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## **Notifications of Notified Bodies in NANDO – requirements of Regulation 765/2008 and Decision 768/2008**

### **1. Introduction**

The New Legislative Framework (NLF) - comprising Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008, and Decision 768/2008/EC of the European Parliament and of the Council of 9 July 2008 - sets out the criteria to be used in designating and notifying conformity assessment bodies. The Regulation entered into force on 1 January 2010. The provisions of the Decision will be legally binding on all Member States once integrated into sector-specific directives. However, Member States are free to use these provisions immediately in selecting the conformity assessment bodies they want to notify.

To meet the requirements of the NLF, the NANDO database has been updated with new features to bring it into line with the relevant provisions of both the Regulation and the Decision. Whereas the provisions of the Regulation are already in force, those of the Decision are only so when aligned Community sectoral legislation enters into force. The first instance of this is the Toys Directive (2009/48/EC). The Commission has to ensure that the requirements of both instruments are met, and this paper outlines the practical implications for doing so in NANDO.

### **2. Implementing the requirements of Regulation 765/2008 and Decision 768/2008 in relation to notified bodies in NANDO**

#### ***2.1. Functioning of the NANDO system since January 2010 to take account of Decision 768/2008***

The Commission provides the NANDO system as a practical solution to enable Member States to meet their obligations relating to notifications of conformity assessment bodies. NANDO has recently been updated to allow for the provisions of Decision 768/2008 to be taken into account in notifications, as described in paragraph 1 above. The following changes have been implemented in the NANDO system since January 2010:

- The notification e-mails are no longer communicated to the Member States via the Permanent Representations, but are sent directly to the notifying authorities. They are filtered according to the directive(s) under the responsibility of the NA (except for notifications relating to details of the organisation – address, etc. – which cannot be so filtered). This change is required to (eventually) enable the MS to lodge an objection to a notification using NANDO-Input.
- There is now a clear differentiation in the information to be submitted with regard to whether a NB is accredited or not.
- Where accreditation is not used to assess the competence of the NB, supporting documentation is requested that describes how the NB has been assessed as qualified to carry out the tasks for which it is notified, and shows that it fulfils the criteria relating to NBs. NANDO has been updated to allow for the uploading of this documentation, in PDF format.
- Questions concerning sub-contracting and membership of a NB coordination group have to be answered (for all NBs) as part of the encoding of a notification in NANDO.
- A list of the national accreditation bodies (NABs) is now published on the public web site (details of scopes and MLA signatory status are restricted to the NANDO-Input part of the database).

Article R23.5 of Decision 768/2008 stipulates that *“The body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two weeks of a notification where an accreditation certificate is used or within two months of a notification where accreditation is not used.”*

The NANDO system is now set up to allow, in time, for the procedure whereby the MS can lodge an objection to a notification within a specified time limit (2 weeks for accredited NBs, 2 months for non-accredited). This facility will not be used until the entry into force of aligned legislation. It will involve a ‘Preliminary notification’ e-mail being sent to the MS, which will open to the recipients of this e-mail the data in NANDO-Input relating to that notification. This will include, in the case of a non-accredited NB, the documentation sent in support of the notification. The information will remain open to the receiving NAs only for the period allowed – 2 weeks or 2 months. If no objection is lodged within this period, the notification will be published on the NANDO web site, and a ‘Final notification’ e-mail will be sent to the MS. If an objection is lodged, then the notification will be suspended until such time as the matter is resolved between the notifying MS, the objecting MS, with input from the Commission.

## ***2.2. Satisfying the requirements of Regulation Article 5.2 pending full implementation of Decision 768/2008***

Article 5.2 of Regulation 765/2008 stipulates that *“When a Member State decides not to use accreditation, it shall provide the Commission and the other Member States with all the documentary evidence necessary for the verification of the competence of the conformity assessment bodies it selects for the implementation of the Community harmonisation legislation in question”*.

This article imposes a clear obligation on Member States to ensure that documentation in support of a notification of a NB that is not accredited is made available to all the Member States in connection with that notification. Until the provisions of the Decision, particularly Article R23.5 relating to the objection procedure, are fully implemented by way of aligned legislation, there is a need for a mechanism to communicate the documentation in support of non-accredited notifications from NANDO to the MS, to be in line with Article 5.2 of the Regulation.

NANDO is already set up to receive and store the documentation for all non-accredited notifications. So, for notifications where the objection procedure cannot be used, the following procedure is proposed as a way to fulfill the requirements of Article 5.2 in cases of such notifications:

- When a draft notification (accredited or non-accredited) is received by the Commission via NANDO-Input, the Commission will forward a copy of the draft notification (in PDF format) by e-mail to those MS notifying authorities that would normally receive the notification – that is, those NAs with responsibility for the directive concerned by the notification in question.
- If the notification involves supporting documentation (if accreditation has not been used) it will be forwarded with the e-mail sent to the NA. Such documentation will generally be available in the language of the notifying MS.
- A two-week period is suggested for comments to be sent back to the Commission (by e-mail), before the notification is published in NANDO. This period could be longer for notifications not based on accreditation that have documentation attached.
- The procedure will apply to new notifications, that is, NBs notified for the first time, and existing NBs notified for the first time under a particular directive. It will also apply to notifications of extensions of scope to existing notifications, and to NBs being re-notified after having had their notification previously withdrawn.

### **3. Conclusion**

While the requirements of Article 5.2 of Regulation 765/2008 must be immediately implemented, those of Decision 768/2008, in particular Article R23.5 relating to objections by Member States, must await the entry into force of legislation that is aligned to the Decision. The purpose of the provisions of the NLF is to allow greater transparency in the notification process, and tighter scrutiny of notifications of NBs. The Commission proposes the procedures outlined above, using NANDO as a way of fulfilling the obligations imposed by Regulation 765/2008 while at the same time allowing for those of Decision 768/2008 to be imposed in a more gradual way, until such time as the Decision is more fully in force through the sectoral legislation.