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DIN

Economic Analysis of Conformity Assessment and Accreditation in Germany

Executive Summary of the Final Report

August 2013

Project goals

In August 2012 the *Bundesministerium für Wirtschaft und Technologie* (BMWi) commissioned a study on the future development of conformity assessment and accreditation in Germany. The project was conducted by Technopolis Group in cooperation with *DIN Deutsches Institute für Normung DIN e.V.* (DIN).

The main **objective** of the study was to assess the economic significance of conformity assessment (CA) and accreditation (Acc) and to provide input for future policy making in this area. The team was tasked with analysing the market for CA in order to draw conclusions regarding the future demand for accreditation in selected sectors.

In addition, **two key questions** concerning the political framework of conformity assessment and accreditation were to be addressed: (1) within which sectors should CA and Acc be legally regulated; and (2) in which sectors should accreditation be used as a means of demonstrating the technical competence of conformity assessment bodies?

The team chose a **qualitative methodology** including document analysis, conducting around 90 interviews and holding several workshops with experts from conformity assessment bodies, industry and industry associations. The study included an analysis of the overall market for conformity assessment, as well as a more detailed examination of seven "key sectors" that were selected by the team together with BMWi. While the validity of the results might be limited in a statistical sense, they can be considered a plausible estimation of the economic significance of conformity assessment and accreditation, as they were triangulated and corroborated in discussion with experts. In addition, the report contains a conceptual piece, which outlines the principles for policy making in this area.

The conformity assessment system from a regulatory policy perspective

The team developed an understanding of CA and Acc from a regulatory policy perspective, which complemented existing legal discussions of the subject and provided the basis for the market analysis and the discussion of the two key questions above.

Confidence in the quality of product and services, as well as the reliability and competence of suppliers is an essential precondition for trade, particularly international trade. This confidence becomes ever more important as the attention in global negotiations shifts from the abolition of tariffs to the reduction of non-tariff trade barriers, such as regulations about health, safety and environmental issues. Similar issues need to be addressed for the successful completion of the internal market. The existing system of standardisation, conformity assessment and accreditation offers an important source of confidence among buyers and sellers, as well as national authorities.

The **conformity assessment system** consists of three elements:

- Definition of requirements, e.g. in performance standards;

- Conformity assessment, i.e. activities, which show that a product, service, system or person meets specified requirements. The assessment can be carried out by the manufacturer, the customer, or an independent conformity assessment body (CAB);
- Confirmation that such a body is competent to carry out specific CA tasks, e.g. through accreditation.

From a regulatory perspective, this system can help to internalise market imperfections such as information asymmetries or external effects. It helps to build the confidence that is required for the effective operation of markets, in particular international markets, among all market actors.

There are **three ways** in which the conformity assessment system can internalise market imperfections, depending on the role that government decides to play:

- In what is called the **voluntary area** (in German "*freiwilliger Bereich*"), private actors initiate and agree on the requirements, the need and ways of CA, as well as Acc. Often the rules for these activities are decided upon at international level, e.g. in the form of norms of the International Organisation for Standardisation (ISO). Governments may participate in the negotiations as one actor among equals.
- In what is dubbed **mandatory area** (or legally regulated area, in German "*gesetzlich geregelter Bereich*"), governments set the rules for all market actors regarding product requirements, the obligation and/or processes of CA, as well as Acc. In the case of the internal market, the rules are adopted by the instuitions of the European Union (EU) in regulations and directives and complemented by harmonised European Norms ("harmonised area"). In addition, national governments may set national rules ("national area").
- Finally, governments may not only regulate requirements, CA and Acc but may also carry out the conformity assessment or delegate it to public agencies. In what we call **sovereign area** (in German "*hoheitlicher Bereich*"), government is the central actor of CA, often assuming competence without any further assessment. This is for example, the case in sensitive areas such as civil security, armaments or public transportation.

From a regulatory policy perspective that emphasises innovation, the economic advantages of using the conformity assessment system consist in its contribution to the internalisation of market imperfections. However, the definition of requirements and rules for CA and Acc always implies a cost for companies and customers, which might represent a barrier to the introduction and diffusion of novel ideas. These aspects require due consideration when shaping the conformity assessment system in a particular industrial sector, be it by private or state actors.

Analysis and forecast of the overall market size

The German market for conformity assessment and accreditation is characterised by a complex group of actors including companies, CABs, permission granting bodies (*Befugnis erteilende Behörden* or BeB) at federal and *Bundesländer* level (they also act as notifying bodies) and the national accreditation body, *Deutschen Akkreditierungsstelle GmbH* (DAkkS). There is

very little data on the market that is systematically collected. According to the information provided by the Federal Statistical Agency (*Statistisches Bundesamt*) and the DAkkS, there were about **5,380 CABs** with approximately 86.100 employees in 2010. Their overall turnover amounted to € 8.8 billion, with around **€ 6 billion sales in Germany** alone. Of the 5,380 companies, an estimated 3,300 firms held about 4,300 accreditations.

However, the economic significance of CA and Acc is much larger due to their indirect effects:

- On the one hand, both instruments are characterised by a "**leverage-effect**", simply because volume of sales made with products and services, which depend on CA and Acc, exceeds the turnover of CABs by a factor of 35-60. Without CA and Acc these products and services could not be traded, as buyers only accept them on the basis of a certificate by a CAB, preferably a CAB that has been accredited.
- On the other hand, the regulatory policy considerations, outlined in chapter 2, demonstrate that **many markets would not operate** at all or not as efficiently, if CA and Acc could not be used for the internalisation of market imperfections.

Based on our analysis we expect the demand for CA and Acc to grow in the coming years. A simple trend analysis of the years from 2008 to 2010 shows that sales might **grow by as much as 10% p.a.**, while the number of CABs will stagnate or even fall. Factors driving this development are the continued growth of international trade, involving an increasing specialisation along the value chain and a regulatory policy that makes increasing use of accreditation, among others.

Analysis and forecast of seven key sectors

Alongside the analysis of the overall market for CA and Acc, the report examines the developments in seven key sectors ("*Schlüsselfelder*"), which were selected together with the client. For each sector we provide a brief characterisation of the economic and legal framework conditions, a market analysis and forecast, as well as conclusions. The following section summarises the most important findings.

Construction products

In 2011 around 5,600 construction product companies with app. 340,000 employees generated sales of circa € 91 billion in Germany. The yearly turnover of independent CABs is estimated to be on the order **of € 100-150 million**, which corresponds to approximately 0.1-0.16% of the sales figure ("CAB-Ratio").

CA in this sector is largely regulated at EU level. On July 1st 2013 the **EU Construction Products Regulation** (EU No 305/2011) entered fully into force. As such, an accreditation is required as a prerequisite for the notification of a CAB. While the German Institute for Construction Technology (*Deutsches Institut für Bautechnik* – DIBt) will continue to notify CABs to the European Commission, it does so now on the basis of an accreditation carried out by the DAkkS.

The **consequences** for the market for CA and the demand for Acc still remain to be seen. Consequently, no final assessment has been offered in this report.

However, the experts interviewed for this study expect a decrease in the number of CABs, as well as structural and qualitative consequences, e.g. the merger of smaller CABs. As such, we would suggest a systematic assessment of the impact of this legal change in around two years time, in order to obtain a better understanding of the effect of the instrument of accreditation.

The switch from an assessment by the DIBt to an accreditation by the DAkkS is considered to be a success by those involved in the process and interviewed for this report. While there were specific legal requirements that were not covered by the accreditation, these could be accommodated through the design of the accreditation rules. They were presented to the representatives of other EU Member States and the model inspired similar solutions in other countries. This strategy – to formulate specific accreditation rules – seems to be a promising way to adapt the instrument of accreditation to the particular needs of the mandatory area, in those cases where the law calls for the assessment of competences in addition to those laid down in international norms.

Medical products

The German market for medical products accounted for about € 24 billion in 2011. The yearly turnover of independent CAB amounted to **€ 50-70 million**, which corresponds to 0.21-0.31% of the overall market.

The production and application of medical products and diagnostics **accreditation remains largely voluntary**, with two exceptions: the screening of newborn babies and pre-implantation diagnostics; in both cases an Acc is legally required. Many CABs seek an accreditation by the DAkkS, given the strong export orientation of their clients. The EU directives for medical products and In-vitro-Diagnostics call upon manufacturers to involve a **notified body** for the CE-labelling. In Germany, the ZLG (short for *Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten*), a joint agency of the *Bundesländer* acts as the notifying body in this sector. The ZLG conducts its own assessments to evaluate the competence of a CAB in the process of notification. Though ZLG and DAkkS have attempted to harmonise their assessments for notification and voluntary accreditation purposes respectively, many of the interviewed experts working for CABs see **considerable room for improvement** in the coordination of their activities.

We expect an increasing demand for CA in the future due to three reasons: the planned adoption of an EU regulation for medical products, the high pace of product innovation and increasing exports of medical products. The latter two factors also point to a rising demand for accreditation.

Toys

Toy companies in Germany produced products worth € 1.53 billion in 2012. The market for CA is dominated by ten independent CABs, which all hold an accreditation. According to the majority of the interviewed experts, the turnover of all CABs amounts to **app. € 3-5 million**, which corresponds to 0.19-0.32% of the production value.

In the **future**, the experts interviewed for this study expect an increasing demand for conformity assessment, as well as for accreditation, due mainly to changes in the regulatory environment, while expectations for voluntary accreditation are mixed.

The **chemical part of the EU Directive** on the Safety of Toys (2009/48/EC) will enter into force in the second part of 2013. However, so far not all harmonised norms have been finalised. As such, manufacturers and CABs expect an increased cost for conformity assessment and as a consequence, the finalisation of all relevant norms should be a priority for all actors involved.

Vocational training

The German market for vocational training has a size of approximately € 35-50 billion. The annual turnover with certification – the only relevant form of conformity assessment in this sector – amounts to **€ 30-70 million**, which implies a CAB-ratio of 0.10-0.14% of the overall market.

All major actors in the market for vocational training hold an accreditation. If service agencies providing vocational training wish to obtain public funds, they require a certification by special certification bodies – *Fachkundige Stellen*, which in turn require a formal assessment of their competence. While the Federal Employment Agency (*Bundesagentur für Arbeit – BA*) carried out this assessment until 2012, it is **now the DAkkS** that assesses the certification bodies and issues an accreditation. An estimated € 24-25 million of the annual turnover of the certification bodies depend directly on accreditation.

The experts interviewed for this study foresee a **continued increasing demand** for CA and Acc. Moreover, they anticipate challenges regarding the extension of certification to additional labour market instruments such as private employment services. In this case the assessment of the competence of certifying bodies is expected to become more demanding.

Several experts call for **improvements in the coordination** of the work between the DAkkS, the *Fachkundige Stellen* and other actors such as the Federal Employment Agency. Moreover, they suggest that a critical review of the rather steep increase in cost that accompanied the switch from an assessment of CABs by the BA to an accreditation by the DAkkS is necessary.

E-Mobility

The market for electromobility (e-mobility) is still rather small with a number of early-stage technologies. The German market for conformity assessment in this sector is estimated to have a size of **around € 5 million**. Large CABs such as VDE or the TÜVs *Nord*, *Süd* and *Rheinland* are currently positioning themselves with test centres, e.g. for batteries. The general insecurity regarding the technology is also reflected at the level of conformity assessment and as such, demand is rather tentative. At the same time, the existing CA-resources are considered to be sufficient in order to meet a potentially rising demand and will not hamper the diffusion of e-mobility.

Currently, there is no legal obligation for any **e-mobility-specific conformity assessment**. In the future a voluntary certification of batteries or charging stations might become instrumental in order to ensure customer acceptance, especially if security concerns rise among potential users.

There is currently, also no **e-mobility-specific accreditation**, e.g. for batteries, a situation that is not expected to change in the near future. However, in light of the concerns raised after the fires of batteries aboard several Boeing 787 Dreamliners, it seems to be advisable to carefully observe

the technological developments, as well as the public debates, as such incidents might undermine public confidence in e-mobility too.

Civil security

In 2012 the market for products and services in the civil security sector in Germany amounted to € 11 billion. It was not possible to establish the turnover generated by independent CABs in this sector. Rather, we focused on two segments that exemplify different parts of this market:

- In the area of **fire alarm systems** CABs are estimated to generate sales on the order of € 4 million per year. Turnover is expected to slightly increase over the next years;
- In the more sensitive area of **aviation security** EU Regulation No 185/2010 created a demand for the assessment of manufacturers who are sending their products by air cargo. Such manufacturers are referred to as a "known consignor". Currently, the Federal Air Traffic Agency (*Luftfahrtbundesamt* – LBA) conducts the assessments and grants the permissions. In other words, state authorities *carry out* the conformity assessment, which is characteristic of the **sovereign area** ("*hoheitlicher Bereich*") of CA. Should the conformity assessment in this segment be deregulated (thereby becoming part of the mandatory area), private CABs could become active in this field. According to the experts interviewed for this study, this could lead to the creation of a market of around € 12 million. The BMWi should, together with the Federal Ministry of Transportation, Construction and City Development (*Bundesministerium für Verkehr, Bau und Stadtentwicklung* – BMVBS), examine to what extent the conformity assessment system could be used to carry out the CA tasks in this segment.

Based on this particular example we suggest more generally that, as part of the impact assessment of any new or renewed EU legislative act, it is systematically checked to determine to what extent conformity assessment activities are affected by the planned act and whether they could be obtained from private actors.

Appointed surveyors and certified experts

In Germany, officially appointed surveyors ("*öffentlich bestellte Sachverständige*") and officially sworn surveyors ("*öffentlich vereidigte Sachverständige*") have for many years carried out tasks that are in other countries done by certified experts. In recent years the certification of persons has become more prominent. The BMWi had asked the team to provide a brief analysis of both approaches. The team examined the segments of real estate and greenhouse gas emissions in greater detail.

As for the **real estate** segment there are currently three bodies operating certification of persons to ISO/IEC 17024. They generate an annual turnover of **€ 1.6-1.8 million**. The cost of their accreditation amounts to 2-3% of their total turnover. The equivalent figures for greenhouse gas emissions could not be established. A major advantage of the certification of persons to ISO/IEC 17024 compared to officially appointed or sworn surveyors, is in the reduction of transaction costs in cross-border operations. This is simply due to the fact that the certification is based on internationally known norms and not on German regulation. Hence, in sectors with a strong international element the

certification of persons should be supported on the condition that the high level of quality provided by surveyors can be assured. As for the latter, some experts expressed scepticism that the conformity assessment system will provide the same high-level quality as the system based on official appointment. In this context it would be useful to assess to what extent the accreditation of CABs would also involve an in-depth examination of the certification programmes.

In the **segment of greenhouse gas emissions** both systems will co-exist in the future. In other words there will be experts certified by CABs with an accreditation of the DAkkS, as well as surveyors officially appointed by the German Agency for the Accreditation and Authorisation of Environmental Surveyors (*Deutschen Akkreditierungs- und Zulassungsgesellschaft für Umweltgutachter mbH* - DAU). Consequently, close coordination between the DAkkS and the DAU will be required after the adoption of the amended law on the greenhouse gas emissions trade.

Proposals for the future development of the CA-system

On shaping the mandatory area

There are two possibilities to alter the shape of the mandatory area: either topics, for which previously market imperfections had been internalised in a voluntary manner, become the subject of regulation; or conformity assessment activities carried out by the state are deregulated and will in future be taken over by private actors according to rules set by government.

Based on the regulatory policy considerations outlined above and the results of our empirical analysis we suggest that the conformity assessment system is used for the **deregulation** of government CA activities. The following indicators point to the possibility that such tasks could be transferred to the conformity assessment system:

- Governmental bodies carry out conformity assessment activities for example testing, verifying, or certifying,
- They do so in a sufficiently high number of cases and
- That sovereign rights are not or only to a limited extent required to carry out those CA tasks.

In a situation where these conditions are met, we suggest a systematic check for the possibility of shifting the CA activities from the sovereign to the mandatory area. However, a comparable level of security and quality needs to be assured when government focuses on setting the rules but leaves the execution of tasks or also the formulation of detailed provisions, e.g. for testing, to private actors. Such considerations should quasi-automatically be considered in the process of formulating new legislation. To this end all departments of government should be informed about the opportunities of using the conformity assessment system for the purpose of deregulation.

For the **regulation** of sectors that have previously been part of the voluntary CA and Acc, the government has three options: it can either regulate the definition of requirements, the process or obligation to assess the conformity of a product, service, person etc. or the obligation to obtain an assessment of the competence of a CAB. From a regulatory policy perspective the first option represents the most important leverage for the internalisation of market

imperfections. Under which conditions a regulation becomes pertinent remains to be seen in every single case. It is for example required if damages to health, environment or climate have occurred or are imminent and cannot be avoided in any other way or if risks, that are little known, have to be reduced or avoided.

The conformity assessment should be regulated if market actors do not have sufficient incentives or the capabilities to internalise the market imperfections. By setting the rules for conformity assessment, government can regulate the market access for CABs.

On the use of accreditation in the mandatory area

The second key question concerned the use of accreditation as a means of demonstrating the technical competence of CABs in the legally regulated area. **Accreditation had originally been developed in the voluntary area** and is based on internationally agreed norms. Only the *New Legislative Framework* (NLF) made accreditation an instrument of safety and quality control in the single market. It made accreditation the preferred way to establish the technical competence of a conformity assessment in order to ensure the necessary level of confidence in the certificates of CABs throughout the single market. However, national authorities may also consider alternative means of evaluating the competence of CABs.

In principle, the NLF assumes that the harmonised European norms, which form one basis for the accreditation of CABs, fully reflect the legal requirements laid down in EU directives or regulations ("presumption of conformity"). In as much as there are **any differences between the requirements of the norms and those of the legal texts**, additional assessments may be required, which is e.g. implied by the proposal for an EU regulation on medical devices (COM(2012) 542 final). In such a situation the question arises, whether and if so how the instrument of accreditation could address the gap between the two sets of requirements.

Our analysis suggests that **accreditation should be consistently used** as the means of demonstrating the technical competence of CABs, if certain conditions are met and if it is made transparent which additional requirements need to be addressed. The conditions include among others the continuous development of independent scientific expertise and the maintenance of a pool of qualified evaluators, which are both fundamental for a high quality assessment.

A major **reason for using accreditation** as the instrument of demonstrating the competence of CABs is the fact that its role in international trade has significantly increased in recent years and is expected to grow further in years to come. Moreover, alternative forms of evaluating the competence of CABs do not have any advantages, as they also imply testing by random sampling, longer processing time and higher risks of objections than a notification based on accreditation.

Gaps between the requirements of norms and legal texts should be taken into consideration by way adapting the **accreditation rules**. The introduction of the Construction Products Regulation might serve as a good example for the success of such a strategy.

Further recommendations

In addition to the rather principled recommendations above we suggest a number of more operative measures:

First, we recommend a systematic collection of information in order to **generate and disseminate knowledge** about the conformity assessment and accreditation. It is essential for the operation of the system to present core concepts in an accessible manner and to outline the purpose and functioning of the conformity assessment system to all relevant stakeholders in the political and economic arena. Additional data is required about the effects of accreditation on market structures and the behaviour of actors, as well as the strengths and weaknesses of the current system.

Moreover, we suggest a closer **coordination between market access control and market surveillance**. The new EU regulation on market surveillance is to enter into force in 2014 (COM(2013) 75 final). Since the competence for market surveillance in Germany rests with the *Bundesländer* the Federal Government should consult with the *Länder* on how to ensure effective market surveillance, making optimal use of the competences and capacities of the conformity assessment system. At EU level the extent to which information collected for market surveillance purposes could systematically be fed back into the improvement of the conformity assessment system should be examined.

Even though it was not part of the project task to evaluate the **operation of the DAkkS**, we would advise a thorough follow up on the concerns expressed by a large majority of all experts interviewed in the course of this study about long processing times, high cost and an increasing formalism of the accreditation. Otherwise, there is a serious risk of delays in the process of accreditation, which would also have negative consequences for product markets.

The **mutual exchange of experience** among accredited CABs is an important instrument to assure a homogenous level of conformity assessment and the acceptance of accreditation as an instrument. Against this background the existing opportunities for mutual learning offered by the DAkkS should be examined with regard to their content, number and evaluation by those for whom they are provided. In this context it should be considered to what extent the existing attribution of costs affects the participation and contribution especially of small and medium-sized CABs.

For the successful completion of the single market it is instrumental to strengthen the confidence of all public and private actors in the system that was created with the New Legislative Framework. It is of particular importance to **ensure fair and equal conditions of competition** among CABs in the entire single market. Consequently, the relevant bodies in EA should be encouraged to ensure a stronger harmonisation of assessment practices across Europe. Moreover, the relationships between EA and the European Commission should be detailed beyond the existing Framework Partnership Agreement. In addition, Member States and the European Commission should consider to what extent a closer cooperation between national accreditation bodies, e.g. by way of specialisation on particular scopes of accreditation, would be useful.

Finally, the European Commission should be supported in its efforts **to promote the European approach** to conformity assessment and accreditation, specifically among strategic partners. With regard to the United States, the negotiations about Transatlantic Trade and Investment Partnership deserve particular attention. Establishing a common understanding and agreeing on rules for CA and Acc present a formidable challenge, but can also be expected to yield considerable economic benefits on both sides of the Atlantic.

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