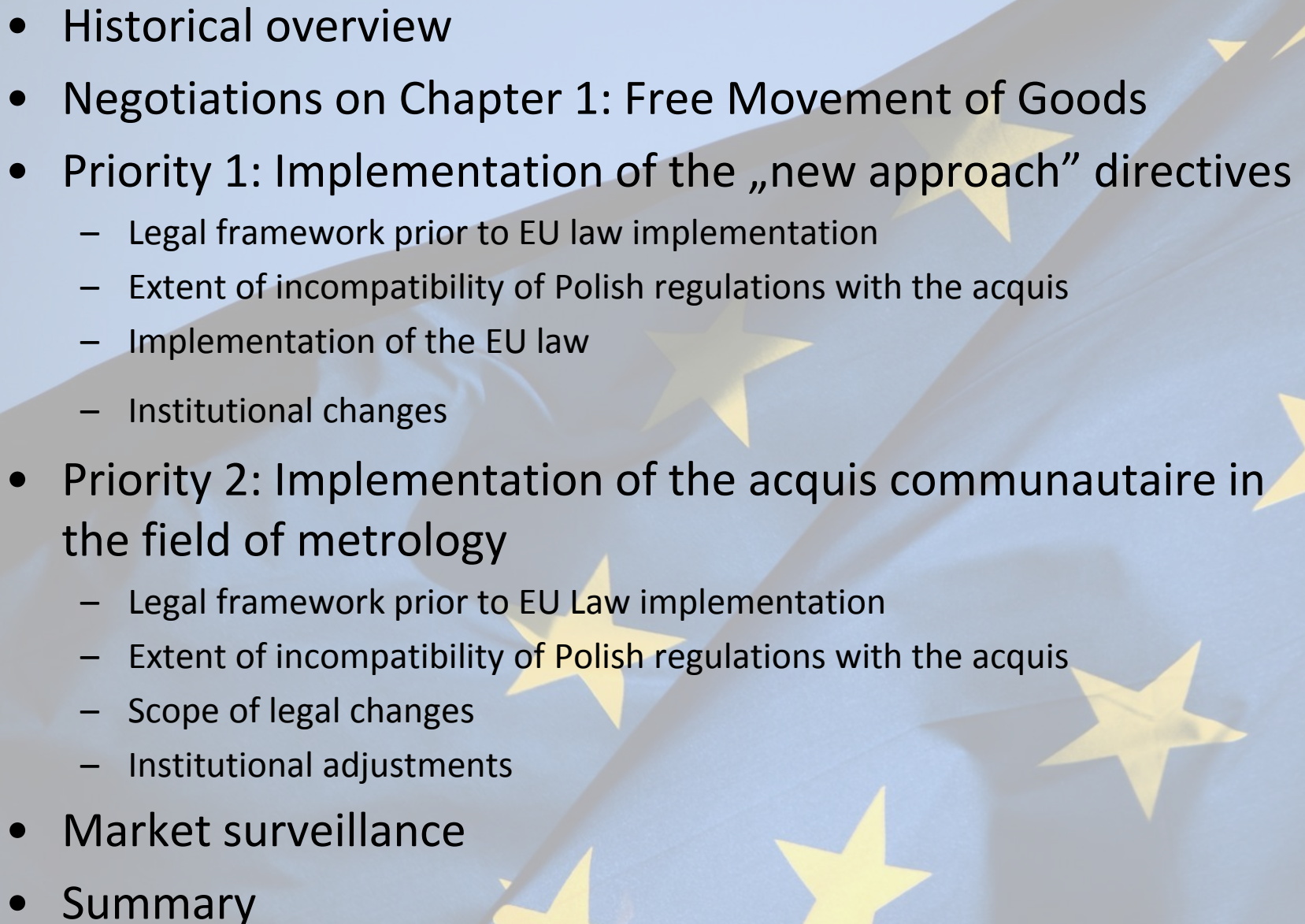




Implementation of the EU regulatory framework in the field of legal metrology - Polish experience

Joanna Sekala, Central Office of Measures (Poland)

Kiev, 22-23 October 2015

- 
- Historical overview
 - Negotiations on Chapter 1: Free Movement of Goods
 - Priority 1: Implementation of the „new approach” directives
 - Legal framework prior to EU law implementation
 - Extent of incompatibility of Polish regulations with the acquis
 - Implementation of the EU law
 - Institutional changes
 - Priority 2: Implementation of the *acquis communautaire* in the field of metrology
 - Legal framework prior to EU Law implementation
 - Extent of incompatibility of Polish regulations with the *acquis*
 - Scope of legal changes
 - Institutional adjustments
 - Market surveillance
 - Summary

Historical overview

December 1991	Association Agreement
April 1994	Poland submitted formal application for the EU
June 1995	<i>"White Paper"</i>
March 1998	Start of negotiations
June 1998	Polish National Programme of Preparation for Membership
July 1998	Agreement regarding a <i>Protocol on a European Conformity Assessment Agreement</i>
December 2002	Accession negotiations successfully concluded
April 2003	Treaty of Accession signed
June 2003	Referendum
1 May 2004	Accession to the EU

6 years

Reports on Poland's progress

July 1997 Opinion

- Poland was **gradually adopting** the Community acquis with regard to the free movement of goods.
- **Some progress** had been made during 1997.
- **Further efforts were required** for implementing the acquis.

November 1998 Report

- Complains about a **certain delay in this process.**

October 1999 Report

- **Poland far from being able to comply** with this fundamental freedom of the single market, since it **had not made significant progress** in implementing the legislative framework concerning this area, particularly as regards the transposition of the "New Approach" Directives.

November 2000 Report

- **Substantial progress had been made** in the adoption of the *acquis* concerning the free movement of goods and the customs union.

November 2001 Report

- **Some progress in the area of free movement** and steady progress on the customs union.

October 2002 Report

- In the area of the free movement of goods, Poland had made **significant progress in certain areas, whilst in others it had taken a step backwards.** It had continued to make progress in adopting the acquis relating to the customs union.

November 2003 Report

- Commission feels that Poland is **essentially meeting the requirements** of the acquis, although a **final push still needs to be made in some areas.**
-

EU harmonised product legislation

“old approach”

imposing precise product specifications

- till the end of 80s;
- **legal metrological control functions are carried out by national authorities;**
- Old Approach Directives are often based on **optional harmonization** leaving a choice to manufacturers :
 - to follow the **harmonized Community rules**, assuring free movement, or
 - to follow **national legislation**, without a guarantee of free movement.

“new approach”

imposing general product requirements

- *Council Resolution of 7 May 1985 on a New Approach to technical harmonisation and standards;*
- **based on total harmonization → replace diverging national legislation;**
- « **Essential Requirements** »
- « **Harmonized Standards** »
 - **voluntary standards,**
 - **presumption of conformity** with the Essential Requirements;
- « **Notified Bodies** » : responsible for the assessment of conformity with the requirements can be private entities, notified by Member States [in Poland in the field of legal metrology only **national authorities** play this role];

National system of type approval & verification

ECC type approval & ECC verification

Conformity assessment

Negotiations: two-pronged approach

CHAPTER 1: FREE MOVEMENT OF GOODS

PRIORITY 1:
IMPLEMENTATION OF THE
„NEW APPROACH”
DIRECTIVES

PRIORITY 2:
IMPLEMENTATION OF THE
ACQUIS
COMMUNAUTAIRE IN THE
FIELD OF METROLOGY

September 1998
bilateral screening
of legislation (incl.
legal metrology)

June 1999
negotiations
opened

December 2002
negotiations closed
(provisionally
closed in March
2001)

Key challenges

TRANSPOSITION
of the EU legislation:
“old approach” &
“new approach”

**REMOVAL
OF BARRIERS**
in the non-harmonised
area

**ADMINISTRATIVE
CAPACITY BUILDING**
in areas of
standardization,
conformity
assessment,
accreditation and
market surveillance

**UPGRADE OF
RESEARCH
CAPACITY**
in the field of
metrology

Priority 1: Implementation of the „new approach” directives

Leading institution:

Ministry of Economy

Legal framework prior to EU law implementation:

Act on Testing and Certification of April 3rd 1993

(Journal of Laws no. 55, item 250)

Act on Standardization of April 3rd 1993

(Journal of Laws no. 55, item 251)

Extent of incompatibility of Polish regulations with the acquis

EUROPEAN UNION

POLAND

Technical requirements

- product safety criteria determined in terms of **objectives to achieve**;
- specific technical parameters defined in **voluntary harmonized standards**;
- safety requirements **defined in detail** for specific products;

Conformity assessment procedures

- conformity assessment procedures **varied and tailored** to the ability of a manufacturer and degree of risk;
- conformity assessment procedures were **not fully adjusted** to the Community procedures: **B-safety certificates** for products originating in the European Community;

Accreditation

- **accreditation system functioning independently from the certification system**, approved by the European Co-operation for Accreditation –EA;
- **accreditation & certification performed simultaneously** by certain departments of the Polish Centre for Testing and Certification (PCBC) and the Central Office of Measures (GUM);

Agreement regarding a Protocol on a European Conformity Assessment Agreement

- signed in July 1998;**
- outlines the implementation strategy of the « new approach » European legal framework ;**
- summarizes required adjustments in the field of legal regulations and institutional resources;**
- sets timetable for implementation.**

Key provisions stemming out from the Agreement regarding the ECAA Protocol

- ☑ technical and financial assistance in particular by the **Phare programme**: upgrade of capacities of the Polish laboratories and certification bodies;
- ☑ **transitional arrangements** regarding harmonization of Polish conformity assessment system with the EC requirements:
 - ▶ reduction of the list of products subject to mandatory B-safety certification;
 - ▶ establishment of an **interim system of designated conformity assessment bodies** (CABs) prior to accession;
- ☑ **separation** of the accreditation and certification activities;
- ☑ **transposition** of the relevant directives;
- ☑ negotiation and signature of the **ECAA Protocol** (Europe Agreement on Conformity Assessment).

The ECAA Protocol

(Europe Agreement on Conformity Assessment)

The **ECAA Protocol** was supposed to enable the candidate countries becoming part of the European Single Market prior becoming the EU Member. In case of Poland it was supposed to cover four technical directives:

- 1) **Low Voltage Directive** 73/23/EEC,
- 2) **Machinery Directive** 98/37/EC,
- 3) **Personal Protective Equipment Directive** 89/686/EEC,
- 4) **Electromagnetic Compatibility Directive** 89/336/EEC.

Negotiations started in **April 2002**.

Signing of the Protocol was dependent on the following conditions:

- ▶ **fully compatible conformity assessment systems;**
- ▶ **full transposition** of the directives & of the harmonized standards
- ▶ **notification procedures** in place;
- ▶ membership of Polish Committee for Standardization in the **CEN/CENELEC;**
- ▶ membership of the Polish Centre for Accreditation in the **EA** and signing of the *European Cooperation for Accreditation Multilateral Agreement*.

The ECAA Protocol with Poland **was never signed** due to negotiation delays. Czech Republic and Hungary signed the Protocol in 2001.

Implementation of the EU law (1)

There was **no progress in the transposition or implementation of the New Approach directives prior to 1999.**

1999

July 1999 :

amendment to the 1993 Act on Testing and Certification

- Removal of long-standing trade barriers;
- Allowed for **reduction of the list of produce subject to obligatory certification;**
- Allowed for **recognition of conformity assessment certificates and conformity declarations** on produce manufactured in countries with which Poland had signed mutual acceptance agreements;

Implementation of the EU law (2)

April 2000 :

new Act on Conformity Assessment and Accreditation

2000

- Entered into force in January 2001;
- Established the **legal framework for the implementation** of the EC law;
- Introduced **conformity assessment procedures** and **notified bodies infrastructure**;
- **Separation of accreditation and certification**: Polish Centre of Accreditation (PCA) on the basis of accreditation departments of the Polish Centre for Testing and Certification (PCBC) and the Central Office of Measures (GUM).

Implementation of the EU law (3)

October 2000 :

amendment to the 1993 Standardisation Law

2000

- entered into force in December 2000,
- allowed for the **implementation of European standards** through the so-called '**cover-sheet method**' (endorsement of European standards in one of the official languages of the European standards organisations without translation into Polish)

January 2000 :

Law on general product safety

March 2000 :

Law on the protection of certain consumer rights and on the liability for damage caused by a dangerous product

- transposing Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products.

Implementation of the EU law (4)

January 2001 :

Polish Centre for Accreditation (PCA) becomes operational

- improvement of **administrative capacities**
- independent and impartial character

2001

November 2001 :

PCA becomes a member of the EA (European Co-operation for Accreditation)

May 2001:

Law on Measures

- entered into force as of January 2003
- vide PRIORITY 2

Implementation of the EU law (5)

August 2002 :

Act on the Conformity Assessment System

2002

- addressing, in particular, the issue of market surveillance;
- market surveillance authority in the field of measurement instruments: **Office of Competition and Consumer Protection (UOKiK)** supervising **State Trade Inspection (PIH)** for directives:
 - Measuring instruments (2004/22/EC and 2014/32/EC) – MID
 - Non-automatic weighing instrument (2009/23/EC and 2014/31/EC) - NAWI

Implementation of the EU law (6)

December 2003 :

Regulation of the Minister for Economic Affairs, Labour and Social Policy on essential requirements for non-automatic weighing instruments subject to conformity assessment

2003

- transposing the NAWI Directive (the only 'New Approach' directive in the field of legal metrology at the time);
 - in 2002 "**blank audit**" conducted by EU experts confirmed GUM's ability to assume a role of the Notified Body for non-automatic weighing instruments (in accordance with Directive 90/384/EEC).

In 2003 horizontal and procedural measures required for the administration of the "New Approach" acquis were in place. **Poland has transposed the majority of the sectoral legislation under the new approach**, but progress still needed to be made with regard to cableways, medical devices, marine equipment, and radio and telecommunications terminal equipment.

Institutional changes

Polish Centre of Accreditation (PCA)

As of January 2001 accreditation falls under competences of **the Polish Centre of Accreditation (PCA)**.

Ministry of Economy (MG)

Notifying Authority for MID (2004/22/EC and 2014/32/EC) and NAWI (2009/23/EC and 2014/31/EC)

Office of Competition and Consumer Protection (UOKiK) & State Trade Inspection (PIH)

Market surveillance authorities.

Central Office of Measures (GUM)

Notified Body for MID (2004/22/EC and 2014/32/EC) and NAWI (90/384/EEC, 2009/23/EC and 2014/31/EC).

The Polish Committee for Standardisation (PKN)

Full membership in CEN and CENELEC as of January 1st 2004.

Priority 2: Implementation of the *acquis communautaire* in the field of metrology

Leading institution responsible for implementation of *the acquis communautaire* in the field of metrology: **Central Office of Measures (GUM)**

- **governmental body** that fulfils needs in the area of legal metrology;
- **national metrology institute (NMI)** focusing both on scientific metrology.

Legal framework prior to EU law implementation:

Law on Measures of April 3rd 1993 (*Journal of Laws no. 55, item 248*)

Intended goal within the second priority:

full implementation of EU law in the field of legal metrology

Extent of incompatibility of Polish regulations with the acquis

Polish law does not provide for:

- **'Unit verification'** - verification without type approval;
- **'Declaration of conformity to type'** on the basis of quality assurance for production;
- Supervision over implemented quality systems.

Different technical requirements set out in EC directives and in Polish regulations as far as the following measuring instruments are concerned:

- Non-automatic weighing instruments (90/384/EEC);
- Water meters (75/33/EEC, 79/830/EEC);
- Meters for liquids other than water (71/319/EEC, 71/348/EEC, 77/313/EEC);
- Gas meters (71/318/EEC);
- Tyre pressure gauges for motor vehicles (86/217/EEC);
- Alcoholometers and alcohol hydrometers (76/765/EEC);
- Taximeters, automatic checkweighers, continuous totalisers (2004/22/EC).

Scope of legal changes

Law on Measures of 11 May 2001

- entered into force as of January 2003;
- **full transposition of the Metrological Control Directive (71/316/EEC), of the Metric Directive (80/181/EEC) and of the NAWI Directive (90/384/EEC);**
- abandonment of authentication (*uwierzytelnienie*) as a form of metrological control [neither calibration nor verification];
- extended the scope of legal metrological control, which from now on covered measuring instruments used: in health, life and environment protection; to protect safety and public order; to protect consumer rights; for the collection of fees, taxes and other budget charges and the determination of discounts, penalties, salaries and compensations; in customs;
in trade;

Law on Measures of 11 May 2001 constituted the basis for issuing regulations transposing into Polish law technical requirements listed in **19 legal metrology directives**:

[1] 71/316/EEC (measuring instruments and methods of metrological control)

[2] 71/317/EEC (5 to 50 kilogramme medium accuracy rectangular bar weights and 1 to 10 kilogramme medium accuracy cylindrical weights)

[3] 71/318/EEC (gas meters)

[4] 71/319/EEC (meters for liquids other than water)

[5] 71/347/EEC (measuring of the standard mass per storage volume of grain)

[6] 71/348/EEC (ancillary equipment for meters for liquids other than water)

[7] 73/362/EEC (material measures of length)

[8] 74/148/EEC (weights from 1 mg to 50 kg of above-medium accuracy)

[9] 75/33/EEC (cold water meters)

[10] 75/410/EEC (continuous totalizing weighing machines)

[11] 76/765/EEC (alcoholometers and alcohol hydrometers)

[12] 76/766/EEC (alcohol tables)

[13] 76/891/EEC (electricity meters)

[14] 77/95/EEC (taximeters)

[15] 77/313/EEC (measuring systems for liquids other than water)

[16] 78/1031/EEC (automatic checkweighing and weight grading machines)

[17] 79/830/EEC (hot-water meters)

[18] 80/181/EEC (units of measurement and repealing directive 71/354/EEC)

[19] 86/217/EEC (tire pressure gauges for motor vehicles)

Main concern:

research infrastructure – constant delays.

In September 2001, **Law on packed goods** transposing the EC acquis on pre-packaging was adopted. The major part of the law entered into force in January 2003, the remaining provisions upon accession.

Institutional adjustments : market surveillance

main market surveillance authority: **Office for Competition and Consumer Protection (OCCP)**; co-operates with: the Central Board of Customs, **the Trade Inspection**, the State Labour Inspection and other inspection bodies

TRADE INSPECTION

1. requests any relevant information;
2. enters the premises;
3. takes sample;
4. **prohibits the further marketing of the product.**

If product does not comply with the essential requirements the Trade Inspection can order to:

1. **withdraw** the product;
2. **ban its further marketing**;
3. **restrict** its further marketing;
4. **destroy** the product in question.

OFFICE OF COMPETITION AND CONSUMER PROTECTION

informs the European Commission of every decision requesting the withdrawal of the product from the market, prohibition or restriction of its marketing.

2003 Commission Report on the state of preparedness for EU membership (1)

At the brink of accession:

- horizontal and procedural measures in place;
- implementation structures for standardisation, metrology, accreditation, conformity assessment and market surveillance were all in place.

2003 Commission Report on the state of preparedness for EU membership (2)

“New approach”

Poland has transposed the majority of the sectoral legislation under the new approach.

Still missing or not yet fully aligned legislation relates to cableways, medical devices, **non-automatic weighing instruments**, marine equipment, and radio and telecommunications terminal equipment. Some adjustments might still be required in other areas.

“Old approach”

Poland has transposed a significant part of the acquis in these product sectors. **Further efforts are required** in the areas of textiles, **legal metrology**, motor vehicles, chemicals, fertilisers, pharmaceuticals, cosmetics and wood.

“Non-harmonised area”

Poland has conducted a screening exercise for national legislation possibly in contradiction with the principle of free movement of goods; this screening must continue and the identified barriers must be removed.

Practical challenges as regards NAWI (1)

Notified Bodies for NAWI (90/384/EEC)

CENTRAL OFFICE OF MEASURES

module B: EC-type examination certificate

module G: declaration of conformity based on unit verification

LEGAL VERIFICATION OFFICES

module F: declaration of conformity to type based on product verification

Practical challenges as regards NAWI (2)

NO TRANSITIONAL PERIOD:

as of May 1st 2004 all the Polish type approval decisions issued prior to accession

BECAME INVALID

Number of EC-type examination certificates issued after accession:

2004 : **37**

2005 : **13**


2006

: **10**

Harmonised standard EN 45501 : 1992 (Metrological aspects of non-automatic weighing instruments) was issued in Poland in 1999, so most of the certificates could be issued on the basis of previous protocols.

Biggest problems

- **Keeping up with timetables;**
- **Didn't manage to transpose all the „old approach” directives;**
- **No transitional period for NAWI;**
- **Market supervision: currently under debate;**
- **Research infrastructure.**

The background of the image is the European Union flag, featuring a blue field with twelve five-pointed gold stars arranged in a circle. The flag is shown with a slight wave, giving it a sense of movement. A semi-transparent white rectangular box is centered horizontally across the middle of the image, containing the text.

Thank you for your attention.