EUROPEAN COMMISSION

Brussels, xxx
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Draft

COMMISSION DECISION

of […]

amending Decision 2002/364/EC on common technical specifications for *in vitro* diagnostic medical devices

(Text with EEA relevance)

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices[1], and in particular the second subparagraph of Article 5(3) thereof,

Whereas:

(1) The common technical specifications for *in vitro* diagnostic medical devices are laid down in Commission Decision 2002/364/EC[2].

(2) In the interest of public health it is appropriate, where possible, to draw up common technical specifications for the devices listed in List A of Annex II to Directive 98/79/EC.

(3) Variant Creutzfeldt-Jakob disease (vCJD) assays for blood screening, diagnosis and confirmation have been added to List A of Annex II to Directive 98/79/EC by Commission Directive … .

(4) Taking into account the state of the art and the current scientific knowledge on Variant Creutzfeldt-Jakob disease, common technical specifications can be drawn up for vCJD blood screening assays.

(5) The measures provided for in this Decision are in accordance with the opinion of the committee set up by Article 6(2) of Council Directive 90/385/EEC[3] and referred to in Article 7(1) of Directive 98/79/EC,

HAS ADOPTED THIS DECISION:

Article 1

The Annex to Decision 2002/364/EC is amended in accordance with the Annex to this Decision.

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1 OJ L 331, 7.12.1998, p. 1.
2 OJ L 131, 16.5.2002, p. 17.
3 OJ L 189, 20.7.1990, p. 17.

Article 2

This Decision shall apply from [application date of the parallel Commission Directive].

However, Member States shall allow manufacturers to apply the requirements set out in the Annex before the date set out in the first paragraph of this Article.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, […]

For the Commission
[…]
Member of the Commission

ANNEX

The following table is added at the end of the Annex to Decision 2002/364/EC:

"Table 11: **Variant Creutzfeldt-Jakob disease (vCJD) assays for blood screening**

	Material	**Number of specimens**	**Acceptance Criteria**
Analytical sensitivity	vCJD brain spikes in human plasma (WHO reference number NHBYO/003)	24 replicates of each of three dilutions of the material WHO number NHBYO/003 ($1x10^4$, $1x10^5$, $1x10^{6)}$	23 of the 24 replicates detected at $1x\ 10^4$
	vCJD spleen spikes in human plasma (10% spleen homogenate - NIBSC reference number NHSY0/0009)	24 replicates of each of three dilutions of the material NIBSC number NHSY0/0009 (1x10, $1x10^2$, $1x10^{3)}$	23 of the 24 replicates detected at 1x 10
Diagnostic sensitivity	A) Specimen from appropriate animal models	As many specimen as reasonably possible and available, and at least 10 specimens	90%
	B) Specimen from humans with known clinical vCJD	As many specimen as reasonably possible and available, and at least 10 specimens	90%

		Only in case where 10 specimens are not available: - the number of specimens tested shall be comprised between 6 and 9 - all available specimens shall be tested	no more than one false negative result
Analytical specificity	Potentially cross-reacting blood-specimens	100	
Diagnostic specificity	Normal human plasma samples from area of low BSE exposure	5,000	At least 99.5%