Crime Directive

- On 2021 December 15th, the EU Commission presented a proposal for a directive of the EU Parliament and of the Council on the protection of the environment through criminal law and replacing Directive 2008/99/EC. Six objectives are targeted by the revision:
 - Improve the effectiveness of investigations and prosecutions; Ensure effective, deterrent and proportionate types and amounts of sanctions for environmental crimes.
 - Promote cross-border investigation and prosecution.
 - Improve the use of informed decision-making in the area of environmental crime through improved collection and distribution of statistical data.
 - Improving the operational efficiency of national enforcement chains to promote investigations, prosecutions, and sanctions. In particular, the Commission sees a need for stronger regulation in the following areas:
 - Placing on the market products that cause significant environmental damage because they are used on a larger scale
 - Serious breaches of the EU chemicals legislation
 - Illegal ship recycling, illegal water extraction, discharge of pollutants from ships, illegal trade of timber,
 - Serious breaches of regulations on the introduction and spread of invasive alien species
 - Severe circumvention of the requirements to conduct an environmental impact assessment
 - Illegal production, placing on the market, import, export, use, emission or release of fluorinated greenhouse gases.
- Numerous new criminal offenses are being created in these areas.
- Although the intention to improve the enforcement of environmental law is fundamentally to be welcomed, its implementation through the proposed tightening of environmental criminal law is neither necessary nor proportionate. The proposal respects neither the requirement of certainty nor the prohibition of excessiveness. Breaches of European environmental law are already subject to adequate and deterrent sanctions, both by the relevant EU regulations and in their implementation by the member states. It would therefore be sufficient to make targeted additions to the existing directive (requirements on preventive measures, personnel capacity in the judiciary, national statistics, electronic publication of relevant environmental offences, etc.).

11. Effects of EU law on approval procedures

- Basically: European environmental law is essentially examined within the framework of approval and planning approval procedures. The extensive examination program of the Industrial Emissions Directive, the Seveso III Directive, the Water Framework Directive, the Flora-Fauna-Habitat (FHH) Directive and the Conservation of Wild Birds Directive is very important. These directives require very time-consuming preparations and studies by the project developers and similarly place a considerable burden on the licensing authorities. The increasingly complex, sometimes unclear legal situation resulting from European law and its implementation complicates planning and approval procedures considerably. Urgently needed changes in European environmental law must be made on the EU level.
- In recent years, the requirements of European environmental law have led to considerable implementation difficulties in practice. In the Commission, the development of new regulations or the amendment of existing ones is largely controlled by the DG Environment. Consideration of economic interests does not take place enough or too late in the Commission and there is an overall lack of a complete, seriously substantiated impact assessment.
- Natura 2000:
 - The FHH Directive also grants strict protection to some species that are not endangered in Germany, which partly even like to settle in the proximity of humans as synanthropes and are therefore of great practical relevance in planning and approval procedures. The lists of species to be protected in the FHH Directive must therefore be updated and supplemented with the non-endangered species.
 - Potentials for effective promotion of biodiversity can be enabled by equivalent alternative measures instead of the identical compensatory measures, which are currently in place. For example, it seems to make more sense to protect particularly endangered species through more intensive compensation measures than less endangered species. The authorities should be given the opportunity to define the requirements flexibly and with common sense

12. CO₂- fleet regulation

- Proposal of the Commission of the 14th of July 2021 as part of the Fit for 55 package.
- For 2030, the EU Commission proposes a very ambitious tightening of the existing CO₂ limits from the current level of 37.5% to 55% for passenger cars and from the level of 31% to 50% for light commercial vehicles by 2030.
- A further tightening of the proposed 2030 fleet limit would significantly increase the already high transformation pressure in the automotive and mechanical engineering industry - especially for many small and medium-sized suppliers - and would therefore not be acceptable.
- As many parameters of the required framework conditions and especially the development of the charging infrastructure are still unknown at this stage, it is not appropriate to set detailed targets for 2035. A strict review clause by 2028 at the latest, identifying the need to set targets for the period after 2030, in particular based on monitoring of a reliable and comprehensive development of charging infrastructure in all member states, is an option that will continue to provide investment certainty for the industry while allowing for further technological development in the meantime.
- To achieve these 2030 targets, it is necessary to create a coherent and technology-open regulatory framework across all dossiers of the "Fit for 55 Pact", in particular with regard to the revision of ETD, RED III, EU ETS, ESR and AFIR, in order to enable the expansion of electric mobility and CO₂-neutral fuels

13. RL-E on the implementation of the global minimum tax in the EU

- Proposal of the EU-COM of the 22nd of December 2021
- The background is a worldwide agreement between around 140 countries on a global minimum tax on corporate profits of 15 percent ("Top-up-Tax"; OECD model legislation of the 20th of December 2021). The EU-COM's RL-E is based on the two-pillar model of the OECD/G20 countries. Pillar I aims to distribute tax revenue from corporate profits more equitably, pillar II aims to achieve a global effective minimum taxation level of corporate profits.
- The minimum tax should only be introduced in the EU as part of the overall concept of the OECD/G20 countries ("two-pillar concept"). The introduction of Pillar I and Pillar II should therefore be legally conditional to each other.
- The global minimum tax is intended to create a "level playing field" in the taxation of corporate profits: Globally active corporations that achieve a total annual turnover of at least 750 million euros and are not subject to an average tax rate of at least 15 percent in one country are to be subject to a "Top-up-Tax".
- For companies, this means: In addition to the previous profit determination, further tax and information returns must be submitted. These must contain far-reaching company data, which today is partly not yet available in the required form. In the future, companies will not only have to prepare existing national and international balance sheets. In addition, comprehensive calculations must be made for the minimum tax.
- The minimum tax can prevent possible excessive tax avoidance by companies. However, a uniform and worldwide implementation of the regulations is important. Disadvantages for German and European industry must be avoided. This requires prompt legal certainty, clear rules and regulations to avoid double taxation.
- The fast schedule for the implementation of the minimum tax in the EU disagrees with the complexity involved. Many regulations are still unclear or not yet sufficiently defined. Companies urgently need more time to integrate the new regulations into their processes, train employees and implement the measures. In concrete terms, this means ensuring (a) simplifying transitional arrangements and (b) a reduction in complexity. If this goal is not achievable, implementation should be postponed by 1 year to 2024. Quality must have priority over speed.

14. Minimum Wage Directive:

- The Commission had presented its proposal for a "Directive on adequate minimum wages in the EU" in October 2020. Both the Parliament and the Council have defined their respective positions and are currently in the "trilogue negotiations". The French Council Presidency is pushing for a rapid conclusion of the process in the first half of 2022.
- The Commission's proposal (which is to be significantly tightened up again by the Parliament) provides, among other measures
 - That member states with a collective bargaining coverage below 70 percent should develop an action plan to promote collective bargaining
 - that uniform criteria for setting national minimum wages should apply throughout the EU, whereby 60 percent of the gross median wage or rather 50 percent of the gross average wage can be used as an indicator for the appropriateness of minimum wages
- Impact: If no solution is found at EU level, whereby the one-time increase in the German minimum wage to 12 euros currently announced by the German government is recognized as full implementation of the Directive, there is a risk of significant distortions in the German collective bargaining system and collective bargaining autonomy. For example, the minimum wage commission's negotiating scope would have to be restricted. The indicator for "appropriate" minimum wages of 60 percent of the gross median wage or rather 50 percent of the gross average wage would create an automatic upward spiral for the minimum wage. This would cover the entire pay structure of all industries through the Lohnabstandsgebot (principle that benefits must be lower than wages). Labour would become even more expensive in high-wage Germany - to the disadvantage of the international competitiveness of our economy.
- The directive interferes with the competencies of member states and social partners in violation of the treaty; the setting of minimum wages threatens to be politicized by threshold values at the EU level. There are problems with the target for collective bargaining coverage with regard to negative freedom of association.

15. Pay Transparency Directive

- Status: Following the Commission proposal in March 2021, trilogues between the Council, Parliament and Commission will probably take place in spring 2022 to adopt the directive. The Council has given its mandate, the EP is still negotiating but is close to a conclusion. This directive is one of the priorities of the French Presidency.
- The directive imposes a large number of detailed information and reporting obligations on companies, which are to be used to determine gender pay gaps.
- The regulations go significantly beyond the German Pay Transparency Act (EntgTranspG), which first came into force in 2017, and would be associated with high additional bureaucratic burdens for companies, e.g.
 - In the EntgTranspG, companies bound by collective agreements and those applying them are explicitly protected due to their compensation structure which has been negotiated in social partnership (so-called "Angemessenheitsvermutung", § 4 Abs.5 EntgTranspG). The Directive, on the other hand, provides all companies with criteria on how to assess "equal work and work of equal value". This is a core task of the collective bargaining partners.
- Collective agreements do not recognize any differences according to gender - but unfortunately, they are not taken into account in the directive, and companies bound by collective agreements are not privileged. A far-reaching exemption for SMEs is also not ensured. In any case, transparency obligations will not change anything about the different career choices of women and men.
- Impact: The directive ignores the autonomy of the social partners to define criteria for a compensation structure themselves by collective agreement. For example, the requirements would lead to companies applying the remuneration framework agreement of the metal and electrical industry (ERA) not being exempted from the requirements. The ERA was intentionally designed to be gender-neutral. If the criteria of the Directive do not match those of the ERA, our collective agreements will be obsolete. In addition, considerable new bureaucracy is being created, especially for SMEs: for example, companies must even calculate a gender pay gap annually according to complicated specifications and, if necessary, conduct a detailed analysis of their salary structures with the works council, equality bodies and supervisory authorities - this is completely absurd if the companies apply a collective agreement.

16. Posting of Workers Directive

- Although this is not a legislative proposal, the Commission is working on a voluntary digital electronic form for the posting of workers
- In the course of the implementation of the Implementing Directive 2014/67/EU on the Posting of Workers Directive, completely different compulsory registrations for foreign assignments of employees were introduced in the EU member states. SMEs in particular can only cope with these national requirements by deploying additional staff or by commissioning external, costly service providers.
- The VDMA estimates the bureaucratic costs of EU work assignments for the German mechanical and plant engineering industry to be at least 51 million euros per year (for 205,000 assignments). However, the financial damage caused by the excessive compulsory registrations is many times higher for the posting companies

17. Coordination of social security systems (Regulation 883/2004)

- Status: Following the Commission's proposal in 2016, negotiations on the revision of the Regulation are locked in a stalemate: a preliminary trilogue result has already been rejected (correctly) twice by the member states.
- Content: In addition to many other regulations, the regulation also deals with the topic of the so-called A1 certificate, which is necessary for the posting of employees within the EU according to social security law.
- Unfortunately, it has still not been possible to achieve an A1 exemption for business trips and short provisions of services, which is absolutely necessary and practicable in business practice.

18. Fit for 55, Farm to Fork Strategy

- Catalogue of measures should be implemented between 2022 and 2024
- Legal framework for sustainable food systems; promote sustainable food consumption and facilitate the shift to a healthy and sustainable nutrition (e.g. sustainability label, origin labelling, reduced use of pesticides, reduced avoidable food waste).
- The EU is planning, among other measures, a mandatory, simplified additional nutrition labelling on the front of food packaging (front-of-pack labelling). An extension to loose goods is under discussion. The subject matter is the EU Food Information Regulation (1169/2011).
 - The introduction of the NutriScore as a voluntary labelling in Germany has shown that companies in the food industry marginally change their recipes or replace ingredients with questionable substitutes in order to obtain better labelling according to the logarithm of the NutriScore.
 - Actually, this deceives both consumers and the political supporters of the NutriScore. In addition, we reject the division into good and bad or especially "healthy" and "unhealthy" foods. Even if I just eat bananas, I will get sick! It has to be balanced including exercising. Therefore, there exists only good/bad or healthy/unhealthy nutrition/lifestyle habits, which are not corrected by green-washing food - especially by the industry.
- Reducing food waste
 - As part of the Farm to Fork initiative, a Commission proposal for binding targets to reduce food waste is to be set by the end of 2023. The same plan is already being followed in Germany. Here, we note that even the initial information is unclear and incorrect.
 - Businesses should be obligated to reduce food waste to an extent over which they have no control at all, since more than 50% of waste is generated at home by consumers and the majority of what is generated in production or trade is generated for reasons of food safety (e.g. destruction of contaminated charges) or due to legal requirements (e.g. retained samples that can no longer be used as food or incorrect labelling).
- Effects on German companies: difficult to calculate in general, e.g. the introduction of the nutritional table on packaged foods has cost two billion euros. The transformation to more climate-conscious production is likely to be much more expensive than the labelling elements.
- Implementing the measures of the farm-to-fork strategy requires a high level of investment on the part of the companies, and many measures are also permanent financial burdens (e.g. the carbon footprint of a food product is subject to fluctuations due to changing raw material suppliers, among other reasons, which is why a sustainability label would have to be constantly recalculated and new labels/packaging would have to be re-printed). Higher production costs are also passed on to consumers. Consequence: more expensive food.

19. Fit for 55, esp. LULUCF regulation

- Currently in the legislative process
- Increasing the CO₂ sink effect on agricultural and forestry land
- Ambitious CO₂ reduction targets without consideration of wood and biomass as a substitute for other raw materials lead to extensive cultivation, which means: less production

20. EU Nature Restoration Law

- Design stage
- Introduction of binding targets for the restoration of natural conditions
- Restrictions on the use and property encroachment of agricultural and forestry land

21. EU Biodiversity Strategy

- Strategy is completed, implementation still open (role of member states? By voluntariness or regulatory law? Baseline? Linkage with other EU plans)
- Protected status with partial ban on use of productive land
- Restrictions on the use and property encroachment of agricultural and forestry land

22. Anti Money Laundering Directive (AMLD 6)

- is in preparation
- already small-scale disclosure of ownership without protection of personal and competition-relevant data - bureaucracy for medium-sized enterprises without any achievement of objectives
- Planned next step: transition from national property registers to a European register. Completely ineffective in sanctioning of oligarchs but burdening medium-sized enterprises

23. Expiration at the end of 2022 of the General Escape Clause from the Maastricht criteria due to Corona has been openly questioned since last week

- Russian War may not be used as a pretext for systematic permanent national debt in Europe.
- Otherwise, inflation will be perpetuated and the ECB will remain permanently inactive. This will have a full impact on companies

24. Further government support options for RE systems through CCfDs + Renewable Energy Directive

- different guidelines at different stages
- The "newer" line of the EU Commission, in contrast to the past, considers a continued support of RE plants through, for example, CCfDs. This support eliminates the market mechanism of emissions trading and results in higher costs for climate protection. These are often covered up by the national GG.
- Costs for companies
 - Weakening of international competitiveness
- Costs for consumers
 - often covered up
- Overall negative economic and environmental impact, no cost- efficient climate policy
- Additionality principle for the expansion of RNFBOs is imposed on the operators. The distinction between direct and indirect electrification is reinforced by the different interpretation of the principle of additionality. While the responsibility for building additional RE capacity lies with RNFBO operators, direct electrification is considered to be more efficient and therefore end users are exempted from the responsibility for ensuring additionality.
- Additional costs of operating renewable gases and fuels compared to other renewables.

25. Market intervention price mechanism for energy

- Being discussed due to the crisis
- Toolbox of the EU, not necessarily first instrument, but a possible option
- In the short term, possible relief/disguised costs, in the long term much more expensive, since the market is turned off
- Definitely higher costs for consumers, question exclusively of cost distribution

26. Fit for 55, here: ReFuelEU Aviation (blending quota): COM (2021) 561

- An increasing blending quota for sustainable aviation fuels (SAF) is to be set for all departures from EU airports.
- Planned quotas: 2025: 2%, 2030: 5% (0.7% PtL), 2050: 63% (28% PtL).
- Commission proposal of the 14th of July 2021 as part of the Fit for 55 package
- The proposal aims to increase the supply and demand for sustainable aviation fuels (SAF) in the EU. This, in turn, should reduce the environmental footprint of aviation and contribute to achieving the EU's climate targets.
- The Commission's proposal in its current form would lead to significant distortions of competition and carbon leakage.
 - Reason: For international long-distance traffic, airlines bundle passenger flows at major air traffic hubs such as Frankfurt, London, Istanbul or Dubai: Anyone who wants to travel by plane from Hamburg to Singapore, for example, can then fly via these different hubs either with Lufthansa, Emirates, Turkish Airlines or British Airways. Passengers are guided primarily by price. With the now legally foreseen obligation to blend SAF/PtL, which is up to 3 to 5 times more expensive, and also the proposals to tighten the ETS and introduce a kerosene tax, air transport will become considerably more expensive.
 - However, the draft laws are now designed in such a way that they massively increase the price of passenger flows with EU airlines via EU air traffic hubs, while this increase in price does not take place for non-EU hubs. As a result, this would mean:
 - Examples (price differences caused exclusively by these regulatory additional costs)
 - Route Stockholm to Bangkok, price difference per passenger in 2030 = € 50.-, in 2035 = EUR 110.- Flight via Istanbul instead of Munich
- Competition-distorting additional costs must be prevented or compensated by appropriate measures to avoid traffic shifts to non-European airlines and airports, which would lead to a shift in emissions. A shift to non-European airports, kerosene providers and airlines and the associated shift of CO₂ emissions should also be avoided at all costs.
- Counterproposal: The blending obligation is initially limited to intra-European traffic only (that is approx. 50% of the volume) and the quota is increased in return. Effect: no disadvantage against non-EU hubs, no distortion of competition, no carbon leakage and - since the quota is set higher - the same climate effect.

27. EU-ETS – Aviation: COM (2021) 552

- Revision of emissions trading in aviation (EU ETS): ETS is to be further developed in such a way that after a transitional period all certificates must be purchased (already today approx. 60% certificates are subject to a charge). ETS only applies to intra-European flights.
- Leads to significant carbon leakage and distortion of competition at the expense of EU airlines and EU airports (see above for justification)
- Counterproposal: Structure the proposal to tighten the ETS in such a way that EU airlines are put on an equal footing with non-EU airlines in international transfer traffic.

28. Revision of the Energy Taxation Directive, ETD (kerosene taxation): COM (2021) 563

- here, a kerosene tax should be applied to all intra-European flights beginning in 2024
- Leads to significant carbon leakage and distortion of competition at the expense of EU airlines and EU airports (see above for justification).
- Proposal: Avoid kerosene taxation; use instead the competition-neutral end-destination-related air traffic tax/passenger tax.

29. Digital Markets Act (Contestable and Fair Markets in the Digital Sector)

- Already existing proposal: Regulation on contestable and fair markets in the digital sector (Digital Markets Act - DMA), legislative, document COM (2020) 842.
- Trilogue negotiations (expected to be concluded by May 2022)
- Implementation still unclear; two or six months after entry into force
- Competition law regulations esp. for large digital gatekeepers, e.g. for calculating user numbers, interoperability, consumer protection, dealing with whistle-blowers etc. + sanctions
- Economic Impact:
 - very high sanctions in case of EP proposal
 - Definition of gatekeepers, i.e. scope of regulation, is very far-reaching (up to smart TVs)
- Note: DEHOGA welcomes the regulation in principle, as an important instrument to tackle the gatekeeper practices of the leading online hotel booking portals. These practices are currently a major obstacle for the digitalization and online strategies of hoteliers. Addressing the gatekeeper practices of the leading OTAs represents an important step towards the digitization of thousands of European tourism businesses.

30. Digital Services Act (Single Market for Digital Services)

- Trilogue negotiation (expected to be completed by June 2022); implementation still unclear; six or 18 months after entry into force
- Rules for the governance of platforms and digital services
- Moderation of content on platforms
- Rules for dealing with targeted advertising
- Exemptions for SMEs
- Platforms will be obligated to remove reported illegal content.
- DSA should complete the e-Commerce Directive; regulation of e-commerce should be adapted to new technical possibilities so that e-commerce is legally secure and legal
- The aim is to make it more transparent according to which criteria the algorithms of the platforms play out content.
- Economic Impact:
 - High effort for reporting and transparency obligations
 - Need to adapt business model if targeted advertising is banned
- Examples:
 - So-called "dark patterns" should be banned. These "dark patterns" are the tricky design of user interfaces that are intended to persuade users to perform certain actions or to refrain from performing them. Statements like "Last chance. We only have 1 room left" will thus finally disappear from online booking portals.
 - Banning targeted ads would have a massive negative impact on the entire advertising ecosystem, such as media outlets, content creators
 - Risk of more advertising directed at consumers since not targeted // or more fee-based services
 - Depending on the design of the DSA, it would be possible to better identify and sanction sellers of counterfeits (e.g. exclude them from a sales platform), warn other buyers, remove counterfeits from the network and prevent distribution, etc. Concrete:
 - Currently, the EP proposal contains a so-called SME waiver, which risks that counterfeiters will switch to small platforms and thus consumers will be at risk in case of purchases there.
 - Problem: Lack of information collection obligations regarding the seller for platforms, regardless of whether they are transaction or interaction platforms.
 - Problem: Possibility to re-upload products identified as counterfeit leads to additional effort for manufacturers to identify products

31. Data Act

- COM proposal published (on the 23rd of February)
- Implementation is expected 12 months after entry into force
- Contents
 - Intensification of data sharing and improvement of data access
 - B2B: obligation to provide data to users and third parties (partly without remuneration), minimum information obligation before conclusion of contract, exemption for SMEs
 - B2G: Provision of data to the state without remuneration, especially in emergencies or to maintain functionality).
 - Ensuring the interoperability of services
- Economic impact
 - Interference with freedom of contract & risk to trade secrets
 - Technical implementation of interoperability regulations still unclear, possible threat to end-to-end encrypted services today
 - Trade secrets and know-how are not sufficiently protected, investments in data generation become partly obsolete, negative impact on global competitiveness especially of SMEs
 - Obligation to share data (partly free of charge), especially with the public sector
 - Legal uncertainty due to unclear definitions
- Additional bureaucratic obligations: Manufacturers of networked machines must provide information about the data generated by the machine and make the data available via the appropriate design of interfaces.
- Existing contractual agreements may have to be revised.
- Threat to investments: It is possible that investments in data generation will decline because corresponding profits from data-based business models will be externalized.

32. AI Act

- COM proposal published (April 2021), discussion in EP Committees and Council Working Group ongoing, implementation expected 24 months after entry into force
 - Core contents:
 - Definition of AI (Artificial Intelligence)
 - Creation of a regulatory approach based on the "risk classification" of an AI or an algorithm (and consequently various obligations for providers/users of the respective AI)
 - Economic impact
 - Legal uncertainty due to currently unclear definitions of terms
 - Delays due to slow standardization process
 - Risk of services unjustifiably receiving a high-risk classification (and resulting effort)
 - Examples:
 - Medical software to detect possible diseases earlier ==> Benefit is sufficiently considered, but definitely outweighs the risk
- Automated claims handling at insurance companies does not create a higher risk for consumers, but creates much more capacity for necessary individual case handling

33. Creating a framework for a European digital identity

- Already existing proposal: Regulation for the amendment of Regulation (EU) 910/2014 with regard to the creation of a framework for a European digital identity
- Application example: Digital check-in at a hotel

34. EU Commission initiative concerning short-term rentals

- The European Commission has announced a legislative proposal concerning short-term rentals for the 1st quarter of 2022 and has opened a consultation on this subject. Short-term rentals are in particular services of the "sharing economy" (rental of vacation homes), which are often marketed via online platforms. These are significant for European tourism - they currently account for 23% of accommodation and continue to grow - and are becoming increasingly professionalized. There are a variety of different regulations regarding the short-term rental market at member state level, which can negatively affect the single market and the economic development of short-term rentals. There is also a deficit of information for authorities about the providers of short-term rental accommodation, as especially the platforms - operating across borders - often do not share their data.
- Objectives:
 - Fair market conditions in the single market and greater transparency in the market for short-term rentals
- Impacts:
 - Registration obligation for lessors of STRs
 - Obligation of the platforms to publish the offers compulsorily under indication of the registration number
 - Obligation of the platforms to transmit data to the responsible national authorities
 - Establishment of an exemplary catalogue of admissible regulatory measures in the EU legislative act

35. Package travel - revision of legislation (alignment with COVID-19 context)

- REFIT Initiative:
 - As announced in the New Consumer Agenda of 2020 and the report of 2021 on the Application of the Package Travel Directive, the COM will assess whether the Directive ensures robust and comprehensive consumer protection on all occasions, also taking into account aspects of insolvency protection and lessons learned from COVID-19. The assessment will take into account the relevant measures of the Sustainable and Smart Mobility Strategy. Based on this assessment, a proposal for a revision of the Directive could be presented by the end of 2022.
 - The revision will also examine the possibility of simplifying or tightening the rules and definitions for linked travel services and their distinction from package travel, in order to make it easier for the industry, consumers and enforcement authorities to determine which rules apply to a given combination of services. The possibility of simplifying information obligations while maintaining consumer protection, clarifying certain other provisions (e.g. on voluntary vouchers), and further alignment of the Package Travel Directive with the Passenger Rights Regulations will be reviewed.
 - legislative, 4th quarter of 2022

36. Right to Repair

- Current status: Consultation
- No regulation exists yet, therefore no content; consultation aims to identify how a consumer right to repair can/should be regulated to achieve greater sustainability
- Not all industries are affected equally, but only manufacturers of products where repair is possible; however, these members are affected depending on how the regulations are designed
- Examples:
 - Depending on how the planned regulation would be designed, manufacturers would possibly be obliged to repair, which could lead to high costs (logistics, storage of spare parts). On the other hand, such a regulation could also deprive manufacturers of the opportunity to repair their products themselves, which could have negative consequences in terms of repair expertise etc.

37. EU Instruments for Counterfeit Protection

- No fixed regulatory content yet, but measures proposed
- Good approaches to combat counterfeiting, but further approaches needed
- Examples:
 - Proposed measures should include e.g. more cooperation between rights holders, better cooperation between national authorities and between member states

38. Green Claims

- Upcoming proposal of the EU Commission to prevent greenwashing; publication planned for July 2022
- Specifications for substantiating statements on environmental properties
- Authorization requirement for environmental claims in advance according with Health Claims Regulation would create bureaucratic obstacles for the marketing of environmentally friendly innovations.
- Examples:
 - Environmentally friendly innovations cannot be marketed due to lack of pre-approval. The replacement of more environmentally harmful products with newer, more environmentally compatible ones is delayed.
 - It is clear, however, that the statements must be substantiated: no data no claim

39. Working conditions of platform employees (Directive on improving working conditions in platform work)

- Status: The Commission presented a proposal for a directive (and a guideline on the right of association) in December 2021, which is now being discussed in the Council and Parliament.
- Content: The Commission wants to improve the working conditions and access to social protection of platform employees, as well as enable self-employed platform employees to organize themselves under collective law. The core element of the directive is the assumption of an employment relationship for certain platform employees.
- The differences between dependent employees and the self-employed professionals anchored in German law must be preserved. Otherwise, there is a risk of effects far beyond the area of platforms.

40. Regulation of machinery products (new version of the Machinery Directive)

- In the legislative process
- The proposal is scheduled to be published on the 30th of March 2022.
- Safety regulations should be adapted to new technologies (AI);
- Commission draft foresees massive extension of third-party certification with the idea of a horizontal product directive for the EU market.
- Includes the revision and opening of the Eco-design Directive in order to be able to address all products throughout their entire life cycle including all environmental parameters in the future. The product passport as an instrument of traceability and transparency.
- The third party certification foreseen in the Commission draft delays the market entry of innovations and is expensive (according to the EU Commission about 170.000 € additional per assessment)
- Regulation of products (indirect impact) that are produced with/on MuA technologies, as for mechanical engineering products themselves (direct impact). Associated with comprehensive product specifications in terms of sustainability and high data effort associated with the DPP.
- In particular, innovations in small series are hindered.
- Possible full declaration of products.
- Costs in data effort and handling.

41. SCIP

- Is applicable since the 5th of January 2021. Submission of information to ECHA.
- Database for information on substances of concern in products established in the framework of Waste Framework Directive.
- Entries in the database are associated with immense bureaucratic and financial effort.
- No actual added value for the environment/sustainability can be identified so far, as most products continue to be handled in recycling as before

42. PFAS

- Individual EU-MS have submitted an application to restrict the PFAS group of substances. A public consultation will be launched at EU level beginning the 15th of July 2022.
- Planned far-reaching restriction of per- and polyfluoroalkyl substances
- Instead of imposing individual substance restrictions as in the past, an entire group of substances (PFAS) should be banned.
- This poses a serious threat to business models in the mechanical engineering sector, since a restriction would mean that most mechanical engineering technologies could no longer be brought to market.
- The named substances are contained, for example, in sealing rings. This means that all components/technologies containing them may no longer be placed on the European market.

43. Energy Efficiency Directive

- In the legislative process
- Revision of the existing directive to meet the increased climate targets.
- Energy audit recommendations with a payback period of less than four years will be mandatory according to the current draft. Could be expensive for larger companies and the shortage of energy audit consultants increases the price. On the other hand, only the companies with slightly higher energy consumption will now be affected by the new proposal.

44. Consumer Credit Directive + Mortgage Credit Directive

- The EU Commission presented a proposal to revise the Consumer Credit Directive on the 30th of June 2021.
- The EU Parliament's Consumer Protection Committee submitted a draft report regarding the Commission's proposal on the 31st of January 2021.
- A consultation is currently taking place regarding a possible revision of the Mortgage Credit Directive by the EU Commission.
- Estimates on the impact for the banking sector / member institutions of the Association of German Public Sector Banks (VÖB)
 - Tightening of the already existing sufficient regulations for consumer loans / residential property loans would lead to considerable additional personnel and technical expenses for all affected member institutions.
 - Due to the internal cost increase caused by the additional expenditure, lending would be reduced for lack of sufficient profitability.
- Concrete examples of the effects
 - Additional required general and pre-contractual information increases the complexity of lending.
 - A tightening of the requirements for creditworthiness checks would possibly exclude certain groups of consumers (e.g. with fixed-term employment contracts) from receiving credit.

45. Digital Operational Resilience Act (DORA)

- The planned harmonization of regulatory requirements for the resilience of ICT infrastructures must not lead to disproportionate additional burdens on the banking industry and ICT service providers.

46. SEPA real-time payment

- The EU Commission would like to oblige all institutions to make SEPA real-time payments through regulation.

47. Alternative Fuels Infrastructure Regulation (AFIR)

- The EU Commission wants to simplify charging at charging stations in Europe.

FROM HERE: ALREADY DECIDED, BUT NEED FOR CORRECTION:

48. Medical Technology

- New EU regulation on medical devices already in force (i.e. stop/slow down no longer possible, but adjustments within the system), poses major challenges to companies, e.g.:
 - Regulation (EU) 2017/745 on medical devices (the so-called Medical Device Regulation; MDR) has been in force since the 26th of May 2021, and newly regulates EU market access for medical devices such as pacemakers, devices for intensive care and diagnostics, and surgical instruments.
 - The implementation of the new requirements is associated with major challenges for all stakeholders involved and in particular for the many small and medium-sized enterprises manufacturers of medical devices.
 - Among other challenges, the companies are facing significant cost increases and there are considerable bottlenecks in the certification system due to a lack of sufficient capacity at the notified bodies. Overall, there is a risk that the new regulation will have a significant negative impact on the innovative strength of the industry and that many important existing products will also be removed from the market.
 - This would not only affect the quality of healthcare, but also the medical technology industry as an important economic factor in Germany in general.
 - Pragmatic solutions are urgently needed here.

49. Public Country by Country Reporting

- Directive adopted in December; implementation into national law by 22nd of June 2024
- Disclosure obligation of country reports of multinational companies with consolidated group sales of more than 750 million euros in two consecutive fiscal years, disclosure to be made for each EU member state of information on the type of business activity, the number of employees, the pre-tax profit and the income taxes incurred
- Member companies fear competitive disadvantages, particularly compared with USA and China, and increasingly far-reaching disclosure obligations after implementation in national law.