An EU-funded project managed by the European Union Office in Kosovo

"Support to the Free Movement of Goods" Project

Ministry of Trade and Industry

Good Regulatory Practice for the Free Movement of Goods

A guide for policy-makers and legislative drafters

June 2016

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ABBREVIATIONS

ACAA Agreement on conformity assessment and acceptance of industrial products
A.I. Administrative Instruction
AOC Attestation of conformity
AVCP Assessment and verification of constancy of performance
CAB Conformity Assessment Body
CPR Construction Products Regulation
DAK Kosovo Accreditation Directorate
EMC Electro-magnetic Compatibility (directive)
EN European Standard
EU European Union
FMG Free Movement of Goods
FPC Factory production control
GPSD General Product Safety Directive
hEN Harmonised European Standard
ISO International Standards Organisation
KSA Kosovo Standards Agency
LVD Low Voltage Directive
MTI Kosovo Ministry of Trade and Industry
NA New Approach
NLF New Legislative Framework
OA Old Approach
ROHS Restriction of hazardous substances (directive)
SAA Stabilisation and Association Agreement between Kosovo and the EU
SPS Sanitary and phytosanitary
TBT Technical barriers to trade
TFEU Treaty on the Functioning of the European Union
WEEE Waste Electrical and Electronic Equipment (directive)
WTO World Trade Organisation

INTRODUCTION – PURPOSE AND SCOPE OF THIS GUIDE

Kosovo is a country in the stages of development, in all respects. It has to develop government policies and respond to societal interests and concerns, and it has committed, through the signature of the Stabilisation and Association Agreement (SAA), in October 2015, to a 10 year plan to move towards greatly enhanced cooperation with the European Union (EU). While this Agreement rightly foresees that Kosovo will progressively transpose, implement and enforce the legislative *Acquis* of the EU, policy makers and regulators in Kosovo need to be aware of the challenges that such transposition can pose. Article 1.2 of the SAA refers to the need to "support the efforts of Kosovo to develop its economic and international cooperation, *should objective circumstance so permit, including through the approximation of its legislation to that of the EU*".

The text in italics above is important. "Should objective circumstances so permit" provides for the possibility that Kosovo may not, early in the 10 year process, be in a position to move that much closer to EU provisions, while "including through the approximation of its legislation" indicates that transposing EU legislation is not the only means for Kosovo to improve its situation. There may be cases where regulation is not the best way of dealing with a particular situation, and there may be cases where the adoption of full or partial EU provisions is not an appropriate approach, either. Prior to any regulatory proposal, Kosovo needs to have a systematic approach to deciding on which approach would currently work best for Kosovo and, having made this decision, ensure that the approach is correctly followed.

Kosovo has made good progress in creating a new regulatory system based on general EU principles, and needs to continue to advance in this. However, creating a new regulatory system involves a great deal more than just transposing the text of EU provisions. Pre-regulatory policy (as described above) needs first to be developed, then a resource and capability assessment performed. If these two indicate that regulation is the best approach, and that regulation based on a relevant EU text can function in Kosovo, then the regulation needs to be drafted correctly to be applicable in Kosovo. Once the regulation has been drafted and approved, it needs to be implemented and enforced, and the effects monitored to ensure that its goals are being achieved. All of these stages are addressed in this Guidance Document, although emphasis is placed on the stage of legislative preparation and drafting.

The EU-funded Free Movement of Trade (FMG) project, launched in October 2014, aims to support the facilitation of free movement of goods in Kosovo, by providing technical assistance for the main institutions involved, in particularly (but not uniquely) the Ministry of Trade and Industry (MTI). A second goal of the project is to ensure that the pillars of the National Quality Infrastructure (standardisation, accreditation, metrology and conformity assessment, to which may be added regulatory provisions and market surveillance) are for the first time well-coordinated as a result of the assistance that will be provided by this project. One of the areas of work of the FMG project has been legislative assessment, under which various Kosovo legislative acts have been evaluated by FMG project experts, both for their correlation with EU provisions and in relation to their implementation and enforcement.

This legislative assessment work has indicated that, while a fair number of EU provisions has been transposed, there is a need, in general, to improve the quality and applicability of these transpositions, and to ensure the overall consistency of the regulatory approach. In addition,

much more emphasis needs to be placed on ensuring that already-transposed acts are enforceable and that they are being enforced. This leads on to the need, before further EU acts are transposed, to assess whether introducing new acts represents the best approach and, if it is, that Kosovo is in a position and has the resources and infrastructure to ensure that they can be appropriately implemented and enforced.

The EU *Acquis* is, in total, made up of 33 chapters. The FMG project concentrates on Chapter 1, *Free movement of goods*, but aspects of Chapter 20, *Enterprise and industry policy* and Chapter 28, *Consumer and health protection* are also relevant. Because of the concentration of the FMG project, and the main interest of MTI being in the area of Free Movement of Good, this Guidance Document is also limited to the FMG area, even if its guidance may be equally relevant to other areas.

The focus of this document is on the need for Kosovo to establish a regulatory system for FMG which *functions effectively and efficiently for the benefit of Kosovo and its citizens*. The main focus of any regulatory system for FMG is on protecting the health and safety of consumers, with an increasing emphasis on environmental protection. This protection applies equally to products made and sold in Kosovo, products coming into Kosovo from the EU and products coming into Kosovo from non-EU countries. The EU system also concentrates on removing technical barriers to trade (TBTs) between its Member States (and therefore between the EU and Kosovo), but these two aspects must always be taken together; Kosovo citizens must be protected from unsafe national products, while free movement of goods into and out of Kosovo must always also ensure proper protection.

At the launch of the FMG project, the commitment of MTI and its staff to cooperation and to achieving greater progress of MTI in the future was stressed. MTI's belief is that in the upcoming years there will be further improvement of the business climate and that this will lead to an increase in Kosovo's competitiveness, which also represent the priorities of MTI. The purpose of this document, therefore, in providing guidance on regulatory policy development, drafting and effective implementation, is to assist MTI and other line ministries to achieve these goals in those areas impacted by regulations.

In drafting this Guidance Document, due account has been taken of the existence of other documents already available in Kosovo. These include, in particular, the "*Practical Guidelines for Legal Approximation of the Legislation of the Republic of Kosovo with the Legislation of the European Union*", produced by GIZ in April 2014, Regulation No. 09/2011 on Rules and Procedure of the Government of the Republic of Kosovo, Regulation No. 13/2013 on the Government Legal Service and Administrative Instruction No. 03/2013 on Standards for the Drafting of Normative Acts. These documents, and other documents to which reference is made and from which provisions are extracted (and which are listed in the Bibliography), all contain useful background information.

This Guidance Document brings together the information from these other documents into a single, practical and easy to read document, specific to the free movement of goods area. It is aimed at regulatory policy makers and regulatory drafters, and takes them through all the necessary stages from assessing the need for regulation, through regulatory drafting, and including implementation, enforcement and follow-up actions. Where there is a need for people to have more information, they are guided to the relevant documents, with only the essential information being reproduced in this Guidance Document. With respect to regulatory policy making and implementation/enforcement, this document covers the factors

which need to be taken into account (such as the need for standards, conformity assessment bodies and market surveillance), but it does not describe in detail how these should best be made available.

Finally, this document needs to be seen as providing guidance, not necessarily solutions. For example, in the chapters on policy making, it discusses the questions which need to be posed to decide whether regulation is the appropriate instrument; in the section on infrastructure/national competence, it identifies what needs to be looked for, while for legislative structure it describes the factors which need to be taken into account in deciding whether text should be presented as primary law in Kosovo, as secondary law or as a combination of both. Policy makers and legislative drafters have to go through these questions in respect of any specific area of FMG legislation, however, to find the specific answers for that area.

CHAPTER 1) WHY REGULATE? ALTERNATIVES TO REGULATIONS

A reminder of what regulation seeks to do and what it seeks to avoid is helpful:

"Regulation is essential to achieve the aims of public policy in many areas, and better regulation is about ensuring that it is only used when appropriate, and about ensuring that the regulation that is used is high quality. Improving the quality of regulation is a public good in itself, enhancing the credibility of the governance process and contributing to the welfare of citizens, business and other stakeholders alike. High quality regulation prevents the imposition of the unnecessary burdens on businesses, citizens and public administration that cost them time and money. It helps avoid the damage to firms' competitiveness from increased costs and market distortions (particularly for small firms). High quality regulation assists in the restoration of confidence in government and is better able to accomplish its desired purpose. Implementation of such regulation is also less problematic for public administration and compliance is easier for citizens. For these reasons it is strongly in the public interest to improve the quality of regulation at all levels."

This Guidance Document focusses on horizontal and vertical legislation in respect of the free movement of goods, although excluding the specific areas of foodstuffs and agricultural products covered by the WTO sanitary and phytosanitary (SPS) Agreement. "Horizontal" in this context refers to legislation which covers all areas or a wide range of areas in one legislative act (an example being the EU's General Product Safety Directive), while "vertical" refers to legislation aimed at specific areas (an example being the EU's Toy Safety Directive). Within these two types of legislation come the following:

- New Legislative Framework (NLF) legislation,
- New Approach Directives (NA, including the Global Approach on conformity assessment),
- Old Approach Directives (OA).

Together, these three areas, with associated supported documents, are known as the "harmonised sectors" because there are harmonised rules throughout the EU. A second area relevant for FMG is that known as the "non-harmonised sector". Non-harmonised sectors are not subject to common EU rules and may come under the national rules. These sectors should still benefit from common principles governing the free movement of goods according to Articles 34 – 36 of the Treaty on the Functioning of the European Union (TFEU), using mutual recognition as the basis. Both harmonised and non-harmonised sectors are covered by this Guidance Document, and lists of the areas within the harmonised sectors are given in Annex 1. From the point of view of aligning its legislation, it is not so important for Kosovo whether a particular area is NLF, NA or OA. It is more important to know what the intention is of introducing any new legislation.

The answer to the question "Why regulate?" (in the FMG area) is relatively simple; it is to provide a system which achieves a high level of consumer health and safety, and environmental protection, which allows for fair trade (including weights and measures, and metrology) and which permits the free movement of goods within a country and between countries, avoiding the difficulties which differences in legislation and the extent of legislative enforcement can bring. Although it is conventional to talk about "consumer

protection", legislation may also protect others in the supply chain (e.g. the ban on asbestos at any stage on the market), while some directives (e.g. lifts and construction products) protect people against risks associated with the use of lifts, and indirectly against risks inherent in buildings and other construction works, even if users of lifts and occupants of buildings would not conventionally be considered as "consumers".
From a regulatory point of view, the aim of consumer protection could be achieved by a simple statement along the lines of "All electrical products placed on the Kosovo shall pose no unacceptable safety risks to anyone using them". Such a law could be enforced, because for some products a simple visual inspection would determine whether a product was safe or unsafe while, for other products, enforcement could be achieved through the courts; the court deciding on what "unacceptable safety risk" is and whether the means used by the manufacturer to show that they are not present were adequate. Such a law would be cumbersome, however, and would do nothing to address free movement of goods with other countries. It is normal, therefore, for regulations to give more details, including in particular the ways by which a manufacturer can show that his product is safe.

In the area covered by this Guidance Document, the combined aims of consumer protection and free movement are usually achieved by regulation of some form or another, and this is likely to be the same for Kosovo as well. In this context, "regulation" may be given the following, general, definition:

"Regulation may widely be defined as any government measure or intervention that seeks to change the behaviour of individuals or groups. It can both give people rights (e.g. equal opportunities), and restrict their behaviour (e.g. compulsory use of seat belts)."

"Changing behaviour" in the FMG area has a number of different aspects. Manufacturers, importers, distributors and retailers have 'restricted' behaviour, in that they are limited to dealing only with products which comply with legal provisions, manufacturers are 'obliged' to ensure that they evaluate their products before they are placed on the market, while consumers are given the right to expect that they will be offered only 'safe' (conforming) products and they should change their behaviour to only purchase safe product.

Regulation can, of course, particularly for a country like Kosovo, have negative effects depending on how and to what extent it is enforced. If a law is enforced on Kosovo manufacturers, this may raise prices by up to 5 %. If the law is not equally enforced on imports, Kosovo manufacturers will lose out. Conversely, if CE marked (regulated) products are entering the Kosovo market and are perceived by consumers as "better", while Kosovo manufacturers cannot compete against them because no equivalent regulatory marking is available in Kosovo, again Kosovo manufacturers will lose out. Finally, if no regulatory system is in place at all, and good Kosovo products are trying to compete with non-conforming, unsafe and low quality imports which are not controlled at all, Kosovo manufacturers lose out once more. Leaving the problems for Kosovo manufacturers aside, any 'unfair' competition from imported products can only further harm Kosovo's negative balance of trade situation.

Nonetheless, as will be discussed in more detail in Chapter 4, regulation in general may not be the optimum solution at any given point in time; careless regulation can have unintended consequences, while inappropriate regulation can make the situation worse instead of better. A few examples illustrate this. Firstly, in 1996 in the UK there was a disaster in Dunblane in which 16 schoolchildren were killed by a gunman and this led to immediate new legislation

controlling firearms (actually a restrictive rather than a free movement measure). This new legislation had no noticeable effect on illegal firearms in the UK (criminals are not the best at complying with laws), while it had much greater effects on legitimate users of firearms, such as those involved in competitive shooting.

Secondly, in 2015 a dangerous substance was found to be present in some foods in the Philippines, and this led to a new law banning that dangerous substance entirely. One consequence was unintended; the substance in question was also present (perfectly safely and appropriately) in varnish used by many furniture makers in the Philippines, but the law made the continued sale of this varnish illegal and there was no alternative varnish available.

Finally, in 2013 Kosovo adopted a new law on construction products which was intended to be a transposition of the EU's construction products regulation (CPR). The Kosovo text was, however, poor and did not reflect any of the main principles of the CPR which fully entered into force in the EU in 2013. The Kosovo regulatory 'system', therefore, as this law established, had no validity in any country other than Kosovo. In addition, the way in which the Kosovo law was written, following the CPR approach of *de facto* mandatory European Standards and, in many case, the mandatory involvement of State-recognised third party conformity assessment bodies (CABs), none of which currently exist in Kosovo, created a legal system which is almost impossible to apply. The only possibility would be for Kosovo manufacturers, at great expense, to use CABs in the EU. Consequently the law is being ignored by almost all Kosovo manufacturers of construction products, and it does nothing to 'recognise' construction products imported from EU and other countries.

Prior to any decision to regulate, therefore, Kosovo authorities need to decide whether regulation is the best approach and, if it is, whether transposition in full or in part of an EU legal instrument is appropriate for Kosovo at the current time. Chapter 4 of this Guidance Document provides guidance to Kosovo authorities on how to make these decisions, and the rest of the document mainly assumes that the decision to transpose EU legislation is the right approach. It is, though, worth briefly discussing alternatives to a regulatory approach. The alternatives are shown in Figure 1.

The first alternative to regulation is for authorities to do nothing, or at least not to do anything at the current time. "Doing nothing", in this context, should be the result of a deliberate policy choice, as opposed to the situation where government does take action but the action leads to no change. It is fundamentally important for Kosovo to avoid creating a regulatory system which either is not or cannot be enforced in Kosovo (where would market surveillance start if everybody in a particular product area was acting 'illegally'?). This includes avoiding imposing unnecessary costs on Kosovo manufacturers, which puts them at a disadvantage compared to their foreign competitors, or which puts Kosovo manufacturers out of business altogether.

The second alternative to regulation is education and/or information/advertising campaigns. Consumers can be 'encouraged' to choose products bearing the CE marking or the Kosovo KK marking, for example, by good advertising. An advertising campaign in the UK had a great influence on drink-driving, more so than any law would have had, simply by changing the perception of drink-driving from previously being considered 'macho' and socially acceptable to being socially unacceptable.

The third option available to Kosovo authorities is to use 'market forces', either by creating markets where none existed before, providing information where information didn't exist before to allow the market to work, or to control a market indirectly instead of directly. Examples of where markets can be created are in pollution control, for example by establishing a system of "Tradable permits" whereby manufacturers take on responsibility for the costs of the pollution they create, or where the government, through financial incentives, creates a market for pollution clean-up. Information and indirect control include, for example, controls on misleading advertising, and either government or voluntary initiatives to provide certain product information. The EU's measures on energy labelling (while these are actually regulatory) do not control the energy usage of appliances but they do require manufacturers to declare the energy usage, giving the choice to consumers to opt for more or less efficient products.

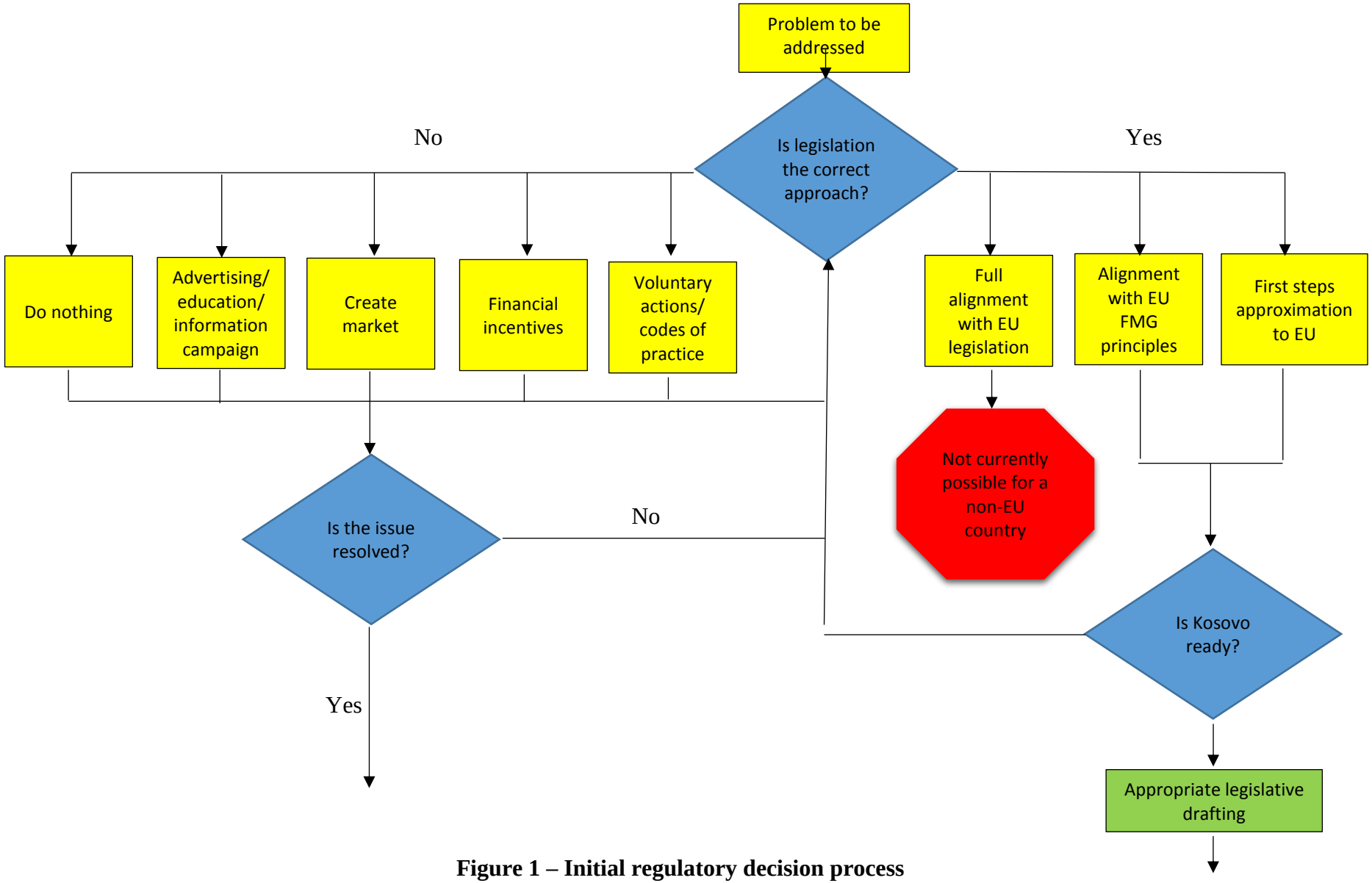


Figure 1 – Initial regulatory decision process

The fourth policy area available, as an alternative to regulation, is financial incentive. This might take the form, for example, of tax reductions on research spending by manufacturers, thereby assisting innovation, it might take the form of government subsidy for infrastructure development) or it may take other forms. As a general rule, systems work better when people are 'encouraged' by positive incentives to act appropriately than where they face the risk of being penalised if they act inappropriately, particularly when there are insufficient resources to enforce the penalties.

Finally, governments may encourage voluntary actions, such as self-regulation and codes of good conduct. Self-regulation, developed by economic operators themselves, may well be more efficient, cheaper and more flexible than regulation. Advertising is often subject to self-regulation, possibly overseen by a body responsible for codes of conduct, while examples of codes of good conduct include the star rating of hotels and "Organically produced" food schemes. Some governments give self-regulation a chance to work before deciding on whether conventional regulation is necessary, but self-regulation does not always work, as the world-wide financial collapse of 2007-2008 indicates. In addition, self-regulation may be more effective in countries which have a history of using it, and less successful in countries with a history of heavy State control.

In summary, most of this Guidance Document is based on the assumption that a 'formal' regulatory approach to the free movement of goods, and associated consumer protection, is correct and appropriate. It should not, however, be automatically assumed that this is always the case, and any decision to move towards a formal regulatory approach needs to be an 'active' one, as later chapters cover in more detail.

CHAPTER 2) BRIEF PRESENTATION OF THE EU REGULATORY SYSTEM

2.1 Introduction

A brief presentation of the EU system for free movement of goods is given in this chapter, while Chapter 3 presents the specific requirements of CE marking (and the equivalent KK marking in Kosovo). An understanding of EU legislation will help the understanding of later chapters.

The EU legislative system is made up of three main levels:

- primary legislation, comprising the Treaties according to which the Union functions,
- secondary 'legislation', comprising five types of instrument: regulations, directives, decisions, recommendations and opinions (recommendations and opinions have no legal force),
- tertiary legislation, national legal acts necessary to bring EU law into force (provisions needed but not described in detail in the EU law, such as penalties for infringements, the notification of conformity assessment bodies mechanism, and the functioning of market surveillance).

Case-law of the European Court may also be considered as a sort of 'primary' or 'secondary legislation' (although it is not usually included in the definitions), when its effects are to clarify or modify the way in which primary of secondary legislation is interpreted and enacted. A fourth 'level', often known as "soft law", is not legislation as such but may establish principles, guidance or intentions.

The primary legislation establishing the European Union is not of particular importance to Kosovo in its work of legislative transposition, unless it is necessary to understand *why* EU legal instruments exist. It is not important, either, for legislative policy makers and legislative drafters in Kosovo to understand the history or development of the current EU legal system, although there is extensive information available on this from other sources. Understanding such legislation will become more important as Kosovo prepares for an ACAA (Agreement on Conformity Assessment and Acceptance of Industrial Products) and, ultimately, for EU membership. For this particular Guidance Document, it is enough to know that there are two founding treaties which create the European Union:

- the Treaty on the European Union (the Lisbon Treaty),
- the Treaty on the Functioning of the European Union (TFEU),

although other treaties remain in place. It is good to understand the different terminology and correspondence between EU and Kosovo legislation. EU primary legislation, while it does not currently apply to Kosovo, is closest in its intention to the Kosovo Constitution. EU secondary legislation is usually transposed in Kosovo as "primary law" (laws or regulations), while tertiary legislation of the EU corresponds most closely to what are often called "sub-legal acts" in Kosovo, in particular Administrative Instructions. The equivalence of EU and Kosovo legislation is shown in Figure 2.

The main area of legislation approximation work by Kosovo is secondary legislation and, for free movement of goods, in particular directives and regulations. Some, especially more recent, EU legislation provides for Delegated Acts (proposals made by the Commission, usually in relation to the details of how the act is applied) and Implementing Acts. An example of Implementing Acts is the EU's Eco-design directive. The directive itself is a framework, which allows eco-design rules for certain products groups to be developed. The rules themselves are then included in a series of Implementing Acts, and the directive does not actually apply to product groups until there is an Implementing Act. Secondary EU legislation as such, Delegated Acts and Implementing Acts can take the form of regulation, directive or decision, although regulations and decisions are most usually the form chosen.

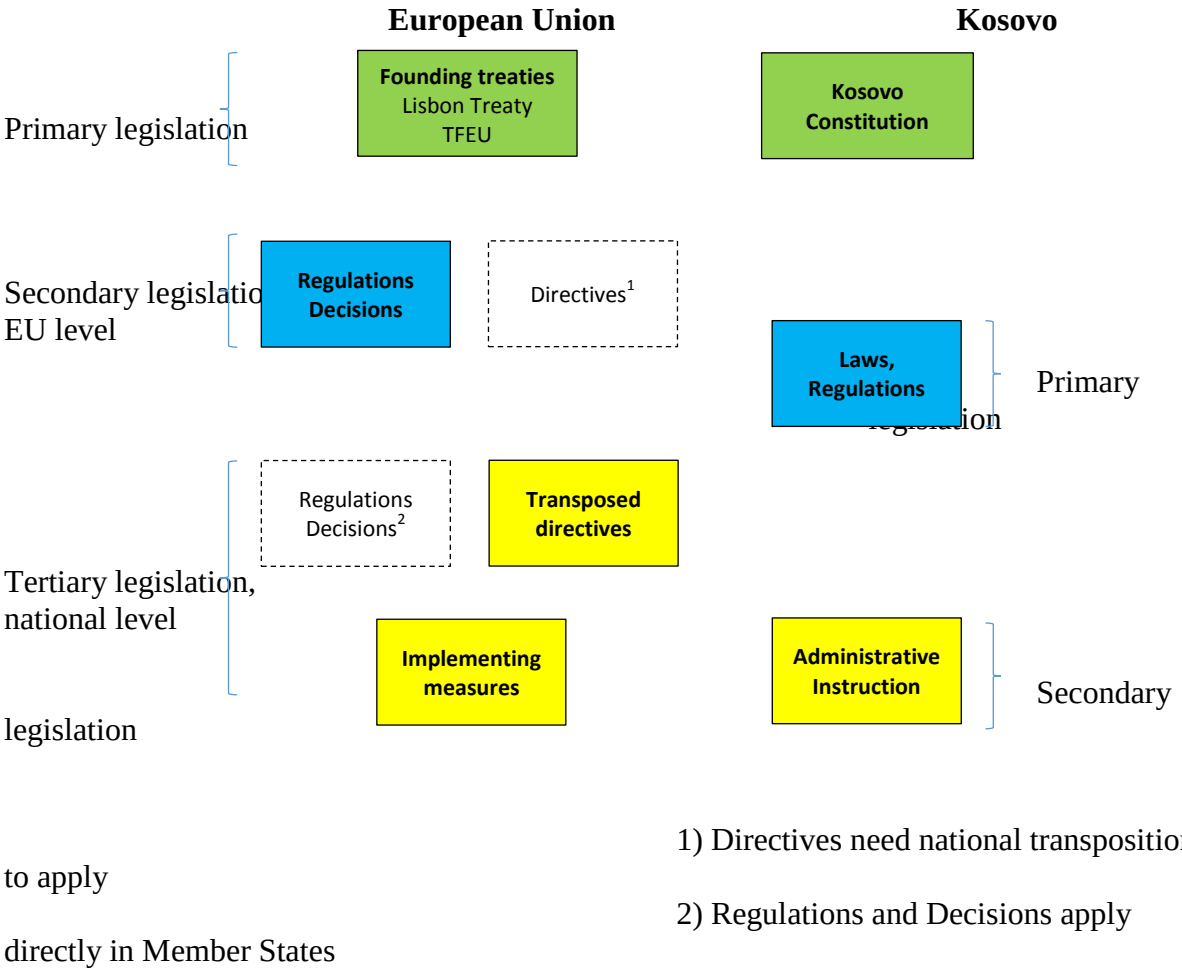


Figure 2 – Simplified legislative 'levels' in the EU and Kosovo

There are now only five types of EU secondary legislation (only three are shown on Figure 2 above), which is a reduction from the 15 different types which existed previously. This does not mean that an act of one of the 10 previous types is withdrawn (they continue to exist), but no new acts of the old type will be issued in the future. Figure 2 needs some explanation. There is no equivalence in Kosovo of "EU level" legislation, but "EU legislation" applies differently: regulations and decisions are "EU level" and apply directly in Member States, whereas directives are "EU level" by only apply at national level when transposed into national law. It is for this reason that Kosovo primary law is shown between "EU level" and "National level", because it is equivalent to both regulations and directives.

Finally, "soft law", while not being a definition contained in the EU treaties, covers all other instruments which have a bearing on the overall legal system. These instruments have no legal force (and therefore include recommendations and opinions even if these are included under the heading of "secondary legislation"), but they also include:

- **preparatory instruments:** Green Papers, White Papers, Action Programmes;
- **informative instruments:** communications;
- **interpretative and decision instruments:** usually communications, which provide for administrative rules for the issue of EU law, interpretative communications, codes and others;
- **formal and informal steering instruments:** Commission recommendations or opinions, etc.

Although not listed in the above, guidance from the Commission (such as the famous "Blue Guide on the implementation of EU product rules", and sector-specific guidance appearing on the Commission's website) may also be considered as 'soft law'. Note that, while a lot of informal 'guidance' exists on the internet, from organisations such as conformity assessment bodies and trade associations, this guidance needs to be used carefully, because it is not always entirely correct.

2.2 Directives, regulations and decisions

As can be seen from the list in Annex 1, the majority of EU acts in the free movement of goods area take the form of directives. The TFEU defines directives as follows:

"A directive shall be binding, as to the result to be achieved, upon each Member State to which it is addressed, but shall leave to the national authorities the choice of form and methods.

The results to be achieved, for FMG, are generally consumer and environmental protection and free movement, or other actions linked to these. When applied in the EU, these results are to be achieved between EU Member States; directives and regulations do not specifically mention the free movement of goods from third countries into the EU, but they do not prevent or exclude it, either. Any manufacturer, from anywhere in the world, who meets EU legislation in full has the implicit right to place his products on the EU market. EU provisions do not, though, address in any respect the possibility of products complying with EU legislation being accepted on the market of third countries.

The same 'results to be achieved' which apply within the EU should also apply within Kosovo and between Kosovo and the EU, and this will become increasingly relevant for Kosovo as it moves towards EU membership. This does not, however, mean that all the results have to be achieved over night!

Because directives set the results to be obtained but do not prescribe the legal form by which each Member State achieves them, directives need to be transposed by each EU Member State into its national legal system, and the same applies to Kosovo when it seeks to create its legal system on the basis of a directive. Because of this 'national freedom' provided by directives, and the fact that not all Member States have, in the past, transposed or applied

directives in the same way, there has been a move, in the EU, away from directives and towards regulations, and this seems likely to continue.

The TFEU also defines an EU regulation as follows:

"A regulation shall have general application. It shall be binding in its entirety, and directly applicable in all Member States."

In the EU, this means that regulations provide no margin for manoeuvre for individual Member States in how they apply the provisions; regulations are not transposed into national law, they are directly applicable and have to be followed word-for-word. As such they have the effect of uniquely establishing the legislative requirements throughout the EU, making the situation in principle a lot easier for manufacturers and other economic actors to know and understand what they have to do (this does not exclude the possibility, however, that some EU regulations contain errors or provisions which cannot actually be applied!). Because it is not an EU Member State, regulations cannot have direct application in Kosovo, and regulations must, therefore, be transposed into national law for them to have effect.

The "direct application" nature of EU regulations applies only to EU Member States and countries having signed an appropriate agreement with the EU; it does not, currently, apply to Kosovo. This means that each obligation of a regulation needs to be considered individually as it is being transposed into Kosovo law. Obligations related directly to consumer protection and free movement of goods should, as a matter of principle but subject to the considerations of Chapter 3, be fully transposed, but other 'obligations' need to be considered on a case-by-case basis.

Two examples illustrate this. It is common that Member States have to establish "National Contact Points", the role of which is to provide advice to economic operators on what they have to do to place products on the market of that country (in respect of the requirements of the specific legislation). There may be advantages in Kosovo also establishing similar Contact Points (as long as the advice they give is correct and definitive), but there is no obligation on Kosovo to do so. As will be discussed in a later chapter, Kosovo laws should avoid placing obligations on the government which are not then satisfied ("Kosovo shall establish a National Contact Point" (the obligation corresponding to that on EU Member States) might better be replaced by "Kosovo may establish a National Contact Point").

Secondly, when an EU Member State takes or intends to take market surveillance action (such as suspending a product from its market), it has to inform the European Commission and other EU Member States of this, and the Commission and/or one or more Member State may object to the proposed action if they believe that it is justified. No equivalent possibility currently exists for Kosovo, and therefore any such obligations should not be included in the Kosovo law (text which says "This provision shall enter into force when Kosovo becomes an EU Member State" (or equivalent) needs to be avoided, too).

If a framework directive comes into force through an Implementing Act in the form of a regulation or decision (see below), the provisions of the regulation or decision are fully, directly binding. Nothing in the tranposition of the directive, therefore, can have the effect of reducing the binding nature of Implementing Acts.

The final secondary legislative act in the EU is the decision, defined by the TFEU as:

"A decision shall be binding in its entirety. A decision which specifies those to whom it is addressed shall be binding only on them."

Decisions may be addressed to all EU Member States together, they may be addressed to individual Member States, to EU institutions or to natural or legal persons. Decisions are often used in the construction products area, for example to set assessment and verification of constancy of performance systems (AVCP, best understood as 'conformity assessment') for certain groups of products, to establish the one or more characteristics which must always be declared with the CE marking, or to establish classification systems or minimum performance levels (threshold values). These are binding on all Member States of the EU and on all manufacturers trading in the EU. Decisions, to have force in Kosovo, also need to be transposed into the Kosovo system.

The only decisions likely to be relevant for Kosovo are those aimed at all EU Member States and which are clearly intended to establish conditions for the placing on the market of products. Kosovo authorities should, however, monitor other decisions to see whether they have equivalent effect.

2.3 Inapplicability of EU law in Kosovo

The Constitution of Kosovo does not allow for any EU legal provisions to have validity in Kosovo. This explains why any EU act intended to be valid in Kosovo needs to be transposed. It also means that Kosovo provisions cannot make direct reference to an EU legal act. The example "For the energy labelling of products in Kosovo, the provisions of Directive 2010/30/EU shall apply" is not permitted.

Where a Kosovo act is a transposition of an EU provision, the EU provision on which the Kosovo act is based needs to be indicated in the "Purpose" section. The only other instance in which reference to an EU provision is permissible is where it is used as one means of satisfying EU regulatory requirements, along the lines of "Machinery bearing the CE marking obtained according to the provisions of EU Directive 2006/42/EC shall be given a presumption of conformity with the requirements of this law [the Kosovo law on machinery]".

2.4 Horizontal and vertical legislation

EU provisions are conventionally described as "horizontal" or "vertical". Expressed simply, a horizontal measure is one which covers the whole of the 'industrial products' area (the areas covered by FMG legislation), while a vertical measure is one which covers only one specific group of products. Examples of horizontal legislation include:

Regulation (EC) 765/2008	Accreditation and the market surveillance of products
Decision 768/2008/EC	Common framework for the marketing of products
Regulation (EC) 764/2008	Application of certain national technical rules to products lawfully marketed in another EU country
Directive 2001/95/EC	General Product Safety
Regulation (EC) 1907/2006	Chemical substances (REACH)

The following are examples of vertical legislation:

Regulation (EU) 305/2011	Construction products (CPR)
Directive 92/42/EEC	Efficiency requirements of hot-water boilers
Directive 2014/33/EU	Lifts
Directive 94/11/EC	Footwear

It is sometimes considered useful to differentiate between "all product requirements" measures and "specific risk" ones. The former cover all or most of the essential requirements of a particular group of products, whereas the latter cover only one specific risk area. Examples of "all product requirements" areas (which are often the same as vertical areas) are:

Directive 2009/142/EC	Gas appliances (GAD)
Directive 89/686/EEC	Personal protective equipment (PPE)
Directive 2009/48/EC	Toys safety

Examples of "specific risk" areas are:

Directive 2002/49/EC	Environmental noise
Directive 2014/30/EU	Electromagnetic compatibility
Directive 2010/30/EU	Labelling and energy consumption

The following two measures have a status somewhat in between the harmonised and non-harmonised sectors. They operate within the non-harmonised sectors (i.e. mutual recognition), but they also set down "common rules" within this area (Regulation 764 is usually considered to be an NLF measure):

Regulation (EC) 764/2008	Application of certain national technical rules to products lawfully marketed in another EU country
Directive 2001/95/EC	General Product Safety

The area considered to be covered by the Old Approach is large and no reliable list of the directives exists. There are about 700 Old Approach directives and it is not, therefore, possible to list them all. The main areas of the Old Approach include vehicles and vehicle components, food, cosmetics and veterinary products, while the following are some *example* directives and regulations:

Directive 94/11/EC	Footwear
Regulation (EU) 1007/2011	Textiles
Regulation (EC) 648/2004	Detergents
Regulation (EC) 1907/2006	Chemical substances (REACH)
Regulation (EC) 1271/2008	Classification, packaging and labelling of chemicals

The details of whether legislation is vertical or horizontal, or single-risk or all-product-requirements is not, in itself, very important. It is important that legislators in Kosovo appreciate the nature of EU regulation, however, for two reasons. Firstly, many products are covered by more than one EU regulatory act (electrical products by at least four and possibly more). It follows from this that, to approximate the Kosovo regulatory system for a particular product sector with that of the EU, all the relevant regulatory instruments need to be transposed. Kosovo manufacturers wishing to export to the EU need to understand the need

to comply with all relevant EU legislation – an electrical appliance manufacturer trying to export to the EU on the basis of complying only with the Low Voltage Directive, ignoring the EMC, ROHS, WEEE, … Directives, should expect his product to be rejected.

Secondly, horizontal legislation applies to all areas unless there is more specific legislation for that area (e.g. if there is no Kosovo legislation on recreational craft, these crafts are covered by the Kosovo transposition of the EU's General Product Safety Directive). However, Kosovo has also transposed EU Regulation 765/2008, as Law No. 04/L-039 on Technical Requirements for Products and Conformity Assessment, which equally sets requirements on all products unless these products are covered by more specific legislation. In this case, therefore, Kosovo has two legal provisions which appear to apply to all such products, a matter which should have been addressed before both laws were enacted.

2.5 The use of EU 'soft law'

'Soft laws' do not need to be transposed in Kosovo, but they may be used by Kosovo in two ways. Firstly, if a document from the European Commission indicates an intention, such as a proposal to amend a directive or convert a directive into a regulation, this may have a bearing on the timing of its transposition into Kosovo law (there is little point in transposing an EU act which, shortly afterwards, is changed). How Kosovo remains aware of EU intentions is discussed in more detail later.

Secondly, there is a series of EU Guidance Documents relating to EU legal provisions as a whole in the FMG area (the 'Blue Guide') and to individual directives. As discussed below, during the drafting phase and once a legal act is transposed into Kosovo legislation, the responsible ministry should consider an information campaign to inform people of its existence. One part of this campaign could be written guidance, possibly based on existing EU guidance (suitably adapted for use in Kosovo).

'Soft laws' will not, generally, have any bearing on legislative drafting. However, if something in an EU act is potentially unclear when transposed in Kosovo, and this is dealt with by EU guidance, legislators might consider using the clarification to improve the text of their legislation.

CHAPTER 3) REGULATORY COMPLIANCE, CE MARKING AND KK MARKING

3.1 Introduction

The previous chapter covers the different types and scope of EU legislation. This chapter covers how these provisions (directives, regulations and decisions) work, and also compares the CE European conformity marking with the Kosovo KK conformity marking. Vertical provisions will be discussed first, because it is these which are mainly of relevance both in the EU and in Kosovo, and horizontal provisions will be discussed at the end of this chapter. The one EU act which works in a somewhat different way to all others is the Construction Products Regulation, so this is described separately.

Although all EU legislation covering the free movement of goods has the same overall aims, and it tends to be written in generally the same way (although recognising that Old Approach and New Approach acts are somewhat different) there are differences in the details of how each legal act works. In a Guidance Document such as this, it is not possible to include all the details of all EU legal acts, but the intention is to give enough detail so that the overall picture can be understood. Where more detailed information is needed, reference should be made to one or more of the documents listed in the Bibliography.

The two fundamental aims of single market product legislation are, firstly, protection of those affected by those products (conventionally referred to as 'consumers') and, secondly, establishing of common requirements and rules which product manufacturers and others have to follow in order to place their products on the market (a few directives, such as Lifts, also cover requirements on installations). If the technical requirements on products (their health and safety performance, their environmental performance and their functionality, usually referred to as 'essential requirements' or 'essential characteristics') are the same throughout the EU, then any product considered to be 'safe' in one Member State has to be considered equally 'safe' in all Member States. In addition, if the mechanisms by which a product is shown to be safe are the same throughout the EU, then the same principle applies; a product which has gone through the procedure of demonstrating its safety in one Member State has satisfied the procedure of all other Member States. By setting common essential requirements and common procedures, EU legislation addresses the dual intentions of 'consumer safety' and free movement.

3.2 CE marking directives and regulations

There is a series of EU directives and regulations which cover different product groups or different specific risks (see Annex 1). Most of these require that, when a product meets the essential requirements, and has gone through the procedure to show that it meets these requirements, the product bears the CE conformity marking. Fundamental to the EU's free movement principle is that, once a product has met the requirements for CE marking, anywhere in the world, it has free access, with no additional assessment or requirements, to all markets where CE marking is accepted.

Essential requirements: directives and regulations dealing with aspects of product performance set out, in general terms, the performance requirements which must be satisfied. A few examples from different directives show these, the first from the Low Voltage Directive (LVD), the second from the Personal Protective Equipment Directive (PPE):

- (LVD) Persons and domestic animals are [shall be] protected against the danger of injury caused by direct or indirect contact.
- The insulation must be suitable for foreseeable conditions.
- (PPE) PPE must not adversely affect user hygiene or health.
- PPE protecting part of the body against static compressive stress must be sufficient to prevent serious injury or chronic complaints.

As can be seen by these examples, the ERs are very general and they apply to all products within the scope each directive as long as they are relevant for those products.

The essential requirements are the same in all EU Member States, and no individual Member State is allowed to add requirements or remove requirements. Not all requirements apply to all products, because this depends on the nature of the product and the function it performs, but which requirements apply to which products is the same throughout the EU. This means that the regulatory system, throughout the EU, is identical in terms of the performance characteristics which products have to satisfy.

The implication for Kosovo, when transposing an EU provision, is that the same performance characteristics as apply in the EU (highly advanced groups of countries) will apply in Kosovo. If Kosovo had previously no regulatory requirements at all in a certain product area, once it has transposed an EU act, it will have the same requirements. If Kosovo transposes the EU's electromagnetic compatibility (EMC) and restriction of hazardous substances directives (ROHS, as just two examples), most electrical equipment in Kosovo will need EMC testing, which requires rather expensive test equipment, while all electrical equipment will need to be assessed against ROHS which, again, requires sophisticated test equipment.

Satisfying essential requirements (ERs): manufacturers usually have two alternatives to demonstrate that their products meet the relevant essential requirements: they can comply with the requirements directly, using whichever test or assessment methods they choose, or they can apply a harmonised European Standard (hEN, see below). The first option, direct compliance, generally requires the manufacturer to perform a risk assessment to identify which essential requirements apply to his product, and then apply the attestation of conformity procedure (see also below). In most cases, applying an hEN represents the easiest way to satisfy the ERs. The route to CE marking is conventionally shown by the following, simplified diagram:

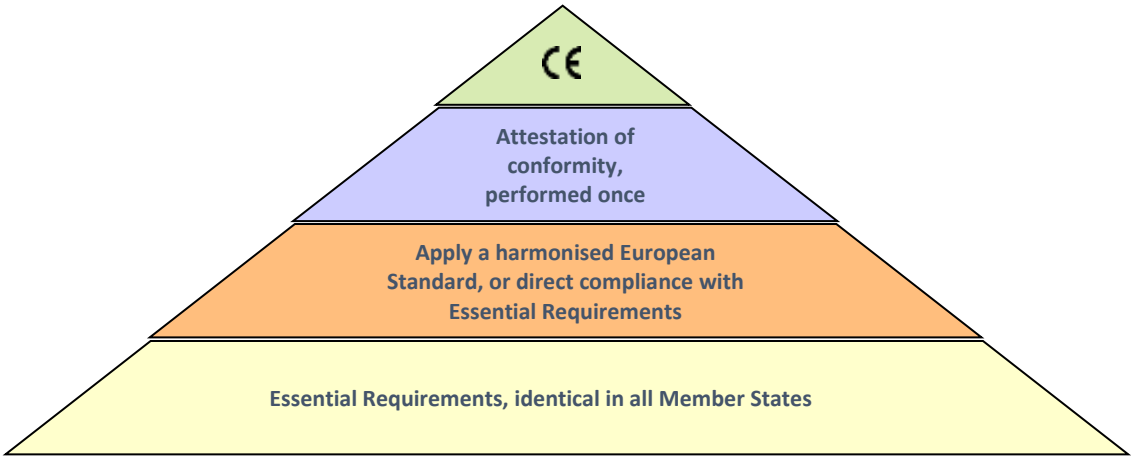


Figure 3 – The route to CE marking

As an exception to this, there are some directives (such as energy labelling and Eco-design) which identify the characteristic(s) to be assessed and declared but do not provide for harmonised standards as the means of assessing these characteristics. There may be European Standards covering these characteristics but they will not be harmonised and their references will not be published by the European Commission. In such cases, the manufacturer has a free choice of whichever assessment method he judges to be suitable.

Harmonised European Standards: hENs are, in terms of their technical content, the same as any normal European Standard. They are, however, produced in response to a mandate (request) given to one of the European standardisation organisations (CEN, Cenelec or ETSI) and usually they contain an Annex ZA (or Annex Z). Annex ZA is informative, in standardisation terms, but it indicates those clauses of the standard which respond to the ERs. To obtain the CE marking, a manufacturer needs only to comply with those clauses of the standard identified in Annex ZA which are relevant for his product (there may be some requirements in the standard which he does not need to comply with).

For a standard to be considered as 'harmonised' (i.e. covering the ERs of one or more EU directives/ regulations), its reference needs to be published in the Official Journal of the EU. Kosovo needs to follow the same procedure when it transposes hENs; a list of hENs recognised by the regulatory authorities in Kosovo (usually a line ministry) as meeting the ERs of Kosovo legislation also needs to be published (KSA, the Kosovo Standards Agency, does not have the right, according to its constitution, to decide for itself that a transposed EN be considered as a harmonised standard in Kosovo).

Obligations on manufacturers: to obtain the CE marking, four main obligations placed on manufacturers need to be satisfied. Firstly (although this is not always explicitly required by the EU directive or regulation), he must prepare a Technical File which describes his product, production and production control procedures, description of how the ERs are satisfied, an example of the marking or labelling of the product and the manufacturer's declaration of conformity. This Technical File is prepared before the product is assessed for conformity to the ERs and, after such assessment, it is completed by the addition of test reports and any other documents (e.g. certificates from suppliers) used in support of the conformity assessment. The Technical File is an important document because, once completed, it

contains all the information necessary to demonstrate the conformity of the product, and may be requested by market surveillance authorities.

Secondly, EU product legislation usually requires the manufacturer to operate a factory production control (FPC) system. The fundamental objective of FPC is that, having had one or a few representative samples of the product tested, the manufacturer then ensures that all future products remain essentially the same as those tested.

Most EU legislation sets only general requirements on FPC, leaving it to individual manufacturers to decide for themselves what an acceptable system is. The one exception to this is the Construction Products Regulation, whose standards are usually quite specific in its requirements, especially in respect of finished product testing. A manufacturer who operates an ISO 9001 Quality Management system specific for his products will satisfy any FPC requirements, but an ISO 9001 system is not a requirement and actually goes beyond the legal requirements for FPC.

What constitutes a satisfactory FPC system depends on the nature of the product involved and, to a certain extent, on the production method. If a manufacturer has good control over raw material and component supply, and the production system involves only the use or assembly of these, a simple visual assessment of finished products may be enough (this might be the case, for example, of protective gloves). On the other hand, if there is poor control of raw materials/components and the manufacturer changes supplier from one day to the next with no assessment of the new raw materials/components, there is a chance that the finished products are different from those initially tested and therefore non-conforming; finished product testing may well be required in this case. For other products, where the production process is more than 'simple' assembly of well-defined components, some testing of the finished products may be necessary, as may be checks and controls during the production process (this is the case for many construction products, for example).

One area which may cause specific FPC and compliance difficulty is electrical equipment and, in particular the ROHS (Restriction of Hazardous Substances) Directive. ROHS requires that some substances are present, if at all, only in very low quantities in electrical equipment. The easiest way for manufacturers to prove this is to obtain reports, from their suppliers, showing that the components comply with ROHS. Where such reports cannot be obtained from suppliers and each component needs to be tested individually for ROHS compliance, this can be particularly onerous and costly for Kosovo manufacturers. ROHS compliance is, of course, mandatory for electrical equipment to be sold in the EU but, at the moment, it is a decision of Kosovo whether compliance with this directive should be equally mandatory in Kosovo.

In summary, a manufacturer operating an ISO 9001 system for his products would meet the legal FPC requirements; him doing no production control at all would not. Whether anything in between these two extremes would be acceptable is a question of judgement for the individual manufacturer and the notified/authorised FPC inspection body if the legislation requires one.

Thirdly, products are generally required to be subject to some form of type testing (performed by the manufacturer himself or by the third party) in order to show that the product meets the relevant ERs. If following an hEN, the manufacturer needs to follow whatever test or assessments are laid down in that standard. Finally, the manufacturer needs to apply whatever

attestation of conformity system the EU legislation specifies for his product. Only once this has been completed can the manufacturer sign his declaration of conformity, the crucial document by which he declares, on his own responsibility, that his products meet all regulatory requirements.

Attestation of conformity: Each directive or regulation prescribes the system of attestation of conformity (AoC) which the manufacturer must follow to obtain the CE marking. Sometimes there are different systems within the same act depending on the 'risks' (more risky products having a more onerous system) and sometimes there is a choice of system for the same product. The AoC system describes what has to be done and by whom (manufacturer or notified body, see below).

AoC covers the design phase and the production phase, and the tasks are defined in so-called 'modules'. The two main tasks of AoC are type-approval testing (design phase) and FPC (production phase, involving testing or quality assurance). In the least onerous system, the manufacturer performs his own type-approval testing. In more onerous systems, a notified body may be involved in performing the type-approval testing, testing during production and/or assessing the manufacturer's FPC system. AoC is performed *before* products are placed on the market (offered for sale), and should not be confused with market surveillance, which is *post-market* verification of conformity.

Notified bodies: The assessment of some products requires the use of third-party notified bodies. Notified bodies undertake the tasks of testing, certification, inspection and calibration; they are recognised by the competent authority in the Member State in which they are based and they remain responsible to that authority. 'Notification', therefore, is a formal procedure by which the competent authority recognised the conformity assessment body (CAB), and which places certain obligations on that body in respect of contact with the authority. Notification cannot be confused with accreditation; accreditation is the process by which a third party accreditation body assesses the technical ability of a CAB, but it does not cover the obligations of contact between notified CAB and authority. Notified bodies do not take responsibility for the conformity of a product, and nor do they 'authorise' the manufacturer to affix the CE marking. They perform 'supporting' activities which, with a positive outcome, may then be used by the manufacturer. CE marking is always based on manufacturer's declaration of conformity, made under the sole responsibility of the manufacturer himself. This is a fundamental and crucial feature of the CE marking system, not always well understood by those used to more active State control.

Notified bodies have a special status within the conformity assessment system, but they are also limited in what they can do and claim as such body. They cannot claim to be a notified body when they perform non-notified tasks. For example, if a test laboratory is notified for some tests but not others, its notified body status cannot appear on test reports for non-notified testing.

Member State rights and obligations: The two main obligations on Member States are to recognise CE marking and not to restrict the free movement or use of CE marked products, and to enforce the system through market surveillance. CE marking is a 'presumption' of conformity, it is not a 'guarantee'. If Member State authorities believe or suspect that a product does not conform (or is dangerous even it does conform), they have the right to take enforcement action. There are, actually, two aspects of CE marking: that the product is 'safe' (meets the ERs) and that it is correctly marked and accompanied by the right documents. A

product without the CE marking (when it is required to have it) or without documentation is in breach of regulatory requirements even if it might be 'safe'. Problems with marking and documentation quite often indicate more fundamental problems, such as the product never having been tested. If one Member State proposes market surveillance action against a product, it must inform the European Commission and other Member States.

Member States also have certain rights: they can object to market surveillance actions suggested by another Member State if they judge the action to be unreasonable. They can also appeal against a harmonised European Standard which they believe does not allow the ERs to be satisfied.

Obligations on others: EU acts also place obligations on importers and distributors, and sometimes on the European Commission. Importers and distributors cannot place a product on the market if they suspect or believe that it does not comply with all regulatory requirements and if it is not accompanied by the correct marking and documentation. The name of the importer must also appear with the product. The main advantage of these obligations is that, if non-conforming products from third countries start to appear on the EU market, enforcement action can be taken directly against importers or distributors, with no immediate need to take action against the manufacturer himself.

Obligations on the Commission can include: dealing with appeals against market surveillance actions, dealing with appeals against hENs, publishing implementing acts necessary for the legislation to come fully into force, and monitoring the effects of the legislation. When EU legislation is transposed in Kosovo, such obligations (if they are needed and/or are appropriate at all) are conferred on the competent Kosovo authority.

3.3 Old Approach directives

The aims of Old Approach directives are the same as those of NA/NLF ones: safety and free movement, but their way of achieving it is somewhat different. Old Approach directives usually contain very detailed technical requirements which products must satisfy and, therefore, they do not rely on hENs. In addition, Old Approach directives do not follow the modules approach to AoC, and they may allow that the State, or a State body, is involved in conformity assessment. Finally, Old Approach directives do not lead to CE marking.

Some Old Approach directives remain in place (see Annex 1), but no more will be published. In addition, whenever an Old Approach directive is updated or amended, the aim is to bring it much more in line with NLF principles. From the point of view of transposition in Kosovo, however, apart from the fact that the details remain different, the same guidance given in this document apply to Old Approach directives as it does to NA/NLF ones.

3.4 The Construction Products Regulation

The EU's Construction Products Regulation (CPR) has a number of important differences when compared to the CE marking described above. It is not considered as a NA/NLF measure and it is no longer covered in the EU's Blue Guide. Because of its importance, however, these differences are briefly described here.

Throughout the EU, Member States regulate on construction *works* rather than directly on construction *products* and, because of recognised differences, such as climate, construction methods and perceived levels of protection required, these works regulations are different from one Member State to another. Consequently, it is not possible to judge whether any construction product is 'safe' (allows works to meet regulatory requirements) because, for most products, this does not depend on the product itself but, instead, on what national regulations demand, how the product is used in the works and how it is combined with other products.

Instead, the CPR requires that manufacturers assess and declare the *performance* of their products against certain characteristics. It is then left to users of the products to decide for themselves whether the products are suitable for a given works or not. CE marking under most legislation means that a product is 'safe', whereas CE marking of a construction product means "the declared performance values are presumed to be correct".

A few other differences are important. The CPR makes CE marking mandatory (like other legislation) but, because of the way the regulation is written, when an hEN exists for a product, the only way of obtaining the CE marking is by following the standard, Unlike other legislation, where standards remain voluntary, this means that hENs under the CPR are mandatory. The CPR does not, either, fix AOC systems for each product or product group. Instead the regulation specifies four different possible systems (with one variant), which range from manufacturer's declaration to full product certification. These, called "assessment and verification of constancy of performance" (AVCP) systems, are not the same as the modules of AOC described above, although the tasks of notified bodies are much the same. Instead, the AVCP systems are set, product group by product group, in Commission Decisions and are then included in Annex ZA of each hEN.

These differences pose a number of problems for transposition of the CPR in Kosovo. Like other legislation, the CPR requires the intervention of notified bodies which do not currently exist in Kosovo. In addition, the mandatory nature of standards, often with prescriptive requirements on FPC, may not be easily satisfied by Kosovo manufacturers. Finally, there are regulatory obligations placed on the competent authority (recognition of authorised (notified) bodies, publication of lists of hENs, publishing AVCP decisions, etc.). At the time of writing this Guidance Document, MTI is currently considering a version of the CPR to be transposed in Kosovo which addresses these problems in a more flexible manner.

3.5 'Horizontal' product legislation

This section covers EU legislation relating to all products not covered by other specific legislation; it does not cover legislation, such as the EMC and ROHS Directives which may be considered 'specific' but also cover large product groups, which are covered by the sections above. The main horizontal EU act is the General Product Safety Directive (GPSD, 2001/95/EC). This may be considered to be a 'catch-all' measure which covers those products which remain outside the scope of any other legislation. Its transposition in Kosovo has a slightly different intention; it regulates all products until Kosovo transposes more specific measures.

The GPSD provides a generic definition of a safe product and requires that only safe products are placed on the market. A product is deemed safe once it conforms to the safety provisions

provided in European legislation or national legislation of Member States adopted in accordance with EU law. In the absence of such legislation or harmonised European Standards, the product's compliance is determined according to other reference documents such as national standards, Commission recommendations or codes of practices.

In addition to the basic requirement to place only safe products on the market, producers must inform consumers of the risks associated with the products they supply. They must take appropriate measures to prevent or reduce such risks and be able to trace dangerous products.

The GPSD is not entirely a 'harmonised' provision (even though there are harmonised rules related to its application and, in some cases, it sets harmonised conditions). It is, instead, based more on mutual recognition between Member States, as laid down in Article 34-36 of the Treaty on the Functioning of the European Union (TFEU). It does not provide for CE marking and nor does it define exactly how manufacturers comply with it. Importantly, while its transposition into Kosovo law establishes a regulatory system requiring safety of all products in general on the Kosovo market (and also provides for market surveillance in support of this), it does not give provisions allowing such products to be traded with the EU.

The second area of 'horizontal' legislation is the New Legislative Framework, made up of three main acts:

Decision 768/2008/EC	Common framework for the marketing of products
Regulation (EC) 765/2008	Accreditation and the market surveillance of products
Regulation (EC) 764/2008	Application of certain national technical rules to products lawfully marketed in another EU country

Decision 768 sets the general requirements, which apply across all product areas, in relation to the placing onto the market of products. It was intended not to set marketing conditions directly but, instead, to identify how other EU legal acts are drafted, by providing text to be included in the acts, to ensure that they all follow the same basic principles.

Regulation 765 covers two provisions which are common to all areas of product marketing, namely accreditation (of conformity assessment bodies, CABs) and market surveillance. In respect of accreditation, it stresses the important role which accreditation plays in ensuring the competence of notified CABs, but it does not make accreditation mandatory. Instead, it sets requirements on national accreditation bodies (those responsible for accrediting CABs) and requires that the work of all EU accreditation bodies is managed by the organisation EA (European cooperation for Accreditation).

For market surveillance, the regulation sets common provisions in respect of the obligations of Member States, in particular for policing the use of the CE marking and for cooperation among Member States and the European Commission, in respect of market surveillance actions.

Decision 768 and Regulation 765 have direct application throughout the EU. Decision 768 mainly comes into force when its provisions are followed in the drafting of other EU legislation, while the provisions of Regulation 765 are, in some cases, repeated (at least in part) in other legislation. The European Commission believes that even these measures have not had entirely achieved the effect intended, and it is possible that Regulation 765, where it

relates to market surveillance, will be replaced, in the near future, with a new regulation covering this subject.

3.6 The KK regulatory conformity marking

There is an Administrative Instruction published in Kosovo which provides the details of how the KK marking is applied. The intention is that it has the same role, in Kosovo, as the CE marking has in the EU. Because EU provisions do not, at present, apply in Kosovo, the KK marking is obtained under Kosovo conditions rather than EU ones. The technical basis (essential requirements) are usually the same (although they may be lower), but where the EU act refers to 'notified bodies', the Kosovo equivalent is 'authorised bodies', where EU acts refer to 'harmonised European Standards', the Kosovo equivalent is "harmonised Kosovo Standards, transposing harmonised European Standards", and any reference to "CE marking" is replaced by "KK marking". KK marking can, therefore, be seen as an important precursor to the ultimate adoption of CE marking by Kosovo, but whether it should be made mandatory or not is discussed in the following chapter.

CHAPTER 4) PRIORITY AREAS FOR REGULATION – CREATION OF THE ANNUAL LEGISLATIVE PROGRAMME

4.1 Introduction

Chapter 1 discussed, in general terms, the question of whether government regulation is the correct approach in the various areas within free movement of goods, and discussed whether alternatives to mandatory regulation exist. This chapter examines this issue in more detail, discussing the questions which Kosovo policy-makers should be asking before taking the decision to regulate. If the decision to regulate is positive, this chapter then considers the form in which such regulation should be developed: national, partial transposition of EU provisions, full transposition of EU provisions or some combination of national and EU positions. The chapter does not provide answers to these questions in any particular area, because the answers can only come as a result of posing and answering the questions presented.

Guidance on this subject exists in many other documents, including documents developed in Kosovo. This guidance is presented in this chapter, however, partially in order to allow this Guidance Document to be comprehensive and self-contained, and partially because it would appear, from the legislative assessment work undertaken by the FMG project, that the guidance available to policy-makers in Kosovo is sometimes not followed or only partially followed.

In presenting the analysis in this chapter, it is recognised that there is already legislation in place in some areas in Kosovo. This chapter does not challenge the decisions which led to this legislation being developed, and it also recognises that there is a difference between taking the decision to legislate and then mistakes being made in the transposition. It is possible, however, that following the approach suggested in this chapter may have led to a different decision or, if not a different decision, then a different approach to the transposition. Finally, it is also recognised that regulatory decisions taken at one point in time can easily change at another time when the situation is different.

Two important facts need to be recognised. Firstly, Kosovo is not an EU Member State and, therefore, it cannot make the CE regulatory conformity marking mandatory. The CE marking is a proprietary marking of the EU and cannot, therefore (despite attempts by some countries to do so), without an agreement with the EU, be adopted as a mandatory marking in other countries. CE marking should, however, be 'recognised'. Secondly, because of this, EU legislation which provides for CE marking, and which uses EU concepts (such as "harmonised European Standards" and "Notified Bodies") *cannot* be transposed word for word into Kosovo law.

4.2 Why regulate?

In the area of free movement of goods, as presented in Chapter 1, there are two goals to be achieved:

- a high level of consumer protection, and

- a system by which safe products can circulate freely between different countries.

Neither of these objectives, on its own, means that mandatory legislation is automatically required. Voluntary actions by a freely-operating market could, in principle, achieve both aims, and some products do circulate freely within the EU without the specific implementation of legislation. The General Product Safety Directive covers all products not covered by more specific legislation but this directive is usually applied 'by default' than actively.
Legislation is conventionally applied, however where, without it, there would not be free movement, and it achieves the two goals above in several ways (in the following, "safe" means "complying with regulatory requirements"):

- it establishes a common definition of "safe products", setting an 'entry level' of safety for products on the market below which a product is not considered 'safe',
- it prevents authorities from requiring more, in respect of safety, than has been commonly agreed,
- it establishes a system for demonstrating and declaring safety, according to which when a manufacturer has demonstrated that his product is safe, once, this demonstration does not need to be repeated,
- it requires that any product shown to be safe cannot be refused market access,
- it allows products to compete in the market on the basis of factors unrelated to safety (price, functionality, quality, etc.).

It may reasonably be assumed that the overall safety levels of products on the Kosovo market are lower than those in the EU or, at least, the degree of certainty in safety levels is lower. While the intention of free market legislation in the EU may therefore be considered as *maintaining* established safety levels, the intention of legislation in Kosovo may also be to raise overall safety levels. By raising safety levels, and improving confidence in these levels, to what is required in the EU, not only are Kosovo citizens better protected but these products also then have access to the EU market.

It may also be assumed that, without mandatory legislation, product safety levels in Kosovo are unlikely to improve. While the need for product safety legislation is therefore established, what type of legislation is needed and when and how it should be imposed are key questions for Kosovo. The two goals above, taken individually, may lead to a somewhat different regulatory approach. If the goal is to raise overall safety levels in a particular product sector to an acceptable 'entry level', this safety level might simply be established by legislation and the market left to achieve it. If the goal is to achieve free trade, where the word 'free' may also mean that Kosovo manufacturers are not put at a commercial disadvantage, then a more 'structured' approach may be required.

As explained in Chapters 2 and 3, there are many advantages in Kosovo basing new legislation in the FMG area on EU principles. Having agreed mandatory health and safety requirements supported by voluntary standards, agreed systems of attestation of conformity with higher systems limited to more risky products, an agree regulatory conformity mark, and so on, are objectively an effective and efficient way to proceed. But this does not mean that Kosovo should move towards full technical equivalence with the EU in one regulatory step, especially when this would have the effect of putting Kosovo manufacturers at a disadvantage.

One example of this is the EU's ROHS (Restriction of Hazardous Substances) Directive for electrical equipment. Its objectives are sound, to protect consumers from the risks of low-level exposure to certain substances perceived as dangerous, although the real risks might be relatively low. Although mandatory for products sold in the EU, the application of this directive requires an infrastructure which does not current exist in Kosovo, and sophisticated test equipment which might also not exist in Kosovo. Kosovo should, therefore, go through the process explained in this chapter before deciding whether to transpose this directive in Kosovo.

Each area of legislation needs to be looked at individually, and the degree to which EU requirements can be adopted decided needs to be decided based on existing Kosovo conditions. A thorough understanding, by those in Kosovo drafting legislation, of what the legislation seeks to achieve, a sound knowledge of Kosovo market and infrastructure conditions, good knowledge of EU legislative principles and a well-founded understanding of the options available to Kosovo in transposing this legislation, are likely to substantially improve the quality of legislation. In the following explanation, it is assumed that the need for legislation is established (although the analysis might lead to this decision being questioned), and that therefore the question is the form that this legislation should take.

The various aspects which need to be considered in this chapter, and the decisions necessary, are summarised in Figure 4 overleaf. Each aspect is then discussed in more detail in the following sections. The figure does not attempt to link one decision to the next, because of the complexity this would lead to, and it is a much simplified view of the decision process. Two aspects of Figure 4 should be explained. The statement "No, or not easily" is response to the question of whether Kosovo manufacturers can satisfy the regulatory requirements relates in particular to what is needed to make application practical, in particular the availability of conformity assessment bodies. While in some areas it may be possible to use a CAB in another country, in other areas this might prove impractical. The conclusion "First steps approximation to the EU" refers to an approach based on EU legislative principles but, as explained above, without necessarily adopting all of these principles or without adopting them at the same level.

4.3 Kosovo market conditions

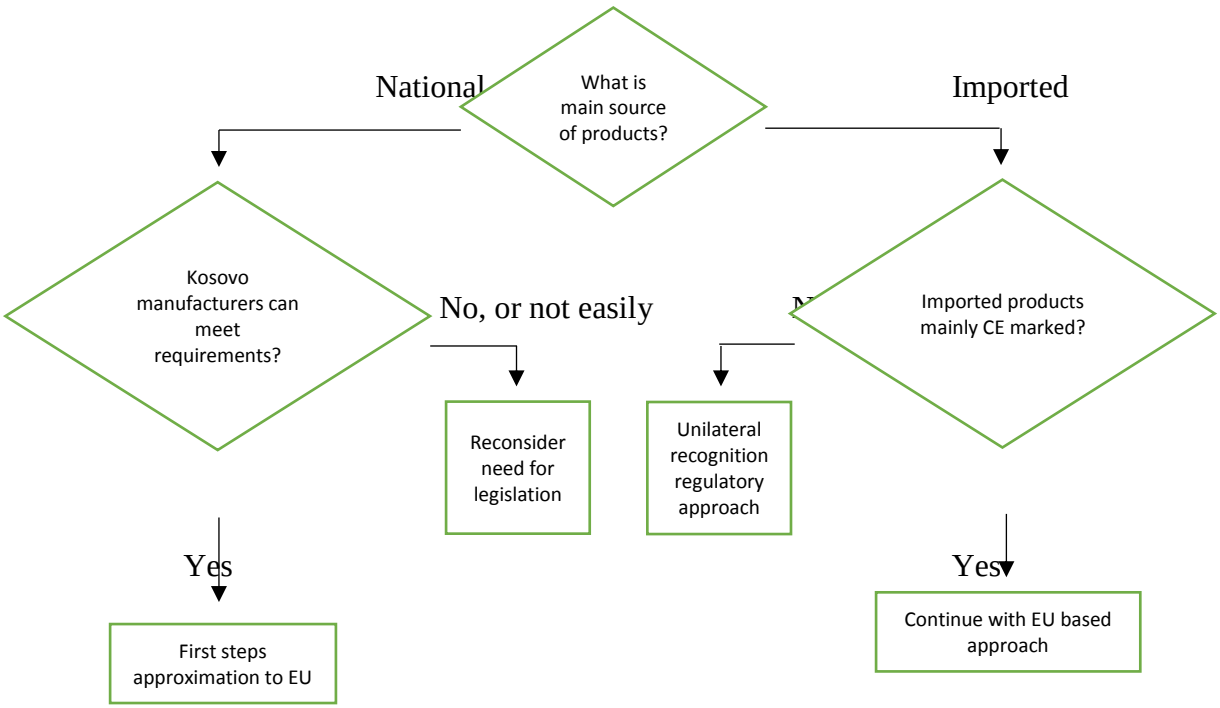
When considering whether to regulate for a particular product area/product group, perhaps the first thing to assess is the current market situation in Kosovo, in particular whether there is any manufacturing/production capability in place, and/or whether such capability might appear in the future. If all products in a particular field are imported into Kosovo, then a somewhat different regulatory approach may be appropriate than if there is local manufacturing/production capability.

Medical devices and cableway installations are examples of where there is no or little national manufacturing, and most if not all products in these areas entering the Kosovo market are likely to be CE marked already in accordance with the relevant EU directives. In these two areas, therefore, almost full transposition of the medical devices and the cableways directives may well be appropriate (although CE marking cannot be made mandatory), but as a means of 'recognising' and controlling imported products rather than as a means of regulating national production or allowing for the export of national products from Kosovo.

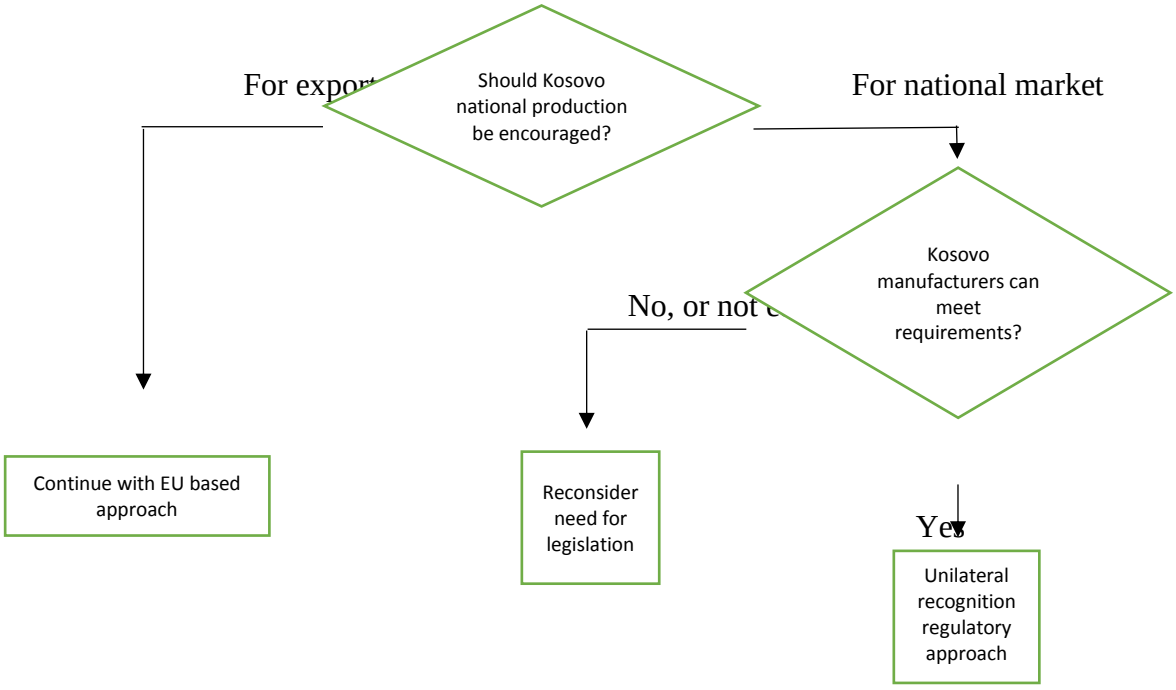
The EU's Cableway Directive has been transposed in Kosovo as Administrative Instruction No. 2008/12. This directive has not been assessed by the FMG project, but a brief review indicates that its approach is largely correct, in that it recognises CE marked products and systems, and it also recognises KK marked products. This means that, if there are any manufacturers in Kosovo at the moment, they are not excluded from the market by the Kosovo legislation. Kosovo Law No. 2003/26 transposes the EU's medical devices directives but, again, no assessment of this has been made by the FMG project.

Areas where there are Kosovo manufacturers include toys, construction products and electrical equipment. For these three product areas the decision to regulate cannot be challenged (they are all regulated within the EU and in many other countries). However, as will be discussed later in this Guidance Document, in the case of construction products, the whole approach to regulation was faulty, while for toys, mistakes during transposition led to problems and, as a result, the regulatory initiative was not effective.

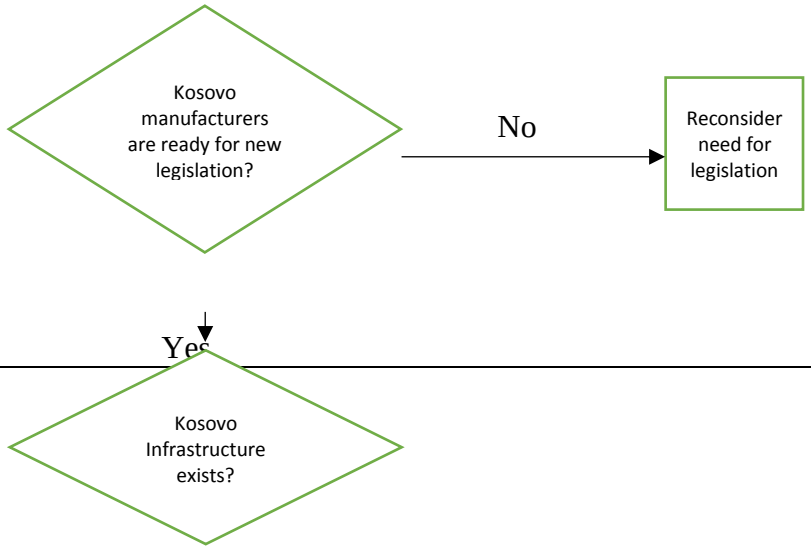
Kosovo market conditions



Kosovo market and regulator intentions



Resource and competence assessment



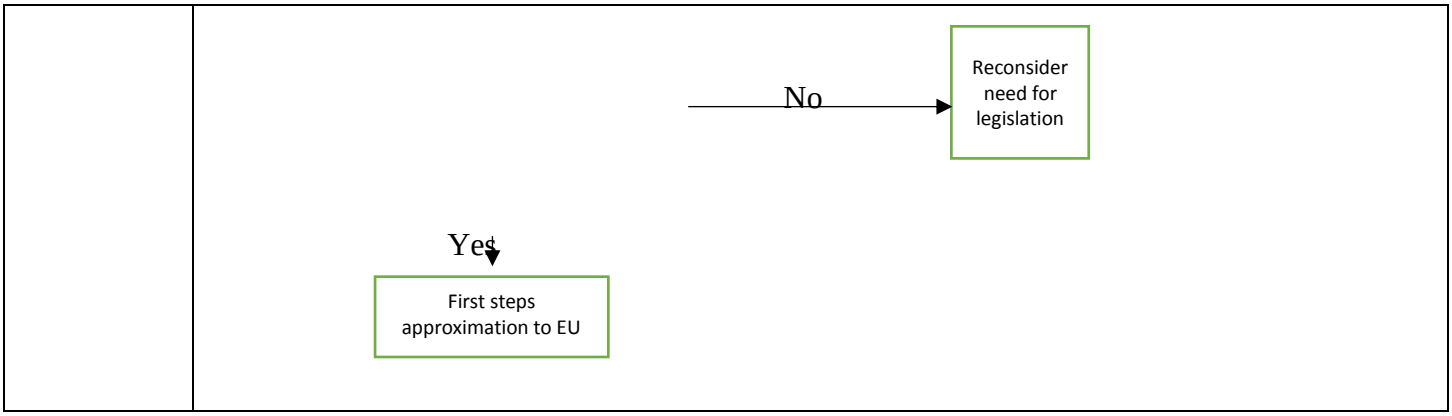


Figure 4 – Decision diagram for regulatory priority assessment

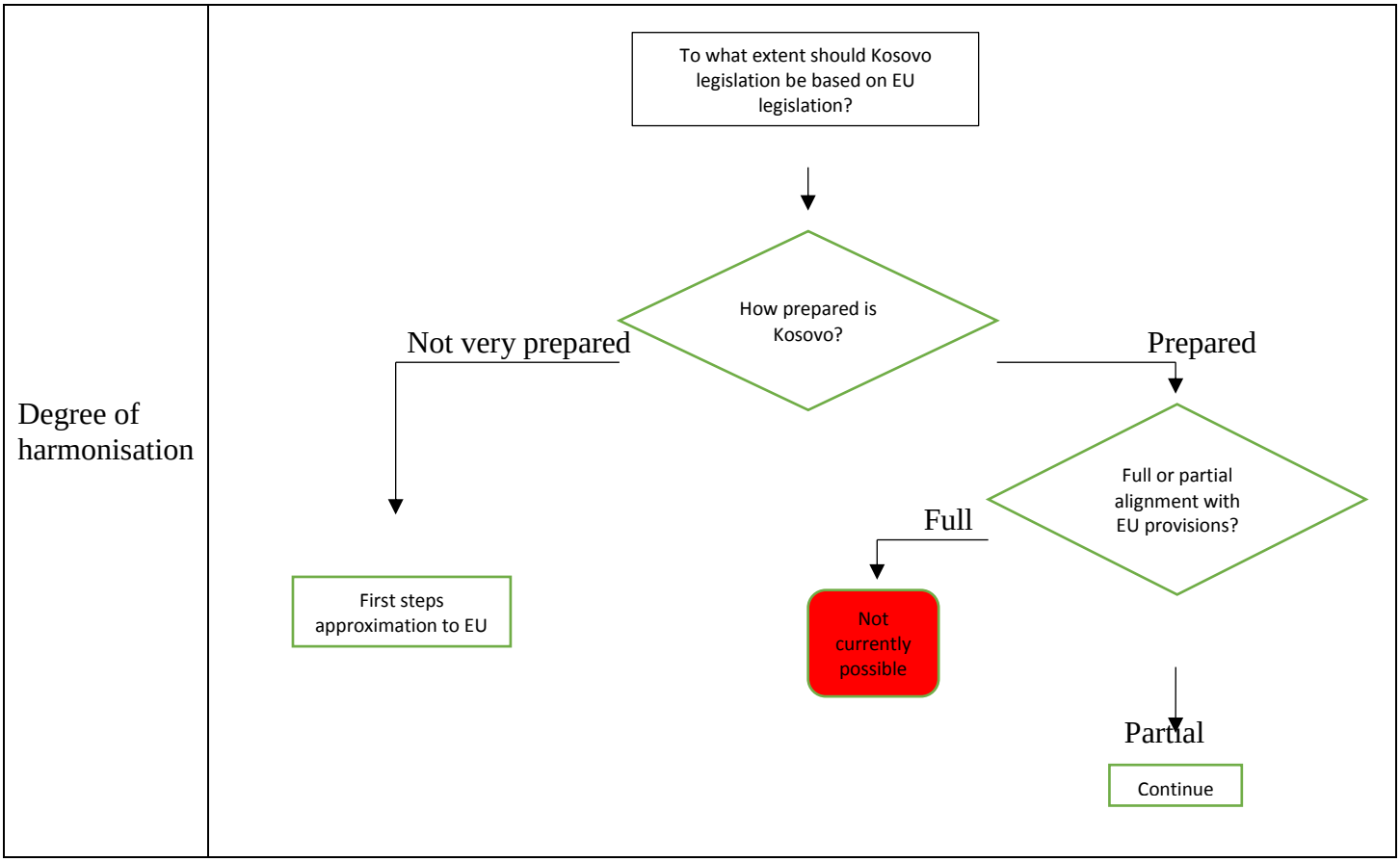


Figure 4 – Decision diagram for regulatory priority assessment (continued)

4.4 Kosovo market and regulator intentions

The next questions which might usefully be asked are related to the possible future development of the Kosovo industry in the areas where legislation is proposed, and therefore where the main emphasis of legislation should lie. Are Kosovo manufacturers able, and wanting, to export their products, especially to the EU, such as in the mining area (this, although covered by Old Approach legislation on classification, labelling and packaging of substances and mixtures, is somewhat on the edge of the FMG area)? Or is their main goal to improve their national position and be better able to compete against imported products (the case, for example, of construction products)? Are there areas where, although the Kosovo industry is small or non-existent, it is hoped that it might develop?

Having identified the market situation and market intentions, it is then a question of whether regulation is the best way to assist Kosovo operators and, if this is the case, whether the regulatory system is one based in mainly or in part on EU principles is appropriate. If the intention is to promote exports to the EU, it might at first be concluded that a regulatory approach based mainly on EU principles and a specific EU directive or regulation would be appropriate. It should be noted, however, that many manufacturers of electrical products from Asia, of personal protective equipment and surgical instruments (medical devices) in Pakistan, and some manufacturers of electrical and construction products in Tunisia (to take just three examples) are able to export successfully to the EU, using the CE marking, without making any attempt to transpose either of the relevant directives; exporters are always able to comply with EU legislation wherever in the world they are based.

If the main intention among Kosovo manufacturers is to develop national markets in Kosovo, possibly with a view to reducing imports, then a regulatory system based less 'tightly' on EU requirements may be preferable. New Approach and New Legislative Approach instruments make the CE conformity marking mandatory; the difficulties inherent in Kosovo manufacturers obtaining CE marking or the equivalent KK marking, when the infrastructure and resources required to do this are neither available in Kosovo nor are easily accessible in EU countries, need to be considered. If import reduction is the intention, then the regulatory system needs to be enforceable and enforced, to protect Kosovo manufacturers from non-conformity imports.

One national alternative to CE marking is the Kosovo KK regulatory conformity marking, which should be seen as the Kosovo 'version' of the CE marking, using in principle the same technical basis but obtained under conditions which exist in Kosovo (the use of authorised conformity assessment bodies instead of notified bodies as often required in the EU, for example). KK marking can, in this way, be seen as a transitional provision towards future CE marking, to be replaced by the CE marking once Kosovo signs an ACAA which allows for the use of the CE marking.

If Kosovo legislation provides for KK marking, care must be taken not to make it the *only* marking recognised. KK marking can currently only be obtained with Kosovo, so making it the only accepted marking would exclude CE marked products and conforming products from non-EU countries from entering the Kosovo market, until these products had been assessed and marked in Kosovo. KK marking should always, therefore, be referred to in parallel with "or other equivalent conformity marking". If KK marking is provided for in Kosovo, however, then the same issues of whether the infrastructure and resources exist in Kosovo to allow it to be obtained need to be addressed.

There is a circular problem which is relevant to considerations of both CE and KK marking, however. The marking of many products, possibly most products, requires the availability of some conformity assessment services. So manufacturers cannot obtain the regulatory marking without access to conformity assessment bodies (CABs) but, conversely, there is little market demand for conformity assessment, and therefore no incentive for CABs to establish themselves in Kosovo, if there is no regulatory system creating the demand.

One area which perhaps contradicts the 'precautionary' approach to regulation, and especially in relation to any mandatory conformity marking, is where the potential risks inherent in any product or range of products is sufficiently high that some third party conformity assessment is considered absolutely necessary to minimise these risks. Examples of this include cement and reinforcing steel for concrete, fire extinguishers and personal protective equipment such as firemen's gloves. In such cases, the Kosovo government might decide that third party conformity assessment is needed when these products enter the Kosovo market, irrespective of whether the resources to do this exist in Kosovo or not. The government would, then, introduce regulations and leave it to the market to decide for itself how to find the CABs required. In this way, the introduction of the regulations may serve to develop conformity assessment services in the country, which differs from the approach above which is to evaluate whether such services exist before deciding to regulate.

4.5 Resource and competence assessment

For any regulation to be effective, it needs to be correctly implemented and enforced. Implementation implies both that manufacturers are in a position to meet the provisions of the regulation (or can be in such a position after some improvements), and that the necessary infrastructure (standards, CAB services, etc.) exist to make this a practical proposition. Enforcement means having adequate resources, in terms of market surveillance and customs control, to ensure that the 'threat' of enforcement action, when taken together with actual enforcement actions, are enough to create a climate where manufacturers and others feel less likely to be subject to enforcement action by complying with the legislation than they do by not complying. Conversely, seeking to enforce a regulation which cannot or cannot easily be complied with is going to be unsuccessful; manufacturers may be forced into trading 'illegally' or, worse, going out of business. To make regulatory decisions, it is necessary to look at the readiness of any Kosovo manufacturers, and also to evaluate the state of the necessary supporting infrastructure and resources.

Manufacturers: As described in the previous chapter, most EC legislation for products requires two things of manufacturers/producers: that they operate some sort of factory production control (FPC) system, and that they have their products tested or otherwise assessed to ensure that they meet regulatory requirements. Any decision related to legislation, and particularly any decision to transpose EU legislation requiring FPC, therefore, needs to consider whether Kosovo manufacturers are already operating FPC or whether they can easily do so, of which a part of this will be an assessment of the availability of any testing resources (of the manufacturer himself or in third party test laboratories).

Supporting infrastructure and resources: The infrastructure and resources needed to implement any legislation will vary depending on the product area being considered and

whether the legislation requires the intervention of recognised third party CABs. The following list indicates what is likely to be necessary:

- *Kosovo standards, transposing European Standards:* strictly speaking, compliance with EU legislation does not, except in the specific case of construction products, need standards, because manufacturers have the right to comply directly with the essential requirements of the relevant legislation. In addition, national transposition of European Standards is not necessary for manufacturers complying directly with EU legislation; the standards needed can be obtained from any National Standards Body in the EU. Nonetheless, using standards to demonstrate regulatory compliance is by far the easiest and most normal means, and Kosovo legislation can refer only to Kosovo versions of European Standards (reference cannot be made directly to "European Standards"). So any efficient implementation of transposed EU legislation will rely on the availability of the necessary European Standards. Note that this extends not only to harmonised European Standards for products but also to all supporting standards (such as test methods) which are called up by these harmonised standards.

The 'recognition' of transposed European Standards as supporting transposed EU legislation in Kosovo is a formal procedure requiring action (publication of a list of harmonised standards in Kosovo) by the government (usually the relevant ministry). An example of how such publication might appear is given in Annex 2.

- *Testing capacity:* most if not all products will require some testing in order to demonstrate that they satisfy the regulatory requirements imposed on them (strictly speaking, other methods of assessment than testing may be possible). Testing capability may exist in manufacturer's own laboratories or it may exist in independent third parties. Where the legislation requires State-recognised test laboratories (see below), the testing capability needs to be available in third parties. Not all testing capability needs to be available in Kosovo, however; specialised tested, such as dangerous substances content where the test is required only once, could be done in a foreign laboratory. It may be useful to consider "initial type-test" resources separately from "FPC testing"; the first are required only once, whereas the second are usually required on an on-going basis, and if manufacturers are having to routinely send products abroad for FPC testing this might be unsustainable.

- *Notified/authorised bodies:* Some EU legislation requires the intervention of CABs recognised as competent by the State, so-called notified bodies in the EU. State recognition should not be confused with accreditation (the recognition of 'technical' competence). Accreditation may be used to demonstrate competence to the responsible authority (usually at Ministry level) for notification, but State recognition is something separate from accreditation. Notified bodies have to be based in an EU Member State (but may operate in other countries) and, consequently, they cannot currently be based in Kosovo. The equivalent term for State-recognised CABs based in Kosovo is "authorised bodies".

  Authorised bodies cannot perform conformity assessment tasks leading to CE marking (but note that suitably-qualified third party laboratories may perform testing of products where CE marking is based solely on "manufacturer's declaration of conformity" with no notified body intervention necessary). If the Kosovo legislation

sets up KK marking as a parallel to CE marking, and CE marking requires notified body intervention, then the Kosovo system must provide for the equivalent authorised bodies (note, too, that a notified body would not be authorised to perform assessment activities in support of KK marking). The types of authorised bodies required are test laboratories, FPC inspection/certification bodies and product type-approval/certification bodies.

Establishing an effective authorised body system in Kosovo requires:

- a mechanism within government for initial authorisation, then monitoring and dealing with extensions/reductions of scope of competence of authorised bodies,
- a mechanism for making the details of authorised bodies known (possibly publication on the Ministry website),
- a functioning accreditation system able to assess the technical competence of all types of authorised bodies,
- a system for assessing the technical competence of candidate authorised bodies where this is not done using accreditation.

- *Market surveillance and customs control:* Enforcement of any Kosovo regulatory provision is a market surveillance responsibility, although customs authorities also play a role in preventing non-conforming products from entering the Kosovo market from other countries. While, strictly speaking, a law may be enacted without such control, this is likely (in Kosovo) to lead to low initial levels of compliance, the continuation of sales of non-conforming products on the Kosovo market, and a general discrediting of the law. The competent authorities need, therefore, to ensure that any decision to regulate is backed up by adequate resourcing and training of market surveillance and customs staff, so that they are able to make adequate controls of unsafe and non-complying products.

4.6 The 'degree' of harmonisation

If the decision to regulate is positive, the final question is the degree to which the regulation is made the same or similar to that of the EU (the form of such regulation, in the Kosovo legal system, is discussed in Chapter 5). This may vary from "little harmonisation" through "partial harmonisation" to "complete harmonisation".

Little harmonisation would be the development of a regulatory system based broadly on EU principles (see above) and one which reflects any international agreements of which Kosovo is a signatory. Kosovo has not signed the WTO's TBT (Technical Barriers to Trade) Agreement, so is not bound by WTO rules. Nonetheless since such rules are mentioned in the SAA between Kosovo and the EU, any legislation should respect WTO principles. Much of the guidance given in Chapter 5 in relation to good regulatory drafting applies to legislation at all levels of harmonisation.

Full harmonisation, while Kosovo has no formal agreement with the EU which provides for this, is not generally possible, at least not where the EU legislation in question contains certain "EU" provisions: CE marking, notified bodies and communication between EU Member States and the European Commission, for example. CE marking may be considered as a sort of "registered trade mark" of the European Union, the ownership of which is limited

to EU Member States. As stated earlier, this does not prevent manufacturers in non-EU countries from applying the CE marking to their products, as long as they follow the defined procedures to do this. It does not, either, prevent non-EU countries from recognising CE marking as having the same meaning (presumption of compliance with EU regulatory requirements) as it does in the EU and, if the regulatory requirements in that country are technically the same as those in the EU, the CE marking may also signify compliance with the national regulatory requirements. But a non-EU country, without an agreement with the EU, cannot 'adopt' the "CE" marking as its own national regulatory conformity marking.

There are some EU legal acts which do not include aspects considered as 'purely EU'. Two examples are the use of the 'Do not discard with normal rubbish' symbol (Figure 5) from the Waste Electrical and Electronic Equipment Directive, 2012/19/EU, or the satisfaction of the ROHS Directive, 2011/65/EU. These two directives specify purely 'technical' requirements, so a Kosovo legal act imposing the same requirements could be considered as "full harmonisation" (the WEEE Directive contains some other requirements beyond the simple use of the symbol, however).

Figure 5 – The 'Do not discard with normal rubbish' symbol of the WEEE Directive

Some of the principles of Regulation (EC) 764/2008, *Application of certain national technical rules to products lawfully marketed in another EU country*, could also be transposed in Kosovo in a way which would constitute full harmonisation.

The more reasonable aim of Kosovo transposition is "technical equivalence" with the corresponding EU legislation. This means that the same 'technical' requirements are imposed on products as are imposed in the EU (usually referred to as "essential requirements" or equivalent term), the same marking and labelling requirements are imposed, the same obligations on economic operators in the supply chain are applied, and the same system(s) of attestation of conformity have to be followed. However, all EU provisions are replaced by equivalent Kosovo ones: CE marking is replaced by KK marking, notified bodies are replaced by authorised bodies, European Standards are replaced by Kosovo Standards, etc. Some obligations placed on the European Commission (such as issuing unique identification numbers to each notified body and reviewing the EU legislative act) are transferred to the competent ministry in Kosovo. The main advantage of a 'technical equivalence' approach is that it allows for relatively easy transfer from the KK to the CE marking, when an agreement between Kosovo and the EU makes this necessary.

The transposed legislation needs to recognise CE marked products entering Kosovo (assigning them a presumption of conformity) in the same way that they are recognised in EU Member States, but any mention of CE marking which talks about how the CE marking is obtained must refer to EU provisions, not Kosovo ones. There is, however, no equivalent recognition by EU Member States of KK marking.

Finally, EU legislation includes the date by which the legislative provisions come into force. Kosovo needs, therefore, to identify in its legal provisions when they come into force, and this may be another means by which the legislation can be made easier to comply with by Kosovo manufacturers. Although it is not used at present in Kosovo, it would be possible, for

example, to make compliance with the essential requirements of a law at an earlier time than making KK marking mandatory.

As already mentioned above, however, the obligations involved in obtaining the KK marking may be difficult or impractical to satisfy by Kosovo manufacturers. Where the status assessment laid out in this chapter indicates that this is likely to be the case, legislators may consider including a third option to demonstrate regulatory compliance; a national system having validity only in Kosovo. This approach has, at the time of writing this Guidance Document, only been suggested in respect of construction products where it was recognised that the requirements of CE marking, and the requirements of KK marking, could not realistically be satisfied by most Kosovo manufacturers. A similar approach could be considered in other product areas, however, particularly where there are or are likely to be manufacturers of such products in Kosovo.

According to the 'combined' approach, the Kosovo legal provision may contain three parallel routes for conformity: CE marking, according to EU provisions, for products exported to or imported from the EU (or other countries where CE marking is often applied); KK marking as the 'technically equivalent' approach to CE marking but based on the Kosovo system; and then the national system. While CE marking is mandatory for products sold in the EU, to avoid the regulatory problems discussed in this chapter, there is no need, at first, to make KK marking equally mandatory.

The national system would be based on the fundamental principle that all products must be "safe", and the same essential requirements could be imposed as for CE or KK marking. However, it can be made technically and administratively simpler than the CE or KK marking systems by, for example, reducing or removing the specific requirements on FPC or permitting less 'formal' means to demonstrate satisfaction of safety requirements. Following the national system would not lead to the use of a regulatory conformity marking. A national regulatory system (particularly where no system existed previously), if properly implemented and enforced, achieves the primary aim of consumer protection, although it does not achieve the second goal of free movement of goods. It should be considered, however, when any more 'formal' system would cause problems and lead to the very low levels of compliance seen with some transposed EU provisions in Kosovo.

With a parallel regulatory system in place, no criticism can be made against Kosovo from the EU, as long as CE marked products are properly recognised. It gives Kosovo a greater margin of manoeuvre, however, in moving towards the EU system, avoiding the immediate problems which may be caused by trying to impose, in one step, the EU system on Kosovo manufacturers. Finally, it does not prevent Kosovo from fully or partially withdrawing the national system where this is desirable (products posing an elevated risk) or possible (infrastructure and resources in place to permit KK marking), in advance of having to do this as a result of an agreement with the EU.

4.7 Preparation of the Concept Document

Before a legislative proposal is approved and gets onto the annual legislative programme, there is a need to prepare a Concept Document to explain and justify the need for the proposal. The Kosovo Concept Document is a sort of Regulatory Impact Assessment, which

is discussed in more detail later. The contents of the Concept Document should include the following:

Chapter 1: Introduction
Chapter 2: Background
Chapter 3: Goals and objectives
Chapter 4: Options
Chapter 5: Summary of options (tabular)
Chapter 6: Analysis of the options
Chapter 7: Comparison of options (SWOT and SMART analysis), including financial consequences of the suggested option
Chapter 8: Consultation
Chapter 9: Recommendations
Chapter 10: Communications

It is beyond the scope of this Guidance Document to describe exactly how the Concept Document should be written (and examples of such documents are available). A few pointers may prove helpful, however. In Background and Goals and Objectives, the need for the legislation has to be explained, together with why any existing legal provisions in Kosovo do not meet these. Among the options, one should be *Status quo*, i.e. the 'Do nothing' option.

SWOT analysis looks at the Strengths, Weaknesses, Opportunities and Threats of the options, and is presented in tabular form. This is the opportunity to summarise the options. When preparing these tables, each of the four sections should present different aspects, e.g. the Weakness section should not simply be the opposite of the Strengths section. SMART analysis checks that the option is Specific, Measurable, Accepted, Realistic and Timely.

The financial considerations included in the Concept Document should go further than just a consideration of the costs to the Kosovo government. This, while important, is too limited. Any financial consideration should also cover the expected benefits (in monetary terms, if possible) to Kosovo as a whole. That way the cost to the government can be directly compared with the benefits.

4.8 Annual legislative programme

The annual legislative programmes, for primary and secondary legislation, are covered by Kosovo Regulation 13/2013 *Government Legal Service* and Regulation 09/2011 *Rules and procedures of the Government of the Republic of Kosovo*. These documents also cover the preparation, drafting, consultation, adoption and possibly repeal stages of legislation. It is beyond the scope of this Guidance Document to present these procedures in detail; it is enough for legislative drafters to be aware that they need to be followed.

CHAPTER 5) MANAGEMENT, PRINCIPLE AND STRUCTURE OF KOSOVO LEGISLATION

5.1 Introduction

The purpose of this chapter is to look at Kosovo legislation as a whole (not only that based on EU provisions) and to discuss the basic principles which this legislation should follow, in terms of how the legislation is drafted and what its effects should be. When transposing EU provisions, it may be assumed that these principles have already been respected by those drafting the provisions in the EU, but it does not automatically follow that the considerations which led to decisions in the EU are the same as those in Kosovo (at least at the current time) and, therefore, consideration of these principles should be a factor in any decision to regulate in Kosovo.

The chapter then looks at how Kosovo legislation might best be structured, in particular with respect to the division between primary and secondary legislation, and the 'position' of new legislation within the existing Kosovo legal system. Finally, it looks at the 'management' of Kosovo legislation, in particular with respect to possible changes in the corresponding EU legal provisions.

5.2 Basic principles of regulation

There are slight differences of approach when it comes to the principles of regulation depending on which document is read. The fundamentals remain much the same, however, in that all government action, whether regulation or not, must have the following attributes:

- necessity (is new regulation needed, see Chapter 1),
- specificity, meaning that the regulation is targetted on the goal to be achieved, and unintended side effects are minimised,
- proportionality (do the advantages of regulation outweigh the disadvantages?),
- accountability (is the action justified and has sufficient consultation taken place?),
- consistency (is the same approach taken in different areas?),
- transparency, ensuring that all interested parties participate in and are consulted on legislative proposals,
- accessibility, meaning that regulations are easily available to everyone affected by them,
- simplicity, ensuring that regulations are easily understandable.

One further principle is applied to EU regulation:

- subsidiarity. This principle does not, perhaps, apply much to Kosovo. In the EU it means that actions should be taken as close to the citizens as possible, so that things would in preference be done at national level rather than EU level. If applied in Kosovo, it might mean local rather than national actions.

Each of these principles is explained in further detail in the following:

Necessity: This has already be discussed in Chapter 1 so is not repeated here, except when it appears under one of the following objectives.

Specificity: Regulations should focus on the specific issue, and should not be broader than is needed to address the issue. Those enforcing the regulation should focus primarily on those organisations whose activities give rise to the most serious risks, and regulations should be regularly reviewed to determine whether they are still necessary and relevant (most transposed EU legislation in the FMG area is very likely to need to remain fully in force). Three examples (but they are only examples) illustrate this principle. If Kosovo has a particular problem with low quality cement and reinforcing steel for concrete, is a regulation covering *all* construction products needed? If these low quality products are mainly imported, should market surveillance authorities pay more attention to importers than to national producers? If Kosovo is worried about the quality of motor fuel imports, is it appropriate to adopt a short-term national regulation imposing testing on all imported fuel to prevent the problem, after which (when such imports have stopped), a 'lighter' regulatory approach is used?

Proportionality: Regulators should only intervene when necessary, and the way in which they intervene should be appropriate to the risk posed, with the associated costs being identified and then minimised. All options for achieving the policy objectives should be considered, not just prescriptive regulation, recognising that alternatives may be more effective and cheaper to apply. Finally, regulation may have a much greater relative effect on small and medium sized enterprises (probably the large majority of Kosovo producers) than it does on large local manufacturers or imported products.

Accountability: Regulators must be able to justify their decisions, and to allow themselves to be subject to government and public scrutiny. This means that proposals to take action should be published and all those affected should be consulted before these decisions are taken. Regulators should also clearly explain how and why their final decisions have been reached. Any government action will have a far greater effect if those covered by it are involved in developing the action and understand it than if a measure is simply 'imposed' on them by the government. One aspect of accountability is that it needs to be clear which authorities are responsible for any regulation, so that interested parties are able to contact them.

Consistency: All government rules should work together, have similar levels of enforcement and penalties, and should be implemented fairly. Regulations should be generally 'predictable' and not subject to frequent changes or different 'interpretations', so that there is stability and certainty amongst those being regulated. While allocation of enforcement resources will depend on specific situations and may change over time, care should be taken to avoid putting all resources into controlling one area, leaving other areas uncontrolled.

Transparency: Regulators need to be open to comments from all stakeholders, and should keep regulations as simple as practicable and also user-friendly. Effective consultation needs to take place before proposals are developed (see the following chapter), to ensure that stakeholders' views and expertise are taken into account, and so that these stakeholders feel 'involved' in the process.

Accessibility: All of those potentially affected by regulations should be easily able to identify and obtain all the relevant regulatory documents they need to fully understand the system and how to apply it. This is, in part, covered by the following section on the 'structure' of Kosovo

legislation and how provisions are split between different documents. Regulatory documents should be obtainable without charge, typically from the webpages of the relevant ministry. When the regulatory provisions are split into a number of different documents (laws and administrative instructions), the ministry concerned should consider grouping these documents together on a single, specific webpage, preventing users having to search several different webpages and lists of documents.

Simplicity: This is largely self-explanatory, although it is worth underlining that there are two aspects of simplicity: simplicity of the system itself, and simplicity of the language used to describe that system. Simplicity is also often linked to some of the previous objectives and also to the efficiency of any measure. A mistake often made is to believe that the greater the intervention of the State (up to and including mandatory certification of products), the greater the 'safety' of the products. This might be true if any such system is fully enforced (it almost never is, because of a lack of resources), but such a system may well be entirely disproportiate to the actual risks involved. A fundamental principle backing up the simplicity of the EU system is to give as much responsibility for product safety to those most directly involved in ensuring it (manufacturers, importers and distributors), and leaving third party or State intervention to the minimum required.

The example of the attempt to transpose the EU's Construction Products Regulation into Kosovo law perhaps best illustrates the problems that can arise. This particular transposition appears not to have respected most if not all of the above principles, with the effect that it was not being enforced at all and had to be withdrawn and replaced with something much more appropriate.

In summary, this section has presented briefly the overall objectives which should be followed when proposing any new regulations in Kosovo. Considering these objectives in Kosovo may not lead to the same conclusions as in the EU. It should always be borne in mind that the EU regulatory system for FMG works best in advanced economies, in which most manufacturers would produce conforming products even if there were no regulatory system, and where the infrastructure and resources allow the system to be implemented. This latter is not usually an issue in the EU, where the main question is cost and effectiveness of implementation, not whether the regulation can be implemented at all, but might be relevant for Kosovo. In the EU, many regulations seek to improve and harmonise existing regulatory systems, whereas in Kosovo new regulations may be created a regulatory system from nothing, where no system existed before.

5.3 Transposition of EU provisions in Kosovo – the Kosovo legislative structure

There are sometimes conflicting interests in how legislation should be structured, between primary and secondary acts, among those drafting them and those using them. Users of legislation (those covered by it and affected by it) usually prefer one or a limited number of documents so that they can find everything they need to know easily; they do not want to be searching a large number of documents to find what they need to know. Drafters, on the other hand, often want 'flexibility', which means that those things which are 'fixed' and form the legislative basis are correctly given in primary law, while those things which may change from time to time are given in secondary legislation so that, if and when they do change, there is no need to go through the whole lengthy process of amending primary law. The skill, of course, is to get this balance correct.

Kosovo has three types of legislative acts: laws and regulations (both considered as primary law) and Administrative Instructions (A.I., secondary legislation). Although these three documents all have the same basic force of law, their main difference is the process by which they are approved and adopted. With a lower level of approval, and signature by the relevant minister, it is a lot easier to adopt or amend an A.I. than it is to approve or amend a law or a regulation, which requires presentation to the Kosovo Assembly.

There are no absolute 'rules' governing the structure of Kosovo legislation, and one case may lead to a different structure than another case. Kosovo A.I. No. 03/2013 sets out the following basic structure for laws and regulations:

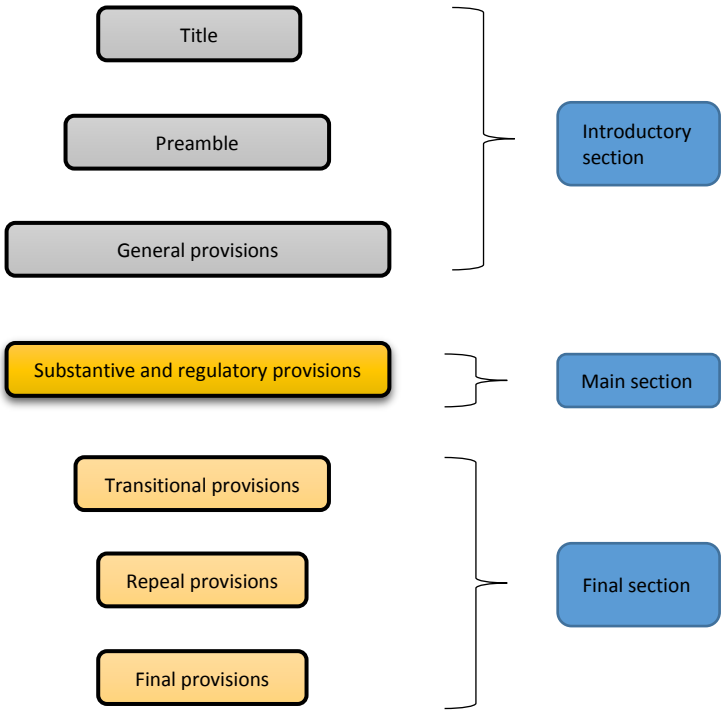


Figure 3 – Overall structure and content of Kosovo laws and regulations

If these are considered in relation to the content of an EU provision or provisions being transposed, then the following guidance on the division between law/regulation and A.I. may be offered:

1) EU directives, regulations and decisions are the equivalent of Kosovo primary law and, therefore, they should be covered in primary rather than secondary law.

2) Those aspects of EU directives or regulations which are unlikely to change (unless as a result of a fundamental review and revision of the EU text) belong in primary law. These include: the Preamble (the reasons for the law), the General Provisions (scope and definitions), the Substantive and Regulatory Provisions (provisions for CE marking, essential requirements, presumption of conformity, attestation of conformity systems, notified bodies, obligations on actors (manufacturer, importer and distributor), market surveillance, any

derogation from the provisions of the directive or regulation, etc.), and transitional, repeal and final provisions.

3) Essential requirements, attestation of conformity systems, content of the Declaration of Conformity, etc. usually appear as annexes to EU acts. Annexes are not favoured in Kosovo primary laws, but these aspects are so much a part of the basis of EU act that they most likely belong in the primary law instead of being separated into secondary laws. To avoid the issue of annexes, annexes in EU acts can appear as normal content of Kosovo law.

4. Market surveillance, in primary law, should be limited in the detail given in the Kosovo law to the same level as in the EU act (this is usually limited in EU acts to the fact that a market surveillance system has to be set up, and that actions have to be taken against non-conformity products). Operational details (actions of market surveillance officers, rights of access to premises and documentation, appeals and levels of fine, etc.) should not be included in primary law.

5. Many of the provisions on which individual EU regulations and directives are based have been 'formalised' in the two NLF provisions, Regulation 765/2008 and Decision 768/2008, both of which have been transposed into Kosovo law by the Law No. 04/L-039 *Technical Requirements for Products and Conformity Assessment*. This provides two basic possibilities: the provisions are repeated in Kosovo texts, or reference is made to Law No. 04/L-039 (or its amendment/replacement). EU acts usually repeat these general provisions (they do not refer to 765/2008 or Decision 768/2008) and Kosovo should follow the same approach.

6. There may be more than one transitional period in the Kosovo legislation (whether this comes from the EU act or not): the date at which the legislation as a whole comes into force, and other dates at which the legislation becomes operational (this may be because of the need for Kosovo to draft secondary legislation, or where an active decision is taken to delay the legislation being made operational); these dates need to be carefully considered in accordance with the guidance given in Chapters 1 and 4 of this document.

7. Care should be taken in setting deadlines (by date) which, if not respected, cause problems of implementation. "MTI shall publish an Administrative Instruction related to … by the 28/06/2017" is an example, because if that A.I. is needed for the Kosovo act to come into operation and, for whatever reason, it is not published, problems may arise with the application of the primary law. Text along the lines of "This law comes into force when the A.I. related to … has been published" avoids this problem, with the date by which the A.I. should be published being decided in the annual legislative programme, not primary law.

8. The chance of there being 'accidental' mistakes in primary law should not be a factor in deciding whether to move some provisions into secondary law.

Two other considerations are relevant for the content of primary law: existing amendments or implementing acts published in the EU, and 'timing'. Timing is considered in the following section, but where an EU act has, at the time it is being transposed in Kosovo, been amended or expanded by an implementing act, the amended or 'expanded' text should be in the Kosovo transposition, and this fact should be made know at the beginning of the Kosovo

document. This does not apply, however, in the case of framework directives which rely on a series of implementing acts for their application (the Eco-design Directive, 2009/125/EC, being a good example), or where an EU act provides for a series of delegated decisions (AVCP and required characteristics decisions under the Construction Products Regulation, for example). In both of these cases, a decision should be taken in Kosovo about how these implementing instruments are best published (recognising that more such instruments may appear in the future),and then existing instruments should be published in the same format (most likely A.I.s) as future ones will be.

Once a decision has been made on the content of the primary law, anything in the EU act not included but necessary needs to appear in secondary law. Secondary laws are also needed to complete the operational details of the Kosovo legislation which are not included in the transposed act, such as the details of market surveillance and the details of the authorisation procedure for conformity assessment bodies.

5.4 Management of Kosovo legislation

This section looks at 'timing' issues, i.e. when Kosovo legislation needs adopting/amending and when EU provisions are likely to be amended. Kosovo drafters need to be aware of proposals within the EU so as to avoid adopting or amending legislation unnecessarily. The EU legislative system is by no means static: new legislative acts are introduced from time to time, existing acts are revised or replaced, and sometimes acts are consolidated or replaced by other acts (it is fairly unusual for an EU act to withdrawn altogether without any replacement). This fact has consequences for Kosovo in terms of setting its legislative programme.

There is little point in Kosovo planning to introduce or update legislation in line with an EU provision if this provision is soon itself to be replaced or revised. This is even true where errors have been detected in Kosovo legislation. If the EU text on which the Kosovo legislation is based is about to be replaced (market surveillance legislation is perhaps a good example), there may be advantages in not correcting the identified mistakes but, instead, waiting until the new EU text is available. On the other hand, there is no point in Kosovo rushing to transpose new EU text; most of the same considerations presented in earlier chapters, in relation to whether Kosovo should regulate, how it should regulate and whether regulation should be based on EU provisions, apply in such cases as well.

It is not always easy to identify when an EU act is likely to change or has changed, but the European Commission's own website, http://ec.europa.eu/index_en.htm, is the best place to start. Clicking on "Departments (Directorates-General) and services" leads to the list of departments, and "Internal Market, Industry, Entrepreneurship and SMEs (DG GROW)" is likely to be the most relevant (although not the only) department relevant for the free movement of goods. The "Single Market and Standards", "Industry" and "Entrepreneurship and SMEs" and "Sectors" tabs are where the Commission usually publishes its proposals for new or modified legislation.

Sometimes a new EU provision will have a wide, horizontal effect, impacting a wide range of existing provisions (Regulation 765/2008 is one example of this, having the effect of changing and extending the details of market surveillance). If such an EU document is going to be transposed in Kosovo, care needs to be taken that the new Kosovo provision has the same wide effect as it has in the EU (otherwise Kosovo provisions are no longer aligned) but,

equally, it should not have effects in areas where it was not intended or where it would be inappropriate. This can only be done by the correct cross-reference between different legal acts.

Care should be taken about the use of 'global' references, such as "Except where covered by more specific requirements, …", because this can raise doubts about whether a general act is "specific" or "general". Where a new act replaces provisions in other acts, it may be best to list all of the acts specifically changed by the new one, because this is then clear.

CHAPTER 6) PREPARATION FOR DRAFTING AND TRANSPOSITION OF THE EU *ACQUIS*

6.1 Introduction

Previous chapters have discussed the need for legislation, the purpose and principles of legislation and the possible structure of Kosovo legislation in any particular area. This chapter assumes that the decision has been taken to legislate and that the Kosovo texts will be based on EU provisions. It therefore presents the procedures which need to be followed to arrive at approved Kosovo legislation (but does not cover in detail the approval procedure itself, which is well defined in other documents), how a Regulatory Impact Assessment is performed (in outline terms) and then, once the legislation is approved, adopted and enforced, how it is monitored and kept up to date.

This chapter, therefore, contains mainly relevant abstracts of the provisions of Kosovo Regulation No. 09/2011 *Rules and Procedure of the Government of the Republic of Kosovo*, Regulation No. 13/2013 *Government Legal Service* and Administrative Instruction No. 03/2013 *Standards for the Drafting of Normative Acts*.

6.2 Responsible ministry and responsible staff

According to the annual legislative work programme, there will be one line ministry which has responsibility for any legislative proposal. This ministry should also, in general, be the ministry responsible for the implementation of that legislation and, if practicable, the ministry responsible for enforcement (this latter is not always possible in Kosovo, because market surveillance is under the responsibility of MTI, while customs comes under the responsibility of the Ministry of Finance). According to Regulation 13/2013, Article 9:

"1. The General Secretary of the respective ministry … assigns the officer in charge of the relevant agency, unit or department … to draft the initial draft law.

3. The responsible official … leads the drafting process in the ministry in cooperation with the legal department of the ministry, and the Legal Office, and ensures that all procedures and principles are approved [as] set forth in the Rules of Procedure of the Government, legislative drafting standards defined by Government and other relevant legislation. In any case, the legal department of the relevant ministry, during the process of drafting a draft normative act, serves as an official advisory authority …".

It is important that there is permanent staff (or a permanent position) in the relevant ministry which assumes responsibility for the legislative drafting and, afterwards, for its implementation, in order to satisfy the need for accountability discussed in the previous chapter. In addition, without permanent staff, it is likely that a lot of the knowledge and understanding of the legislation will be lost. It is also important that the legal department of this ministry is well aware of the drafting work, so that any advice it offers during the drafting phase is consistent and appropriate.

The text of Regulation No. 13/2013 continues:

"4. The responsible official coordinates the process of drafting the draft law with all units within the ministry, that are obliged to offer assistance as required, and as appropriate coordinates the work with the Legal Office and other ministries and the Ministry of European Integration and the EU Legal Department."

6.3 Regulatory Impact Assessment (Kosovo Concept Document)

The role of a Regulatory Impact Assessment (RIA) is to provide a detailed and systematic appraisal of the potential impacts of a new regulation in order to assess whether it is likely to achieve the desired objectives. The need for RIA arises from the fact that regulation commonly has numerous impacts and that these are often difficult to foresee without detailed study and consultation with affected parties. There is also a reasonably high risk that regulatory costs may exceed benefits. From this perspective, the central purpose of RIA is to ensure that regulation will be welfare-enhancing from the societal viewpoint, i.e. that benefits will exceed costs. There are a number of different ways in which RIA can be conducted (cost/benefit, cost/efficacy or risk analysis). It is beyond the scope of this Guidance Document to present the details of RIA, but the outlines are given here. The content of the Kosovo Concept Document is actually very much the same as a typical RIA, although the current model Concept Document does not, perhaps, go far enough into the economic analysis presented here.

An initial RIA should be prepared when a first proposal for regulation is being considered. This allows a decision to be made on continuing to the development of the proposal (the decision could also be not to proceed). A second, partial, RIA should be prepared before stakeholder consultation takes place, and it is highly recommended that the RIA is made available with the proposed legislation, to give stakeholders the chance to comment not only on the regulatory text but also on the RIA used to justify it. Finally, a complete RIA should be made at the end of the regulatory drafting process but before the text passes into the approval stages. Three analytical tools which can be used in RIA are the following.

Cost-benefit analysis (CBA): With this method, an attempt is made to quantify, in monetary terms, the likely benefits from the regulation compared to its costs. This analysis demands significant technical skills and analytical capacity, and also that the necessary data are available or can be reasonably predicted, all of which may be problematic in Kosovo at the current time. CBA tends to be limited to 'immediate' costs and benefits; for example, if 10 % of Kosovo's balance of payment deficit of €100M is assumed to be saved, this is a 'benefit' of €10M per year. In reality, however, if one new member of staff is employed in the ministry to achieve this, that is a 'cost' of, say, €20 000 per year. But the €10M per year saving is something that did not exist in Kosovo before, and if invested, could bring other, non-quantifiable, benefits, while the ministry employee is likely to use, say, 80 % of their income paying taxes and buying goods in the Kosovo market, also contributing to Kosovo's economy.

Two further problems exist with CBA: some things are difficult to quantify in monetary terms (what, for example, is the value of 5 lives saved as a result of building a better road?), and in any case it can only ultimately be used as a tool towards a decision. If no budget exists to employ anyone new in a ministry, the project will not be able to go ahead, irrespective of how beneficial it might be. If CBA is going to be used in Kosovo, therefore, it is suggested

that it looks only at 'broad' costs and benefits, because a more detailed assessment is probably not currently possible.

Cost/efficacy analysis: This technique is used to compare the costs of different options against the intended results, but where the results are not expressed in monetary terms (examples may be lives saved or pollution reduced). It is normally used to compare different options to achieve the same result, with the lowest cost option being chosen. It suffers from similar limitations as CBA, though, in that the data might not exist in Kosovo to make an accurate assessment or a sensible prediction (for example, will regulation lead to more companies setting up in Kosovo and employment therefore rising, or will importation increase, thereby making the situation worse in Kosovo?). In addition, it tends to exclude options other than the lowest cost one and, where government investment resources are limited, it does not allow a comparison to be made between investing in one particular regulatory action as opposed to investing the money in some other government initiative.

Risk analysis: This technique aims to assess the risks which the regulation tries to address, together with the consequences of something going wrong, and then chooses the option which best works to eliminate or minimise these risks. It is, therefore, particularly useful when the issues are health, safety or environmental protection, i.e. exactly the same issues as are involved in the FMG area. It may be the best option for Kosovo in developing its Concept Documents.

Even risk analysis does not guarantee that the regulation will achieve the anticipated risk reduction, especially if the initiative is not adequately supported and financed by the government. Regulations which are not enforced, even if they are the correct legal tools, will probably achieve very little.

In summary, the use of Concept Documents in Kosovo, as Regulatory Impact Assessments, is a good initiative. Limiting the financial considerations only to the cost of government staff and resources may be sensible when the data are unavailable to reasonably assess the benefits, whether financial or other. The lack of information on benefits, however, means that the main basis on which government decisions should be made is missing.

6.4 Appointment and work of the Project Team

At the beginning of the drafting process, it is normal to create a Project Team, as Regulation No. 13/2013 states:

"5. In the preliminary drafting process according to the need and proposal of the respective official, the team on drafting the law is appointed. The appointment of the team responsible for reviewing the draft law shall be made by the Secretary General. Team members may be appointed by official agencies and other units within the Ministry and relevant institutions.

6. The responsible officer … is assigned as team leader, which includes at least an Official from the legal department, and [an] official from the relevant department for coordination of policy and European integration, the budget official and experts of relevant fields."

The inclusion of "experts of relevant fields" is one of the most important areas for appointment to the Project Team. These experts should possibly include a representative from DAK (where authorised bodies are needed), from KSA and from market surveillance, but they should also include experts from industry, in particular manufacturers and conformity assessment bodies. These latter need to be carefully selected, however, so that they are knowledgeable, objective, independent and fair and, if possible, they should represent both SMEs and larger manufacturers. It may need to be considered that some industry representatives might seek to 'benefit' from mandatory regulation, rather than having the two primary objectives of safety and free movement in mind.

6.5 Drafting procedures for normative acts

The overall procedure for normative acts is defined in Regulation No. 13/2013 as follows:

"Article 8
Legislative process

The legislative process shall pass [through] to following steps:

1.1 Preliminary draft of the draft law;
1.2 Preliminary consultation;
1.3 Public consultation;
1.4 Final draft law;
1.5 Submission procedures for review and approval by the Government;
1.6 Review and approval by the Government;
1.7 Review and approval by the Assembly;
1.8 Proclamation by the President of the Republic of Kosovo;
1.9 Publication in the Official Gazette and
1.10 Ensure the implementation of [secondary legislation]."

For secondary legislation, 1.7 and 1.8 of the above article do not apply. Between 1.4 and 1.5, when transposing EU legislation, comes the stages of preparing tables of concurrence and other transposition statements (covered below), while probably after 1.4 comes the stage of Regulatory Impact Assessment (also covered below). Before 1.1, however, comes the preparatory stages.

6.6 Preparations for drafting

This section assumes that the decision has already been taken to proceed with legislation and that this legislation is going to involve transposition of EU provisions. It is then necessary to make a collection of all relevant EU texts (the base regulation or directive, any amendments, any Implementing Acts (Delegated Acts, Decisions, any other legislative acts referred to, etc.) from which the Kosovo text will be prepared. The responsible officer should, ideally, study the relevant principles behind the EU system, the history of its development, and any relevant guidance (from the EU and other). As discussed in an earlier chapter, the intentions of the European Commission should also be studied, because if a change to the EU texts is imminent, it may be better to postpone the development of the Kosovo legislation.

6.7 Internal and external consultation/dealing with comments

Regulation 13/2013 covers the consultation process as follows:

"Article 10
Preliminary consultation and public process

1. Ministries [responsible] for drafting the draft normative acts through the consultation process should seek public opinion on draft normative acts, [from] those that want [the] draft.

2. The consultation process takes place before and during the drafting of the draft normative act.

4. During the course of the preliminary consultation process and public consultation, methods and forms should be used appropriate to achieve the proper effect … .

5. In order to have a higher public participation in the process of consultation, the initiator of the draft normative act may apply other alternative forms of public consultation development, with [the condition] that applied forms [are] approriate for interest groups that are affected by the draft normative act. Alternative forms of public consultation can be used but must adhere to the principles of democratic governance aimed at obtaining relevant stakeholders opinion on certain issues.

Article 11
Prelimary consultation

1. [The] responsible official shall ensure that all bodies that the Government is obliged to consult in accordance with the RRPGRP [Rules of Procedure of the Government of the Republic of Kosovo], or whose work may be affected by the draft normative [act], have the opportunity to comment on the proposal.

3. All ministries are obliged to publish draft normative acts on the website.

Article 12
Public consultation

1. Following preliminary consultation and eventual incorporation of comments, the relevant Ministry shall publish on the website the content of the draft normative act for public comments and specifically seek comments by the groups of interest that are affected by the proposal.

2. According to the needs and requirements, the Legal Office shall coordinate the process of public consultation on the draft normative acts of Ministries, along with legal departments or [the] official responsible for drafting the draft laws of the relevant ministries.

3. Results of the consultation process will be part of the explanatory memorandum. [The] Memorandum presents the results from the consultation."

The text above permits various different types of consultation. A 'passive' approach (such as only publishing proposals and drafts on webpages) is unlikely to be successful and, instead, consultation should be 'active'. With relatively few organisations and manufacturers in any of the areas likely to be covered by regulations, it should be easy to contact them all. It may be best for the ministry making the consultation to send out a questionnaire with a number of specific questions to which answers are wanted, rather than a simple, open request for comments.

The Project Team then needs to deal with the comments received. Not all comments need to lead to modifications to the draft act, but all have to be recorded, considered and the responses given. As a part of satisfying the accountability and transparency principles, everyone who comments on a draft needs to be able to see that their comments were not ignored, even if they were not accepted.

6.8 Tables and forms of concurrence

The need to assess the accordance between Kosovo legislation and the EU provisions it intends to transpose, together with the statement of concurrence and the tables of concurrence, is fully described and included in A.I. No. 13/2013. This Guidance Document does not repeat these statements and tables, but does give some general guidance on how these should be completed. The text of the A.I. requires the following:

"Article 30

1. During the process of drafting normative acts, the proposing body prepares a Statement of Compliance and a Table of Compliance with the EU *Acquis*.

2. The Tables of Compliance and Statement of Compliance should be prepared by the Line Ministries which are initiators of draft normative acts.

3. The Tables of Compliance and Statement of Compliance are working comparative documents that demonstrate the level of compliance between a domestic draft normative act and the EU *Acquis*.

4. The Ministry of European Integration issues a Legal Opinion on Compliance with the EU *Acquis*."

The outline of the Table of Compliance is the following:

1. Title of the normative act: Law on xxx
2. Proposing body: Ministry of xxx
3. Table: date/month/year
4. List of relevant EU legislation (full title of the act and number) with which the normative act of the Republic of Kosovo is compliant
5. The level of compliance (fully compliant, partially compliant, not compliant or not applicable) of the normative act with EU legislation

a)	b)	c)	d)
Provisions of the normative act of Kosovo (article, paragraph, sub-paragraph, etc.)	The EU normative act (article, paragraph, sub-paragraph, etc.)	Compliance of Kosovo legislation with EU legislation (fully compliant, partially compliant, non-compliant or not applicable	Comments on reasons for partial compliance or non-compliance and the period foreseen for achieving full compliance
Article 1			
Article 2			

There is a second version of this table, in which Columns a) and b) are reversed, so as to provide for the 'reverse verification'; the table presented above compares the Kosovo text with that of the EU text, while the second table compares the EU text with that of the Kosovo text. This idea of 'forward' and 'reverse' comparison is good, but to be effective it is important that the person performing the reverse comparison is different and independent from the person performing the forward one.

As has already been discussed earlier in this Guidance Document, at the current time there are probably only a few cases where the Kosovo text can be fully compliant with the EU text and, indeed, full compliance is not always what should be aimed at. Such full compliance of a document as a whole can only be achieved once there is an agreement between the EU and Kosovo according to which Kosovo legislation has to be the same as the EU text. At this time, some of the obligations which, in Kosovo texts, are assigned to Kosovo competent authorities will be transferred to the European Commission.

Some EU acts will be closer to being compliant than others, especially where the act contains very few 'European' provisions, such as CE marking and notified bodies; examples of this being the Energy Labelling and Eco-design Directives. Many individual articles of a Kosovo law can (and should) be fully compliant (e.g. definitions), but the main intention of the Kosovo text is to be 'equivalent'. The Kosovo Toy Safety Directive is 'fully compliant' with the EU's directive because it is a direct copy of the EU text. But this has to be a negative situation, because none of the 'European' provisions, above all CE marking, can be obtained at present in accordance with a Kosovo legal act.

"CE marking", "notified bodies", "Member States" and "European Standards" should not, as a general rule, appear in Kosovo legislation. If the terms used are "KK marking", "authorised bodies", "Kosovo" and "Kosovo Standards" respectively, then the text can be indicated as "equivalent". The one case where "CE marking" needs to appear in Kosovo texts is to confer on CE marked products the same presumption of conformity with the essential requirements as in the EU text.

6.9 Publication of legal texts, development of guidance documents, post-regulatory actions and publications (e.g. authorised bodies, harmonised standards)

Primary and secondary Kosovo legislation is published in the Official Gazette but Regulation 09/2011 requires more than this:

"Article 71
Information

1. The Government shall inform the public and media about its work and decisions.

2. In order to ensure effective communication of Government policies and activities to citizens, the full range of communication methods should be used, including the media, websites, advertising, local presentations, literature and methods appropriate for reaching ethnic communities."

The obligation to inform Kosovo citizens and economic operators of the existence of new regulations is entirely correct. This should, however, be extended, in particular, to importers and manufacturers intending to send their products to Kosovo. This is particularly true if the regulations introduce requirements which have not existed before. Any serious attempt at enforcement is likely to fail if foreign manufacturers are unaware of the new regulatory requirements and continue to send products to Kosovo without taking these requirements into account. Details of legislation should, therefore, appear not only in the Official Gazette but on websites where potential exporters to Kosovo are likely to look. These include ministry websites but also websites set up to be found using search terms such as "Export products to Kosovo".

There is usually a need to provide specific training and assistance to market surveillance and customs authorities, because it is these which take on responsibility for enforcement. This brings with it the need to ensure that sufficient resources are made available for these activities, to ensure that they are not over-burdened with additional obligations imposed on them by new regulatory requirements.

As an aside, care needs to be taken about making "KK" marking mandatory. The KK marking is something which current exists only in Kosovo and would be difficult to obtain in another country. KK marking can only be obtained by applying a Kosovo standard and, therefore, strictly speaking, even if the Kosovo standard is a direct transposition of, say, a European Standard, the manufacturer would need to hold a copy of the Kosovo standard. This problem can be overcome by using "KK or equivalent regulatory conformity marking" instead of making KK marking itself mandatory.

A recent EU publication has indicated that, in some product areas, the levels of conformity remain low, between 30 and 50 %. One of the main reasons for this is often simple unawareness of the legal requirements and/or uncertainty on how to satisfy these requirements. General and more specific guidance documents have proved very valuable, as are documents which 'lead' manufacturers through the stages required for regulatory conformity. There is usually guidance on EU acts available on the European Commission's website, although this often covers 'legal clarifications' rather than 'guidance on practical application'.

EU guidance may helpfully be used as the basis on which guidance for economic operators in Kosovo is developed, but it is probably most useful for this guidance to concentrate on step-by-step practical application. Providing specific guidance to individual manufacturers also generally proves very valuable, not only for the manufacturer being assisted but also to provide evidence of any practical problems involved in applying the regulatory requirements. In fact, drafting "practical application" guidance can be a very illustrative way of identifying

problems with new legislation, even if it is somewhat too late in the process for these to be identified.

The adoption of new legislation in Kosovo often brings new obligations on responsible line ministries. These include but are not necessarily limited to: the publication of lists of Kosovo standards considered to provide a presumption of conformity with Kosovo legislation (this is a ministry, not a Standards Body, function); the recognition of authorised conformity assessment bodies, and publication of lists of such bodies; and the drafting of secondary legislation. Plans for these actions should be made well in advance of the publication of new legislation, and any possible delays which may arise with their implementation should be built into the transitional period of the legislation. The non-availability of harmonised Kosovo standards or the unavailability of authorised bodies (where necessary) will make the new legislation impossible or impractical to apply or enforce, even if manufacturers are ready to apply it.

6.10 Effective enforcement/monitoring/revision

The best time to ensure effective application and enforcement of any new legislation is in the period up to and immediately after its adoption. This is the period during which consultations have been taking place, economic operators are aware of the new legislation, knowledge in the relevant ministry is high and everyone is expecting the new law to have an effect. Market surveillance activities against non-conforming products immediately after the legislation enters into force also gives a clear message to economic operators that they should no longer be supplying non-conforming products. If this message becomes widely known, it can help reduce the need for future enforcement action.

An important aspect of enforcement is to set an appropriate transitional period during which all parties involved have the chance to make the necessary preparations (the only exception to this would be legislation intended to remove dangerous products from the market). In the free movement of goods area, legislation generally requires action in four areas:

- ministries, publishing lists of harmonised standards, authorising conformity assessment bodies, ensuring that market surveillance has appropriate trained resources, etc.,
- manufacturers, establishing manufacturing control procedures, ensuring that their products are of the required quality, preparing documentation and having conformity assessment performed,
- importers and distributers, ensuring that they source only conforming products,
- conformity assessment bodies, verifying that they have the competence to perform conformity assessment tasks, whether as authorised/notified bodies or not.

Implicit in this is the assumption that some other organisations are fully functioning, in particular the national standards body KSA and the accreditation body DAK, and that calibration services are available where these are needed for calibrating test equipment. The time needed for transition should not be under-estimated, however: conformity assessment by manufacturers can easily take from three months to one year, even if no problems are encountered. Importers and distributers, in addition, should be given the chance to sell existing stock. Both of these should be considered when setting the transition period, but

assistance should be offered to economic operators and this can effectively be done through a process known as “assisted implementation”.

Experience shows that it is appropriate to set actions to promote and facilitate implementation, i.e. “assisted implementation”. This is a process that is planned to implement the legislation that includes proactive cooperation between the regulatory authority and stakeholders. Such cooperation includes providing information and may well go as far as practical assistance provided to manufacturers.

Providing information should start very early in the legislative development process, through stakeholder consultation although, particularly for micro and small companies, it is important to remember that it is not always easy to get information to such companies. It is necessary to help them process the information in such a way that they understand exactly what they have to do to satisfy the requirements of the legislation. It is necessary to keep the micro and small companies from being surprised by the legislation if and when “inspection knocks on their doors”.

Written information will only, however, go some way to explaining the new legislation. It is only when economic operators (in particular manufacturers and CABs) start trying to apply it that the real problems will be identified. If resources and expertise allow, therefore, the competent ministry should consider providing practical expertise to organisations until such time as it can be demonstrated that products meet the requirements and that attestation of conformity has been carried out correctly.

Market surveillance authorities, properly trained in the new legislation, should be able to assist manufacturers in the procedural aspects of conformity and correct documentation. This can help avoid problems before they arise. The specific detailed requirements of any product, however, may require specific assistance.

Some care may need to be taken, in providing advice and assistance to manufacturers, importers, distributers and TABs, that this does not conflict with conformity assessment and/or enforcement responsibilities. DAK, for example, should not provide specific advice to a CAB which will later seek accreditation from DAK, and a CAB should not provide advice to a manufacturer which will later seek conformity assessment from that CAB.

Finally, any new legislation should be monitored to ensure that it is being effectively implemented, is achieving its objectives and is not having unintended effects. EU legislation often requires that the European Commission reports on the implementation after 5 years, and this is an obligation which is usefully placed on the appropriate Kosovo ministry. Information in support of this can come from a wide range of different sources, but in particular CABs, market surveillance authorities, manufacturers and importers and it does not always need to be detailed or statistically accurate to be useful. A CAB established in Kosovo, for example, which is not receiving requests for conformity assessment tasks from all Kosovo manufacturers of any product in question leads immediately to the question of what manufacturers are doing in respect of conformity assessment.

There are not many possibilities available to the Kosovo government to modify the basic provisions of legislation which is based on EU legal acts, but this does not mean that there are none. Ultimately, Kosovo legislation can be withdrawn in its entirety if it is found, at that time, to be inappropriate. Although a proper regulatory impact assessment should prevent

inappropriate legislation from being published in the first place, it should always be allowed that infrastructure developments that had been anticipated (manufacturer development, test laboratory development, etc.) do not happen and the legislation therefore becomes impractical or impossible to apply.

The situation to avoid (although it appears often to be the case in Kosovo) is for the country to have a large number of legal provisions which are largely or completely being ignored. This gives an incorrect illusion that unsafe products are being removed from the Kosovo market, it does nothing to assist Kosovo manufacturers to export or to allow them to compete effectively against imports, and it does nothing to move Kosovo closer to greater integration with the EU. Ultimately it has to be understood that 'transposition' (publication) of legislation is never the goal on its own; only transposition followed by effective application and enforcement is the goal; ineffective or deficient legislation has to be improved or withdrawn.

CHAPTER 7) LEGISLATIVE DRAFTING ISSUES

7.1 Introduction

This chapter provides guidance on the process of actually writing legislation, once the decision has been taken that legislation is required. It concentrates on the transposition of EU legislation and, where appropriate, it gives examples both of good drafting practice and poor drafting practice. The examples given in the chapter are only used for the purpose of illustrating the principles; any specific drafting situation may require different solutions than those proposed here. The examples given in this chapter come mainly from actual Kosovo text, but might not correspond fully to the real text.

7.2 Layout and numbering

Many EU legislative acts start with a series of "Having regard to …", "Acting in accordance with …", "Considering …" and "Whereas …" clauses. The first of these refers to the legislative basis on which the act is made, the second indicates a reference to the process of developing legislation, while the final two cover the reasons and justifications for the act. It may be useful for Kosovo drafters to read and understand these clauses, in particular to understand why the EU act is written in the way that it is, but these clauses do not need to be included in the Kosovo text.

The one exception to the above is that Article 1 of Kosovo legal documents is usually entitled "Purpose", which does not appear in EU acts. It may be that some of the key "Whereas …" clauses can be used as the basis for writing the "Purpose" clause. An example from the EU Toys Directive illustrates this:

"Council Directive 88/378/EEC … was adopted in the context of establishing the internal market in order to harmonise the safety levels of toys throughout the Member States and to remove obstacles to trade in toys between Member States."

becomes, in the Kosovo Toys Regulation:

"This Regulation sets out the requirements to be met concerning the safety of toys aiming to ensure their free movement, placing on the market, health protection and safety of their users."

Chapter 5 discussed how EU legislation should be divided or combined into primary Kosovo law and secondary laws. Once this has been decided, there is no obligation that the Kosovo legislation follows the same layout and numbering as the EU legislation, but there may be advantages in following, as far as is practicable, these aspects. The advantages of this are, firstly, that it is systematic, with the EU document being transposed clause by clause from beginning to end, minimising the chances of provisions being accidently omitted. Secondly, it helps minimise mistakes in cross-referencing, which can become particularly difficult if, after initial drafting, new clauses are added or the positioning of clauses is otherwise changed. Finally, it makes the preparation of comparison tables easier.

In order to retain the same layout and numbering in the transposed document, it is permissible to used "void" text, as the following example shows:

"Article 18
Formal objection against harmonised standards

Void."

This article was just one in a long series of transposed articles where there was no need for text in the Kosovo document. MTI will recognise harmonised standards in Kosovo through the publication of a list, and if any problems with a recognised standard arise, that standard can be removed from the list or other conditions associated with the use of that standard could be indicated in the same list. Consequently MTI has no need of the right to object to a Kosovo harmonised standard. When Kosovo signs an ACAA with the EU and starts to use harmonised European Standards published by the European Commission, then Kosovo will have the right to object, and appropriate text can be added. The use of "void" here allowed the numbering of all other articles to remain the same as the EU text.

A second example also illustrates this point:

"Article 60
Delegated acts

For the purposes of making construction products available on the market, the following matters shall be delegated to MTI:

(a) the determination of the essential characteristics which the manufacturer shall declare;

(b) Void.

(c) the amendment of the period for which the manufacturer shall keep the technical documentation."

The original text delegated the listed actions to the European Commission, most of which are delegated to MTI under the Kosovo law. (b), however, covering the electronic supply of the declaration of performance, does not need to be delegated to MTI because the Commission has already established the conditions and these are included elsewhere in this law. Because this is a list of eight different actions, using "void" against (b) means that any cross-reference to specific actions of this list from elsewhere in the text does not need to be changed.

Kosovo primary laws do not generally contain annexes, whereas annexes are common in EU directives and regulations. Where consideration of the structure of Kosovo provisions shows that such annexes should be included in the primary law, these annexes can be converted into "Chapters" and inserted towards the end of the law.

7.3 Language and translation

Many small, or more significant, problems of agreement between EU and Kosovo documents come from poor use of English (no comment is made here on the accuracy of the Albanian or Serbian language versions of the Kosovo documents). The reference language from which the Kosovo documents will be drafted is generally English, however.

Apart from where it is necessary to modify text, usually to refer to Kosovo conditions instead of EU ones, the English version of the Kosovo document should copy the EU text word-for-word. This avoids the sorts of problems currently seen in transposed texts, and also makes preparing comparison tables easier. The following are examples of where different English between the EU and Kosovo documents have changed the meaning:

EU text: 3. Where specific legislation does not impose specific dimensions, the CE marking shall be at least 5 mm high.

Kosovo text: The CE mark must have vertical dimension, which may not be less than 5 mm.

The EU text allows the CE marking to be any size, including smaller than 5 mm if specific legislation permits this, whereas the Kosovo text requires that the CE marking is always at least 5 mm. The Kosovo text here comes from Regulation 06/2013 on the Conformity Mark, a horizontal measure applying to all uses of the CE marking. If, subsequently, other legislation was transposed permitting the CE marking to be, say, 3 mm then, without the general derogation text "Unless provided for differently by other legislation" (or equivalent), there would be a conflict between the new legislation and Regulation 06.

EU text: 1. The CE marking shall be affixed only by the manufacturer or his authorised representative.

Kosovo text: 2. Affixing of the conformity mark on a product shall be made only by the manufacturer or his authorized representative, who also take the responsibility for the product, and this is done following the conformity assessment procedures by the conformity assessment body.

There are two mistakes introduced by the longer Kosovo text. Firstly, it states that responsibility for (conformity of) the product may fall on the authorized representative. This is incorrect, because responsibility for the product always remains with the manufacturer; only some tasks may be delegated to the authorized representative. Secondly, the Kosovo at least implies that there is always a conformity assessment body involved. Again this is untrue, because the product may be subject to only manufacturer's declaration of conformity, with no CAB involvement.

The use of the same English is particularly important in the case of definitions, as the examples in 7.5 below show.

7.4 Verb forms

The main purpose of most legislative acts is to give 'rules' which need to be followed by those covered by the act and, in some cases, to provide options and/or give permission. It is not usually the purpose of legal acts to give 'advice'. With this in mind, drafters in Kosovo

need to be aware of the different verb forms which give ‘rules’ and the verb form used to give permission.

In English there are a number of different verb forms which give rules:

- shall …	- must …
- need to …	- have to …

EU legal texts generally use “shall” or “must” (although “must” is not permitted in European Standards). While each of the above have equal “weight”, it is preferable (as discussed under “Language” above) for the Kosovo text to use the same verb form as the original EU text, and also that the same verb form is used consistently.

There is no need to try to “strengthen” the obligation given by the above verb forms, because they are ‘absolute’ on their own. “Shall always” is not ‘stronger’ than “shall”, while attempts to qualify “shall” should be avoided; “shall generally” (or equivalent) always raises the question of what are the “general” situations when the requirement applies, and what happens in conditions other than the general ones.

The passive verb form, “is” (or equivalent) should be avoided when the intention is to give a rule. As an example, “All fire extinguishers are red” is simply a statement which might not be true; to ensure that all fire extinguishers are red, the correct text is “All fire extinguishers shall be red”.

The verb forms to avoid or to use with care are “should” and “ought”. These do not have the force of rules but, instead, give advice. Both verb forms mean “does not have to be”, and a simple way to verify whether either verb form is correct is to replace the verb by “does not have to be”. In this way: “All fire extinguishers should be red” = “All fire extinguishers do not have to be red”, which is clearly not what was intended. When a choice is offered, the verb form is still “shall”, as in the example:

“Products shall be tested by Method A or by Method B”

This means that only Methods A or B may be used, with no preference between them. “Products should be tested by Method A or Method B” means, by inserting “do not have to be”, that “Products do not have to be tested by Method A or by Method B”, i.e. that any test method may be used, which is probably not what the text intends.

When text is being drafted and is being discussed in the Task Group, it is not correct to use “should” simply because no agreement on reaching “shall” can be reached. Because “should” would, in the published text, give the wrong sense as the examples above show, if agreement cannot be reached on a particular text, then discussions have to continue until appropriate text giving the rule is found.

An obligation should not be followed by an alternative, because this can lead to confusion and alternative wording can always be found. “All fire extinguishers shall be red. As an exception to this, fire extinguishers in restaurants may be blue” contains an internal ‘conflict’ between “all” and products covered by the exemption and, by giving permission using “may”, it is unclear whether extinguishers in restaurants are allowed to be some other colour

than red or blue. “Fire extinguishers for all locations except restaurants shall be red; fire extinguishers in restaurants shall be red or blue” removes both of these problems.

‘Permission’ in legal text is given by “may” rather than “can”, because “can” usually means “it is physically possible”. One example illustrates this point:

“The CE marking symbol may be placed on the product itself, on the packaging or on the accompanying commercial documents” means that any one of these locations is acceptable, but does not limit the marking to be in one of these places. For this text to be correct, however, it needs to be written as an obligation but with choice, such as “The CE marking shall be placed either on the product itself, …”.

“The CE marking symbol can be placed on the product itself, on the packaging or on the accompanying commercial documents” means that it is physically possible to put the CE marking in either of these locations (a statement which might not actually be true), it does not correctly indicate the need to use one of the locations.

7.5 Definitions

Definitions are crucial in the application of any legal provisions. They need to be carefully written because, in many cases, they establish what the act covers or how it functions. As stated above, definitions are perhaps the key area where, in the English version of a Kosovo legislative act, the same wording as in the original EU English version of the text needs to be used, unless there are genuine reasons not to do so. Examples which highlight the problems which poor definitions can cause include:

EU text: 3. ‘manufacturer’ shall mean any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under his name or trademark;

Kosovo text: 1.3. **Manufacturer** - any natural or legal person that produces the product, or who has shaped or manufactured the product and marketed it under his name or trade mark;

The Kosovo text is not the same as the EU text. The EU text specifically covers the situation of a product made by one person but sold in the name of another person, the person named being the ‘manufacturer’, whereas the Kosovo text does not address this situation.

EU text: Producer shall mean other professionals in the supply chain, insofar as their activities may affect the safety properties of a product;

Kosovo text: Producer shall mean … any other person whose activity in the supply chain may affect to that extent the safety of product’s features

“Professional” has a much more restricted meaning than “other person”. Although the situation is perhaps unlikely to ever arise, the Kosovo text could make a family friend responsible for causing harm to someone by giving a product to a member of the family having taken that product out of its packaging and thereby removing some safety instructions.

7.6 Obligations on Member States, the European Commission or other organisations

There are usually, in EU legislation, a number of possibilities or options given to EU Member States, the European Commission or other organisations. A decision needs to be taken as to whether these can be assigned to the competent authority in Kosovo or whether they should be removed from the transposed text. Examples of these obligations are the following, with each example followed by how the provision might be transposed into a Kosovo act:

"**Obligations on importers**

Furthermore, where the product presents a risk, importers shall immediately inform the competent national authorities of the Member States in which they made the product available to that effect".

This provision can exist in a Kosovo act, although the "competent authorities of the Member States" needs changing to "competent authority in Kosovo", and there is no need for the importer to inform any other country.

"**Formal objection to a harmonised standard**

1. When a Member State or the Commission considers that a harmonised standard does not entirely satisfy the requirements which it covers, the Commission or the Member State concerned shall bring the matter before the Committee set up by Article 5 of Directive 98/34/EC, giving its arguments."

As discussed above, Kosovo has no right to object to harmonised European Standards, and there is little point providing for the competent authority in Kosovo to object to a harmonised Kosovo Standard which that authority itself has recognised. In addition, Directive 98/34/EC has no validity in Kosovo at present. Despite this, it is possible to allow people or organisations (such as market surveillance) to object to a Kosovo standard, in which case the objection would be made to the competent authority in Kosovo which recognised the standard and published its reference.

If text to this effect is included, there would need to be additional text saying what the competent would do in response to such an objection. Such text could be:

"**Formal objection to a harmonised Kosovo standard**

1. When any person considers that a harmonised Kosovo standard does not entirely satisfy the requirements which it covers, that person shall bring the matter to the attention of the responsible ministry. The ministry shall, in discussion with the Kosovo Standards Agency, decide to withdraw the standard, to retain it with a more limited scope or to maintain it. In the case of withdrawal or reduction of scope, the decision shall be published by the responsible ministry."

If the EU text is:

"**EC Declaration of Conformity**

It shall be translated into the language or languages required by the Member State in which market the product is placed or made available."

Then, firstly, the title of this article would need changing, to replace the letters "EC" (European Community). Beyond that, the text may be included in a Kosovo document, replacing "the Member State" with "Kosovo" and deleting "language or", because Kosovo has two official languages. Note, however, that this text says "languages required" rather than "official languages". This allows the possibility for Kosovo to accept other languages, such as English. If, for any particular legislative area, Kosovo intends to accept languages other than Albanian and Serbian (or to accept only one of these languages), then this should be made clear somewhere.

"**Notification**

Member States shall notify the Commission and the other Member States of bodies authorised to carry out third-party conformity assessment tasks."

This text, although it does appear in some Kosovo texts, is inappropriate for Kosovo at the current time. For one thing, Kosovo cannot have any notified bodies and, for another thing, since authorised bodies in Kosovo are able only to perform work in support of KK marking, neither the European Commission nor EU Member States need to know about these bodies.

"**Notifying authorities**

1. Member States shall designation a notifying authority that shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies.

2. Member States may decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by a national accreditation body within the meaning of and in accordance with Regulation (EC) No. 765/2008."

This text is appropriate in Kosovo, although "notifying" needs replacing by "authorising" and "notified" needs replacing by "authorised". In addition, because Regulation 765/2008 has no validity in Kosovo but the national accreditation body is known to be DAK, the text starting "by a national accreditation body" can be replaced by DAK.

"**Identification numbers and lists of notified bodies**

1. The Commission shall assign an identification number to each notified body."

Kosovo authorised bodies should be given identification numbers, but the responsibility placed on the European Commission can be placed on the competent authority responsible for authorising bodies under that Kosovo act. It may be worth adding that identification numbers used in Kosovo should be different from those used in the EU, to avoid confusion when Kosovo starts having notified bodies.

"**Challenge of the competence of notified bodies**

1. The Commission shall investigate all cases where it doubts, or doubt is brought to its attention regarding, the competence of a notified body or the continued fulfilment by a notified body of the requirements and responsibilities to which it is subject."

This text may be relevant for Kosovo, the obligation being placed on the Kosovo competent authority instead of the Commission. Because this is an obligation on the European Commission, not on Member States, care needs to be taken that the obligation on the competent authority given here does not duplicate the same obligation on Member States (transposed as Kosovo) elsewhere in the text.

"**Exchange of experience**

The Commission shall provide for the organisation of exchange of experience between the Member States' national authorities responsible for notification policy."

This text is not relevant for Kosovo, because there is no other country which needs to know about how Kosovo currently authorises its bodies. It might, however, be relevant for Kosovo to review its own authorisation procedure from time to time, although this is probably an 'administrative' task which is not needed in primary law. In addition, Kosovo authorities should maintain awareness of any changes to notification policy in the EU, in case a change in the EU merits a change to the Kosovo authorisation policy.

Although not covered by the above text, some directives have notified body groups, which meet to discuss aspects of the work of notified bodies (this is particularly the case for construction products). Kosovo authorised bodies should maintain awareness of the work of notified bodies groups, because it may be relevant for the work of authorised bodies in Kosovo.

"**Procedure for dealing with products presenting a risk at national level**

4. Where the relevant economic operator does not take adequate corrective action within the period referred to, the market surveillance authorities shall take all appropriate provisional measures to prohibit or restrict the product's being made available on their national market, to withdraw the product from that market or to recall it.

They shall inform the Commission and the other Member States, without delay, of those measures."

This text also appears in some Kosovo acts, but the second paragraph is inappropriate. There is no mechanism for Kosovo to inform either the European Commission or EU Member States. Having said that, if Kosovo does take market surveillance action, particularly against a dangerous product, and an agreement exists for Kosovo to inform the European Commission of this (where such information would be useful in the EU), then the text may include the possibility of Kosovo market surveillance authorities informing the Commission. The Commission is unlikely to be interested in every market surveillance action taken in Kosovo, so the text should be adjusted to replace the obligation to inform the Commission of all action either with a possibility "They may inform the Commission" or with specific obligations such

as “They shall inform the Commission when the measure is to prevent a product from being placed on the Kosovo market or to recall or withdraw it”.

Finally, in this section, care needs to be taken not to impose obligations on organisations in Kosovo which they cannot hope to achieve but which may pose problems for them. This is particularly the case for obligations on market surveillance authorities. An example of this would be “The competent authority shall ensure, through market surveillance, that all non-conforming products are removed from the market”. This is, in practice, impossible to achieve in any country. But its inclusion could open the competent authority up to legal challenge if someone were injured by a non-conforming product and complained that they were injured because of the legal obligation on the competent authorities to remove *all* unsafe products, which they had failed to do.

Care is also needed when setting deadlines by which government bodies shall act or respond (it is more reasonable to impose deadlines on economic actors). An example of this is “The Kosovo Product Contact Point shall respond to all requests for information within 2 days”. The time taken to respond to a particular request may depend on the nature of the request, and what happens in the EU is that any such binding statement often leads only to a ‘holding’ response (“We have received your request. We will respond as soon as we are able to.”). More appropriate text, in general following this example, would be “The Kosovo Product Contact Point shall respond to all requests for information within a reasonable period of time.”

The one exception to this is where government inaction might damage the justified interests of an economic actor. Perhaps a good example of this is the maximum time period during which customs authorities may withhold products from the market before, either, releasing them onto the market, requesting more time to complete their work, or taking specific action to prevent them being released.

7.7 Checking the draft

When a draft is complete, but before it goes through the stage of preparing tables of concordance, it should be carefully checked. Checking the equivalence of the Kosovo text with that of the EU is not quite the same as checking the correctness of the Kosovo text, and it should not be assumed that later stages of the draft will identify substantial mistakes. This checking stage, which would normally come once the Task Group has completed the draft for the first time, is therefore crucial, because it is probably the last time when mistakes and omissions can be identified.

Checking legislative drafts is a particular skill, requiring certain abilities if it is to be done correctly. Among the skills of a good legislative checker are:

- reasonable knowledge of the subject area, sufficient to be able to judge whether the legislation is practicable in Kosovo,
- good understanding of EU principles and the differences between the EU and Kosovo,
- good attention to detail, necessary to check the internal consistency of the text (e.g. internal cross references),
- sound knowledge of EU terminology and its equivalence in whatever language the text is being checked,

- thorough knowledge of this Guidance Document.

It is well recognised that those involved in drafting a document are not able, at least for some time, to check it. Drafters often read their own documents as they *believe* they are written, rather than as they are *actually* written. Legislative checking should, therefore, wherever possible, be done by someone independent, who was not involved in the original drafting.

Checking needs to be a systematic process, during which the person performing the checking is entitled to question all or any of the provisions in the text (but probably not the decision to develop legislation in the first place). Nonetheless, if some of the comments made by the checker indicate that the draft cannot be effectively implemented in Kosovo, then those who made the original decision to legislate may need to think again or, at least, to reconsider the approach. The checking done during this stage is effectively the summary of what has been covered by this Guidance Document, and the sorts of questions which the checker should be considering while read the draft include:

- is the scope correct, does it correspond to the intention, and does it bring some products within the scope of the law which were not intended to be included, or are some excluded?
- can the draft be implemented and enforced in Kosovo? This is not a repeat of the detailed pre-legislative assessment but, instead, an 'overview' of the practicalities of the provisions;
- have "EU" provisions been correctly replaced by Kosovo ones?
- does the text place 'unrealistic' obligations on some organisations to which it is addressed? Could the wording be modified to remove these obligations?
- is the text internally consistent? Do some provisions conflict with others, and are all internal cross-references correct?
- is the text consistent with other legislation? Do some provisions duplicate or conflict with those in other legislation?
- are there editorial and/or language mistakes? Although they do not always identify all mistakes, as a very minimum any text needs to be checked using both a spell checker and a grammar checker.

The introduction, by the relevant Ministry in Kosovo, of good post-drafting checking by someone with the right aptitudes is likely to be the one major change which would improve the quality of Kosovo legislation.

ANNEX 1) REGULATORY PROVISIONS IN THE HARMONISED SECTORS

The following is a list of areas conventionally considered to fall within the New Approach and Global Approach, and the New Legislation Framework areas. It is unnecessary to attempt to separate these, because some provisions previously considered to be New Approach are now NLF, while the Global Approach has been replaced by the NLF and, as existing acts are amended, there will be further transfer from New Approach to NLF. Note, too, that there is no unique definition of what is a New Approach and what is an Old Approach measure, particularly areas such as cosmetics and dangerous substances (REACH), which started as Old Approach but which have been updated since the New Approach/NLF were introduced.

Directive 89/686/EEC	Personal protective equipment (PPE)
Directive 90/385/EEC	Medical devices: active implantable
Directive 92/42/EEC	Efficiency requirements of hot-water boilers
Directive 93/42/EEC	Medical devices (MDD)
Directive 94/62/EC	Packaging and packaging waste
Directive 98/79/EC	Medical devices: in vitro diagnostic
Directive 2000/9/EC	Cableway installations
Directive 2000/14/EC[1]	Noise emission by outdoor equipment
Directive 2006/42/EC	Machinery (MD)
Directive 2008/57/EC	Rail system: interoperability
Regulation (EC) 765/2008	Accreditation and the market surveillance of products
Decision 768/2008	Common framework for the marketing of products
Directive 2009/142/EC	Gas appliances (GAD)
Directive 2009/128/EC	Inspection of pesticide application equipment
Directive 2009/125/EC	Eco-design and energy labelling
Directive 2009/48/EC	Toys safety
Regulation (EC) 1221/2009	Eco-management and audit scheme (EMAS)
Directive 2010/30/EU	Labelling and energy consumption
Directive 2011/65/EU	Restriction of the use of certain hazardous substances (RoHS)
Regulation (EU) 305/2011	Construction products (CPR)
Directive 2012/19/EU	Waste Electrical and Electronic Equipment (WEEE)
Directive 2013/29/EU	Pyrotechnic articles
Directive 2013/53/EU	Recreational craft
Directive 2014/30/EU	Electromagnetic compatibility (EMC)
Directive 2014/34/EU	Equipment for explosive atmospheres (ATEX)
Directive 2014/28/EU	Explosives for civil uses
Directive 2014/33/EU	Lifts
Directive 2014/35/EU	Low Voltage (LVD)
Directive 2014/90/EU	Marine Equipment
Directive 2014/32/EU	Measuring instruments (MID)
Directive 2014/31/EU	Non-automatic weighing instruments (NAWI)
Directive 2014/68/EU	Pressure equipment (PED)
Directive 2014/15/EU	Radio and telecommunications terminal equipment (RTTE)

[1] Not conventionally a New Approach or NLF directive, but does require CE marking.

Directive 2014/29/EU	Simple Pressure Vessels

The following two measures have a status somewhat in between the harmonised and non-harmonised sectors. They operate within the non-harmonised sectors (i.e. mutual recognition), but they also set down "common rules" within this area (Regulation 764 is usually considered to be an NLF measure):

Directive 2001/95/EC	General Product Safety
Regulation (EC) 764/2008	Application of certain national technical rules to products lawfully marketed in another EU country.

The area considered to be covered by the Old Approach is large and no reliable lists of the directives exist. It is estimated that there are about 700 Old Approach directives and it is not, therefore, possible to list them all. The following identifies the main areas, and gives *example* directives and regulations only:

Directive 69/493/EEC	Crystal glass
Directives 71/349/EEC, 71/347/EEC, 71/317/EEC	Metrology
Directive 94/11/EC	Footwear
Directives 97/37/EC, 96/74/EC, 96/73/EC, 73/44/EC	Textiles
Directive 98/8/EC	Biocidal products
Regulation (EC) No. 2003/2003	Fertilisers
Directives 2004/24/EC, 2001/83/EC	Medicinal products
Directive 2004/28/EEC	Veterinary medicinal products
Regulation (EC) No. 648/2004	Detergents
Directive 2005/40/EC	Safety belts/restraint systems
Regulation (EC) 1907/2006	Chemical substances (REACH)
Directives 2007/37/EC, 2001/116/EC	Type approval of vehicles
Directive 2007/34/EC	Vehicle exhaust systems
Regulation (EC) 1271/2008	Classification, packaging, labelling
Directive 2008/47/EC	Aerosol dispensers
Regulation (EC) 1223/2009	Cosmetics
Directive 2009/61/EC	Lighting for agricultural vehicles

ANNEX 2) POSSIBLE FORMATS FOR PUBLICATIONS OF HARMONISED KOSOVO STANDARDS IN SUPPORT OF TRANSPOSED EU LEGISLATION

This annex contains two examples of possible publications of lists of harmonised Kosovo Standards used to support transposed EU legislation: an example from the Low Voltage Directive, which could also be used for most other transposed EU directives/regulations which refer to harmonised standards, and the specific case of construction products where standards have a *de facto* mandatory status.

These examples show only very short lists of standards; lists will actually be much longer than these examples. Moreover, whichever Kosovo competent authority is responsible for publishing each list needs to keep these lists fully up to date, reflecting changes in European Standards and taking the decision of whether a change in the EU in respect of conditions for CE marking are also going to apply in Kosovo in respect of KK marking (in most cases they should, but this is not 'automatic').

In the example of standards for low voltage products, it needs to be understood by regulators and users that that use of the standards cited under the Kosovo Low Voltage Law would satisfy the requirements of that law. There are, however, possible other Kosovo laws relevant for low voltage products (electromagnetic compatibility, restriction of hazardous substances, waste electrical and electronic equipment, Eco-design, etc.). It would be acceptable for the publication, as this example shows, to advise manufacturers of the existence of other possibly relevant legislation.

The EU's Low Voltage Directive does not rely uniquely on European Standards; Harmonised Documents developed by one of the European Standards Organisations may also be used (as may other documents without giving a presumption of conformity). The example below indicates Harmonised Documents but it would be a decision for the Kosovo Standards Agency (KSA) whether to transpose these as such, or as Kosovo Standards.

Example 1 – Publication of standards for low voltage products

Communication of the Ministry of Trade and Industry in the framework of the implementation of Rulebook No. 02/2012 on electrical equipment designed for use within certain voltage limits:

Publication of titles and references of harmonised Kosovo standards supporting the Rulebook.

Publication number and date.

Warning: Other regulatory requirements, whether leading to KK marking or not, may apply to electrical equipment, the satisfaction of which may not be covered by the following listed standards. It is the manufacturer's responsibility to ensure that all relevant regulatory requirements are complied with.

Originating European Standards Organisation	Reference and title of the standard (and reference document)	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard[1]
CEN	KS EN ISO 11252:2013 Lasers and laser-related equipment – Laser device – Minimum requirements for documentation (ISO 11252:2013)	KS EN ISO 11252:2008	1.9.2014
Cenelec	KS HD 21.8 S2:1999 Polyvinyl chloride insulated cables of rated voltages up to and including 450/750 V – Part 8: Single core non-sheathed cables to decorative chains		
Cenelec	KS EN 60335-1:1994 + A11:1995 Safety of household and similar electrical appliances – Part 1: General requirements IEC 60335-1:1991 (Modified)		
Cenelec	KS EN 60335-2-5:2015 Safety of household and similar electrical appliances – Safety – Part 2-5: Particular requirements for dishwashers IEC 60335-2-5:2012 (Modified)	KS EN 60335-2-5:2003	9.8.2016

1) Generally, the date of cessation of presumption of conformity will be the date of withdrawal ("DOW") set by the Kosovo Standards Agency. A date given in this column shows that a different cessation date than the DOW is set.

The EU's Construction Products Regulation, still to be transposed in Kosovo, is somewhat different from other EU product legislation, because each harmonised standard requires a date when it becomes applicable and a date when it becomes mandatory. These dates in the EU are decided by the European Commission, but Kosovo needs to decide them for itself and may use dates different from those in the EU.

Example 2 – Publication of standards for construction products

Communication of the Ministry of Trade and Industry in the framework of the implementation of Law No. XX/2017 on construction products

Citation of harmonised Kosovo standards and co-existence periods.

Publication number and date.

The following standards shall be applied, for products placed on the Kosovo market, except where the performance of the products is demonstrated by application of the European Standard in another country.

The AVPC system(s) included in annexes to these standards shall be the system(s) applied for KK marking, unless otherwise indicated. Where the AVCP system shown in the table is different from that given in the standard, products evaluated to the system in the standard are accepted.

Number	**Title**	**Date of applicability(1)**	**Co-existence period end date(2)**	**KK marking(3)**	**AVCP system**
KS EN 197-1:2011	Cement – Part 1: Composition, specifications and conformity criteria for common cements	01/03/2017	28/02/2018	Mandatory	As in KS
KS EN 12004:2007 + A1:2012 Replaces KS EN 12004:2002	Adhesives for tiles – Requirements, evaluation of conformity, classification and designation	01/10/2018	30/09/2020	Optional	4
(1) On this date, conformity with the standards, and KK marking, become possible. (2) On this date, conformity with the standards becomes mandatory and all conflicting specifications shall be withdrawn, and KK marking becomes mandatory if indicated. (3) Other, equivalent, regulatory conformity markings are also accepted.					

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