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STATE OF THE IMPLEMENTATION OF THE NEW LEGISLATIVE FRAMEWORK (NLF)

The new regulatory Framework (more often called New Legislative Framework – NLF) is a general measure of the internal market whose objective is to strengthen the effectiveness of the Union's legislation on product safety, its implementation mechanisms, and ensure a greater consistency throughout all the different economic sectors. The Framework is also part of the Union's policy in terms of simplification of regulations and the reduction of administrative burdens.

Its effective implementation brings about a modernised and simplified legal environment for the companies, strengthens the safety of products available on the market, and ensures a better functioning internal market through, inter alia, equal treatment of economic operators on the market.

The NLF is made up of two distinct and intrinsically complementary texts which cannot be dissociated: Regulation (EC) No. 765/2008 of the Parliament and the Council of 9 July 2008 outlining the requirements concerning accreditation and surveillance for the marketing of products¹, and Decision No. 768/2008/EC of the Parliament and Council Decision of 9 July 2008 relating to a common framework for the marketing of products².

Regulation (EC) No 765/2008 came into force on January 1st 2010, while Decision 768/2008 has to have its content included in the existing legislation by aligning texts in future revisions.

Both texts mainly aim at:

- putting in place a European policy regarding accreditation to evaluate the competence of testing laboratories as well as certification and inspection bodies; strengthening the foundations of an effective policy at the level of the Union as regards market surveillance and controls of products from third countries and by consequence, strengthening the reliability of CE marking through this policy; and
- consolidating and standardising the various technical regulatory instruments to ensure greater consistency of the technical legislation related to standardisation so

¹ OJEU L 218/30 of 13.8.2008

² OJEU, L 218/82, of 13.8.2008

as to guarantee product safety, and therefore contribute to the improvement and simplification of Community legislation.

The implementation of the NLF has required, and will continue to require for a certain time, that Member States make important administrative and regulatory changes at the national level. This proved true for a limited number of Member States in the field of accreditation (in particular Germany and Italy where it was necessary to reduce the number of accreditation bodies to only one operating at the national level) and true for a large majority of Member States in the field of market surveillance and controls on products from third countries.

Since the adoption of these texts on 9 July 2008, the Commission undertook to accompany Member States in their implementation in order to ensure consistency at the level of the Union, in the field of accreditation and market surveillance as well as import controls.

All the Member States undertook an important in-depth examination of their national situations to identify the measures necessary for the implementation, and showed a strong willingness to conform to the Regulation as of January 1st 2010.

However, implementation still remains a work in progress because effective coordination and cooperation between national authorities require, to allow market surveillance and imports control make their effects felt, permanent and continuous work, much more than an action limited in time. Measures which have been and are currently being put in place are therefore established to manage the infrastructures and ensure cooperation over time.

The Commission pursues its cooperation with Member States through, in particular, the Senior Officials Group responsible for standardisation and conformity assessment (which has been supporting it now for more than 35 years in this sphere of activity), through a more specialised group dedicated to market surveillance created especially for this purpose in 2008 and also in coordination with the Committee of the General Product Safety Directive in its field of activities. The Commission also closely works with national experts in various groups of sectoral experts. It has clearly committed itself to closely cooperate with the European Parliament, especially through its IMCO Committee, and to inform it regularly of developments in this area.

The subject of this report is therefore to describe the situation, shortly after the entry into force of Regulation (EC) No 765/2008, as regards the implementation of the NLF by the Member States and the Commission, and to identify priorities for the future. This report concentrates only on the Member States of the Union and does not include data on the EFTA/EEA countries or on Turkey.

NECESSARY MEASURES FOR IMPLEMENTATION AND WHAT HAS BEEN DONE

Since the adoption of the NLF, the Commission has organised a series of meetings with the competent national authorities to coordinate activities related to implementation of the package. That was done in particular through 8 meetings of the Senior Officials Group responsible for standardisation and conformity assessment, and 9 meetings of a sub-group especially devoted to market surveillance.

This work consisted in examining the measures to be taken, the interpretations to be given, the priorities to be established, identifying problems common to all Member States, as well as preparing answers and monitoring national developments. More particularly in the field of market surveillance and controls of products from third countries, there was a need to develop the elements of a work programme and start preparing common tools, such as a template for the presentation of the national surveillance programmes.

1. COMMUNICATIONS

All Member States took the deadline of January 1st 2010 very seriously. Under the terms of the provisions of Regulation (EC) No 765/2008, they had to communicate to the Commission the name and the fields of activity of their national accreditation organisation, the name(s) of their authorities responsible for market surveillance with their various responsibilities, their market surveillance programmes for 2010, and the measures taken to implement sanctions against bad marking and sanctions against infringements to the provisions of the Regulation. For all these various communications, the Commission has received communications from all Member States on all elements, except for the general sanctions against the infringements of the Regulation, which for many Member States will be covered by other national legislation.

2. ACCREDITATION

Regulation (EC) No 765/2008 contains several provisions in this area which should trigger regulatory or administrative changes in a number of Member States.

2.1. Member States

Firstly, Member States have to ensure that there is only one recognised national body for accreditation. The majority of Member States only had one body before the regulation, but it was not necessarily recognised as the only body, and without having necessarily the field of activity provided by the regulation. The two Member States which had the most serious problem as regards numbers, Germany and Italy, managed to amend their regulatory texts and to make the basic structural adaptations on time for January 1st 2010. All bodies are members of the European Co-operation for Accreditation (EA). Information received from Member States is under examination.

2.2. The Commission

The Commission has to initially establish the contractual relations with EA. The political Guidelines were signed on 1 April 2009, between EA, the Commission, the EFTA Secretariat, the national authorities of Member States, the EFTA Member States and Turkey. They are published in the OJEU C116/6. As regards the Framework Partnership Agreement which has to be signed between the Commission and EA to support the EA operating costs and the strengthening of the "peer evaluation", it was signed on 30 June 2010. The delay in signing did not prevent EA from taking the necessary

initiatives to prepare for its new role under the Regulation: restructuring the organisation to strengthen the peer evaluation system, reviewing the criteria and procedures, enhancing the role of the secretariat, etc.

2.3. Market surveillance

The provisions on market surveillance require most efforts from all concerned parties (i.e. the numerous national authorities including customs and the Commission), because they contain new obligations. The regulation takes further the experience built up under the General Product Safety Directive and some specific sectoral Directives, making explicit the connection with the sectoral regulations and between internal controls on the Union market and controls at entry of products from third countries.

In addition, the degree of obligation is more stringent in the harmonised area by obliging Member States to act in the presence of non conforming or dangerous products, and by extending with respect to harmonised products the requirements for Member States, inter alia, to coordinate their actions, both internally and with the national authorities of other Member States, coordinate with customs authorities, have the means to carry out all these inspections and elaborate national market surveillance programmes.

Since the adoption of the Regulation, the sub-group of Senior Officials responsible for standardisation policies and conformity assessment dedicated to market surveillance has played a major role in the coordination and informal harmonisation in view of implementation. The Group plays a double role: it enables Member States and the Commission to follow developments in all Member States and identify the problems of each one of them, and consequently identify the remaining problems which have to be considered in the future; it makes it also possible to develop standard solutions for some of the obligations of Member States before they adopt non-harmonised implementation. Thus it allows the monitoring of the implementation and the development of harmonised initiatives which go sometimes beyond the provisions of the Regulation itself. Moreover, a special group of national experts was created by DG TAXUD to examine how customs authorities will have to fulfil their role under Regulation (EC) No 765/2008 (see below).

It should be noted that almost half of the Member States have already announced that they do not envisage any increase in the resources and means for the implementation of market surveillance and controls of products from third countries. However, the Regulation obliges Member States to make adequate resources available. It is difficult at this time to estimate the needs because these will mainly depend on the intensity of the actions to be undertaken following various joint programmes, but also on the joint action and cooperation mechanisms between Member States, which could lead to a division of resources and therefore to a possible reduction in the individual needs for each Member State.

3. MEMBER STATES

Regulatory and administrative adaptations

It appears from the new obligations contained in the Regulation and from its broad implementation scope³ that the majority of Member States have had to take implementation measures. At present, more than half (18) have already had to amend their laws. Many had to make administrative adjustments, including 12 generally to ensure inter-ministerial coordination and/or between national authorities in the field and 17 to coordinate work in the customs field. Moreover, 9 Member States have announced the need for in-depth restructuring.

Given the extremely varying situations in Member States before the adoption of the Regulation, the new national texts are very different and often deal with very different elements. Thus a coherent image does not come out from all these changes yet. Structural modifications and coordination mechanisms will certainly take a certain time before becoming fully operational and effective.

National market surveillance authorities

Under the provisions of Article 17 of the Regulation, Member States have to communicate information on the national market surveillance authorities, both regarding who is responsible for what, and the contact details of the various authorities. The Commission has received communications from all Member States and has put all this information on its web site (http://ec.europa.eu/enterprise/policies/single-market-goods/regulatory-policies-common-rules-for-products/index_en.htm). The presentation of all this information will be reviewed in order to give it a more harmonised format.

National market surveillance programmes

Article 18 of the Regulation obliges Member States to establish and update national market surveillance programmes. This field is a good example of the role that the group of experts dedicated to market surveillance can play. Indeed, ever since its first meeting, this group has asked the Commission to help it develop a common approach for the elaboration of the national programmes, to develop a matrix in order to be able to establish a general overview of all surveillance activities in the Union, and to ensure that programmes are comparable in order to help identify common concerns, European priorities and the sectors where it would be more advantageous to conceive joint actions.

At the end of 2009, it was possible to obtain a consensus on a common methodology for the presentation of both sectoral and general national programmes. It was however too late for all Member States to present their programmes for 2010. Despite that, a number of Member States were able to submit their programmes for 2010 according to the agreed matrix. At present, the Commission has received one general programme, 12 which are sectoral and general at the same time, and 14 which are only sectoral.

³ which covers not only a large number of industrial sectors but also other concerns such as the sole protection of safety and health (consumer protection, the protection of workers, environmental protection...)

4. THE COMMISSION

The Commission was also very active in monitoring the implementation at different levels and went beyond the implementation of Articles 22 and 23 of the Regulation (RAPEX and general database) which relate more particularly to its responsibilities. Indeed, it considered all the provisions of the Regulation and contributed to the implementation by national authorities as indicated above.

Concerning more particularly the links between Regulation (EC) No 765/2008 and the GPSD Directive, the Commission has drafted guidelines⁴ and a communication on the interim solution for notifications of measures taken against dangerous products under both instruments.

Coordination of Member States

Since 2008, in addition to the work already mentioned above, the Commission started some technical discussions to bring closer the working methods of national authorities in the field, not only in relation to national programmes, but also as regards the methodology used by national authorities at the time of product controls, in order to ensure a certain transparency and similarity of results beyond what already exists in the consumer product area (RAPEX management guidelines Commission Decision of 16 December 2009 laying down guidelines for the management of RAPEX)⁵ Other discussions will thus soon be initiated on the notions of "risk" and "serious risk", for example.

Moreover, initiatives were launched to examine the situation of customs authorities. A special working group was created by DG TAXUD to concretely examine how customs authorities can implement in the most effective way, controls of products from third countries (Articles 27-29). This working group is to establish a consensus guide for customs authorities for the beginning of 2011. It is envisaged to organise a joint meeting of this group with the group of Senior Standardisation Officials in November 2010 to ensure consistency and the coordination of internal and external controls.

RAPEX (Art. 22 of the Regulation) and general Database (Art. 23)

The Commission started work to extend and adapt the RAPEX system to the measures adopted against products and risks not covered by the GPSD, but falling under the Regulation (Article 22) and to prepare the development of a single information system. Difficulties and delays have intervened in this case. Due to the need to preserve the correct functioning of the RAPEX system and the complex relationship between the two instruments, the Commission had to set up the provisional measures mentioned above.

As regards the database of Article 23, the Commission is seeking a solution which would enable it to use an already existing database for the implementation of the Regulation. During the negotiation of the Regulation, many negotiators had in mind the use of the database ICSMS- Information and Communication System for Market Surveillance,

⁴ Working paper on the relationship between the General product Safety Directive 2001/95/EC and the market surveillance provisions of Regulation (EC) No 765/2008 dated 3 March 2010

⁵ COMMISSION DECISION of 16 December 2009 laying down guidelines for the management of the Community Rapid Information System 'RAPEX' established under Article 12 and of the notification procedure established under Article 11 of Directive 2001/95/EC (the General Product Safety Directive)

which was conceived and developed by and for the authorities of a consortium of inspectors from a number of Member States. As the Regulation does not expressly name this database, the Commission is examining the means, in conformity with the Financial Regulation, of using it nevertheless. Discussions are under way with the persons responsible for ICSMS and Member States. Here, as is the case for RAPEX, the Commission has set up temporary means of communication, via CIRCA.

5. ALIGNMENT OF EXISTING LEGISLATION WITH THE NLF

On 9 July 2008, the Council and the European Parliament adopted at the same time as the Regulation, Decision 768/2008 concerning a common framework for the marketing of products. It contains a complete range of the consolidated and standardised technical horizontal instruments to ensure better consistency of existing Community regulations. The Decision being *sui generis*, its provisions have to be incorporated or be referenced in existing legislation. This integration can be made as is the case for the new Toy Safety Directive (Directive 2009/48 of 18 June 2009), at the time of revision or update. The Commission has committed to examine during the preparation of all its new regulations on product safety, as well as during its proposals for revision of the *acquis*, the possibility of incorporating as systematically as possible the instruments of Decision 768/2008. This alignment will be done therefore progressively according to legislative needs.

However, the Commission has identified a number of existing directives for which a revision is not envisaged in the near future, which could benefit from a simple alignment without affecting sectoral elements (levels of safety or protection, the choice of conformity assessment procedures etc). Thus, the Commission is currently preparing a "package" of ten directives for a horizontal alignment. Depending on the results of current consultations, this involves the following directives: low voltage, electromagnetic compatibility, electrical products for use in explosive atmospheres (ATEX), simple pressure vessels, pressure equipment, civil explosives, pyrotechnic articles, measuring instruments, non-automatic weighing instruments and lifts. In the current state of affairs, the first recasting texts have been developed and a comprehensive impact assessment is currently being prepared. Public consultations are under way. The Commission intends to make this proposal during the first quarter of 2011.

6. CE MARKING – THE INFORMATION CAMPAIGN

At the time of adoption of the package, the European Parliament asked that the Commission launches an information campaign concerning CE marking since Regulation (EC) No 765/2008 clarified its scope and set up the means and obligations for Member States to make an effective supervision of the market and therefore strengthen the credibility of CE marking. Therefore, the Commission engaged a contractor and effectively launched the campaign during the "Messe" fair of Hannover on 19 April 2010. This campaign envisages participation in a large number of events, fairs, seminars, and the development of video clips and written material (booklets/data sheets etc) in all languages. It is designed to last two years for a total cost of slightly less than 2 million €. It is addressed above all to the SMEs but contains information items for consumers as requested by Parliament and confirmed by Vice President Tajani during his hearing in the EP.

WHAT REMAINS TO BE DONE – PRIORITIES AND NEXT STEPS

Much still remains to be done because after the infrastructures, procedures and rules have been adapted, the functioning of the system will require daily efforts over time. The Regulation is obviously directly applicable, but despite that, the functioning of the system requires a great deal of concrete implementation work in the field in order to be effective and efficient.

The first essential task will be to verify that all Member States have taken all necessary measures to ensure the proper functioning over time, and therefore examine all information communicated to the Commission. A major part of this information being in national languages, the processing of national data will take a certain time due to the need for translations, and this will be all the more so when Member States will be involved in processing the data (for example the examination of national programmes).

Following on from this, different initiatives will have to be taken in the various fields identified above:

1. ACCREDITATION

- Examine regulatory texts setting the framework for accreditation at the national level.
- Manage the Framework Agreement with EA.
- Complete the first initiatives for the strengthening of the peer assessment system.
- Examine with EA and its members how to "Europeanise" the national accreditation certificates to make multiple accreditations less appealing.
- Complete the interpretation work and organise the cooperation with members of EA regarding the problems of cross-border accreditation provided in Article 7 of Regulation (EC) No 765/2008.
- Set up the means for the technical examination of notifications provided for bodies which are notified without the support of accreditation.
- Within the general framework of the accreditation, launch an examination of all bodies notified in relation to the new criteria contained in the NLF.

2. MARKET SURVEILLANCE

- Examine the national programmes provided for 2010 and subsequent years, with the aim of establishing a snapshot of national activities in the field, and of ensuring their comparability, checking the degree of adaptation of the matrix to the practical control related needs, defining community priorities, and in the future to establish coordinated programmes.
- Finish setting up the new information system for RAPEX (GRAS-RAPEX) and the system for the follow up of the measures taken with respect to dangerous products and safeguard clauses, and the process of transforming national measures into EU measures.

- Conclude the negotiation for the implementation of the general database (ICSMS?) for Article 23 of the Regulation in respect of all Member States and ensure appropriate Community management.
- Perform a follow up of the conformity assessment processes in cases where products are nevertheless dangerous and/or non-conforming in spite of such processes.
- Set up cooperation mechanisms in the field between national authorities at the national and European levels.
- Determine the role and working methods of customs authorities for the controls of products from third countries in close cooperation with internal authorities.
- Establish guides for customs officers on how to effectively control the conformity and the safety of products from third countries.
- Develop an overall cooperation policy of the Union with the surveillance authorities of third countries.
- Develop and set up an accidents database.
- Establish and manage common training programmes.
- Establish and manage joint visits and joint actions programmes (both internally within the Union and in third countries).
- Establish and follow-up on the implementation of technical guides inter alia, on the methodologies related to product controls, on risk assessment, on the establishment of the common concepts of risk, serious risk, acceptable risk, etc.
- Develop the concept of a multiannual programme for an overall implementation, identify the technical means, the resources and the budgets necessary for its implementation. Such a programme should contribute to the implementation of the elements listed above, in particular.
- Follow-up on the development of the organisation and the national resources allocated for the functioning of market surveillance and controls of products from third countries, and take appropriate measures and initiatives.

3. CE MARKING

- Intensify the information campaign.
- Complete the registration procedures for the CE marking.

4. ALIGNMENT OF EXISTING LEGISLATION

- Complete the proposal of the package of ten horizontal alignments for the first quarter of 2011.

- Set up a system of systematic examination of each revision proposal of an existing text or any new proposal for the technical harmonisation of products in relation to the provisions of the NLF.
- Pursue the extension of the NLF to sectors other than the "new approach".