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NOTE TO THE EXPERT GROUP ON THE INTERNAL MARKET FOR PRODUCTS (IMP)

Title:	CERTIF 2013-11-REV1 – Time frames for notification of NBs following the entry into force of the Alignment Package		
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	<p style="text-align: center;">Abstract:</p> <p>The purpose of this paper is to inform Member States of the deadlines for transposition of the legislation in the Alignment Package, and to advise on how to ensure that the notification of notified bodies under the new legislation will be processed in good time.</p>		
Keywords:	Notified Bodies, NANDO, notification procedure, NLF, Alignment Package		
References:	Decision No 768/2008/EC on a common framework for the marketing of products		



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Time frames for notification of NBs following the entry into force of the Alignment Package

1. Transposition

- 1.1. The NLF Alignment Package involves recasting the existing directives, and Member States will have to transpose the new and modified provisions into their national laws within the time frame specified in the directives. For a full list of the directives, see point 2 below.
- 1.2. The deadline set for application of the directives in the Package is 20 April 2016. On this date, the old directives will be repealed and replaced by those of the Alignment Package.
- 1.3. The deadline for Directive 2013/53/EU of the European Parliament and of the Council of 20 November 2013 on recreational craft and personal watercraft and repealing Directive 94/25/EC is 18 January 2016.
- 1.4. The deadline for Directive 2013/29/EU of the European Parliament and of the Council of 12 June 2013 on the harmonisation of the laws of the Member States relating to the making available on the market of pyrotechnic articles (recast) is 1 July 2015.
- 1.5. The deadline for Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 99/5/EC is 12 June 2016.

2. List of aligned legislation

- 1) DIRECTIVE 2013/29/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 12 June 2013 on the harmonisation of the laws of the Member States relating to the making available on the market of pyrotechnic articles (recast)
- 2) DIRECTIVE 2013/53/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 20 November 2013 on recreational craft and personal watercraft and repealing Directive 94/25/EC
- 3) DIRECTIVE 2014/28/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 26 February 2014 on the harmonisation of the laws of

the Member States relating to the making available on the market and supervision of explosives for civil uses (recast)

- 4) DIRECTIVE 2014/29/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of simple pressure vessels (recast)
- 5) DIRECTIVE 2014/30/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility (recast)
- 6) DIRECTIVE 2014/31/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of non-automatic weighing instruments (recast)
- 7) DIRECTIVE 2014/32/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of measuring instruments (recast)
- 8) DIRECTIVE 2014/33/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 26 February 2014 on the harmonisation of the laws of the Member States relating to lifts and safety components for lifts (recast)
- 9) DIRECTIVE 2014/34/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 26 February 2014 on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres (recast)
- 10) DIRECTIVE 2014/53/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC

3. Notified Bodies

- 3.1. One of the objectives of the NLF is to improve the quality of notified bodies and the transparency of the assessment of their competence. New requirements are set out regarding the obligations on notified bodies and the procedure for their notification, including the introduction of an ‘objection period’ for each notification (see below). The new legislation will therefore require new notifications of all notified bodies.
- 3.2. In order to ensure that the notified bodies can be fully operational at the moment the directives begin to apply, the transitional period will allow for the notification of notified bodies before the transposition deadline. It will therefore be possible for a notifying authority to place a notification in NANDO as soon as that Member State has transposed the relevant legislative act into national law. A notified body may thus be notified under both the old and the new legislation during the transitional period, but the notification

under the old legislation will expire automatically on the date of application of the new legislation.

- 3.3. At the end of the transitional period, all lists of notified bodies for the old legislation will be removed from the ‘current’ to the ‘expired/withdrawn’ list on the NANDO web site. Only those notified bodies which are then notified under the aligned legislation will be authorised to operate.

4. Objection procedure

- 4.1. The notification process will have a new feature, namely the possibility for other Member States to formally object to a notification. For notifications based on accreditation the period for raising such objections is two weeks, whereas for notifications not based on accreditation the period is two months (reference provision R23.5 of Decision No 768/2008/EC).
- 4.2. The NANDO notification system (the restricted NANDO-Input part which is accessible only to the notifying authorities) has been set up to handle the objection procedure. The objection procedure is initiated by a ‘preliminary notification’ e-mail being sent from NANDO to the notifying authorities that are competent for the sectoral legislation concerned. At that point they can use the NANDO-Input facility to lodge an objection. Any objection received can be viewed by all the concerned notifying authorities.
- 4.3. A notification will only appear in the public part of NANDO at the moment of ‘final notification’, so that the objection procedure will be restricted to the notifying authorities, and not available as public information.

5. Requirements for notifying authorities

- 5.1. The new directives will introduce requirements for notifying authorities relating to their responsibilities in assessing, notifying and monitoring notified bodies (reference provision R14 of Decision No 768/2008/EC).
- 5.2. A further set of criteria seeks to guarantee the impartiality and to avoid conflicts of interest (reference provision R15 of Decision No 768/2008/EC).
- 5.3. Alignment will furthermore reinforce the notification requirements and introduce a number of information obligations for the notifying authorities (reference provisions R16 and R17 of Decision No 768/2008/EC).
- 5.4. The re-notification of notified bodies will require Member States to review all the existing notifications in the light of the new requirements. This will mean an increased workload for notifying authorities during the transitional period.
- 5.5. In order to avoid a backlog of pending notifications of notified bodies at the end of the transitional period, Member States are strongly advised to ensure early transposition of the legislation, and subsequent notification of notified bodies.**

- 5.6. Notifications should be sent to the Commission preferably 6 months - and at the very latest 2-3 months - before the deadline date, in order to take into account the objection procedure as well as the potential volumes of notifications to be processed in the time leading up to the end of the transitional period.

6. Requirement concerning notification procedures

- 6.1. The provisions in the aligned directives that incorporate those of Article R16 of Decision No 768/2008/EC will require that Member States “*inform the Commission of their procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, and of any changes thereto*”. The Commission must then make that information publicly available.
- 6.2. A template for providing this information was approved in the IMP meeting of 11 April 2013 (*Working document IMP N008*).
- 6.3. That template was subsequently incorporated in the NANDO system and is now available for Member States to encode their notification procedures directly using NANDO-Input.
- 6.4. Notifying authorities must send their notification procedures either before or at the same time as sending any notifications of notified bodies under a particular directive. A notification of a notified body cannot be published in NANDO unless the notification procedures for that directive are also present on the web site.
- 6.5. Once validated, they will be published on the NANDO website page of the notifying authority concerned.