Prevention, control and eradication of certain transmissible spongiform encephalopathies (TSEs)

1998/0323(COD) - 19/06/2003 - Implementing legislative act

ACT: Commission Regulation 1053/2003/EC amending Regulation 999/2001/EC of the European Parliament and of the Council as regards rapid tests.

CONTENT: the purpose of this implementing legislative act is three-fold fold. Firstly, to change the reference to the Greek “national reference laboratory” for the monitoring and carrying out of tests on transmissible spongiform encephalopathy (TSE’s). Secondly, one of the companies authorised to test for TSE’s under the terms of Regulation 999/2001, has informed the Commission of its intention to market its test under a new trade name. Thirdly, the Scientific Steering Committee has recommended the inclusion of two new tests for monitoring bovine spongiform encephalopathy (BSE). The producers of both tests have provided enough data to conclude that their tests may also be used for the monitoring of TSE in sheep. In order to ensure a high level of performance after approval of a test, a new procedure has been laid down for possible modifications to the test or the test protocol.

Bearing the above in mind, the Commission has amended Annex X of Regulation 999/2001. The amended Annex now includes new reference details for the authorised Greek national laboratory. Further, Chapter C on “Rapid Tests” has been modified so as to include the new testing methods. As far as the new procedure is concerned the following shall apply.

The producer of the rapid tests must have a quality assurance system in place agreed by the Community reference laboratory which ensures that the test performance does not change. The producer must provide the test protocol to the Community reference laboratory. Modifications to the rapid test or to the test protocol may only be made following advance notification to the Community reference laboratory and provided that the Community reference laboratory finds that the modification does not reduce the sensitivity, specificity or reliability of the rapid test. The findings shall be communicated to the Commission and to the national reference laboratories.

ENTRY INTO FORCE: 10 July 2003.