www.defra.gov.uk

Sheep & Goat EID
Approval Process & Requirements

defra
Department for Environment
Food and Rural Affairs

Sheep & Goat EID
Approval Process & Requirements

Author: Andrew Gray (FFG, Livestock and Livestock Products Hub)

Owner: Andrew Gray / Terry Gurnhill (FFG, Livestock and Livestock Products Hub)

File Reference: TBA

Version: 3.1

Approved By: Andrew Bishop (FFG, Livestock and Livestock Products Hub)

Date: 19 May 2010

DOCUMENT CHANGE CONTROL

Status	Date Issued	Description / Reason for change
0.1	17/10/2008	1st draft for review
0.2	24/10/2008	2nd draft incorporating amendments
0.3	04/11/2008	3rd draft updating costs
1.0	04/11/2008	Paper approved as version 1.0
1.1	17/02/2009	Update, following revised costs, proposed changes to approval process & additions to permitted identifiers
1.2	19/02/2009	Update, incorporating comments received on version 1.1
1.3	23/02/2009	Update, incorporating comments from Tag Suppliers Meeting of 23/02/2009
1.4	24/03/2009	Update, incorporating comments from Sheep EID Co-ordination Group Meeting of 18/03/2009
1.5	20/05/2009	Update, referencing publication of ISO 24631
2.0	01/06/2009	Paper approved as version 2.0
2.1	08/07/2009	Update, incorporating comments from Sheep EID Co-ordination Group Meeting of 17/06/2009 & Tag Suppliers Meeting of 02/07/2009
3.0	16/07/2009	Paper approved as version 3.0
3.1	19/05/2010	Update, following amendment to Commission Decision 2006/968 & comments from tag suppliers

Distribution			
Name	**Contributor**	**Reviewer**	**Approver**
Andrew Bishop (FFG)		X	X
Terry Gurnhill (FFG)		X	X
Pat Brophy (FFG)		X	
Susan Warner (FFG)		X	
Sue Mellor (RPA)		X	
Karen Corby (RPA)		X	
Sunny Dermott (RPA)		X	
EID Co-ordination Board members		X	

Related Products / Documents		
Title	**Version**	**Location**
Pasterns Options Paper	0.3	

Contents

1 INTRODUCTION 5
2 BACKGROUND 5
2.1 TRANSPONDERS 5
2.2 READERS 6
3 PROCESSES 6
3.1 ICAR APPROVAL 6
3.1.1 Transponders *6*
3.1.2 Readers *7*
3.2 EID APPROVAL 7
3.2.1 Transponders *7*
3.2.2 Readers *7*
3.3 PAS 66 APPROVAL 8
3.4 FINAL UK APPROVAL 8
4 ROLES & RESPONSIBILITIES 9
5 CONCLUSION 10
ANNEX A – OUTLINE APPROVAL PROCESSES 11
ANNEX B – ROLES IN APPROVAL PROCESS 13

1 Introduction

Regulation (EC) 21/2004 sets out the requirements for EID equipment accreditation and approval. This paper sets out an outline process for the testing and approval of EID equipment, in order to meet these requirements. It also sets out an outline of the roles and responsibilities for this approval work. An emphasis has been placed on the impact on and role of RPA, as they act on behalf of the GB Competent Authority (i.e. Defra and devolved administrations of Scotland and Wales) in the EID approvals process. For Northern Ireland, DARD undertakes this role.

2 Background

There are a number of pieces of legislation/regulation which impact on the requirements for EID testing and approval. These are listed below:

- Regulation (EC) 21/2004 as amended by Council Regulations 1791/2002, 1560/2007 and 933/2008.
- EID Technical Guidelines
- Commission Decision (2010/280/EU) of 12 May 2010, amending Commission Decision 2006/968
- ISO 11784 & 11785
- PAS 66
- ISO 24631
- ISO 17025

These documents have been used as the basis for establishing the processes described later in this paper.

2.1 Transponders

An ISO standard – ISO 24631: Radio Frequency of Animals - confirms the formal agreement between ISO and ICAR for the appointment of ICAR as Registration Authority (RA) and sets out procedures for testing transceivers and transponders against ISO 11784/5. It also covers how to apply for a manufacturer code and sets out standards for representation of the animal identification information (i.e. visual display and data transfer).

Commission Decision (2010/280/EU) of 12 May 2010, amending Commission Decision 2006/968 also allows for the Competent Authority to apply other performance criteria for identifiers, should they see fit.

Regulation (EC) 933/2008 allows for the use of pastern marks and injectable transponders as identification devices. However, the EID Technical Guidelines currently only reference electronic ear tags, boluses and injectable transponders, ruling out injectables until specific problems have been resolved. The Guidelines will need to be revised to take account of this change to the Regulation. The Sheep EID Co-ordination Board has agreed that pasterns (both electronic and conventional) should be considered as a means of identification in the UK, but have rejected

injectables for the time being. A separate options paper is being drawn up in relation to pasterns, but for the purposes of this paper, they should be considered as one of the permitted identifiers.

2.2 Readers

The Commission has stated that there is no regulatory requirement for readers to receive specific approval from a Competent Authority. However, at the UK EID Project Board of 11 May 2009, it was agreed that, given the concerns about equipment reliability, the UK would include a requirement in legislation for readers to be approved. The UK EID Project Board also confirmed that tests provided for in Chapter III of Commission Decision 2006/968 would apply. This should give UK keepers confidence in the equipment and provide assurances that readers meet the standards necessary to operate under UK farming conditions. It should also be borne in mind that readers will need to have met all the required non-EID standard testing and approvals, e.g. CE testing procedures, for this type of equipment before being submitted for the EID certification process. Additionally, it was agreed at a Tag Suppliers meeting, held on 23 February 2009, to include the standards encompassed in Part 6 of ISO 24631, relating to the display format, in the requirements for EID reader certification. This part of the new standard is not yet published, but its contents are not contentious and suppliers are broadly content with these specific requirements.

3 Processes

There are a number of stages that EID equipment needs to progress through before full approval. Chapter II of Commission Decision (2010/280/EU) of 12 May 2010, amending Commission Decision 2006/968 sets out the requirements for transponders and Chapter III sets out the requirements for readers. These are set out in more detail below

3.1 ICAR Approval

3.1.1 Transponders

Certification must be supplied which confirms compliance with ISO standards 11784 and 11785 in accordance with the method specified in point 7 of ISO 24631-1, and achievement of minimum performance on reading distances, as laid down in point 2, in accordance with the procedures specified in point 7 of ISO 24631-3. The testing can be carried out by any laboratory which meets the appropriate ISO standards (17025). Full ICAR testing and provision of product/manufacturer code is optional. However, if the transponder is intended for sale elsewhere than in the UK, it is likely that full ICAR testing will be required but the supplier should check with the appropriate CA.

If testing is carried out by an ICAR-approved laboratory[1], this gives the manufacturer/supplier the option of using the transponder with either a country code or product/manufacturer code.

3.1.2 Readers

There are no regulatory requirements for readers to receive specific approval under Regulation 21/2004 and Commission Decision (2010/280/EU) of 12 May 2010, amending Commission Decision 2006/968. However, Competent Authorities may impose specific performance criteria on readers if deemed necessary for local geographic, climatic and/or management conditions. The UK has deemed this certification to be required and further details are set out in paragraph 3.2.2 below.

3.2 EID Approval

3.2.1 Transponders

In accordance with Commission Decision (2010/280/EU) of 12 May 2010, amending Commission Decision 2006/968, Chapter II, point 4, Competent Authorities may also require additional tests in accordance with Part 2 of the EU Technical Guidelines. The UK will require all transponders approved for use in the UK to meet the additional tests for robustness and endurance in Part 2 of the JRC Technical Guidelines. The testing can be carried out by any laboratory which meets the appropriate ISO standards (17025). Currently, the JRC is designated as the UK test laboratory for EID testing, although other laboratories may put themselves forward as designated EID test laboratories in the future.

3.2.2 Readers

In accordance with Commission Decision (2010/280/EU) of 12 May 2010, amending Commission Decision 2006/968, Chapter III, the UK may require specific performance criteria, if deemed necessary for local geographic, climatic and/or management conditions. The UK will require readers to comply with the additional requirements as laid out in Part 2 of the Technical Guidelines (paragraph 3.6). Whilst this does not preclude readers not meeting these requirements being sold and used in the UK, only those readers with certification proving they meet these requirements will be listed on the RPA website.

Additionally, the requirements for reader display format set out under draft ISO 24631-6 will need to be met. Including this requirement will help to ‘future-proof’ reader certification. This will ensure readers will already meet the requirements and will not require re-testing at some point in the future. This only applies to readers used for official EID use. Readers used only for farm management use do not need to meet this specific requirement, although it will be up to the individual keeper or organisation involved to decide whether they submit such equipment for this testing voluntarily.

[1] ICAR-approved test centres are based at: IMA Wageningen, Netherlands; JRC, Ispra, Italy; CETIM, Nantes, France

3.3 PAS 66 Approval

This stage relates specifically to UK approval of ear tags and can be carried out either before or after the EID testing regime. When considering UK EID approval, one further factor that needs to be taken into account is the fact that conventional ear tags have to satisfactorily complete the PAS 66 test procedure. All ear tags have to pass the requirements of PAS 66 before they can be approved for use in the UK. This remains the same for EID ear tags. This means that, in addition to the EID approval under Regulation 21/2004 and Commission Decision (2010/280/EU) of 12 May 2010, amending Commission Decision 2006/968, the tag will also need to be tested under PAS 66. As a consequence, PAS 66 has been updated and now incorporates a simple read test for EID tags to ensure the PAS 66 requirements do not adversely affect the electronic elements of these tags.

3.4 Final UK Approval

Irrespective of the identifier type or reader being tested, following a successful passage through the above stages, the final step is to receive UK approval. For GB, this will involve submission of the relevant certification to RPA Workington, who will then publish the information on the approved list of UK EID equipment on the internet. In Northern Ireland, DARD will take on this function and will publish the Northern Ireland list of approved equipment on their website.

The full list of approvals required for EID accreditation can therefore be summarised as below:

- **ICAR approval** *(testing to confirm compliance with relevant ISO/ICAR provisions)*
- **EID approval** *(testing to confirm compliance with Part 2 of the Technical Guidelines)*
- **PAS 66 approval** *(for ear tags only)*
- **Final UK approval** *(publication of equipment details on website)*

These approvals can be further broken down into specific requirements, as set out below:

- **Identifiers**
  - *Conformance with ISO 11784/11785 in accordance with point 7 of ISO 24631-1*
  - *Achievement of minimum performance on reading distances, as laid down in point 2 of Commission Decision (2010/280/EU) of 12 May 2010, amending Commission Decision 2006/968, in accordance with the procedures specified in point 7 of ISO 24631-3*
  - *Part 2 of the EID Technical Guidelines relating to robustness and endurance of identifiers*
  - *PAS 66 (ear tags only)*

- **Reading Equipment**
  - *Tests, as defined in Part 2 (paragraph 3.6) of the EID Technical Guidelines*
  - *Compliance with ISO 24631-6*

An outline approval process flowchart for identifiers and readers, including references to the appropriate section of the relevant guidance or legislation for each step of the process, can be found at Annex A. The process flowcharts and associated guidance on how to apply for each stage of approval will be published on the Defra and DARD websites in due course.

4 Roles & Responsibilities

A number of organisations are involved in the EID approvals process. A summary of the main areas of responsibilities can be found in the EID Technical Guidelines. The process, as identified for UK purposes, involves the following key players:

- **Defra** – responsible for drawing up the approvals policy
- **Manufacturers** – designing and submitting equipment for approval
- **ICAR-approved laboratory** – testing to ISO 11784/5 criteria and issue of manufacturer/product codes under ISO 24631
- **ISO 17025 accredited laboratory**– testing to ISO 11784/5 criteria and EID criteria
- **BSI (or other laboratory able to carry out PAS66 testing)** – PAS66 testing and approval
- **RPA** – granting UK approval and maintaining the UK list of approved equipment
- **DARD** – granting Northern Ireland approval and maintaining the NI list of approved equipment

A simple flowchart of the roles each of the above play in the approval process can be found at Annex B.

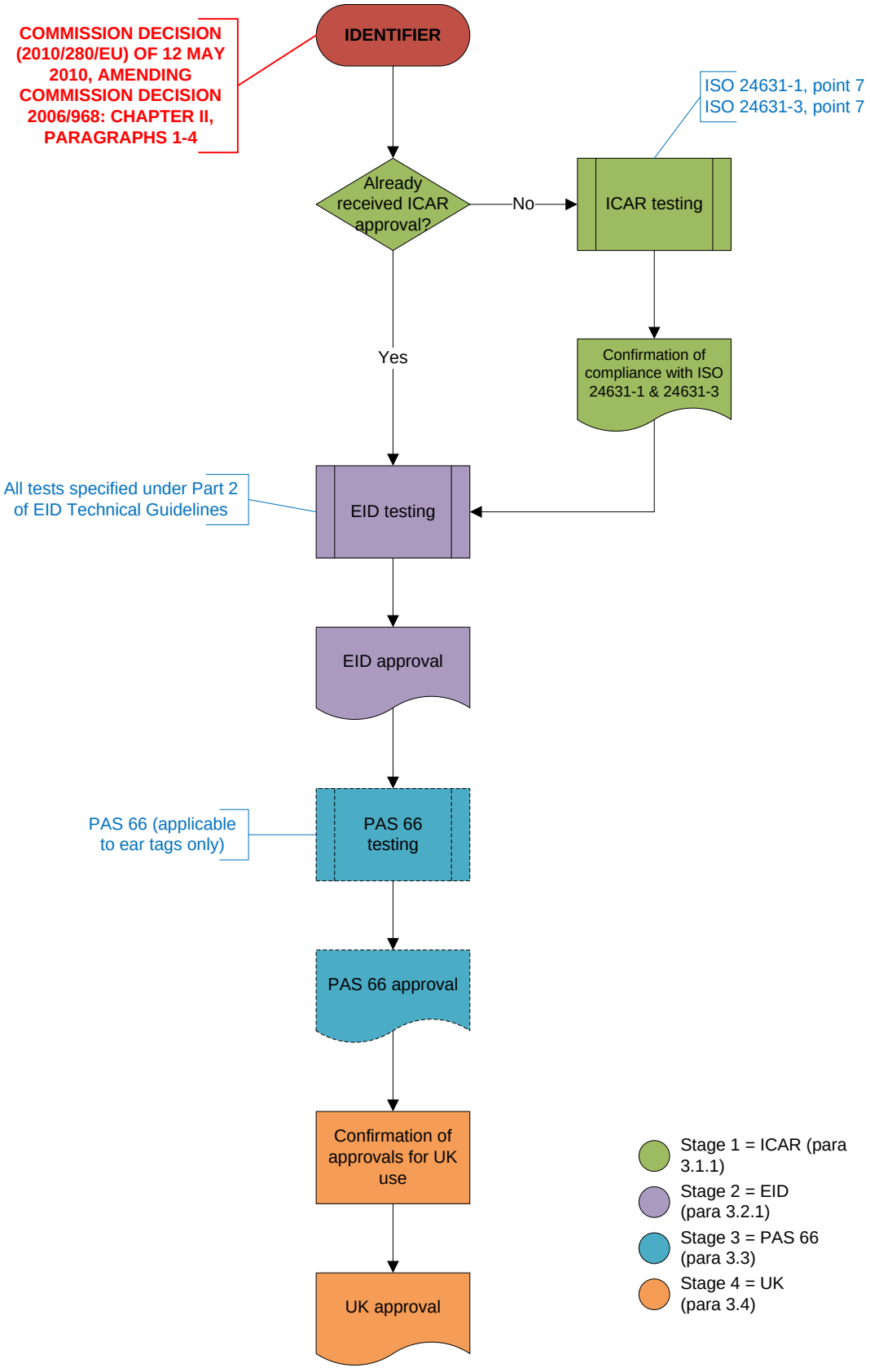
RPA/DARD are not responsible for the development of process. This has been agreed by the UK EID Project Board. Certification of EID equipment is carried out by an approved reference laboratory, overseen by a NRL/CRL (the JRC currently undertake the CRL role). On production of appropriate certification, RPA/DARD maintains a list of approvals to EU, ISO/ICAR and UK standards, along with conventional tags. The PAS 66 standard continues to apply and there are no changes to the existing role RPA/DARD carry out in relation to this. PAS 66 has been amended to reflect EID, and Defra worked with RPA to achieve this. PAS 66 changes in relation to EID are funded by Defra.

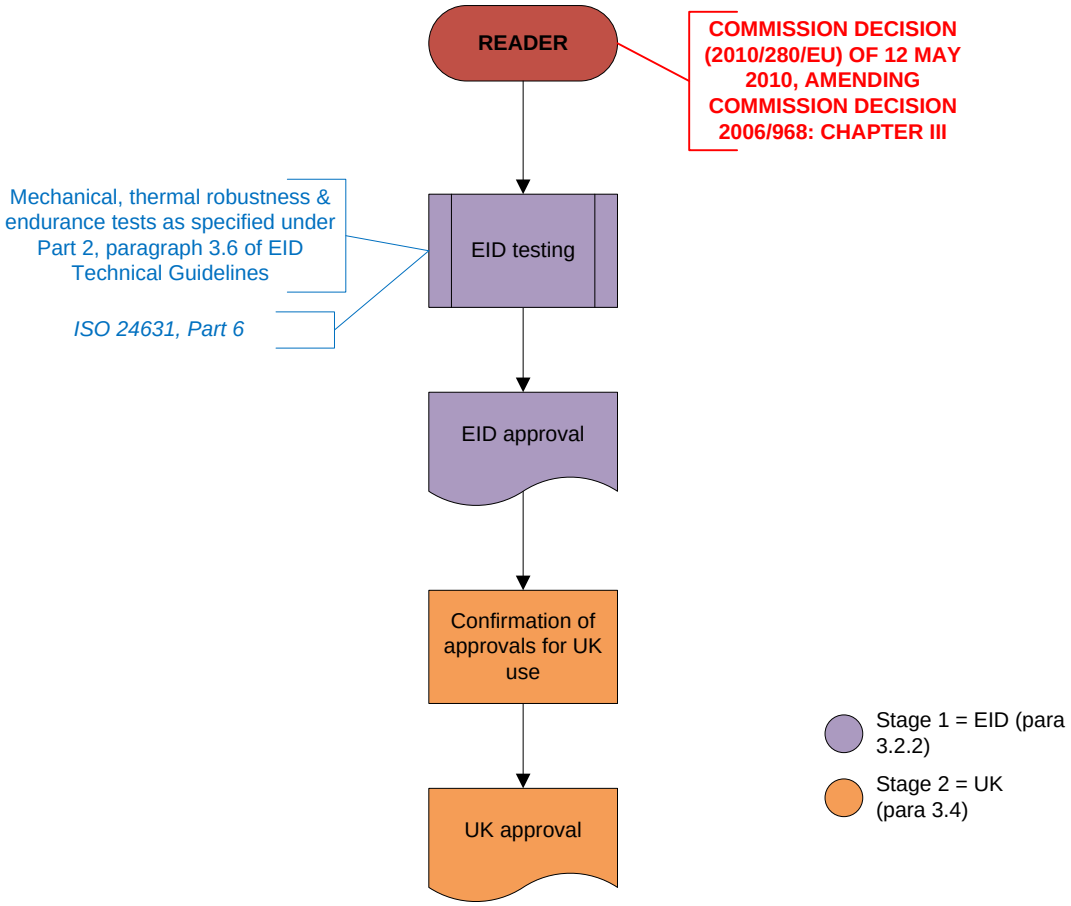
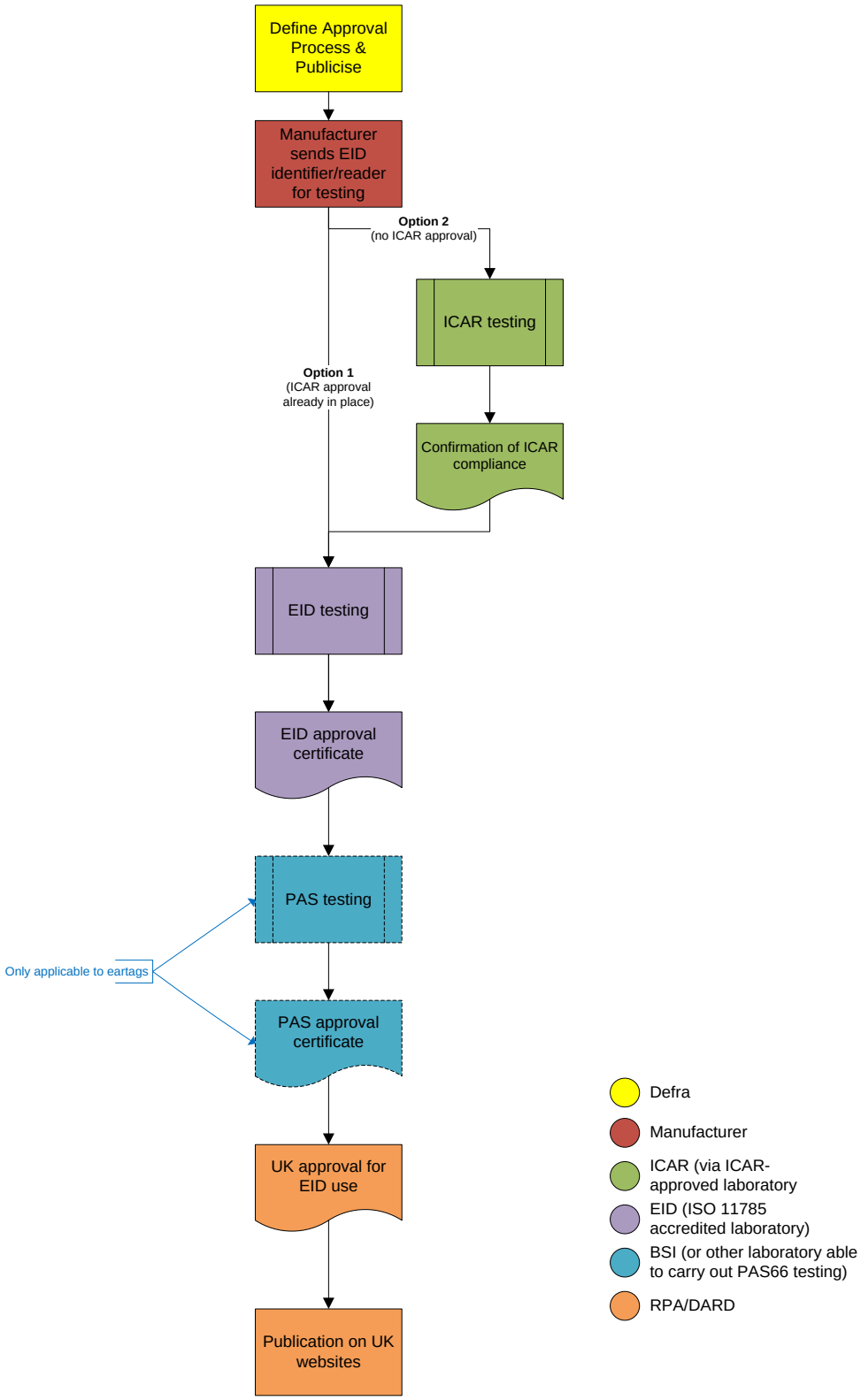
5 Conclusion

The UK adopted as simplified an approach to authorisation for sale in the UK of EID devices and reading equipment as was possible.

In order to obtain authorisation in the UK, a supplier will need to submit the appropriate application documentation and provide evidence that the EU standards have been met. This process is identical to that undertaken in respect of conventional eartags and ETAS. Given RPA's existing delivery responsibility for PAS 66 approvals and ETAS, they were the obvious choice to act as Defra's delivery agent for authorisation of electronic devices and reading equipment, as this work was a straightforward extension of their existing responsibilities with regard to sheep identification.

Annex A – Outline Approval Processes




READER
COMMISSION DECISION (2010/280/EU) OF 12 MAY 2010, AMENDING COMMISSION DECISION 2006/968: CHAPTER III
Mechanical, thermal robustness & endurance tests as specified under Part 2, paragraph 3.6 of EID Technical Guidelines
ISO 24631, Part 6
EID testing
EID approval
Confirmation of approvals for UK use
UK approval
Stage 1 = EID (para 3.2.2)
Stage 2 = UK (para 3.4)

Annex B – Roles in Approval Process