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**NEGOTIATING REGULATORY ALIGNMENT
IN CENTRAL EUROPE: THE CASE OF THE
POLAND EU EUROPEAN CONFORMITY
ASSESSMENT AGREEMENT**

Christopher Preston and Arkadiusz Michonski

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**IN CENTRAL EUROPE: THE CASE OF THE
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ASSESSMENT AGREEMENT**

Christopher Preston and Arkadiusz Michonski

This paper draws on the direct experience of the two authors in dealing with issues of regularity alignment at first hand.

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INTRODUCTION

The challenges of enlargement posed to both the existing EU and the 10 applicant states of Central and Eastern Europe are qualitatively different from those faced in the past. The political and economic diversity of the applicants, all of which are undergoing a fundamental systemic transformation in parallel with the accession process raises new questions about the capability of the traditional EU model to facilitate political and economic integration in the wider Europe.

Full membership of the EU has always required applicants to harmonise their domestic laws in full with the *acquis communautaire*. Only some exceptional, time-limited transition periods have been negotiable, in very limited areas considered not to undermine the principle of the integrity of the *acquis* as a whole.

This process is asymmetric. Where there is harmonised EU legislation it takes precedence over national legislation. In previous enlargement rounds this “regulatory gap” was relatively narrow. Except in some specific sectors, most particularly agriculture, national regulatory practices remained, albeit increasingly subject to EU rules. In the most recent, post-internal market, EFTA enlargement, some of the distinctive regulatory preferences of the applicants (for instance the Scandinavian preference for controlling alcohol abuse through restrictions on its sale) were accommodated through ingenious qualifications to Community rules.

Such options have yet not been made available to Central and East European applicants. The EU’s strategy for eastern enlargement, developed over the last five or so years, has been based on the strong assumption that a substantial measure of pre-accession regulatory alignment in the region is a necessary precondition of successful enlargement. The tools that the EU has developed, including the White Paper on the Internal Market, the Phare programme, and now the Accession Partnerships with the applicants, are all designed to preserve the incrementalism of the classical method. The principles, both explicit and implicit, that the EU has established over four rounds of enlargements put the burden of adaptation to enlargement onto the applicant state. No permanent opt-outs from the *acquis* are available and only some time limited transition periods can be negotiated. Member states are reluctant to undertake major reforms of the *acquis* to accommodate the policy preferences of applicants, or to contemplate radical institutional reform during accession negotiations, however pressing the need might appear (Preston 1995). Yet this reform process forced on applicant states is fraught with difficulties. Whilst parts of the *acquis* may provide useful templates for sector reform, taken as a whole they can be overwhelming, mixing economic, political and administrative factors. Some parts of *acquis* may

prove to be burdensome for transition economies and their present high economic growth rates.

This paper explores these issues through a case analysis of one component of the pre-accession process: the negotiation of the European Conformity Assessment Agreement (ECAA) between Poland and the EU. ECAs are intended to extend EU technical requirements, particularly concerning “new approach” directives, to applicant countries to facilitate market liberalisation in given sectors. The specific incentive to conclude an agreement quickly is the opening of specific product markets in advance of full membership, once the EU has deemed the applicant’s system to be equivalent to that of the EU. ECAs therefore provide a possible “fast track” to economic integration, and have been offered to Poland, Hungary and the Czech Republic as the front runners for EU membership.

Negotiations opened with Poland in 1994 and have proved more difficult than anticipated. Legal, political and administrative problems have arisen both in Poland and on the EU side. The scale and scope of the adaptation process, in moving from a centrally regulated system to a producer-based self-regulated system, are considerable. A wide range of governmental and producer interests in Poland and the EU have been drawn into the process. These negotiations, however, illuminate a number of issues pertinent to the academic and practitioner debate about the pre-accession process.

Four sets of issues are relevant here. The first, most pressing to practitioners, concerns the practicalities of managing the pre-accession process. The philosophy underpinning ECAA negotiations is that the tangible benefits of concluding an agreement can facilitate and leverage the change process. The extent to which this is so will be explored by a detailed examination of the dynamics of the negotiations.

The second concerns the emerging debate, amongst both academics and practitioners, concerning the prioritisation and sequencing of the pre-accession process. Some commentators (Smith *et al* 1996) have sought to draw a distinction in the *acquis* between product regulations, those relating to safety of products, and process regulations, **relating to** how goods are made, arguing that only the former, necessary for free movement of goods, need to be adopted early. They argue that the latter are expensive, are inappropriate for transition economies, and will not facilitate real economic convergence. Conformity assessment is the definitive issue for product regulation. The extent to which the ECAA negotiations produce results is therefore a key test of whether this product/process distinction is really sustainable.

The third issue concerns the continuing debate about the development of the internal market, and the extent to which it is dependent on harmonised regulatory

requirements. Research into the process of internal market building has tended to conclude that the mutual recognition principle, seen by market builders in the 1980s as an alternative to detailed harmonisation, works only when there is a pre-existing high level of equivalence between national regulatory regimes (Woolcock 1994). No such equivalence exists between existing EU member states regimes and those of EU applicant states. The extent to which the ECAA negotiations accelerate this alignment process will itself illuminate the process of enlarging the internal market, and provide a guide to whether further reforms to the whole process of consolidating and extending the market will be necessary.

The fourth issue concerns the balance of interests shaping the enlargement process. Product market regulation involves complex patterns of interaction between public and private interests. Recent research has shown the extent to which sectoral, particularly producer, interests in the EU can capture the policy making process in specific areas. Trade policy towards applicant countries has been particularly vulnerable to this (Sedelmeier 1994). Given the range of actors involved in conformity assessment, this case will illuminate the policy making process, both within the EU and within an applicant state.

This paper will therefore cover five areas:

1) Technical harmonisation and the internal market

An examination of the role of **standards and technical harmonisation** in the development of the EU's internal market, and an analysis of the system of conformity assessment that EU applicants are expected to adopt.

2) The pre-accession context

An overview of the key issues and tools of the pre accession process, with particular reference to the free movement of goods and conformity assessment.

3) The Polish system

An analysis of the origins, development and operation of the Polish system of **standardisation and conformity assessment**, and the implications this has for economic operators.

4) The ECAA negotiations

A detailed account of the negotiations to date, paying particular attention to the role of Polish and EU producer groups, and their role in influencing the negotiating process.

5) Conclusions: Whose interests dominate?

This section will explain the progress of the negotiations to date. The paper will conclude by evaluating the lessons that can be drawn from the case for the pre-accession process as a whole.

Technical harmonisation and the internal market

The potential for technical regulations to act as barriers to intra-Community trade has long been well recognised. Indeed from the early 1980s EU policy makers concentrated on technical harmonisation as the main component of internal market building. Prior to this period the EU had concentrated on trying to negotiate common harmonised rules applicable across the whole EC. Even among only nine member states this proved to be time consuming and cumbersome. In response to a potential trade dispute between France and Germany caused by differences between DIN and AFNOR standards (Woolcock 1994), EC policy makers developed the “new approach”, in which only minimum essential health and safety requirements would be specified in EU directives. Above this level the mutual recognition of national standards would apply.

The new approach was preceded by the landmark *Cassis de Dijon* judgement (1979) of the European Court of Justice, ruling that a product legally sold and marketed in one member state should by and large be able to be sold in any other member state, subject to minimum health and safety regulations. After agreement on the 1985 Single Market White Paper the mutual recognition principle became established as the cornerstone of market-building, and was gradually extended beyond trade in goods to services such as banking, and even to professional qualifications.

Although the principle of mutual recognition is straightforward, its development in practice is more complex. All member states have an extensive range of institutions responsible for implementing technical regulations. Many of these institutions required reconfiguration in order to operate within the internal market. Implementing technical regulations involves a range of interlocking activities. Standard setting involves defining the characteristics and performance criteria of particular product categories. Traditionally the responsibility of national bodies such as Deutsches Institut für Normung (DIN), Association Française de Normalisation (AFNOR) and British Standards Institute (BSI), standards are increasingly set at European level through such bodies as European Committee for Standardisation (CEN) and European Committee for the Co-ordination of Electrical Standards (CENELEC) for electrical products. Certification involves a statement by an impartial

body that a product conforms to a particular standard. Accreditation of these bodies and testing laboratories is the responsibility of an impartial national authority.

Although member states vary in how they operate these procedures, certain common features are necessary for the mutual recognition principle to work. A high degree of transparency in the whole system and mutual trust between regulators are essential. This was soon recognised by the Commission after the 1992 implementation deadline for the internal market as the critical factor determining the success or otherwise of the whole project (Commission 1993, Sutherland 1993). A key feature of the system has been the extent to which it has involved a shift towards self regulation (except for product categories deemed to be high risk) in which companies take increasing responsibility for their own declaration of conformity with EU rules. Having made such a declaration, manufacturers are entitled to use the “CE” mark on their products. This acts as a “passport” for marked products to free circulation throughout the internal market, as well as rendering the manufacturer liable for any damages caused by such marked products

This transparency and mutual trust have, inevitably, taken time to develop. Despite the establishment of new pan-European organisations, such as the European Organisation for Testing and Certification (EOTC) in 1993, national bodies have often differed in their interpretation of national standards (Butt Philip and Porter 1995). In their report on the implementation of the internal market the Economic and Social Committee (ECOSOC) noted that “..there is insufficient application of the mutual recognition of standards in many areas. This leads to the persistence of technical barriers to trade e.g. in food additives, nutritional labelling, pesticides in fruit, electronic and electrical equipment, weighing equipment, and weights and dimensions of vehicles”. (ECOSOC 1994). To a large extent this is due to the embeddedness of technical standards within wider national regulatory systems which express different preferences and priorities (Woolcock 1994). Food labelling, for instance, is particularly strongly influenced by this.

All of these factors are pertinent to the debate concerning regulatory alignment in central and eastern Europe. Applicants are expected to take on the full *acquis* in this area, and to reconfigure their standards and testing organisations so as to operate the mutual recognition principle. Yet the regulatory gap is considerably wider than between existing EU member states. Central and eastern European states have hardly yet participated in pan-European standards and testing organisations, and have therefore not developed the organic linkages necessary to develop the trust of other regulators. Moreover, the effect of the pre-1989 system, combined with inexperience in managing trade liberalisation, has been to entrench a range of national standards and institutions which have developed with little reference to West European trends.

Indeed in many cases standardisation and conformity assessment systems were not even compatible within Comecon countries, and were only sometimes subject to mutual recognition agreements.

The pre-accession context

The EUs strategy towards enlargement to central and eastern Europe has been cautious. The core element of the strategy has therefore been to set out in explicit detail precisely what applicant states need to do in order to reach the membership threshold. Although applicants are expected in due course to take on the whole *acquis*, there has been a strong preference, articulated by the Commission, to give priority to internal market legislation, since this was considered to facilitate market liberalisation and economic growth, thereby speeding up the transition process. Thus the key element of the pre-accession strategy, as expressed in the conclusions to the Essen European Council in December 1994 was the preparation of a White Paper defining internal market legislation and describing the measures necessary to implement them (Commission 1995).

Free movement and safety of industrial products feature prominently in the White Paper. Concerning standardisation, the Commission stressed the need to move to a system of voluntary application, based on agreement between economic operators. This, it argued, needed to be sufficiently different from the experience of industry under the centrally planned economy. "It is important," the Commission noted, "that regulators do not regard technical regulation as one step better than a standard, but as something different in both intention and content" (Commission 1995, p.14).

Concerning conformity assessment, the Commission noted that regulations should be restricted to the protection of public policy interests, such as health and safety and "should be appropriate to the nature of the risks involved, and should avoid imposing unnecessarily onerous procedures" (Commission 1995, p.15). Finally, concerning market surveillance, the Commission urged applicants to adopt appropriate legislation and enforcement mechanisms by institutions separate from those that assess conformity, to ensure that products already on the market meet the specified standards. The Commission's policy towards the development of market surveillance systems in applicant countries is, however, unclear. In the absence of harmonised structures of market surveillance in EU member states, the Commission

finds it difficult to present ready-made solutions to candidate countries. It is therefore difficult for candidates to establish new structures and for the Commission to assess the compatibility of proposed solutions with the institutional arrangements in existing EU member states.

This sector of the White Paper alone represents a formidable reform agenda for an applicant state. Full adaptation to the *acquis* involves a series of interlocking components. Three stages are involved (Preston 1998). First, legal harmonisation requires that existing national legislation is amended to make it compatible with the relevant EU Directives. Second, at the implementation stage, new institutions have to be established, or existing ones substantially reformed, to take responsibility for new legislation and procedures. Third, new rules have to be enforced in a transparent manner, leading to observable changes in the behaviour of economic operators. Problems can occur in any of these stages, which in practice are not necessarily linear. Some legal harmonisation problems may not reveal themselves until enforcement is attempted. Indeed, given that much legal harmonisation will not take place until immediately before accession, there is the potential for considerable confusion on the part of economic operators as to the appropriate legal and institutional framework within which they will work. Disaggregating the whole process, its timing and sequencing, so that it can be separated into manageable parcels, is itself a major challenge for reformers.

The complexity of the process has stimulated a debate about the most appropriate way to keep the reform process in the applicant countries on track, whilst adhering to the fundamental principle, reinforced over the four previous rounds of enlargement, that the *acquis* itself is not negotiable. Although the Commission's 1995 White Paper, prepared by DG XV, deliberately focused on the internal market, this itself raises a new set of questions about how to phase the introduction of the internal market into transition economies. Some commentators (Smith *et al* 1996) have been struck by the extent to which the White Paper on the internal market, supposedly concerned with the essential components guaranteeing the free movement of factors of production, has been extended to include sectors such as social policy, the costs of which may be hard for transition economies to bear. They argue strongly in favour of concentrating on sequencing the alignment process with priority given to rules, strictly defined, ensuring free movement of goods, leaving the more expensive process regulations until later, possibly until after full membership.

The focus on product regulations highlights some important aspects of the political economy of trade liberalisation. As Smith *et al* point out, CEEC firms exporting to the EU within the terms of the Europe Agreement already have to meet EU product standards. The incentive CEEC firms really need, they argue, is EU

acceptance of testing to EU standards by their own testing agencies in order to improve on the present situation. “Without more reciprocity than has yet been apparent from the EU side”, they argue, “the pre-accession strategy provides the CEECs with little additional incentive to undertake the potentially painful reform of their regulatory regimes.” (Smith *et al* 1996, p.10)

Reciprocal agreements on technical standards have, since the implementation of the internal market been an integral component of the EUs trade policy instruments, in order to reduce expense and improve the predictability of regulations for market operators. Where the EU has significant, e.g. trade interests, it has sought agreement on the mutual recognition of conformity assessment.¹ The EU is presently pursuing such agreements with the US, Japan, Switzerland, Canada, Australia and New Zealand (Liberos 1997). Through such an MRA each party is given the authority to test and certify products against the regulatory requirements of the other party. Mutual recognition can function without harmonised or equivalent rules for each party, since what is being recognised is the competence of each party to certify the conformity of products to the others’ rules, even where these rules are different. For the EU, MRAs with third countries such as the US and Japan have been negotiated, because there is no immediate prospect of convergence in technical regulations, but the competence of their national testing and certification bodies is not in question.

Mutual recognition of unharmonised rules can however be problematic where these reveal more fundamental differences of approach (Woolcock 1994, p.43). In general the gains from MRAs are made when mutual recognition is achieved against a background of harmonised rules, so that a single test and approval is sufficient for both domestic and MRA partner markets. Given that the CEECs all aspire to full EU membership the overall objective of the EU has been to propose the introduction of mutual recognition within the context of a staged alignment of the whole system of conformity assessment in the CEECs. The scheduling and sequencing of these stages is itself critical to building the mutual confidence on which the whole system depends.

The Polish System of Standardisation and Conformity Assessment

The Polish system, in common with those of other CEEC applicant states, differs fundamentally in both principle and practice from that now operating in the EUs internal market. There are three key areas of difference. The first concerns the dominance of mandatory third party certification during the pre-marketing phase. A

¹ The Council Decision of 21st September 1992 authorises the Commission to undertake and conclude negotiations between the Community and third countries on mutual recognition agreements.

very wide group of product categories require to be tested and certified before they are allowed on to the Polish market. Most of the currently established Polish norms are based on European norms (for instance from CEN and CENELEC). In principle, as in the EU, they are voluntary. However, in practice sectoral ministries can make their use compulsory by means of regulations. This is usually justified on the basis of health and safety, environmental protection, as far as possible consistent with the logic of EU legislation under Article 36 of the Treaty. Arguably compulsory compliance with obligatory norms results in a highly regulated framework with a high degree of administrative surveillance. However, in practical terms the number of compulsory standards is so large that it has not been possible to monitor their implementation.

The justification for the extent of mandatory third party certification is linked to the second important difference between the Polish and EU systems concerning the legal liability for defective goods. In Poland liability is determined by the general principles of tort stipulated in the Civil Code, in force since 1965, in which the burden of proof rests with the person suffering damage. If proven, liability can lie with the manufacturer, importer, wholesaler or retailer. Damages caused by faulty services are not covered by present legislation. By contrast the EU system is based on the assumption of producer's liability upon whom is placed the burden of proof of innocence.

The third major difference concerns methods of market surveillance. Currently in Poland only fragmented institutional arrangements exist for monitoring compliance with safety standards. The law provides for the monitoring of commercial operators in retail outlets, but contains no provisions concerning producers. The State Commercial Inspectorate (PIH) monitors the compliance of consumer goods and can order the destruction of specific goods that do not meet Polish standards. However, it is not empowered to sanction the producers of the goods, nor to order the removal of whole product lines from the market. Also, the State Sanitary Inspectorate and the regional offices of SANEPID, the network of sanitary inspection bodies responsible to the Ministry of Health, monitor conditions in premises that deal in food preparation.

These principles are rooted in the old centrally planned economic system, characterised by a lack of concern for consumers' interests, a limited and unsophisticated range of products in the market, low levels of import penetration, and a strong bias towards detailed and prescriptive technical regulations as the main mechanism for the mutual reassurance of manufacturers, retailers and consumers. Such principles are, of course, not unique to the regimes of Central Europe. They characterised the pre 1992 EU system and, as noted earlier as still proving resistant to change in some sectors. Yet the range of these Polish institutions, their legal basis and

political influence is qualitatively different to the post 1992 EU system and represents a major regulatory gap to be closed.

The present system of conformity assessment in Poland is based on the Law on Certification of April 3 1993. It created at the apex of the system the Polish Centre for Testing and Certification (PCBC) replacing the previous Central Bureau for Product Quality (CBJW), which was a part of the Polish Committee for Standardisation, Measures and Quality (PKNiM). In order to introduce more transparency into the system, and to allocate responsibilities more in line with mainstream European practice the centralised Committee was dismantled to create three new institutions. The Polish Committee for Standardisation (PKN) was created to deal with standards, Metrology became the responsibility of the Central Board of Measures (GUM), whilst Conformity Assessment became the responsibility of the PCBC which took over the testing laboratories and R&D institutes of the CBJW.

The mandatory third party certification system was consolidated by the Ordinance of the Director of the PCBC (July 21 1994). This specified the list of products subject to obligatory certification, known as the “B” marking. The list was extensive, covering approximately 1400 products, including steel industry, machines, electric and information equipment, chemicals, construction products, glass and ceramic materials, wood and paper products and toys. “B” mark certificates could be issued by 17 certification bodies, with testing done by the 130 laboratories linked to these 17 institutions. The introduction of the new system was highly restrictive. Producers and importers had only four months to comply with the new rules, or their products would be withdrawn from the market. Detailed information was difficult to obtain, since the executive acts providing for the procedural requirements of conformity assessment and accreditation were not published in the Polish Official Government Journal (*Dziennik Ustaw*), but were available only on a commercial basis from the PCBC, through its periodical, available only on subscription.

The system has undoubtedly caused problems for traders, and particularly importers from the EU. The time and financial resource implications of obtaining the “B” certificate acts as a real disincentive to enter the Polish market, particularly for smaller companies. Research undertaken on behalf of UK companies found a wide range of certification problems (SITPRO 1998)². Much of this is due to the commercial interests of the conformity assessment bodies and their testing laboratories, who all derive the bulk of their income from compulsory testing. Any

² In some cases the cost of testing the product exceeded the value of the product itself. In one case the import of a single steel pipe fitting item worth £500 required the purchase and destruction testing of an identical item, as well as the costs of the testing itself. This, in effect, increased the import cost by 300%. Supplementary certification in addition to full EU certification was in some cases, (particularly cosmetics) demanded. Confusion about whether a specific product actually requires a “B” mark compound the difficulties. Similar problems have arisen with other EU based manufacturers and importers.

opening up of the system, implicit in adopting the EU system would involve extensive restructuring of these bodies, many of which may not be commercially viable in a more open system. However, the introduction of a new system, clearly divergent from EU arrangements, following the conclusion of the Europe Agreement, and after Poland's application for full EU membership was made (in April 1994) reflects the balance of political forces within the Polish system, with a clear bias towards the organisational interests grouped around the PCBC. The law established the Council for Testing and Certification. Under the provision of the law it was intended to ensure a broad range of interests were represented on the Council. However, the Council was chaired by the Director of PCBC, who prepared the agenda of the Council, as well as drafts of procedural regulations concerning accreditation and certification. The Council therefore quickly became a forum for the consolidation of the position of the testing laboratories and certification institutions directly dependent on the PCBC.

EU industry associations responded strongly to the introduction of the new system in 1994, claiming that it constituted a breach of the standstill clause in Poland's Europe Agreement, designed to prevent the erection of new trade barriers. The Polish Chamber of Informatics and Telecommunications, the Association of Car Importers and the Association of Producers of Cosmetics and Detergents issued a common position paper on the law in mid 1995, proposing the introduction of a 2 year phasing in period. Their concerns focused on the impact of the new law on small and medium sized enterprises and on the possible emergence of monopoly producers in some product categories. The associations lobbied Polish ministries and organised seminars for officials and companies. They also threatened legal action in the Polish Supreme Administrative Court, and pressed for the issue to be raised at the Poland-EU Association Committee.

The Poland EU Conformity Assessment Agreement Negotiations

As already noted, conformity assessment affects a wide range of commercial and organisational interests, both in the EU and the applicant state. Broadly, three sets of interests can be identified as stakeholders in the negotiations. Within these three sets further specific interests can be identified. First, within Poland the dominant position has been occupied by the PCBC and the network of testing bodies and conformity assessment dependent on it. In marked contrast to the EU system, the PCBC both owns and accredits a number of these bodies, in effect conflating the interests of the regulator and the regulated. The 1993 law vested considerable powers in the Director of the PCBC who was directly appointed by and responsible only to the Prime

Minister. The Director had the power to add or remove products from the compulsory “B” list with limited intra-governmental consultations. These involved a number of ministries which continued to keep links with conformity assessment institutes, since these research and testing bodies were once part of ministries.

This lack of transparency concealed the extent of the close linkages between these governmental organisations and Polish domestic producer interests. These linkages were built up under the state planning system before national, legal technical standards were deemed to be a trade barrier. Thus, while the Polish Standards Committee (PKN) has, for a number of years, been looking to EU standards, the gap between the Polish and EU systems is still very wide.³ Unsurprisingly Polish manufacturers, particularly those with little experience of exporting, have absorbed these national standards into their manufacturing processes, and have been reluctant to look beyond them.

Beyond these sectoral interests, wider Polish interests have also been involved. Since 1994 official Polish Government policy has been to pursue full EU membership. The policy framework for the necessary alignment work is contained within the Europe Agreement, concluded within the legal framework for association, based on Article 238 of the Treaties. Both the general and specific aspects of harmonisation were covered in the Agreement. Article 10 (4) abolishes quantitative restrictions and measures having equivalent effect on imports from the EU. Article 68 requires that “..Poland shall use its best endeavours to ensure that future legislation is compatible with Community legislation,” whilst Article 69 identifies the priority areas for harmonisation, including technical rules and standards. These provisions are strengthened by Article 74 which calls on Poland specifically to reduce differences in standardisation and conformity assessment, to encourage Poland to participate in the work of pan European standards and testing bodies, and to conclude mutual recognition agreements in these areas. The institutional framework for this harmonisation work is the Poland-EU Association Committee. The Committee meets annually, but delegates most of the technical work to a series of technical sub-committees, including one for trade and industry which deals with matters of technical harmonisation.

Lead responsibility for monitoring the implementation of these provisions in Poland rests with the Committee for European Integration (KIE) established to co-ordinate overall policy towards European integration. The technical services of KIE (Office of the Committee for European Integration - UKIE) lead on negotiations over the Europe Agreement within the Association Committee. Its technical sub

³ The Commission identified that of the PKNs standards portfolio (in November 1997) of 16,936 standards, 2,855 (16.9%) are based on international (IEC and ISO) standards and 488 (2.9%) on European standards. The balance of 13,593 (80.3%) were purely Polish National standards (Commission 1997).

committees are run by competent line ministries who report to the Committee. Thus the management of these sectoral interests is itself a part of the negotiating process.

The second set of interests are those of the EU institutions, more specifically the European Commission. On the EU side the Commission is responsible for pursuing the objectives of the Europe Agreement, and therefore managing the Association Committee. Yet within the Commission itself there are different interests at work. Lead responsibility for negotiations with applicants lies with DG IA, which services the Association Committee and its technical subcommittees. However DG I leads on external trade negotiations and is therefore responsible for negotiating mutual recognition agreements with major trading partners on the basis of Article 113 (Common Commercial Policy). DG Is negotiating strategy is therefore driven by commercial calculations of where the EUs trade interests lie, rather than by considerations of regulatory alignment. Responsibility for standards and conformity assessment lies with DG III (Industry), whose key interest has been to ensure that applicants adopt the EUs conformity assessment practices in their entirety to a level of mutual confidence to allow the EU to accept Polish test certificates, preferably in advance of full EU membership. DG XV (Internal Market) has played only a limited role, as responsible for horizontal product liability legislation. The interplay of interests within the Commission has resulted in an agreement incorporating these different approaches into the texts of the ECAA.

The third set of interests concern those of EU member states and their commercial interests. For EU-based companies the overwhelming priority has been improved market access to Poland. Where certification problems have arisen companies have lobbied their own governments, both in national capitals through trade ministries, and through the commercial sections of their embassies in Poland, in addition to pressing contacts with the European Commission in Brussels. Given the complexity of the issues, member state's governments are highly dependent on companies informing them of certification issues, and have therefore tended to respond when commercial pressures have built up. Individual concerns raised by EU exporters to Poland has resulted in the creation of the Article 113 Committee data base which comprises cases of barriers to trade which arise in trade relations with the Associated Countries.

EU-based notified bodies also have economic interests at stake. Testing and conformity assessment are competitive commercial activities in their own right, estimated in the UK alone to be worth up to £20bn (DTI 1995). These bodies are interested in preserving the *status quo* in Poland, since the acceptance of Polish certificates limits their potential share of a growing "market" for testing, given the increasing number of EU companies locating in Poland.

The certification issue has appeared on the agendas of all the Association Committees to date. It was raised at the first meeting of the Committee in June 1994, at which the EU side requested information on the introduction of the new law on certification. In replying, the Polish delegation argued that its new system was compatible with the EU system in that it was designed to limit the circulation of dangerous products in the market. The delegation stressed that the new law was not discriminatory, since it was equally binding on Polish and EU operators. The EU side was unconvinced by these arguments. At the second meeting of the Association Committee in December 1994 the Polish side agreed to postpone entry into force of the new law pending further analysis of its compatibility with the EU system. A working group on certification comprising specialists from both sides was established. During the third meeting of the Association Committee in June 1995 the EU side explicitly criticised the new legal framework on Poland and requested amendments to the law to make it compatible with the EU system.

During this early phase of the negotiations the size of the gap between the Polish and EU positions was revealed and the main elements of conflict staked out. During 1995 the EU side concentrated on trying to reduce the list of EU origin products subject to mandatory third party certification in Poland. A number of specific products came under scrutiny during this period. The most contentious were:

- Automobiles and automobile parts. The Commission criticised the double conformity requirements for this product group. In Poland cars which had already received type approval in the EU still had to go through the same certification procedures as a set of spare parts.
- Ferrous and non-ferrous metal products. Polish certification requirements were based on mandatory quality standards. In the EU Commission's view most products in this group in most OECD countries are not subject to certification unless they are destined for special use (such as in atomic reactors).
- Ceramic products, such as tiles and sinks, and wood and paper products, and chemical products, (particularly cosmetics), not considered to be dangerous products subject to mandatory conformity assessment anywhere in the OECD.

The composition of these agenda items reflects the lobbying of the EU producer groups in question, and is strongly correlated with the structure of Poland's trade with the EU. From the European Commission's perspective the focus on reducing the "B" list reflected the commercial priorities of DG I. Electrical engineering products

constitute the leading commodity group both for exports to the EU (22.1% of trade in 1995) and imports to Poland (37.5% of trade in 1995). This is followed by chemical products, accounting for 19.4% of trade. In both these commodity groups Poland has a trade deficit with the EU. Fear of the trade gap widening, even if not founded in a rational analysis of the real impact of technical regulations if certification requirements were relaxed, clearly shaped the Polish position during 1995. Furthermore, during this period the Polish delegation was led by the Director of the PCBC, or his deputy. In working meetings in June, August and October, at which the Polish side put forward their assessment of the risks posed by these products, following pressure from the EU side, the Polish side agreed to review the “B” list and subsequently agreed to remove a number of the contentious products, including some metal and ceramic products, from the list by the end of 1995.

However, already by the second half of 1995 the possibility of negotiating a mutual recognition agreement was being discussed in the technical working group. In November 1995 an agreement between the Commission and the Polish delegation, forming the basis of future negotiations, was initialed. The agreement provided for the gradual replacement of the “B” safety mark by the CE mark, supplemented by the incremental recognition of Polish-designated certification institutions as notified bodies for new approach directives. The EU would gradually recognise Polish conformity assessment bodies as competent to test Polish products against the essential requirements of the new approach directives.

The agreement was, however, never formalised because of discrepancies about its interpretation. The November agreement did not stipulate the procedure for designating conformity assessment bodies, nor did it envisage a timetable and procedures for the recognition of CE marking in Poland. Key provisions of the agreement were differently interpreted by both sides.⁴ The dominance of the interests of the PCBC ensured that the provisions of the agreement were never implemented. The PCBC argued that the lack of proper institutional structures inhibited implementation of the provisions of agreement, which were in effect blocked in 1996, despite continuing pressure from the EU side. During 1996 certification was one of a number of contentious issues (tariffs on steel imports to Poland being the other most acrimonious) that affected Poland’s relations with the EU. During the summer and autumn of 1996 the European Commission was starting to prepare its Opinion on the preparedness of Poland to start full accession negotiations, working from the answers provided to the Commission’s questionnaire.

⁴ The EU side expected the unconditional acceptance on the Polish market of CE marked products. However, the Polish side would only accept CE marks after further 3rd party testing.

This process had the effect of galvanising the Polish Government into making some of the domestic reforms necessary to meet the EU's requirements. In October 1996 the Committee for European Integration was created. Chaired by the Prime Minister, supported by its own Office (UKIE), and headed by a Secretary of State, this also had enhanced legal powers to check conformity and to ensure the compliance of Polish legislation with EU norms. In December 1996 the Polish Government took a new initiative in an attempt to resolve the certification issue. The Committee appointed a new chief negotiator from the newly established Ministry of the Economy (which replaced the Ministry of Industry after a reform of central government in autumn 1996), thereby reducing the blocking power of the PCBC, which had previously led the negotiations.

Negotiations on a draft protocol, which was intended to supplement and explain the provisions of the November 1995 agreement, opened in December 1996 and continued until March 1997, when the agreement was initiated. The agreement was understood to be an interim legislative solution. As the Protocol to European Conformity Assessment Agreement it was designed to prepare the ground for the Agreement itself.

Changes on the EU side also had an effect. An internal debate within the Commission, which was triggered by the talks in Poland over the November 1995 agreement, led to a change of emphasis. On the basis of the analysis of the failure of its implementation, a modified approach towards MRAs with associated countries on the side of the Commission was adopted. The possibility of a new agreement was presented to the Internal Market Advisory Committee with representatives of the CEECs in September 1996. It was recognised that the priority given to pressing EU commercial interests, by focusing only on reducing the "B" list and pressing for a classic mutual recognition agreement had not generated progress. DG III therefore proposed a new approach, based on a longer term strategy of regulatory alignment. This involved increased technical assistance from the EU in the context of an agreed schedule for the introduction of both EU horizontal product liability legislation, and sectoral new approach directives. Such agreements were to be called European Conformity Assessment Agreements, to distinguish them from classic mutual recognition agreements. As DG III argued in its internal Commission briefing: "...the determining factor does not concern the number of sectors to be included in the agreement to obtain the critical mass required for the justification of the agreement on the commercial level but the capacity of the applicant states to specifically implement without delay the parts of the Community *acquis* which will be adopted in the agreement". (European Commission, DG III 1997(a)).

The key elements of the Protocol were that Poland agreed to submit new horizontal legislation to the Parliament by the end of 1997 so as to implement an EU-compatible conformity assessment system and product liability legislation. In the interim period, until the new legislation comes into force, Polish conformity assessment bodies will give a “B” safety certificates on presentation of the relevant documents, both for products originating in the EU which are subject to mandatory third party certification, and for those which are subject to the producer’s declaration of conformity. In return the EU will accept certificates issued by Polish CABs once they have been deemed competent by the EU. An implementation schedule for the introduction of new approach directives, and for the evaluation of the competence of the relevant CAB’s was appended to the protocol. A further reduction in the “B” list was envisaged to be implemented by mid -1997.

Agreement on the Protocol marked a major breakthrough in the process of regulatory alignment by clarifying mutual expectations between the key negotiators on each side. However, the implementation of the agreement still encountered obstacles. It took until November 1997 for the EU Council to adopt the Agreement. On the Polish side complications arose following the adoption of the new Polish Constitution on 17 October 1997. This prevented bodies such as the Certification Council and the PCBC from issuing regulations, as had been foreseen in the agreement. Also, following the establishment of a new Polish Government after parliamentary elections in September 1997, the draft of the product liability law was withdrawn from the parliamentary commission and amended to include new provisions on consumers’ rights. These legal complications delayed both the reduction in the “B” list (hitherto the responsibility of the PCBC), and the proposed implementation schedule for the new approach directives, as originally envisaged in the March agreement. The new Constitution changed the conditions of law-making in Poland. It is now only higher rank secondary legislation like regulations of the Council of Ministers and regulations of ministers which have binding effect. Lower secondary legislative acts have lost their binding effect. Consequently, governmental agencies like the Polish Centre for Testing and Certification (PCBC) and the Office for Technical Inspection, major actors in the area of conformity assessment, lost their delegated law-creating powers. Some of the delayed provisions were dependent heavily on legal actions undertaken by the PCBC (such as the reduction of the list of products subject to third party certification in Poland and the amendment of the Law on testing and certification). Under these new conditions the rearrangement of institutional competencies proved to be necessary, which delayed implementation of provisions of the Protocol.

In December 1997 the certification issue was again raised at the Trade and Industry subcommittee of the Association Committee. The Polish side indicated that the framework law on Certification should be cleared by the Polish Council of Ministers by May 1998, and that a draft would be discussed for consultation with the Commission when it became available. At the sixth meeting of the full Association Committee in March 1998 the Polish side reiterated its readiness to formalise the Protocol, and to start negotiations on the Agreement itself. In the National Programme for the Preparation for Membership, prepared in March 1998 in response to the requirements of the Accession Partnership, the key short-term priorities were identified as the completion of the framework law by the Ministry of the Economy, the establishment of a group for the co-ordination of technical harmonisation policy, the preparation of a draft law on liability for defective products, in the form of an amendment to the civil code, and the preparation of a draft law on the general safety of products by the Office for Competition and Consumer Protection. The Programme stated the intention that Poland should have an EU compatible conformity assessment system before the end of the year 2000 (NPPM 1998). Meeting such a deadline represents a formidable challenge to Poland. Yet, if met it would satisfy the underlying justification for negotiating ECAAs, to improve the free movement of products in advance of full EU membership. Despite deficiencies of the alignment process in Poland up to date, the Protocol on ECAA was signed on 30 July 1998 in Brussels.

The EU has sought similar framework agreements with all the associated countries. The process was started with a multi-country seminar organised by the European Commission. Substantive negotiations have only been pursued with the Czech Republic, Hungary and Poland, and have moved forward more quickly with the first two. Hungary transposed the product liability directive as early as 1992, whilst the Czech Republic had by 1997 already transposed the majority of new approach directives on the basis of a framework law on conformity assessment.

Conclusions

To date the Poland-EU Conformity Assessment negotiations have proved much more protracted than envisaged, and have fallen well behind the pace of the negotiations with Hungary and the Czech Republic. Yet the analysis of the negotiations sheds some light on the realities of the pre-accession process, and the practitioner and academic debate outlined earlier.

First, the Protocol on the European Conformity Assessment Agreement negotiations highlights the complexity of the pre-accession process, the difficulties of managing its component parts, and the challenge of maintaining the momentum of trade liberalisation in the context of numerous cross cutting pressures. The negotiations have involved a complex mix of legal, organisational, economic and political change, affecting powerful vested interests in both Poland and the EU. Problems have arisen because of unpredicted obstacles, such as the provisions of the new Polish Constitution. The extent to which progress in specific areas has been held up by more fundamental reform problems, in particular the lack of a legal framework for product liability is striking. Thus the original justification for opening negotiations, that tangible economic benefits would accrue and speed up the integration process, is not yet proven. Whilst the possibility of economic benefit may have been a necessary reason for opening negotiations it has not yet proved sufficient to overcome forces resisting change.

Second, the negotiations highlight the extent to which prioritising and sequencing the introduction of the *acquis* raises many new questions. Whilst the intellectual justification for taking the free movement of goods first is accepted by both Polish and EU negotiators, and the ECAA protocol contains an implementation schedule that phases in sectoral legislation using economic criteria, no tangible results have yet been achieved. If full implementation of the Agreement could be achieved by 2000 then some real benefits might accrue in advance of full membership, assuming this does not take place before 2003/4. However, given the difficulties that have already arisen, it is questionable whether this timetable can be maintained. Although the ECAA has been given a high priority in pre accession negotiations this has not been to the exclusion of other areas. Conformity assessment has therefore had to bid for the attention and resources of a limited number of negotiators and their technical support staff as the demands of the pre-accession process—and now full accession negotiations — multiply.

This is not to argue that the ECAA negotiations have yet to achieve anything. They have already proved invaluable in familiarising each side with the principles and practices of each other's systems. Two distinct phases of the negotiations can be identified. The first, from 1994-96 was the familiarisation phase, largely driven by the problems raised for EU traders of the new 1994 law. This phase revealed the size of the gap between the Polish and EU systems, and was characterised by misunderstandings on both sides about the objectives and methods of each system. The second negotiation phase from 1996 to date has seen some progress, albeit slower than predicted, in regulatory alignment, at least to the extent of agreed on common

objectives. This is still considered a critical issue by the EU. In its first annual report on Polish progress towards accession, the European Commission noted that “the delay in this key reform, which will have an important horizontal impact on Poland-EU trade and internal market preparation, presents evidence of a divergence between pre-accession policy and practice” (European Commission 1998).

These negotiations highlight the asymmetry of the pre-accession process. It is for Poland to take on the EU system of conformity assessment in its entirety. Substantive negotiations have been concerned only with the phasing of the implementation schedule. The arguments put forward by Poland in defence of its existing system during the early phases of the negotiations were never accepted by the EU side. Arguably extensive mandatory third party testing constitutes a national regulatory policy preference, insofar as it has historical roots and commands public support. Yet its retention has been judged by the EU to be fundamentally incompatible with the principles of the internal market, and therefore unsustainable in an enlarged EU. The partial retention of the “B” safety list was accepted as an interim stage only pending the introduction of EU-compatible product liability legislation. The EFTA option of retaining some national standards is not yet acceptable in this enlargement round and confirms the view that the EU can more readily absorb countries with higher standards (Young 1995).

The dynamics of the negotiations also highlight the extent to which extending the single market depends on developing trust and mutual understanding between regulators, which is best ensured on the basis of harmonised standards. The EU side has placed considerable emphasis in the Protocol on providing technical support to conformity assessment bodies so as to accelerate the alignment process. The PRAQ programme, funded under Phare, provides for experts from national and European standards, certification, accreditation and metrology organisations to work in groups to support this process, and to assess the competence of these bodies for designation under the Agreement. The criteria for assessing competence are detailed and demanding (European Commission 1997b). To date the Polish side has put forward three conformity assessment bodies for approval and designation, but this work is as yet uncompleted.

The issue of whose interests have dominated underpins this analysis of the negotiations. During the early phase of the negotiations the lead initiative came from EU-based companies faced with trade barriers arising from the new Polish law of 1994. Although there was no large scale organised lobbying campaign, pressure was exerted on the Commission and on member states. Industry sector groups close to DG I were active in providing evidence of the negative trade implications of the Polish system. The commercial sections of EU Embassies in Warsaw have also acted as

lobbying channels when specific problems have been brought to their attention. During the more recent phase of the negotiations this balance changed, as the longer-term regulatory alignment issues lead by DG III came to the foreground. Thus the strategy of the Commission has been to “depoliticise” the process to some degree, and to try and keep member states’ own commercial interests at least at arm’s length from the detailed negotiations.

Yet despite the strength of the trade interests involved, these had only limited impact on Polish practice, at least until 1997. The blocking power of the PCBC and its client organisations proved decisive. Only when the Committee for European Integration was strengthened, and the negotiations led by the Ministry of the Economy was the issue unblocked. Absent from the Polish side have been those Polish commercial interests (identified by Smith *et al*), which might gain from having their Polish certificated products accepted on the EU market. Although it is the case that some Polish industrial sectors (steel and ceramics for instance) are well organised, the majority are not. The domestic electrical engineering industry for instance, a sector subject to extensive mandatory third party testing, is highly fragmented, domestically oriented and to a large degree dependent on outdated national standards, which are only slowly being harmonised with those of CEN and CENELEC. They have shown little interest in international markets, and have therefore not acted as a countervailing influence to the protectionist instincts of the PCBC. Overall the lack of transparent and organised interest articulation in Poland, as in other applicant states is a weakness that has broader implications for the pre accession process, and, eventually for the role that these new members will play in the enlarged EU.

In conclusion the ECAA negotiations represent a strengthening of the classical method of enlargement rather than its substantial modification. Poland’s room for negotiating manoeuvre has been extremely constrained, with no opportunity to accommodate any features of the pre existing system into the new one. This may have wider implications for the enlargement process. Even though the overall objective of EU membership is widely accepted, some of the specific consequences are much less attractive to specific interest groups. As the accession process proceeds the EU side will need to remain sensitive to these implications and to distinguish between blatant defence of sectional interests and wider concerns in applicant states about the pace and shape of change. The dynamics of the ECAA negotiations demonstrate how important striking this balance can be.

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