



EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Single Market for goods

Internal Market for Goods and Market Surveillance

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

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| Title: | CERTIF 2015-01 REV2 – The functioning of NANDO with regard to providing accurate information, objection periods, notification procedures and notified bodies groups | | |
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| <u>Abstract:</u> | | | |
| This paper sets out the Commission position on the following issues concerning the functioning of NANDO: | | | |
| 1. Providing accurate information on notified bodies over time in NANDO | | | |
| 2. Notification under newly aligned legislation | | | |
| 3. How to manage the objection period for notification updates | | | |
| 4. Notification procedures in NANDO | | | |
| 5. Notified body participation in notified bodies groups | | | |
| Keywords: | Notified Bodies, notification, NANDO, aligned legislation, objection procedure, notification procedure, Notified body groups | | |
| References: | Regulation (EC) No. 765/2008, Decision 768/2008/EC | | |



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CERTIF 2015-01 – The functioning of NANDO with regard to providing accurate information, objection periods, notification procedures and notified bodies groups

1. PROVIDING ACCURATE INFORMATION OVER TIME

1.1. Objective

NANDO is an administrative facility made available by the Commission to the Member States for the notification and listing of their notified bodies. It is an informative tool, and full legal responsibility for the designation and notification rests with the Member States. Having said that, the Commission's obligation in this is to ensure that NANDO provides all stakeholders (economic operators and Member State authorities) with accurate information on the notified bodies which are competent to perform conformity assessment activities in each Directive and that the lists are kept up-to-date. This is not possible if there is a significant number of notifications with information that is either deficient or misleading.

A survey carried out in 2014 on the NANDO database revealed more than 800 notifications that had not been updated since before 2007. All of these notifications had been entered in the database with unlimited duration. Further to this, the Commission continues to receive a very large number of queries from users of the NANDO web site relating to the confusion caused by the divergence visible on the web site with regard to end-of-validity dates – some being limited to a specific cut-off date, some without any limit, and some with rather bizarre end-dates such as '31/12/2099', and pointing out that the standards referred to in some notifications are outdated - the 45000 series. (Examples of such notifications are annexed to this paper).

In addition to the above, the Commission has also received complaints from notified bodies themselves, and from their representative associations, that such divergence in the information available on NANDO creates distortion in the conformity assessment market, favouring notified bodies with notifications of unlimited duration in NANDO over those with a visible end-date.

In light of these considerations, the Commission proposes to take a pragmatic and practical approach to finding a solution to these issues.

It is essential to ensure that notified bodies remain competent over time and that this can be made transparent via NANDO to the Member States and the Commission. Regardless of the national regime in any particular Member State for the designation and notification of notified bodies (national implementing legislation), the

legislation at EU level clearly requires the national competent authorities to regularly monitor and assess the continuing competence of the bodies they have notified and that are listed in NANDO. The NANDO web site should be transparent for these ongoing processes that back up the notification system.

1.2. Adapting NANDO

The Commission endeavours to meet the needs of the Member States with regard to their task of notifying notified bodies by providing NANDO-Input for this purpose. It nevertheless has its own obligation with regard to notifications of notified bodies, which is to publish lists of notified bodies (on the NANDO web site) that provide up-to-date and accurate information relating to notified bodies to manufacturers and citizens who are the end-users of the NANDO web site. It also has the task of ensuring that the Member States fulfil their obligations with respect to the continuous monitoring of the competence of the notified bodies they notify.

With regard to the question of how long information published in NANDO can be deemed reliable, the Commission proposes the following approach:

- (1) All notifications of notified bodies, whether accredited or unaccredited, that are entered in the NANDO database, will have a 'review' date set in NANDO of maximum five years, in line with the normal accreditation cycle and with the requirement on notifying authorities to ensure the continuous monitoring of notified bodies [e.g. Article R14 of Decision 768/2008/EC].
- (2) The review date inserted by the notifying authority will remain internal in the database and will not appear on the web page.
- (3) The review date will itself generate an automatic email to be sent to the notifying authority at a 6-, 3- and 1 month interval prior to that date, to alert the authority that the notification needs to be extended in NANDO. This will allow adequate time for the notification to be updated before the review date.
- (4) If by that date the notification is not updated with the relevant new data – relating to accreditation or other if the notification is unaccredited (in particular, a report concerning the assessment process i.e. document review, on-site assessment, systematic surveillance including on-site visits and demonstration of the authority's technical competence to conduct the assessment) – it will be highlighted on the web site to indicate that the information regarding the continued competence of the NB has not been provided by the notifying authority.
- (5) A notification will be sent from the Commission to the notifying authority indicating that it has reason to question the continued competence of the notified body according to Article R26 of Decision 768/2008/EC, and that the notifying Member State has to provide the Commission with all information relating to the maintenance of the competence of the body concerned.

2. NOTIFICATION UNDER ALIGNED LEGISLATION

With the entry into application during 2015 of 1 new directive and during 2016 of 12 new directives that are aligned to Decision 768/2008/EC (list given at the bottom of this document), the notification procedure in NANDO should be streamlined to ensure that the information on the NANDO web site is clear, up-to-date and sufficiently transparent, as set out below. Directive 2009/48/EC on the Safety of Toys, Directive 2010/35/EU on Transportable Pressure Equipment, and Regulation (EU) 305/2011 laying down harmonised conditions for the marketing of construction products, being aligned to Decision 768/2008/EC, are also subject to the procedure described below.

The alignment of technical harmonisation legislation to Decision 768/2008/EC raises some questions with regard specifically to the notification of notified bodies and to some new elements in the notification procedure, such as the objection period (Article R23 of Decision 768/2008/EC), the requirement for the notifying authority notification procedures relating to a particular directive to be published (Article R16), and the obligation on notified bodies to participate in their respective notified body groups (Article R30).

The national notifying authorities will be able to place a notification in NANDO as soon as that Member State has transposed the relevant legislative act into national law, so as to ensure that the notified bodies can be fully operational at the moment the directives begin to apply. A notified body may thus be notified under both the old and the new legislation during a transitional period (from the transposition of the new Directive into national law until the date the Directive starts applying), but the notification under the old legislation will expire automatically on the date of application of the new legislation.

Article 48 of Directive 2014/53/EU on Radio Equipment states that:

“Member States shall not impede, for the aspects covered by this Directive, the making available on the market or putting into service of radio equipment covered by this Directive which is in conformity with the relevant Union harmonisation legislation applicable before 13 June 2016 and which was placed on the market before 13 June 2017.”

Directive 99/5/EC will thus remain applicable during the transitional period. Consequently, the lists of notified bodies notified under Directive 99/5/EC will remain on the NANDO web site until 13 June 2017.

Similarly, Directive 2013/53/EU on Recreational Craft and Personal Watercraft has a transitional period until 18 January 2017, so the list of notified bodies notified under Recreational Craft Directive 94/25/EC will remain on the NANDO web site until that date.

2.1. The objection procedure

A new notification in NANDO – whether a first-time notification of a notified body or a first-time notification of an existing notified body under a particular directive – will always involve the objection period. But when a notification is updated in NANDO, how and when will the objection period apply?

How will the objection procedure for notifications be handled in the following cases of notification updates, and extensions?

- a. The notified body changes from being accredited to not accredited, or vice versa: the notification is treated with the same procedure as a new notification, and so is subject to the objection period.
- b. The scope of the notification is extended: the notification for the extended scope is treated with the same procedure as a new notification, and so is subject to the objection period.
- c. The scope of the notification is restricted: the notification is treated as a 'notification update', and the objection period is by-passed.
- d. The update is to upload new accreditation or supporting documents only when the reassessment is due: the notification is treated as a 'notification update', and the objection period is by-passed.
- e. Termination of a suspension of a notification: the notification is treated as a 'notification update', and the objection period is by-passed.

For those updates where there is an extension in time only, if the Commission doubts that the notified body remains competent, or doubt is brought to its attention based on the supporting documentation provided, the procedure set out in Article R26 of Decision 768/2008/EC will apply and, if this is considered justified, the Commission may request the notifying authority to withdraw that notification.

For unaligned legislation, the provisions of Article 5 of Regulation (EC) No. 765/2008 apply. As agreed in *CERTIF 2010-06 Notifications of Notified Bodies in NANDO – requirements of Regulation 765/2008 and Decision 768/2008*, the timeframes for objections are the same as for aligned legislation. The same approach is suggested for the specific scenarios above, when there are changes to notifications.

2.2. Notification procedures

Article R16 of Decision 768/2008/EC requires the notify authorities to '...inform the Commission of their procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, and any changes thereto.'

The NANDO-Input notification tool allows the notification procedures to be uploaded directly in the database, in a manner similar to uploading the notified body notifications. The procedures are subsequently published on the web site within the page dedicated to the notifying authority concerned.

The procedures must be uploaded in NANDO ahead of or along with the first notified body notification under any new legislation.

2.3. Participation in notified bodies groups

Article R30 of Decision 768/2008/EC stipulates that ‘Member States shall ensure that the bodies notified by them participate in the work of that or those group or groups, directly or by means of designated representatives.’

All notifications submitted in NANDO for bodies that are already notified must indicate, by filling in the appropriate section, that the notified body being notified fulfils this requirement. For bodies being notified for the first time, it should be indicated that the body has undertaken to apply for membership of the coordination group, either directly or by means of designated representatives, as soon as it becomes a notified body.

Notified bodies are obliged to participate in meetings at European level unless they keep themselves informed of the activities of the coordination group, and apply the administrative decisions and documents produced by their group. The relevant working documents, meeting reports, recommendations and guidelines produced by the sectoral and inter-sectoral groups of notified bodies or their subgroups should be made available to all notified bodies forming part of those groups, whether they have taken part in the meetings or not. The information exchange and communication can be enhanced by use of a platform such as CIRCABC, hosted by the Commission.

3. REQUIREMENTS OF REGULATION 920/2013/EU CONCERNING NOTIFIED BODIES UNDER MEDICAL DEVICES LEGISLATION

As the Directives on Medical Devices – Directive 90/385/EEC on Active implantable medical devices, Directive 93/42/EEC on Medical devices and Directive 98/79/EC on In vitro diagnostic medical devices - have not been aligned with Decision 768/2008/EC, the provisions of this Decision do not apply in the medical devices sector.

However, specific legislation has been adopted in the field of active implantable medical devices and medical devices (Commission Implementing Regulation (EU) 920/2013 on the designation and the supervision of notified bodies) which prescribes detailed rules for the designation of notified bodies (including a procedure of consultation of the Member States) and for the extension and renewal of designations.

4. LIST OF ALIGNED LEGISLATION

- **DIRECTIVE 2009/48/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 June 2009 on the safety of toys**
- **DIRECTIVE 2010/35/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 June 2010 on transportable pressure equipment and repealing Council Directives 76/767/EEC, 84/525/EEC, 84/526/EEC, 84/527/EEC and 1999/36/EC**

- REGULATION (EU) No 305/2011 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC
- 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)
- 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
- 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)
- 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)
- 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)
- 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)
- 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)
- 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)
- 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)
- DIRECTIVE 2014/35/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 electrical equipment designed for use within certain voltage limits

- 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
- DIRECTIVE 2014/68/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 May 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment (recast)
- DIRECTIVE 2014/90/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 23 July 2014 on marine equipment and repealing Council Directive 96/98/EC

5. LIST OF UNALIGNED LEGISLATION

- COUNCIL DIRECTIVE of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment
- COUNCIL DIRECTIVE of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices
- COUNCIL DIRECTIVE 92 / 42 / EEC of 21 May 1992 on efficiency requirements for new hot-water boilers fired with liquid or gaseous fuels
- COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices
- DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on in vitro diagnostic medical devices
- DIRECTIVE 2000/9/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 20 March 2000 relating to cableway installations designed to carry persons
- DIRECTIVE 2000/14/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 8 May 2000 on the approximation of the laws of the Member States relating to the noise emission in the environment by equipment for use outdoors
- REGULATION (EC) No 552/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 10 March 2004 on the interoperability of the European Air Traffic Management network
- DIRECTIVE 2006/42/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 17 May 2006 on machinery, and amending Directive 95/16/EC (recast)
- DIRECTIVE 2008/57/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 17 June 2008 on the interoperability of the rail system within the Community (Recast)

- DIRECTIVE 2009/142/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 relating to appliances burning gaseous fuels
- COMMISSION DECISION of 6 October 2009 on the definition of the European Electronic Toll Service and its technical elements