OIE Procedure for Registration of Diagnostic Kits

OIE Regional Workshop for OIE National Focal Points for Veterinary Products
Maputo, Republic of Mozambique
3 – 5 December 2013

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OIE Scientific and Technical Department

Background of the initiative

- Two Consultants Meetings: one in 2002 and a second one in 2003 after the adoption of the Resolution No. XXIX in May 2003
- Resolution No. XXIX, at the 71st General Session of the OIE in May 2003
- The OIE Procedure was launched in May 2005

Aim and Scope of the Procedure

- Developed to meet the needs of OIE Member Countries, the aim of this procedure is:

  1. to certify a kit as validated fit for specific purpose(s).

  2. to produce an OIE register of recognised diagnostic kits (available on the OIE website).

- All diagnostic kits for animal diseases, including zoonosis, can be validated and certified by the OIE through the procedure.

Procedure in brief 1/3

- Procedure based on the submission of a dossier by a kit manufacturer wishing to have its kit certified by the OIE as validated fit for some specific purpose(s);
- Fees requested for the initial assessment and then annual fee if diagnostic kit included in the OIE Register;
- Reassessment of the validation data of the kit included in the OIE Register every 5 years;
- Dossier, that has to be filled in, downloadable from the OIE website;
- Dossier based on the OIE validation pathway.

Procedure in brief 2/3

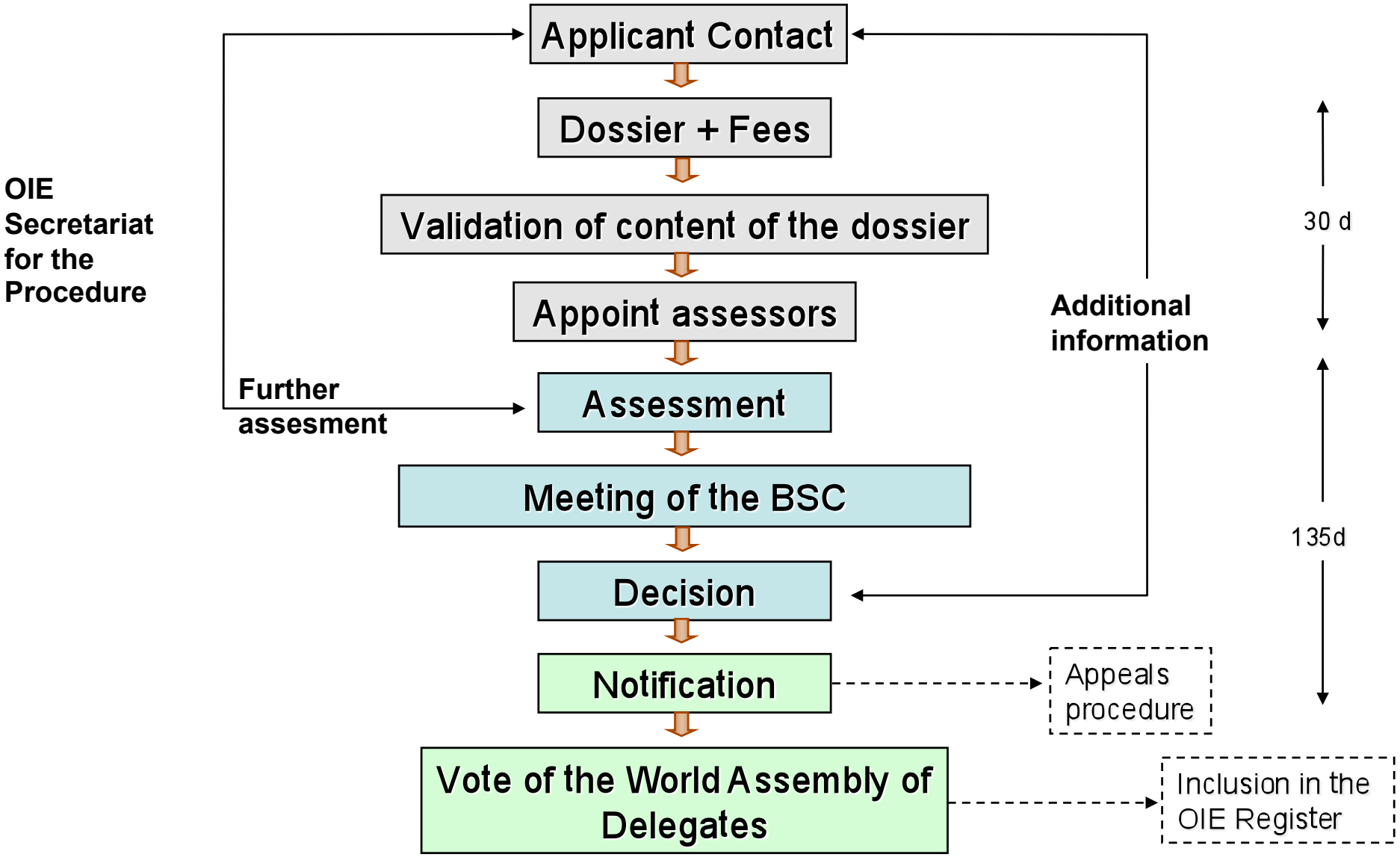
- Once a dossier has been submitted to the OIE, an administrative revision is carried out to check if the dossier is complete;
- Scientific evaluation of the dossier by a group of 2 – 3 independent and internationally recognised experts selected by the OIE;
- Scientific evaluation in 2 or 3 steps with exchanges between the panel of experts and the kit manufacturer through the OIE secretariat for the procedure;
- At the end of the scientific evaluation, final report from the panel of experts which is forwarded to the relevant Specialist Commission.

Procedure in brief 3/3

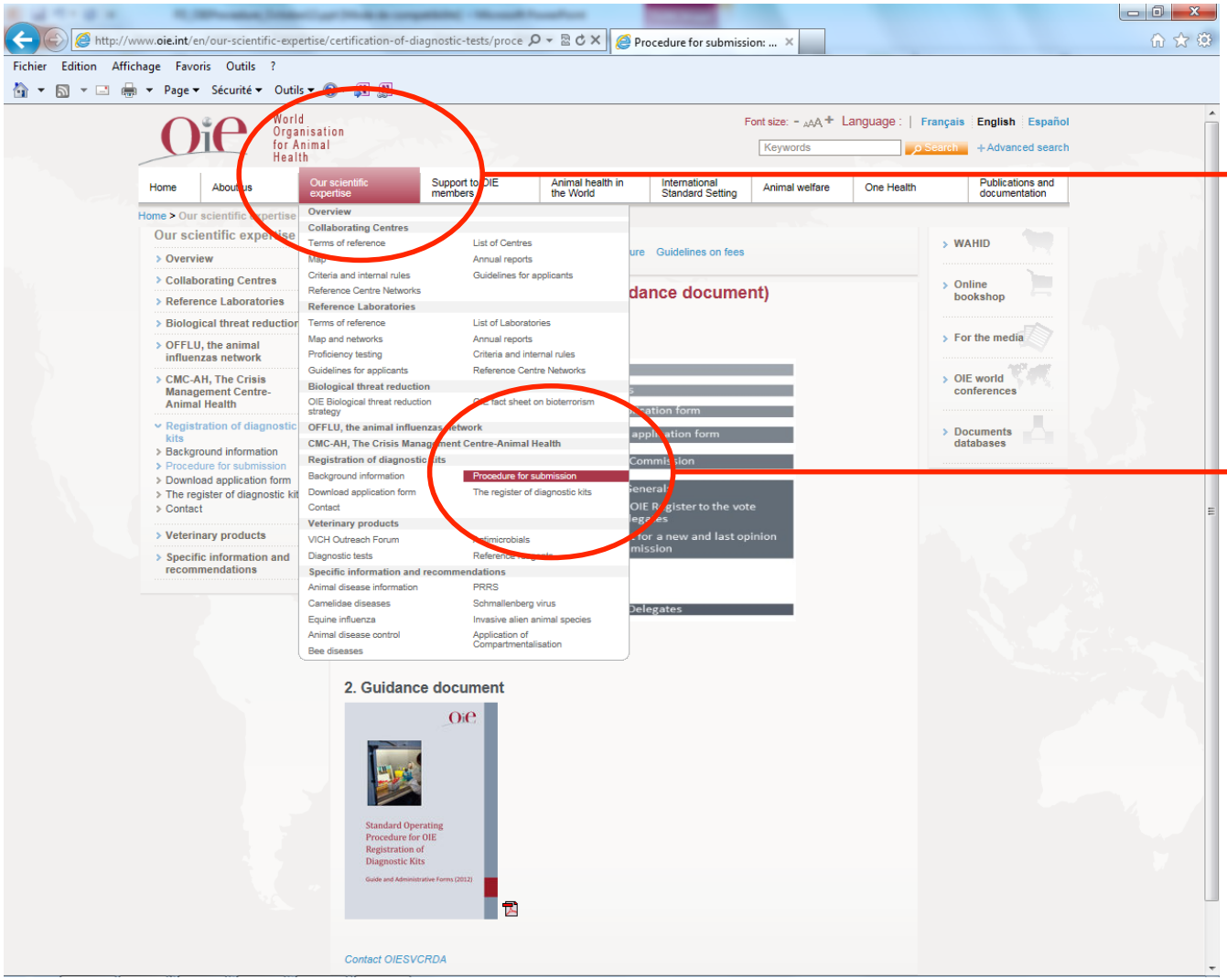
- The relevant Specialist Commission provide an opinion to propose or not the diagnostic kit for inclusion in the Register for some specific purposes to the vote of the World Assembly of Delegates:
  - Favourable opinion: the diagnostic kit will be proposed for adoption through a resolution to the vote of the World Assembly of Delegates by the OIE Director General;
  - Unfavorable opinion: the OIE Director General informs the applicant in writing that the application does not satisfy the criteria for inclusion of the kit in the OIE register, together with the reasons for rejection – Appeal procedure possible
- Vote of the World Assembly of Delegates during the next General Session

OIE Procedure for Registration of Diagnostic Kits

Outline of all the process



Standard Operating Procedure 1/2



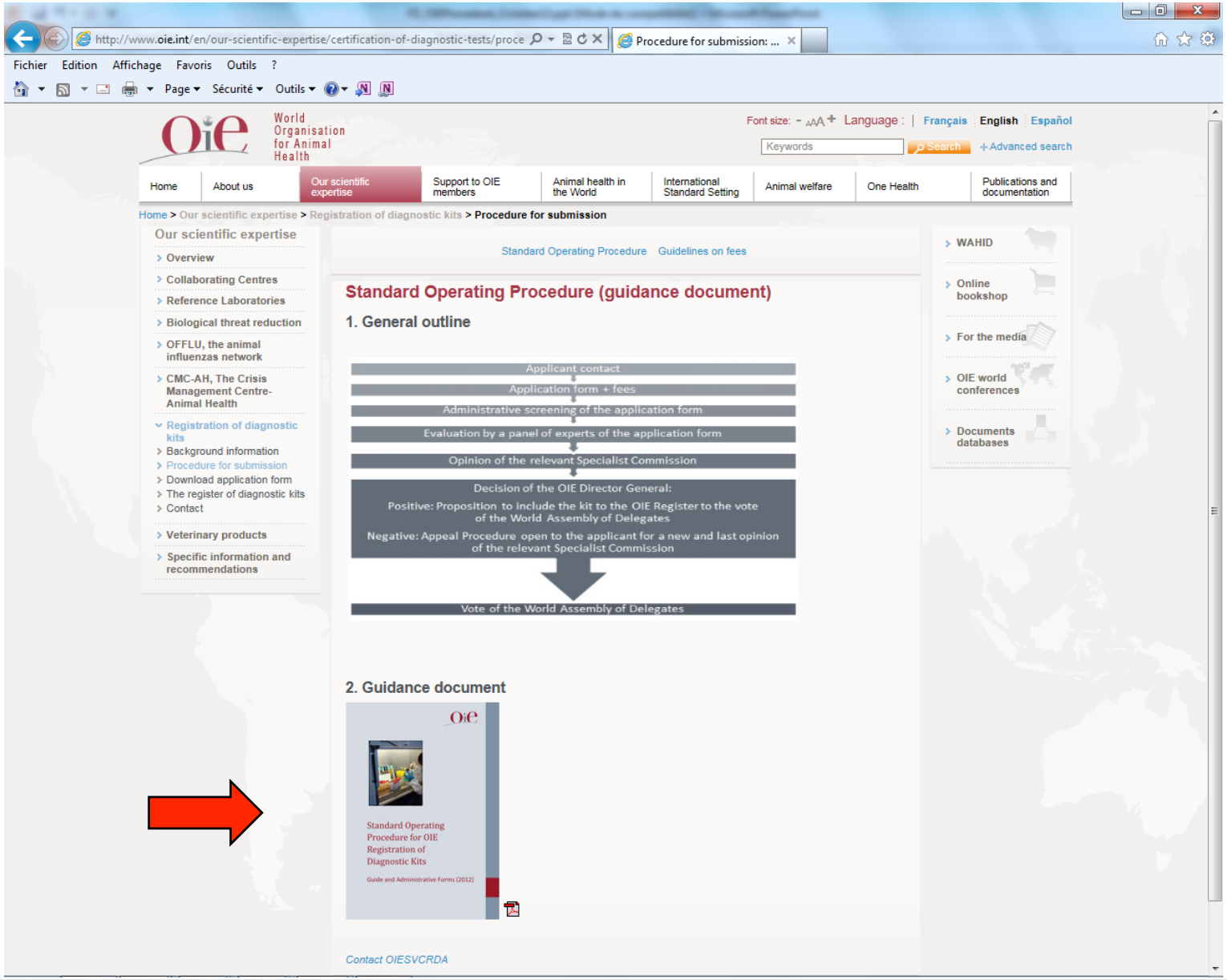
Our Scientific Expertise

Registration of diagnostic kits

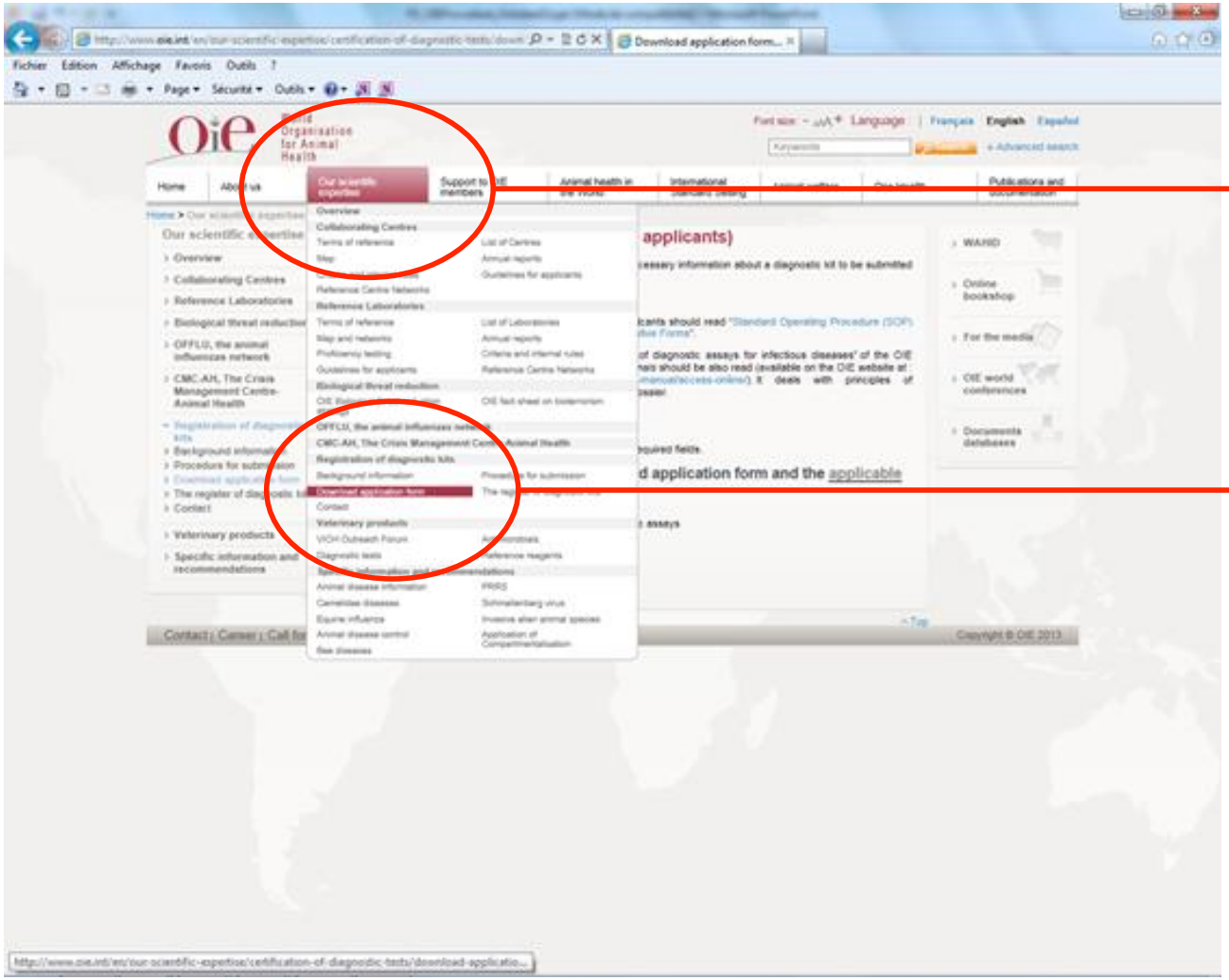
- Procedure for submission

http://www.oie.int/en/our-scientific-expertise/certification-of-diagnostic-tests/procedure-for-submission/

Standard Operating Procedure 2/2



Dossier 1/3



Our Scientific Expertise

Registration of diagnostic kits

- Download application form

http://www.oie.int/en/our-scientific-expertise/certification-of-diagnostic-tests/download-application-form/

Dossier 2/3


Download application form...
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Download the Application form (for applicants)
This is the application form for the dossier containing the necessary information about a diagnostic kit to be submitted to the OIE for certification of "fitness for purpose".
1. General Information
Before filling in the form and submitting an application, applicants should read "Standard Operating Procedure (SOP) for OIE Registration of Diagnostic Kits, Guide and Administrative Forms".
The chapter 1.1.5., "Principles and methods of validation of diagnostic assays for infectious diseases" of the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals should be also read (available on the OIE website at: http://www.oie.int/en/international-standard-setting/terrestrial-manual/access-online/). It deals with principles of validation and therefore could be helpful when filling in this dossier.
2. Application form (version 1.6., 2012)
Click on the link above and save this file in your local disk.
Open it in MS Word, filling the necessary information in the required fields.
3. The applicant shall send the completed application form and the applicable fee to the OIE:
Director General
OIE procedure for validation and certification of the diagnostic assays
OIE
12, rue de Prony
75017 Paris
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Dossier 3/3

Word document – Content:

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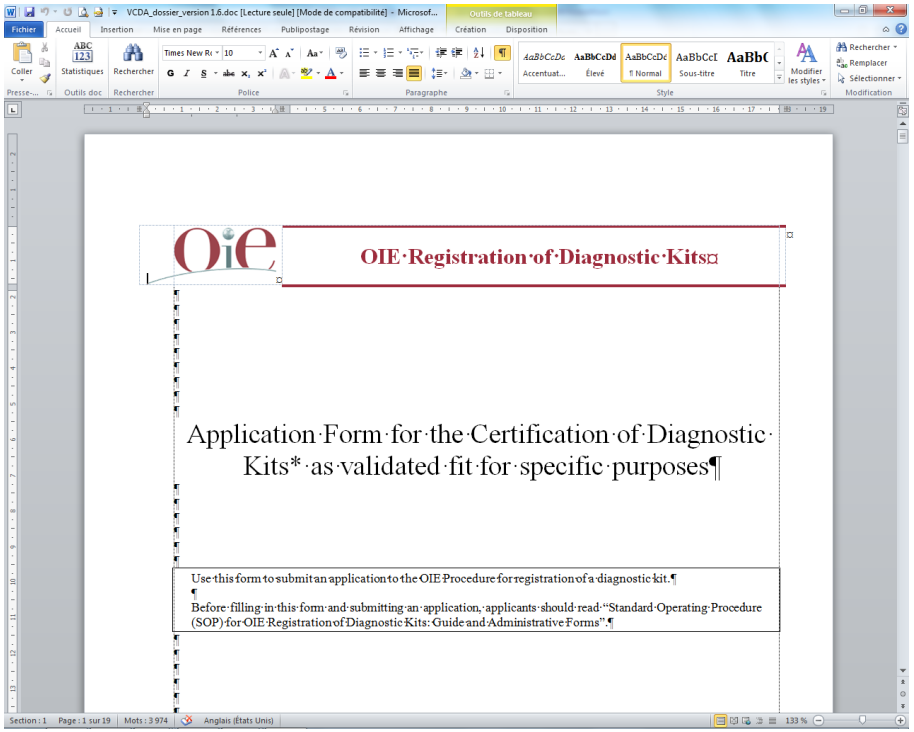
Section 2: General information

Section 3: Development & Validation

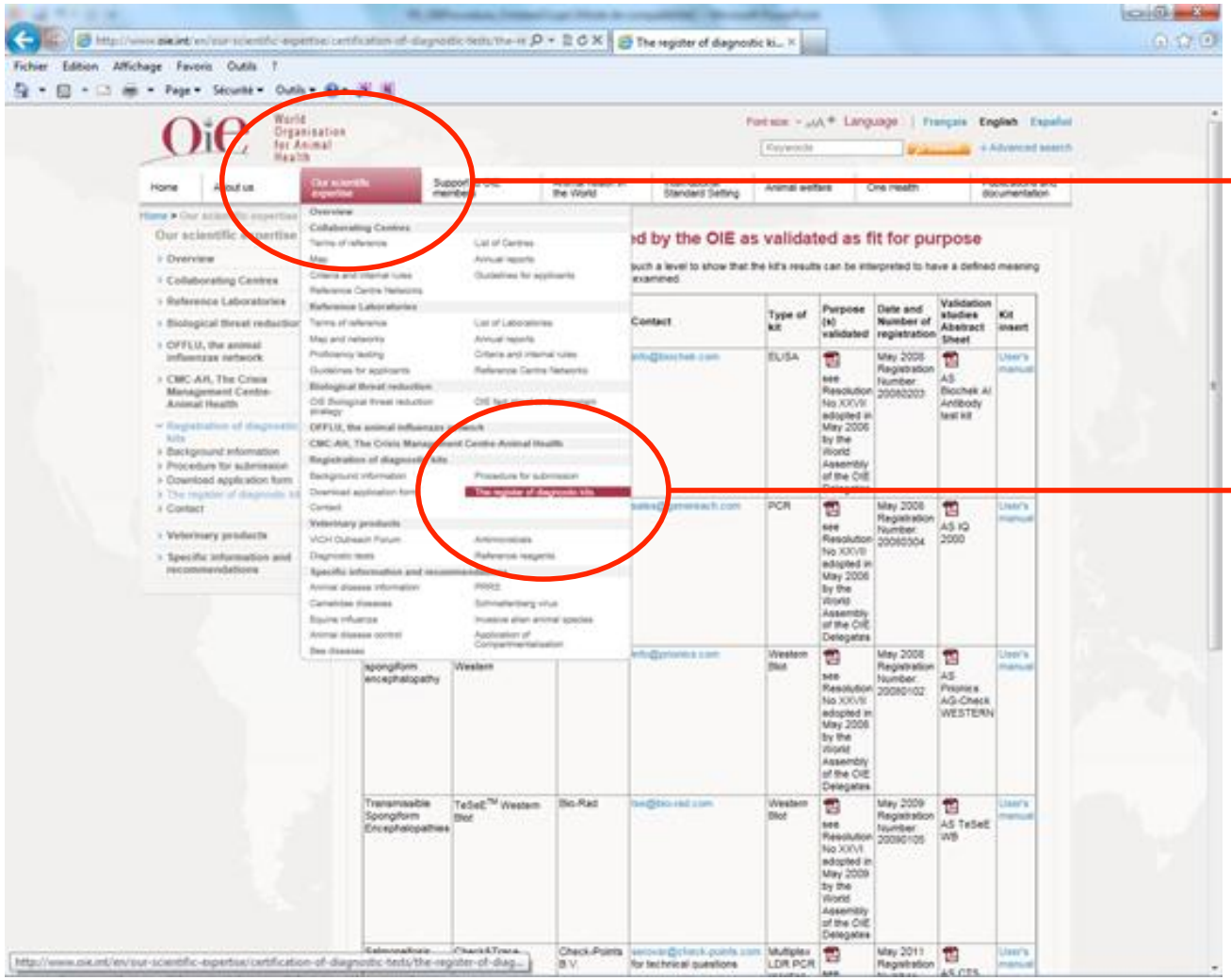
Section 4: Performance summary

Section 5: Additional data

Section 6: References

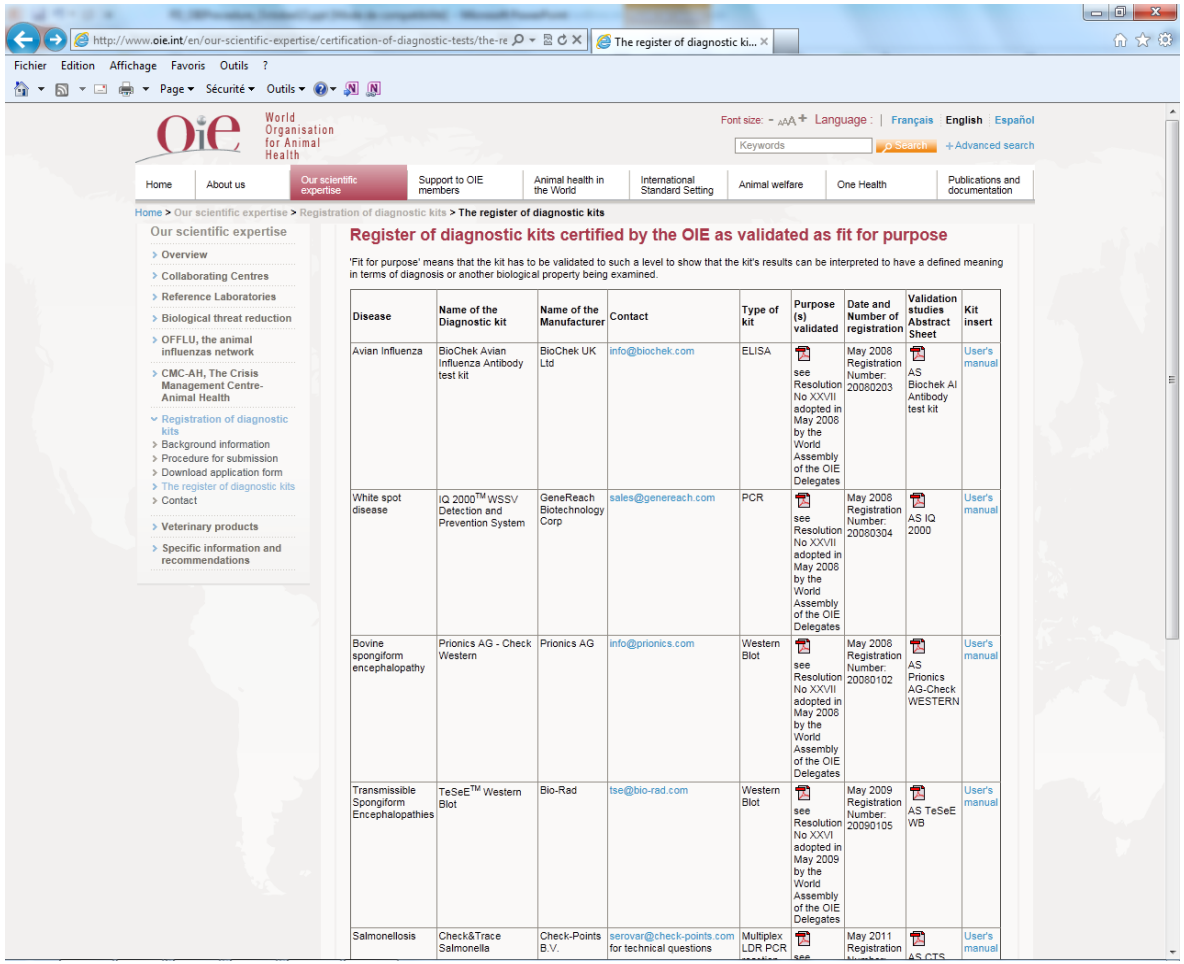


OIE Register 1/3



http://www.oie.int/en/our-scientific-expertise/certification-of-diagnostic-tests/the-register-of-diagnostic-tests/

OIE Register 2/3



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Our scientific expertise

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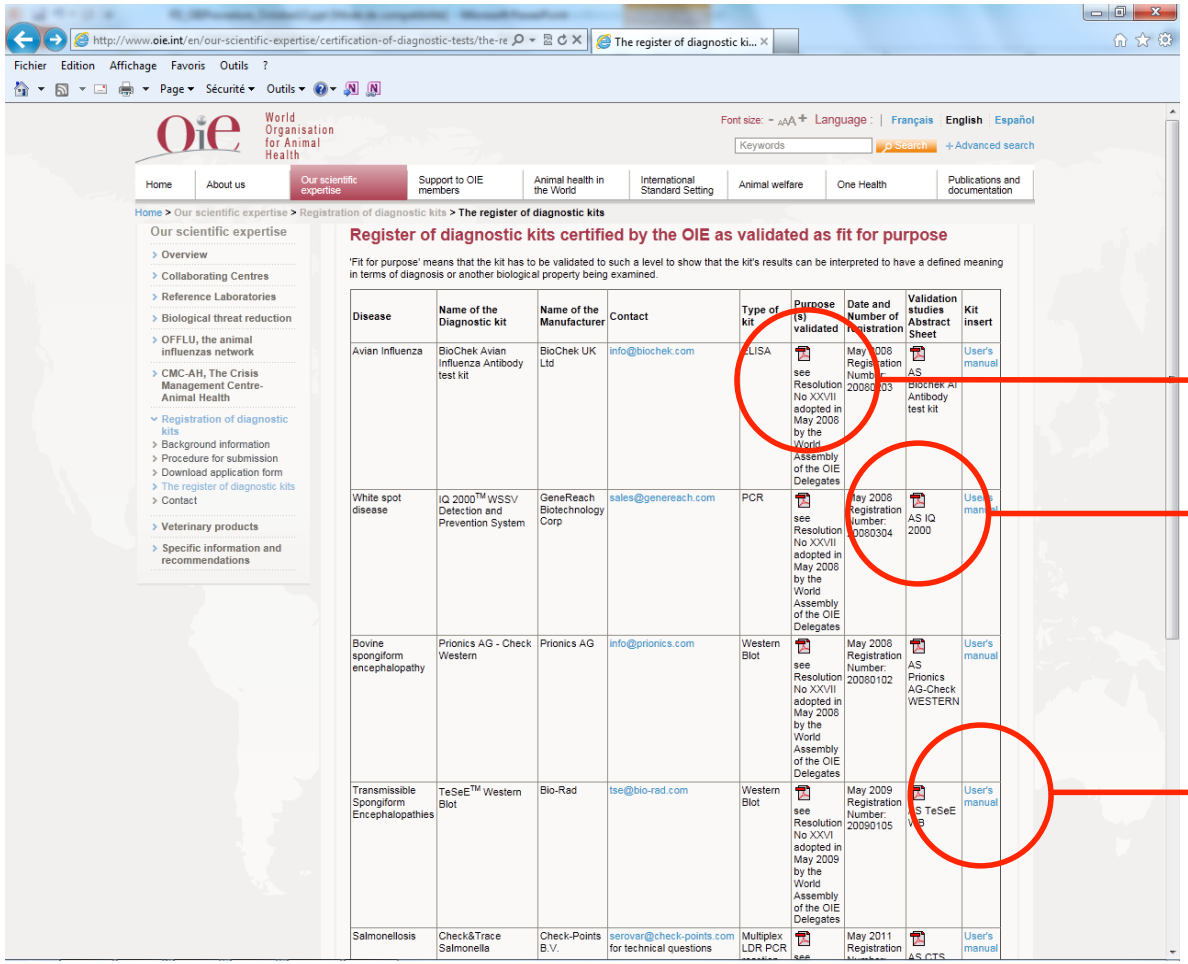
Register of diagnostic kits certified by the OIE as validated as fit for purpose

'Fit for purpose' means that the kit has to be validated to such a level to show that the kit's results can be interpreted to have a defined meaning in terms of diagnosis or another biological property being examined.

Disease	Name of the Diagnostic kit	Name of the Manufacturer	Contact	Type of kit	Purpose (s) validated	Date and Number of registration	Validation studies Abstract Sheet	Kit insert
Avian Influenza	BioChek Avian Influenza Antibody test kit	BioChek UK Ltd	info@biochek.com	ELISA	see Resolution No XXVII adopted in May 2008 by the World Assembly of the OIE Delegates	May 2008 Registration Number: 20080203	AS Biochek AI Antibody test kit	User's manual
White spot disease	IQ 2000™ WSSV Detection and Prevention System	GeneReach Biotechnology Corp	sales@genereach.com	PCR	see Resolution No XXVII adopted in May 2008 by the World Assembly of the OIE Delegates	May 2008 Registration Number: 20080304	AS IQ 2000	User's manual
Bovine spongiform encephalopathy	Prionics AG - Check Western	Prionics AG	info@prionics.com	Western Blot	see Resolution No XXVII adopted in May 2008 by the World Assembly of the OIE Delegates	May 2008 Registration Number: 20080102	AS Prionics AG-Check WESTERN	User's manual
Transmissible Spongiform Encephalopathies	TeSeE™ Western Blot	Bio-Rad	tse@bio-rad.com	Western Blot	see Resolution No XXVI adopted in May 2009 by the World Assembly of the OIE Delegates	May 2009 Registration Number: 20090105	AS TeSeE WB	User's manual
Salmonellosis	Check&Trace Salmonella	Check-Points B.V.	serovar@check-points.com for technical questions	Multiplex LDR PCR	see	May 2011 Registration	AS CTS	User's manual

OIE Register currently comprises **7 diagnostic kits** (kits for AI, Bovine tuberculosis, BSE/TSE, Salmonella typing, and White Spot Disease)

OIE Register 3/3



Resolution with the specific purposes certified by OIE

Summary of the validation data for the diagnostic kit

Diagnostic kit's insert

Resolution No. XXXII, General Session 2006:

Recognition and implementation of OIE standards for the validation and registration of diagnostic assays by Member Countries

2. Member Countries of the OIE are encouraged to **harmonise their standards** for the validation and registration of diagnostic assays **with the standards, guidelines and recommendations** in the **OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals** and where such standards are absent or not yet developed, to **apply the standards in the Manual and in the OIE test register for the registration of such products within their countries**.

Thank you for your attention

Organisation Mondiale
de la Santé Animale

World Organisation
for Animal Health

Organización Mundial
de Sanidad Animal

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