Rialtas na hÉireann
Government of Ireland

Procedure for the appointment of a Notified Body

Department of Enterprise, Trade and Employment
October 2021

1 Application Process

Applications for Notified Body status should be made to the Department as the Notifying Authority for the directives set out in Appendix 1 using the Application Form in Appendix 2. These prospective Notified Bodies must seek accreditation from INAB before the

Department can make an assessment as the Notifying Authority. Once INAB has decided on the accreditation application the Department will then consider the merits of the applicant as a candidate for Notified Body status. No formal application from a prospective Notified Body should be accepted without being accompanied by the appropriate accreditation from INAB.

The application to the Department should be accompanied by the following:

- Proof of the applicant's legal establishment in Ireland
- A description of the activities to be performed by the applicant, related to conformity assessment, periodic inspection, intermediate inspection, exceptional checks or reassessment of conformity
- The procedures relating to the activities for which the applicant claims to be competent
- The products (by reference to harmonised European standards) for which the applicant wishes to be notified
- An accreditation certificate and schedule, issued by INAB, attesting that the applicant meets the requirements laid down in the relevant directive(s). The scope of accreditation should match the scope of notification sought • A current Tax Clearance Certificate
- Proof of insurance cover.

Any further assessment of a prospective Notified Body can be decided on a case by case basis. Such additional assessment criteria may take into account advice from competent authorities, market surveillance authorities, other Member States or bodies such as An Garda Síochana.

As applications are subject to Ministerial approval, once the Minister is satisfied that the applicant, within the scope identified, is fit for notification for the purpose of the relevant directives, correspondence will issue outlining details of notification, stipulating the scope of notification and the conditions for operating as a Notified Body. Such conditions may include, but are not limited to, the following:

- Agreement to comply with the operational obligations of Notified Bodies, to carry out conformity assessment, periodic inspection, intermediate inspection, exceptional checks and reassessment of conformity
- Agreement to comply with the information obligations of Notified Bodies (see Section 4)
- Agreement to participate in co-ordination activities at both Irish and European levels, including the work and activities of the coordinating group of Notified Bodies (see Section 4)
- The requirement for surveillance, annually, or at whatever intervals are thought appropriate by the Department, and
- The requirement for a full reassessment, every 5 years, or at whatever intervals are thought appropriate by the Department.

A list of recommended or preferred harmonised standards will be drawn up for each directive under the Department's responsibility and prospective Notified Bodies will be accredited according to the particular harmonised standard(s) for the relevant directive. The ultimate reference for which harmonised standard(s) should be used for each directive will be the European Accreditation Document on Accreditation for Notification Purposes .

Following receipt of acceptance on the conditions of notification, the Department will notify the European Commission and the other Member States by publishing details on NANDO (the information system developed and managed by the European Commission).

A two week period is allowed for the European Commission or other Member States to raise an objection to the proposed notification. At the end of the two week period and subject to no objections being raised, the applicant will be considered a Notified Body for the particular directive(s), and will be issued with a unique notified body number to be used as the official identification of that notified body.

2. Accreditation

Bodies seeking to be notified for the purpose of the stated directives in Appendix 1 should apply to INAB for accreditation.

INAB will undertake an assessment of the applicant against the relevant harmonised European accreditation standard(s) to ensure that the applicant complies with the requirements of the relevant directive(s) and has the necessary product knowledge and capability to carry out the proposed activities. The scope of accreditation (and notification) will be determined by reference to the harmonised European standards and systems specified in the application. All applicants will need to be able to demonstrate their professional ability and a necessary level of understanding of both the relevant directives and relevant harmonised European standards.

Applications should be submitted directly to INAB and full details of the accreditation process are available from the INAB website at www.inab.ie

Simultaneous to the submission of its application for accreditation to INAB, the applicant should also send a copy to the Department (as the notifying authority).

Once INAB has completed its assessment and accreditation, it will issue an accreditation certificate and schedule to the prospective Notified Body. The applicant should then submit this certificate and schedule as part of the application for notified body status to the Department.

3 Monitoring of Notified Bodies

Reassessment and surveillance will be carried out by INAB in line with usual accreditation practice. A report on all reassessment and surveillance should be sent to the Department by the Notified Body. This report should be accompanied by all relevant documentation.

INAB will advise the Department of the outcome of each annual surveillance, 5 yearly reassessment and any other necessary monitoring in the intervening period and any implications for notification.

The Department may request further information about the reassessment and surveillance activities, as required.

4 Information Obligations

Notified Bodies shall agree to keep the Notifying Authority informed of the following:

- Any refusal, restriction, suspension or withdrawal of the conformity of a product issued under the scope of notification
- Any circumstances affecting the scope of and conditions for the notification
- On request, of all activities performed both within and outside the scope of the notification, including subcontracted tasks and cross border activities
- Any requests for information received from market surveillance authorities

Notified Bodies shall agree to provide relevant information relating to conformity assessment and inspection results to other Notified Bodies carrying out activities on the same product.

Notified Bodies will be requested to agree to participate, either directly or by a designated representative, in the work of a coordinating group of Notified Bodies established under the relevant directive(s).

Notified Bodies will, in addition, be requested to agree to participate in the activities of the coordination group and/or ensure that its assessment personnel are kept informed and apply the relevant guidance and standardisation procedures arising from the work of the group.

5 Insurance

In accordance with Article R17(9) of Decision 768/2008/EC of the European Parliament and of the Council on a common framework for the marketing of products, all applicants will be required to demonstrate that they have adequate public and professional indemnity insurance for the activities they wish to carry out. Evidence of this should be submitted to the Department at the point at which an application to be notified is made. Applicants will be required to show that indemnity insurance is kept up to date for the period covering the appointment as a Notified Body.

Such cover should extend to the whole of the European Union, the EEA, or, if the applicant intends to carry out work outside these areas, world-wide. The Department will not in relation to any case or circumstance cover a notified body's liability.

6 Appeals Procedure

Any prospective Notified Body may appeal a decision of the Minister, acting as a Notifying Authority. The Irish legislation transposing each of the directives in Appendix 1 allows an appeal to the Minister and the Minister will then set up an appeals panel of between 3 and 5 people to decide on the merits of such an appeal.

Appendix 1

LIST OF EU LEGISLATION FOR WHICH THE DEPARTMENT IS THE NOTIFYING AUTHORITY

Directive	***Contact Details***
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)[1]	Safety, Health and Chemicals Policy Unit, Department of Enterprise, Trade and Employment, Earlsfort Centre, Lower Hatch Street, Dublin 2, D02 PW01 Ireland Email: healthandsafetypolicy@enterprise.gov.ie
Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys.[2]	Product Safety Section Department of Enterprise, Trade and Employment Earlsfort Centre Lower Hatch Street Dublin 2, D02 PW01 Ireland Email: conspol@enterprise.gov.ie

[1]:OJ L.157, 09.06.2006, p. 24
[2]OJ L 170, 30.6.2009, p. 1

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[3]	Safety, Health and Chemicals Policy Unit, Department of Enterprise, Trade and Employment, Earlsfort Centre, Lower Hatch Street, Dublin 2, D02 PW01 Ireland Email: healthandsafetypolicy@enterprise.gov.ie
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[4]	Product Safety Section Department of Enterprise, Trade and Employment Earlsfort Centre Lower Hatch Street Dublin 2, D02 PW01 Ireland Email: conspol@enterprise.gov.ie

[3] OJ L 165, 30.6.2010, p. 1
[4] OJ L 96, 29.3.2014, p. 45

Directive 2014/31/EU (ex-2009/23/EC) 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[5] **NOTE:** For 2014/31/EU, accreditation to EN ISO/IEC 17020 (inspection) is preferred by DETE for conformity assessment to module F rather than EN ISO/IEC 17065 (product).	NSAI Liaison Unit Department of Enterprise, Trade and Employment 23 Kildare Street, Dublin 2 D02 TD30 Ireland Email: NSAIliaison@enterprise.gov.ie
Directive 2014/32/EU (ex-2004/22/EC) 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) [6] **NOTE:** For 2014/32/EU, accreditation to EN ISO/IEC 17020 (inspection) is preferred by DETE for conformity assessment to module F rather than EN ISO/IEC 17065 (product).	NSAI Liaison Unit Department of Enterprise, Trade and Employment 23 Kildare Street, Dublin 2 D02 TD30 Ireland Email: NSAIliaison@enterprise.gov.ie

[5] OJ L 96, 29.3.2014, p. 107
[6] OJ L 96, 29.3.2014, p. 149

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[7]	Safety, Health and Chemicals Policy Unit, Department of Enterprise, Trade and Employment, Earlsfort Centre, Lower Hatch Street, Dublin 2, D02 PW01 Ireland Email: healthandsafetypolicy@enterprise.gov.ie
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)[8]	Safety, Health and Chemicals Policy Unit, Department of Enterprise, Trade and Employment, Earlsfort Centre, Lower Hatch Street, Dublin 2, D02 PW01 Ireland Email: healthandsafetypolicy@enterprise.gov.ie

[7] OJ L 96, 29.3.2014, p. 251
[8] OJ L 96, 29.3.2014, p. 309

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)[9]	Safety, Health and Chemicals Policy Unit, Department of Enterprise, Trade and Employment, Earlsfort Centre, Lower Hatch Street, Dublin 2, D02 PW01 Ireland Email: healthandsafetypolicy@enterprise.gov.ie
Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council Text with EEA relevance[10]	NSAI Liaison Unit Department of Enterprise, Trade and Employment 23 Kildare Street, Dublin 2 D02 TD30 Ireland Email: NSAILiaison@enterprise.gov.ie

[9] OJ L 189, 27.6.2014, p. 164
[10] OJ L 316, 14.11.2012, p. 12

Regulation (EU) 425/2016 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC[11]	Safety, Health and Chemicals Policy Unit, Department of Enterprise, Trade and Employment, Earlsfort Centre, Lower Hatch Street, Dublin 2, D02 PW01 Ireland Email: healthandsafetypolicy@enterprise.gov.ie
Regulation (EU) 426/2016 of the European Parliament and of the Council of 9 March 2016 on appliances burning gaseous fuels and repealing Directive 2009/142/EC.[12]	Product Safety Section Department of Enterprise, Trade and Employment Earlsfort Centre Lower Hatch Street Dublin 2, D02 PW01 Ireland Email: conspol@enterprise.gov.ie

[11] OJ L 81, 31.3.2016, p. 51
[12] OJ L 81, 31.3.2016, p. 99

Appendix 2

APPLICATION FOR NOTIFICATION

1. Please complete the details in the following tables and post or email the form to the relevant Unit (see Appendix 1) of the Department of Enterprise, Trade and Employment:
Table 1

Company Name	
Address	
Telephone	
Website	
Contact Name	
Title	
Telephone	
Email	

2. Please indicate in Table 2 the activities for which the applicant is applying for Notified Body status in accordance with the relevant directive(s).
Table 2

		Tick as appropriate
Appropriate Directive	Conformity assessment:	
	• type approval	
	• supervision of manufacture	
	• initial inspection and test	
	Periodic inspection	
	Intermediate inspection	
	Exceptional checks	
	Reassessment of conformity	

3. Please attach proof of the company's legal status in Ireland.
(Complete questionnaire at Appendix 3 to assist)

4. Please provide the information in Table 3 and attach any other relevant information on separate sheets.
Table 3

Please list all products for which competency is claimed, along with relevant standards as listed in European Accreditation Document on Accreditation for Notification Purposes[13]:
Please provide a description of activities related to conformity assessment, periodic inspection, intermediate inspection, exceptional checks or reassessment of conformity:
Please provide references for the procedures relating to the activities listed above:

[13] ea-2-17

5. Provide a copy of the accreditation certificate and schedule to the relevant unit in the Department of Enterprise, Trade and Employment:

☐ I confirm that the information I have provided is correct.

Signed :

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Dated :

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Appendix 3

COMPANY ESTABLISHMENT IN IRELAND QUESTIONNAIRE

Company Details:		
Phone:		
Email:		
Application for Appointment as	Notified Body:	☐
	Conformity Assessment Body:	☐
	Other: Please give further details:	☐
Applicable EU Directive(s)/ Regulation (s):		

Please provide answers to the following questions:	
1. Is your company established in Ireland?	YES / NO
2. Does your company have premises in Ireland?	YES / NO
3. What activities relating to this appointment will take place in Ireland?	(Provide Details)
4. What activities relating to this appointment will take place in another State?	(Provide Details)
5. Is your company a subsidiary of a company established outside Ireland?	YES / NO

6. If so, can you give details of the contractual relationship between the two companies, including details of where the Head Office is established?	
7. Will the company established in Ireland be responsible for all aspects of conformity assessment?	YES /NO
8. If not, please detail which aspects will be the responsibility of the company established in Ireland and which aspects will be the responsibility of a company, or companies, outside Ireland?	
9. Please give details of the degree of technical competence available in the Irish company.	

10. Please also give full details of the level of activities that the Irish company will engage in	
11. Please give full details of what aspects of the business is relocating to Ireland?	
12. Will your company outsource any of the operations pertinent to your business?	YES / NO
13. If so where will the operations be outsourced and how will this outsourcing be managed by the Irish company?	

14. How many members of senior management will be located in Ireland?	
15. How many current members of staff will be located in Ireland?	
16. Will employees be permanently based in Ireland, seconded to Ireland or employed on a contract for services basis?	YES / NO (Please give a full breakdown)
17. Does your company currently provide assessment services in Ireland?	

18. Can you provide documentary proof that your company is incorporated in Ireland?	YES / NO (Enclose documents)
19. Will the Irish company's board meetings take place in Ireland?	YES / NO
20. Will other key meetings take place in Ireland?	YES / NO (Please give details.)

Signed :

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Dated :

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Please return all completed documents to relevant Unit (see Appendix 1) in Department of Enterprise, Trade and Employment: