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II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) No 1151/2010

of 8 December 2010

implementing Regulation (EC) No 763/2008 of the European Parliament and of the Council on population and housing censuses, as regards the modalities and structure of the quality reports and the technical format for data transmission*(Text with EEA relevance)*

THE EUROPEAN COMMISSION,

HAS ADOPTED THIS REGULATION:

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

*Article 1***Subject matter**

Having regard to Regulation (EC) No 763/2008 of the European Parliament and of the Council of 9 July 2008 on population and housing censuses ⁽¹⁾, and in particular Articles 5(5) and 6(3) thereof,

This Regulation lays down the modalities and structure of the quality reports to be submitted by Member States on the quality of the data they transmit to the Commission (Eurostat) from their population and housing censuses for the reference year 2011, as well as the technical format for data transmission, to fulfil the requirements of Regulation (EC) No 763/2008.

Whereas:

*Article 2***Definitions**

(1) Regulation (EC) No 763/2008 establishes common rules for the decennial provision of comprehensive data on population and housing.

The definitions and technical specifications set out in Regulation (EC) No 763/2008 and Commission Regulations (EC) No 1201/2009 ⁽²⁾ and (EU) No 519/2010 ⁽³⁾ shall apply for the purpose of this Regulation. The following definitions shall also apply:

(2) In order to assess the quality of the data transmitted to the Commission (Eurostat) by the Member States, it is necessary to define the modalities and structure of the quality reports.

1. 'statistical unit' means the basic observation unit, namely a natural person, household, family, living quarter, or conventional dwelling;

(3) In order to ensure the proper transmission of the data and metadata, the technical format should be the same for all Member States. It is therefore necessary to adopt the appropriate technical format to be used for data transmission.

2. 'individual enumeration' means that information on each statistical unit is obtained so that their characteristics can be recorded separately and cross-classified with other characteristics;

(4) The measures provided for in this Regulation are in accordance with the opinion of the European Statistical System Committee

3. 'simultaneity' means that the information obtained in a census refers to the same point in time (reference date);

⁽¹⁾ OJ L 218, 13.8.2008, p. 14.

⁽²⁾ OJ L 329, 15.12.2009, p. 29.

⁽³⁾ OJ L 151, 17.6.2010, p. 1.

4. 'universality within a defined territory' means that data are provided for all statistical units within a precisely defined territory. Where statistical units are persons, 'universality within a defined territory' means that data are provided which are based on information for all persons that have their usual residence in the defined territory (total population);
5. 'availability of small-area data' means the availability of data for small geographic areas and for small groups of statistical units;
6. 'defined periodicity' means the capacity to conduct censuses regularly at the beginning of every decade, including the continuity of registers;
7. 'target population' means the set of all statistical units in a defined geographical area at the reference date which qualify for reporting on one or more specified topics. The target population includes each valid statistical unit exactly once;
8. 'estimated target population' means the best available approximation of the target population. The estimated target population consists of the census population plus under-coverage minus over-coverage;
9. 'census population' means the set of statistical units which is factually represented by the census results on one or more specified topics for a specified target population. The data records for the census population are the data records in the data source for the specified target population, including all imputed records and excluding all deleted records. If a data source comprises, as a matter of methodological principle, data records for only a sample of the statistical units in its estimated target population, the census population comprises, in addition to the statistical units in the sample, the complementary set of statistical units;
10. 'complementary set of statistical units' means the set of those statistical units that belong to an estimated target population, but about which the data source contains no data records as a result of an applied sampling methodology;
11. 'coverage assessment' means a study of the difference between a specified target population and its census population;
12. 'post-enumeration survey' means a survey conducted shortly after the enumeration for coverage and content assessment purposes;
13. 'under-coverage' means the set of all statistical units that belong to a specified target population, but are not included in the corresponding census population;
14. 'over-coverage' means the set of all statistical units that are included in a census population used to report on a specified target population without belonging to that target population;
15. 'record imputation' means the assignment of an artificial but plausible data record to exactly one geographical area at the most detailed geographical level for which census data are produced, and the imputation of that data record into a data source;
16. 'record deletion' means the act of deleting or ignoring a data record that is included in a data source used to report on a specified target population, but does not report any valid information on any statistical unit within that target population;
17. 'item imputation' means the insertion of artificial but plausible information into a data record where the data record already exists in a data source but does not contain this information;
18. 'data source' means the set of data records for statistical units and/or events related to statistical units which forms a basis for the production of census data about one or more specified topics for a specified target population;
19. 'register-based data' means data that are in or originate from a register;
20. 'questionnaire-based data' means data that are originally obtained from respondents by the means of a questionnaire in the context of a collection of statistical data which refer to a specified point in time;
21. 'register' means a repository which stores information about statistical units and is directly updated in the course of events affecting the statistical units.
22. 'record linkage' means the process of merging information from different data sources by comparing the records for the individual statistical units and merging the information for each statistical unit where the unit to which the records refer is the same;

23. 'matching of registers' means a record linkage where all matched data sources are contained in registers;
24. 'data extraction' means the process of retrieving census information from information contained in a register and relating to individual statistical units;
25. 'coding' means the process of converting information into codes representing classes within a classification scheme;
26. 'identifying variable' means a variable in the data records in a data source or any list of statistical units which is used
- to evaluate whether the data source (or list of statistical units) includes no more than one data record for each statistical unit, and/or
 - for a record linkage.
27. 'capturing' means the process by which collected data are put into a machine-readable form;
28. 'record editing' means the process of checking and modifying data records to make them plausible while at the same time preserving major parts of these records;
29. 'generation of a household' means the identification of a private household according to the household-dwelling concept as defined in the Annex to Regulation (EC) No 1201/2009 under the topic 'Household status';
30. 'generation of a family' means the identification of a family based on information on whether the persons live in the same household, but with no or incomplete information on family relationships between persons. The term 'family' is specified as 'family nucleus' in the Annex to Regulation (EC) No 1201/2009 under the topic 'Family status';
31. 'unit no-information' means the failure to collect any data from a statistical unit that is in the census population;
32. 'item no-information' means the failure to collect data on one or more specified topics for a statistical unit that is in the census population, while data on at least one other topic can be collected for that statistical unit;
33. 'statistical disclosure control' means the methods and processes applied in order to minimise the risk of disclosing information on individual statistical units while releasing as much statistical information as possible;
34. 'estimation' means the calculation of statistics or estimates using a mathematical formula and/or algorithm applied to the available data;
35. 'coefficient of variation' means the standard error (square root of the variance of an estimator) divided by the expected value of the estimator;
36. 'model assumption error' means an error due to assumptions underlying the estimation and containing uncertainty or lack of detail;
37. 'data structure definition' means a set of structural metadata associated with a data set, which includes information about how concepts are associated with the measures, dimensions, and attributes of a hypercube, along with information about the representation of data and related descriptive metadata.

Article 3

Metadata and quality reporting

1. Member States shall report to the Commission (Eurostat), by 31 March 2014, the background information specified in Annex I to this Regulation as well as the quality-related data and metadata specified in Annexes II and III to this Regulation, with reference to their population and housing censuses for the reference year 2011 and to the data and metadata transmitted to the Commission (Eurostat) as required by Regulation (EU) No 519/2010.

2. To meet the requirements of paragraph 1, Member States shall make a coverage assessment for their population and housing censuses for the reference year 2011 as well as an assessment of the imputation and deletion of data records.

3. Regulation (EC) No 223/2009⁽¹⁾ and the Euro SDMX Metadata Structure as defined in Commission Recommendation 2009/498/EC⁽²⁾ for the production and exchange of reference metadata (including quality) shall apply in the context of this Regulation.

⁽¹⁾ OJ L 87, 31.3.2009, p. 164.

⁽²⁾ OJ L 168, 30.6.2009, p. 50.

*Article 4***Data sources**

Any data source shall be able to contribute information needed to fulfil the requirements of Regulation (EC) No 763/2008, in particular to

- meet the essential features as listed in Article 2(i) of Regulation (EC) No 763/2008 and defined in Article 2 (2) to (6),
- represent the target population,
- respect the relevant technical specifications laid down in Regulation (EC) No 1201/2009, and
- contribute to the provision of data for the programme of statistical data set out in Regulation (EU) No 519/2010.

*Article 5***Access to relevant information**

At the request of the Commission (Eurostat), Member States shall provide the Commission (Eurostat) with access to any

information relevant to the assessment of the quality of the transmitted data and metadata as required by Regulation (EU) No 519/2010, excluding the transmission to and storage at the Commission of any microdata and confidential data.

*Article 6***Technical format for data transmission**

The technical format to be used for the transmission of data and metadata for the reference year 2011 shall be the Statistical Data and Metadata eXchange (SDMX) format. Member States shall transmit the required data conforming to the data structure definitions and related technical specifications provided by the Commission (Eurostat). Member States shall store until 1 January 2025 the required data and metadata for any later transmission requested by the Commission (Eurostat).

*Article 7***Entry into force**

This Regulation shall enter into force on the twentieth day following its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 8 December 2010.

For the Commission

The President

José Manuel BARROSO

ANNEX I

Background information

The structure of the background information to the population and housing censuses conducted in the Member States for the reference year 2011 comprises the following sections:

1. OVERVIEW
 - 1.1. **Legal background**
 - 1.2. **Bodies responsible**
 - 1.3. **References to other relevant documentation (e.g. national quality reports) (optional)**
2. DATA SOURCES ⁽¹⁾
 - 2.1. **Classification of the data sources according to Article 4(1) of Regulation (EC) No 763/2008**
 - 2.2. **List of the data sources used for the 2011 census ⁽²⁾**
 - 2.3. **Matrix 'Data sources x Topics'**
 - 2.4. **Extent to which the data sources meet the essential features (Article 4(4) of Regulation (EC) No 763/2008)**
 - 2.4.1. *Individual enumeration*
 - 2.4.2. *Simultaneity*
 - 2.4.3. *Universality within the defined territory*
 - 2.4.4. *Availability of small-area data*
 - 2.4.5. *Defined periodicity*
3. CENSUS LIFECYCLE
 - 3.1. **Reference date according to Article 5(1) of Regulation (EC) No 763/2008**
 - 3.2. **Preparation and execution of data collection**
 - 3.2.1. *Questionnaire-based data*
 - 3.2.1.1. Design and testing of questionnaires (including copies of all final questionnaires)
 - 3.2.1.2. Preparation of any address lists, preparation of the field work, mapping, publicity
 - 3.2.1.3. Data collection (including field work)
 - 3.2.2. *Register-based data*
 - 3.2.2.1. Creation of new registers from the year 2001 onwards (where applicable)
 - 3.2.2.2. Re-design of existing registers from the year 2001 onwards (including changes in the contents of registers, adaptation of the census population, adaptation of definitions and/or technical specifications) (where applicable)
 - 3.2.2.3. Maintenance of the registers (for each register used for the 2011 census), including
 - content of the register (registered statistical units and information on the statistical units, any record editing and/or item imputation in the register)
 - administrative responsibilities
 - legal obligation to register information, incentives for providing truthful information or possible reasons for providing false information

⁽¹⁾ The reporting for section 2 must be comprehensive and free of overlaps in the sense that it is possible to allocate each topic to exactly one data source.

⁽²⁾ For data sources that result from a record linkage, the list comprises information on the new data source and on all original data sources from which the new data source has been derived.

- delays in reporting, in particular legal/official delays, data registration delays, late reporting
- evaluation of and clearance for non-registration, non-deregistration, multiple registration
- any major register revision that affects the 2011 census data, periodicity of register revisions
- stability (comparability of information on the registered population over time) (optional)
- usage, including 'statistical usage of the register other than for the census' and 'usage of the register other than for statistical purposes (e.g. administrative purposes)'

3.2.2.4. Matching of registers (including identifying variable(s) used for record linkage)

3.2.2.5. Data extraction

3.3. **Processing and evaluation**

3.3.1. *Data processing (including capturing, coding, identifying variable(s), record editing, record imputation, record deletion, estimation, record linkage including identifying variable(s) used for the record linkage, generation of households and families)*

3.3.2. *Quality and coverage assessment, post-enumeration survey(s) (where applicable), final data validation*

3.4. **Dissemination (dissemination channels, assurance of statistical confidentiality including statistical disclosure control)**

3.5. **Measures to ensure cost effectiveness**

ANNEX II

Quality-related data and metadata

The quality-related data and metadata about the data sources and topics comprise the items listed below.

1. RELEVANCE**1.1. Adequacy of data sources**

Member States have to report on the adequacy of the data sources, in particular on the impact of any major deviation from the essential features of population and housing censuses and/or from the required definitions and concepts where this seriously impairs the adequate usage of the transmitted data.

1.2. Completeness

The following data have to be provided for

— all geographical areas at the following levels: national level, NUTS 1, NUTS 2,

— all hypercubes ⁽¹⁾ and all primary marginal distributions ⁽¹⁾:

(1) number of all special cell values 'not available'

(2) number of special cell values 'not available' flagged as 'unreliable'

(3) number of special cell values 'not available' flagged as 'confidential'

(4) number of numerical cell values flagged as 'unreliable'

2. ACCURACY

The following information:

— has to be provided for each data source (section 2.1.) and each topic (section 2.2.), referring to person counts ⁽²⁾ and

— may be provided for data sources (section 2.1.) and topics (section 2.2.), referring to counts of statistical units other than persons (optional)

2.1. Data sources ⁽³⁾

The data as required under point 2.1.1. have to be provided for all geographical areas at the following levels: national level, NUTS 1, NUTS 2. The explanatory metadata as required under point 2.1.2. have to be provided for the national level.

2.1.1. Data

(1) Census population: absolute value and percentage of the estimated target population;

(2) Estimated target population ⁽⁴⁾: absolute value;

(3) Under-coverage (estimated): absolute value and percentage of the census population;

(4) Over-coverage (estimated): absolute value and percentage of the census population;

(5) Number of all record imputations ⁽⁵⁾: absolute value and percentage of the census population;

- (6) Number of all record deletions ⁽⁶⁾: absolute value and percentage of the census population;
- (7) Additionally, for samples: complementary set of statistical units ⁽⁷⁾: absolute value;
- (8) Number of non-imputed records in the data source for statistical units belonging to the target population: absolute value ⁽⁸⁾, percentage of the census population ⁽⁸⁾, percentage of the estimated target population ⁽⁹⁾, and percentage of all non-imputed records in the data source (before any record deletion) ⁽¹⁰⁾;
- (9) additionally, for questionnaire-based data in the data source: ⁽¹¹⁾ unit no-information (before record imputation): absolute value and percentage of the census population.

2.1.2. Explanatory metadata

The explanatory metadata contain descriptions of

- the operation to assess under-coverage and over-coverage, including information on the quality of the estimates for under- and over-coverage,
- any method used to impute or delete records for statistical units,
- any method applied to weigh data records for statistical units,
- additionally for questionnaire-based data in the data source: ⁽¹¹⁾ any measures to identify and limit unit no-information or other measures to correct errors during the collection of data.

2.2. Topics

The data required under point 2.2.1. have to be provided for all geographical areas at the following levels: national level, NUTS 1, NUTS 2. The explanatory metadata required under point 2.2.2. has to be provided for the national level.

2.2.1. Data

- (1) Census population ⁽¹²⁾: absolute value;
- (2) Number of data records ⁽¹³⁾ that contain information on the topic: non-weighted ⁽¹⁴⁾ absolute value, non-weighted ⁽¹⁴⁾ percentage of the census population;
- (3) Number of imputed data records ⁽¹³⁾, ⁽¹⁵⁾ that contain information on the topic: non-weighted ⁽¹⁴⁾ absolute value, non-weighted ⁽¹⁴⁾ percentage of the census population;
- (4) Item imputation ⁽¹³⁾ ⁽¹⁵⁾ for the topic: non-weighted ⁽¹⁴⁾ absolute value, non-weighted ⁽¹⁴⁾ percentage of the census population;
- (5) Item no-information ⁽¹³⁾ (before item-imputation) for the topic: non-weighted ⁽¹⁴⁾ absolute value, non-weighted ⁽¹⁴⁾ percentage of the census population;
- (6) Number of non-imputed observations on the topic: ⁽¹³⁾, ⁽¹⁶⁾ non-weighted ⁽¹⁴⁾ absolute value, non-weighted ⁽¹⁴⁾ percentage of the census population;
- (7) Transmitted data ⁽¹⁷⁾ for the hypercube set out in the table in Annex III for the topic in question ⁽¹⁸⁾: absolute value, percentage of the census population;
- (8) Number of non-imputed data records ⁽¹³⁾ that contain non-imputed information on the topic broken down according to the hypercube set out in the table in Annex III for the topic in question ⁽¹⁸⁾: non-weighted ⁽¹⁴⁾ absolute value, non-weighted ⁽¹⁴⁾ percentage of the census population;

- (9) Additionally, for topics about which information has been collected by means of a sample: coefficient of variation ⁽¹⁹⁾ for the cells in the hypercube set out in Annex III for the topic in question ⁽¹⁸⁾.

2.2.2. Explanatory metadata

The explanatory metadata contain descriptions of the method used to treat item non-response for the topic in question.

For topics about which information has been collected by means of a sample, the metadata also contain descriptions of

- the sampling design,
- possible biases in the estimation due to model assumption errors,
- formulae and algorithms used to calculate the standard error.

3. TIMELINESS AND PUNCTUALITY

The following information has to be provided for the national level:

- (1) Calendar date(s) of the transmission of data to the Commission (Eurostat), broken down by hypercubes ⁽¹⁾;
- (2) Calendar date(s) of major revision(s) of the transmitted data, broken down by hypercubes ⁽¹⁾;
- (3) Calendar date(s) of transmission of the metadata ⁽²⁰⁾.

In the case of major revisions on 1 April 2014 or after, Member States have to report the respective calendar date(s) separately to the Commission (Eurostat) within one week after each major revision.

4. ACCESSIBILITY AND CLARITY (OPTIONAL)

Member States may report on the conditions for access to the data and metadata they make available from their 2011 censuses of population and housing, including on those relating to media, support, documentation, pricing policies, and/or any restrictions.

5. COMPARABILITY

For each topic, Member States have to report on any definition or practice in the Member State which could impair the EU-wide comparability of the data.

6. COHERENCE

For each topic referring to person counts ⁽²⁾, Member States have to provide the average absolute deviation ⁽²¹⁾ for the cell values in the hypercubes set out in Annex III ⁽¹⁸⁾.

⁽¹⁾ As listed in Annex I to Regulation (EU) No 519/2010.

⁽²⁾ Topics, or data sources for topics, for which the total shown in the table in Annex III is the total population.

⁽³⁾ The reporting on the data sources must be comprehensive and free of overlaps in the sense that it is possible to allocate each topic to exactly one data source about which information is provided in this section. If a record linkage has led to the creation of a new data source, Member States have to evaluate the new data source rather than the original data sources from which the new data source has been derived.

⁽⁴⁾ $((1) + (3) - (4))$, referring to the data in point 2.1.1. of this Annex, given in absolute values.

⁽⁵⁾ Any record imputation increases the size of the census population. In a data source resulting from a record linkage, only the records that have been imputed into any of the original data sources, thereby increasing the size of the census population, have to be counted as imputed records in the new data source.

If a data record is weighted in the process of generating the required statistical output for the target population with a weight w_{orig} bigger than 1, it has to be counted as an imputed record with the weight $w_{\text{imputed}} = w_{\text{orig}} - 1$. The reference hypercube for the weights w_{orig} is the one listed below the table in Annex III for the statistical units on which the data source reports.

⁽⁶⁾ Any record deletion decreases the size of the census population. In a data source resulting from a record linkage, only the records that have been deleted in any of the original data sources, thereby decreasing the size of the census population, have to be counted as deleted records in the new data source.

If a data record is weighted in the process of generating the required statistical output for the target population with a weight w_{orig} smaller than 1, it has to be counted as a deleted record with $w_{\text{deleted}} = 1 - w_{\text{orig}}$. The reference hypercube for the weights w_{orig} is the one listed below the table in Annex III for the statistical units on which the data source reports.

⁽⁷⁾ If a data source comprises, as a matter of methodological principle, data records for only a sample of the statistical units in its estimated target population, the size of the complementary set of statistical units is calculated according to the sampling design.

- ⁽⁸⁾ $((1) - (4) - (5) - (7))$, referring to the data in point 2.1.1. of this Annex, given in absolute values, respectively $100 * ((1) - (4) - (5) - (7)) / (1)$.
- ⁽⁹⁾ $100 * ((1) - (4) - (5) - (7)) / ((1) + (3) - (4))$, referring to the data in point 2.1.1. of this Annex.
- ⁽¹⁰⁾ $100 * ((1) - (4) - (5) - (7)) / ((1) - (5) + (6) - (7))$, referring to the data in point 2.1.1. of this Annex.
- ⁽¹¹⁾ In a data source resulting from a record linkage of more than one questionnaire-based data sources, the information has to be provided for each original questionnaire-based data source.
- ⁽¹²⁾ As identified under point 2.1.1. (1) of this Annex for the data source from which census information on the topic is derived for the target population.
- ⁽¹³⁾ For the census population in the data source from which census information on the topic is derived.
- ⁽¹⁴⁾ If the data records are weighted in the process of generating the required statistical output for the topic in question, 'weighted' means that these weights are applied to the data records for the count, 'non-weighted' means that these weights are not applied to the data records for the count. The reference hypercubes for the weights are those listed for the topics in the table in Annex III.
- ⁽¹⁵⁾ An item imputation has no effect on the size of the census population. For a topic belonging to a data source resulting from a record linkage, any record that contains information on that topic as a result of a record imputation into any of the original data sources is counted as a record imputation if the imputation increases the size of the census population, and as an item imputation for that topic if the imputation does not increase the size of the census population.
- ⁽¹⁶⁾ $((2) - (3) - (4))$, referring to the data in section 2.2.1. of this Annex.
- ⁽¹⁷⁾ The data transmitted on the basis of Regulation (EU) No 519/2010 in the hypercube listed for the respective topic in the table in Annex III.
- ⁽¹⁸⁾ The geographical area for which the information has to be provided is indicated in the table in Annex III.
- ⁽¹⁹⁾ Where a numerical cell value is smaller than 26, the coefficient of variation can be replaced by the special value 'not available'.
- ⁽²⁰⁾ As listed in Annex II to Regulation (EU) No 519/2010.
- ⁽²¹⁾ The arithmetic average of the absolute (positive) value of the difference between the numerical cell value and its arithmetic average, with the arithmetic averages being calculated for all hypercubes (as listed in Annex I to Regulation (EU) No 519/2010) in which the respective hypercube as set out in Annex III is contained.
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ANNEX III

Cross-tabulations for the quality assessment

For the hypercubes set out below, the following data have to be provided:

- all topics as required by Annex II, points 2.2.1. (7) and (8),
- the topics about which information has been collected by means of a sample, as required by Annex II, point 2.2.1. (9), and
- the coherence between the hypercubes ⁽¹⁾ as required by Annex II, point 6.

Topic(s)	No. of reference hypercube (*), (**)	Cross-tabulations for the quality assessment	
		Total	Breakdowns (***)
Sex, Age	42	Total population	GEO.L. SEX. AGE.H.
Current activity status	18	Total population	GEO.L. SEX. AGE.M. CAS.L.
Location of place of work	22	Total population	LPW.L. SEX. AGE.M.
Locality	4	Total population	GEO.L. SEX. AGE.M. LOC.
Legal marital status	18	Total population	GEO.L. SEX. AGE.M. LMS.
Occupation	13	Total population	GEO.L. SEX. AGE.M. OCC.
Industry	14	Total population	GEO.L. SEX. AGE.M. IND.H.
Status in employment	12	Total population	GEO.L. SEX. AGE.M. SIE.
Educational attainment	14	Total population	GEO.L. SEX. AGE.M. EDU.
Country / place of birth	45 26	Total population	GEO.L. SEX. AGE.M. POB.M. GEO.N. SEX. AGE.M. POB.H.
Country of citizenship	45 27	Total population	GEO.L. SEX. AGE.M. COC.M. GEO.N. SEX. AGE.M. COC.H.
Year of arrival in the country	25	Total population	GEO.L. SEX. AGE.M. YAE.L.
Place of usual residence one year prior to the census	17	Total population	GEO.L. SEX. AGE.M. ROY.
Household status	1	Total population	GEO.L. SEX. AGE.M. HST.H.
Family status	6	Total population	GEO.L. SEX. AGE.M. FST.H.
Type of family nucleus, Size of family nucleus (optional)	52	Number of all families	GEO.L. TFN.H. SFN.H.
Type of private household, Size of private household (optional)	5	Number of all private households	GEO.L. TPH.H. SPH.H.
Tenure status of household (optional)	5	Number of all private households	GEO.L. TSH. SPH.H.
Housing arrangement	38	Total population	GEO.L. SEX. AGE.M. HAR.L.
Type of living quarters (optional)	59	Number of all living quarters	GEO.L. TLQ.
Occupancy status of conventional dwellings (optional)	53	Number of all conventional dwellings	GEO.L. OCS.

⁽¹⁾ As listed in Annex I to Regulation (EU) No 519/2010.

Topic(s)	No. of reference hypercube (*), (**)	Cross-tabulations for the quality assessment	
		Total	Breakdowns (***)
Type of ownership (optional)	41	Number of all occupied conventional dwellings	GEO.L. OWS.
Number of occupants, Useful floor space and/or number of rooms of housing unit (optional)	41	Number of all occupied conventional dwellings	GEO.L. NOC.H. (UFS. or NOR.)
Number of occupants, Density standard (optional)	41	Number of all occupied conventional dwellings	GEO.L. NOC.H. (DFS. or DRM.)
Water supply system (optional)	41	Number of all occupied conventional dwellings	GEO.L. WSS.
Toilet facilities (optional)	41	Number of all occupied conventional dwellings	GEO.L. TOI.
Bathing facilities (optional)	41	Number of all occupied conventional dwellings	GEO.L. BAT.
Type of heating (optional)	41	Number of all occupied conventional dwellings	GEO.L. TOH.
Dwellings by type of building (optional)	53	Number of all conventional dwellings	GEO.L. TOB.
Dwellings by period of construction (optional)	53	Number of all conventional dwellings	GEO.L. POC.

(*) As listed in Annex I to Regulation (EU) No 519/2010.

(**) For topics where data records are weighted in the process of generating the required statistical output, the weights used for the reference hypercube below provide the basis for the quality-related data as required by Annex II, points 2.2.1. (7), (8) and (9).

(***) The code identifies the breakdown as specified under this code in the Annex to Regulation (EC) No 1201/2009.

The reference hypercubes ⁽¹⁾ for the weights w_{orig} mentioned under Annex II, points 2.1.1. (5) and (6) are:

- hypercube ⁽¹⁾ No 42 for natural persons ⁽²⁾;
- hypercube ⁽¹⁾ No 52 for families ⁽²⁾;
- hypercube ⁽¹⁾ No 5 for private households ⁽²⁾;
- hypercube ⁽¹⁾ No 59 for living quarters ⁽²⁾;
- hypercube ⁽¹⁾ No 53 for conventional dwellings ⁽²⁾.

⁽¹⁾ As listed in Annex I to Regulation (EU) No 519/2010.

⁽²⁾ Statistical units on which the data source reports.

COMMISSION REGULATION (EU) No 1152/2010**of 8 December 2010****amending, for the purpose of its adaptation to technical progress, Regulation (EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1907/2006 of 18 December 2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC⁽¹⁾, and in particular Article 13(3) thereof,

Whereas:

- (1) Commission Regulation (EC) No 440/2008⁽²⁾ contains the test methods for the purposes of the determination of the physico-chemical properties, toxicity and eco-toxicity of substances to be applied for the purposes of Regulation (EC) No 1907/2006.
- (2) It is necessary to update Regulation (EC) No 440/2008 to include with priority two new in vitro test methods for ocular irritation recently adopted by the OECD, in order to obtain a reduction of the number of animals to be used for experimental purposes, in accordance with

Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes⁽³⁾. Stakeholders have been consulted on this draft.

- (3) Regulation (EC) No 440/2008 should therefore be amended accordingly.
- (4) The measures provided for in this Regulation are in accordance with the opinion of the Committee established under Article 133 of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS REGULATION:

Article 1

In Part B of the Annex to Regulation (EC) No 440/2008, Chapters B.47 and B.48 are added as set out in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the third day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 8 December 2010.

*For the Commission**The President*

José Manuel BARROSO

⁽¹⁾ OJ L 396, 30.12.2006, p. 1.

⁽²⁾ OJ L 142, 31.5.2008, p. 1.

⁽³⁾ OJ L 358, 18.12.1986, p. 1.

ANNEX

B. 47. BOVINE CORNEAL OPACITY AND PERMEABILITY TEST METHOD FOR IDENTIFYING OCULAR CORROSIVES AND SEVERE IRRITANTS

INTRODUCTION

1. The Bovine Corneal Opacity and Permeability (BCOP) test method is an *in vitro* test method that can be used, under certain circumstances and with specific limitations, to classify substances and mixtures as “ocular corrosives and severe irritants” (1) (2) (3). For the purpose of this test method, severe irritants are defined as those that induce ocular lesions that persist in the rabbit for at least 21 days after administration. While it is not considered valid as a complete replacement for the *in vivo* rabbit eye test, the BCOP is recommended for use as part of a tiered-testing strategy for regulatory classification and labelling within a specific applicability domain (4) (5). Test substances and mixtures (6) can be classified as ocular corrosives or severe irritants without further testing in rabbits. A substance that tests negative would need to be tested in rabbits using a sequential testing strategy, as outlined in OECD Test Guideline 405 (7) (chapter B. 5 of this Annex).
2. The purpose of this test method is to describe the procedures used to evaluate the potential ocular corrosivity or severe irritancy of a test substance as measured by its ability to induce opacity and increased permeability in an isolated bovine cornea. Toxic effects to the cornea are measured by: (i) decreased light transmission (opacity), and (ii) increased passage of sodium fluorescein dye (permeability). The opacity and permeability assessments of the cornea following exposure to a test substance are combined to derive an *In Vitro* Irritancy Score (IVIS), which is used to classify the irritancy level of the test substance.
3. Ocular irritants that induce lesions that resolve in less than 21 days and non-irritants have also been tested using the BCOP test method. However, the accuracy and reliability of the BCOP test method for substances in these categories have not been formally evaluated.
4. Definitions are provided in Appendix 1.

INITIAL CONSIDERATIONS AND LIMITATIONS

5. This test method is based on the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) BCOP test method protocol (8), which was developed following an international validation study (4)(5)(9), with contributions from the European Centre for the Validation of Alternative Methods (ECVAM) and the Japanese Center for the Validation of Alternative Methods (JaCVAM). The protocol is based on information obtained from the Institute for In Vitro Sciences (IIVS) and INVITTOX Protocol 124 (10), which represents the protocol used for the European Community-sponsored prevalidation study of the BCOP assay conducted in 1997-1998. Both of these protocols are based on the BCOP assay methodology first reported by Gautheron *et al.* (11).
6. The identified limitations for this test method are based on the high false positive rates for alcohols and ketones and the high false negative rate for solids observed in the validation database (see paragraph 44) (5). When substances within these chemical and physical classes are excluded from the database, the accuracy of BCOP across the EU, EPA, and GHS classification systems is substantially improved (5). Based on the purpose of this assay (*i.e.*, to identify ocular corrosives/severe irritants only), false negative rates are not critical since such substances would be subsequently tested in rabbits or with other adequately validated *in vitro* tests, depending on regulatory requirements, using a sequential testing strategy in a weight of evidence approach. Furthermore, the current validation database did not allow for an adequate evaluation of some chemical or product classes (*e.g.*, mixtures). However, investigators could consider using this test method for all types of test material (including mixtures), whereby a positive result could be accepted as indicative of an ocular corrosive or severe irritant response. However, positive results obtained with alcohols or ketones should be interpreted cautiously due to risk of over-prediction.
7. All procedures with bovine eyes and bovine corneas should follow the testing facility's applicable regulations and procedures for handling animal-derived materials, which include, but are not limited to, tissues and tissue fluids. Universal laboratory precautions are recommended (12).
8. A limitation of the test method is that, although it takes into account some of the ocular effects evaluated in the rabbit ocular irritancy test method and to some degree their severity, it does not consider conjunctival and iridal injuries. Also, although the reversibility of corneal lesions cannot be evaluated *per se* in the BCOP assay, it has been proposed, based on rabbit eye studies, that an assessment of the initial depth of corneal injury can be used to distinguish between irreversible and reversible effects (13). Finally, the BCOP does not allow for an assessment of the potential for systemic toxicity associated with ocular exposure.

9. Efforts are ongoing to further characterize the usefulness and limitations of the BCOP assay for identifying non-severe irritants and non-irritants (see also paragraph 45). Users are also encouraged to provide specimens and/or data to validation organizations for a formal evaluation of possible future uses of the BCOP test method, including for the identification of non-severe irritants and non-irritants.
10. For any laboratory initially establishing this assay, the proficiency chemicals provided in Appendix 2 should be used. A laboratory can use these chemicals to demonstrate their technical competence in performing the BCOP test method prior to submitting BCOP assay data for regulatory hazard classification purposes.

PRINCIPLE OF THE TEST

11. The BCOP test method is an organotypic model that provides short-term maintenance of normal physiological and biochemical function of the bovine cornea *in vitro*. In this test method, damage by the test substance is assessed by quantitative measurements of changes in corneal opacity and permeability with an opacitometer and a visible light spectrophotometer, respectively. Both measurements are used to calculate an IVIS, which is used to assign an *in vitro* irritancy hazard classification category for prediction of the *in vivo* ocular irritation potential of a test substance (see Decision criteria).
12. The BCOP test method uses isolated corneas from the eyes of freshly slaughtered cattle. Corneal opacity is measured quantitatively as the amount of light transmission through the cornea. Permeability is measured quantitatively as the amount of sodium fluorescein dye that passes across the full thickness of the cornea, as detected in the medium in the posterior chamber. Test substances are applied to the epithelial surface of the cornea by addition to the anterior chamber of the corneal holder. Appendix 3 provides a description and a diagram of a corneal holder used in the BCOP. Corneal holders can be obtained commercially from different sources or can be constructed.

Source and Age of Bovine Eyes and Selection of Animal Species

13. Cattle sent to slaughterhouses are typically killed either for human consumption or for other commercial uses. Only healthy animals considered suitable for entry into the human food chain are used as a source of corneas for use in the BCOP. Because cattle have a wide range of weights, depending on breed, age, and sex, there is no recommended weight for the animal at the time of slaughter.
14. Variations in corneal dimensions can result when using eyes from animals of different ages. Corneas with a horizontal diameter $> 30,5$ mm and central corneal thickness (CCT) values $\geq 1\,100$ μm are generally obtained from cattle older than eight years, while those with a horizontal diameter $< 28,5$ mm and CCT < 900 μm are generally obtained from cattle less than five years old (14). For this reason, eyes from cattle greater than 60 months old are not typically used. Eyes from cattle less than 12 months of age have not traditionally been used since the eyes are still developing and the corneal thickness and corneal diameter are considerably smaller than that reported for eyes from adult cattle. However, the use of corneas from young animals (*i.e.*, 6 to 12 months old) is permissible since there are some advantages, such as increased availability, a narrow age range, and decreased hazards related to potential worker exposure to Bovine Spongiform Encephalopathy (15). As further evaluation of the effect of corneal size or thickness on responsiveness to corrosive and irritant substances would be useful, users are encouraged to report the estimated age and/or weight of the animals providing the corneas used in a study.

Collection and Transport of Eyes to the Laboratory

15. Eyes are collected by slaughterhouse employees. To minimize mechanical and other types of damage to the eyes, the eyes should be enucleated as soon as possible after death. To prevent exposure of the eyes to potentially irritant substances, the slaughterhouse employees should not use detergent when rinsing the head of the animal.
16. Eyes should be immersed completely in Hanks' Balanced Salt Solution (HBSS) in a suitably sized container, and transported to the laboratory in such a manner as to minimize deterioration and/or bacterial contamination. Because the eyes are collected during the slaughter process, they might be exposed to blood and other biological substances, including bacteria and other microorganisms. Therefore, it is important to ensure that the risk of contamination is minimized (*e.g.*, by keeping the container containing the eyes on wet ice, by adding antibiotics to the HBSS used to store the eyes during transport [*e.g.*, penicillin at 100 IU/mL and streptomycin at 100 $\mu\text{g/mL}$]).
17. The time interval between collection of the eyes and use of corneas in the BCOP should be minimized (typically collected and used on the same day) and should be demonstrated to not compromise the assay results. These results are based on the selection criteria for the eyes, as well as the positive and negative control responses. All eyes used in the assay should be from the same group of eyes collected on a specific day.

Selection Criteria for Eyes Used in the BCOP

18. The eyes, once they arrive at the laboratory, are carefully examined for defects including increased opacity, scratches, and neovascularisation. Only corneas from eyes free of such defects are to be used.
19. The quality of each cornea is also evaluated at later steps in the assay. Corneas that have an opacity greater than seven opacity units (NOTE: the opacitometer should be calibrated with opacity standards that are used to establish the opacity units, see Appendix 3) after an initial one hour equilibration period are to be discarded.
20. Each treatment group (test substance, concurrent negative and positive controls) consists of a minimum of three eyes. Three corneas should be used for the negative control corneas in the BCOP assay. Since all corneas are excised from the whole globe, and mounted in the corneal chambers, there is the potential for artefacts from handling upon individual corneal opacity and permeability values (including negative control). Furthermore, the opacity and permeability values from the negative control corneas are used to correct the test article and positive control-treated corneal opacity and permeability values in the IVIS calculations.

PROCEDURE**Preparation of the Eyes**

21. Corneas free of defects are dissected with a 2 to 3 mm rim of sclera remaining to assist in subsequent handling, with care taken to avoid damage to the corneal epithelium and endothelium. Isolated corneas are mounted in specially designed corneal holders that consist of anterior and posterior compartments, which interface with the epithelial and endothelial sides of the cornea, respectively. Both chambers are filled to excess with pre-warmed Eagle's Minimum Essential Medium (EMEM) (posterior chamber first), ensuring that no bubbles are formed. The device is then equilibrated at 32 ± 1 °C for at least one hour to allow the corneas to equilibrate with the medium and to achieve normal metabolic activity, to the extent possible (the approximate temperature of the corneal surface *in vivo* is 32 °C).
22. Following the equilibration period, fresh pre-warmed EMEM is added to both chambers and baseline opacity readings are taken for each cornea. Any corneas that show macroscopic tissue damage (e.g., scratches, pigmentation, neovascularisation) or an opacity > 7 opacity units are discarded. The mean opacity of all equilibrated corneas is calculated. A minimum of three corneas with opacity values close to the median value for all corneas are selected as negative (or solvent) control corneas. The remaining corneas are then distributed into treatment and positive control groups.
23. Because the heat capacity of water is higher than that of air, water provides more stable temperature conditions for incubation. Therefore, the use of a water bath for maintaining the corneal holder and its contents at 32 ± 1 °C is recommended. However, air incubators might also be used, assuming precaution to maintain temperature stability (e.g., by pre-warming of holders and media).

Application of the Test Substance

24. Two different treatment protocols are used, one for liquids and surfactants (solids or liquids), and one for non-surfactant solids.
25. Liquids are tested undiluted, while surfactants are tested at a concentration of 10 % w/v in a 0,9 % sodium chloride solution, distilled water, or other solvent that has been demonstrated to have no adverse effects on the test system. Semi-solids, creams, and waxes are typically tested as liquids. Appropriate justification should be provided for alternative dilution concentrations. Corneas are exposed to liquids and surfactants for 10 minutes. Use of other exposure times should be accompanied by adequate scientific rationale.
26. Non-surfactant solids are typically tested as solutions or suspensions at 20 % concentration in a 0,9 % sodium chloride solution, distilled water, or other solvent that has been demonstrated to have no adverse effects on the test system. In certain circumstances and with proper scientific justification, solids may also be tested neat by direct application onto the corneal surface using the open chamber method (see paragraph 29). Corneas are exposed to solids for four hours, but as with liquids and surfactants, alternative exposure times may be used with appropriate scientific rationale.
27. Different treatment methods can be used, depending on the physical nature and chemical characteristics (e.g., solids, liquids, viscous vs. non-viscous liquids) of the test substance. The critical factor is ensuring that the test substance adequately covers the epithelial surface and that it is adequately removed during the rinsing steps. A closed-chamber method is typically used for non-viscous to slightly viscous liquid test substances, while an open-chamber method is typically used for semi-viscous and viscous liquid test substances and for neat solids.

28. In the closed-chamber method, sufficient test substance (750 µL) to cover the epithelial side of the cornea is introduced into the anterior chamber through the dosing holes on the top surface of the chamber, and the holes are subsequently sealed with the chamber plugs during the exposure. It is important to ensure that each cornea is exposed to a test substance for the appropriate time interval.
29. In the open-chamber method, the window-locking ring and glass window from the anterior chamber are removed prior to treatment. The control or test substance (750 µL, or enough test substance to completely cover the cornea) is applied directly to the epithelial surface of the cornea using a micropipette. If a test substance is difficult to pipette, the test substance can be pressure-loaded into a positive displacement pipette to aid in dosing. The pipette tip of the positive displacement pipette is inserted into the dispensing tip of the syringe so that the material can be loaded into the displacement tip under pressure. Simultaneously, the syringe plunger is depressed as the pipette piston is drawn upwards. If air bubbles appear in the pipette tip, the test article is removed (expelled) and the process repeated until the tip is filled without air bubbles. If necessary, a normal syringe (without a needle) can be used since it permits measuring an accurate volume of test substance and an easier application to the epithelial surface of the cornea. After dosing, the glass window is replaced on the anterior chamber to recreate a closed system.

Post-Exposure Incubation

30. After the exposure period, the test substance, the negative control, or the positive control substance is removed from the anterior chamber and the epithelium washed at least three times (or until no visual evidence of test substance can be observed) with EMEM (containing phenol red). Phenol red-containing medium is used for rinsing since a colour change in the phenol red may be monitored to determine the effectiveness of rinsing acidic or alkaline materials. The corneas are washed more than three times if the phenol red is still discoloured (yellow or purple), or the test substance is still visible. Once the medium is free of test substance, the corneas are given a final rinse with EMEM (without phenol red). The EMEM (without phenol red) is used as a final rinse to ensure removal of the phenol red from the anterior chamber prior to the opacity measurement. The anterior chamber is then refilled with fresh EMEM without phenol red.
31. For liquids or surfactants, after rinsing, the corneas are incubated for an additional two hours at 32 ± 1 °C. Longer post-exposure time may be useful in certain circumstances and could be considered on a case-by-case basis. Corneas treated with solids are rinsed thoroughly at the end of the four-hour exposure period, but do not require further incubation.
32. At the end of the post-exposure incubation period for liquids and surfactants and at the end of the four-hour exposure period for non-surfactant solids, the opacity and permeability of each cornea are recorded. Also, each cornea is observed visually and pertinent observations recorded (e.g., tissue peeling, residual test substance, non-uniform opacity patterns). These observations could be important as they may be reflected by variations in the opacitometer readings.

Control Substances

33. Concurrent negative or solvent/vehicle controls and positive controls are included in each experiment.
34. When testing a liquid substance at 100 %, a concurrent negative control (e.g., 0,9 % sodium chloride solution or distilled water) is included in the BCOP test method so that nonspecific changes in the test system can be detected and to provide a baseline for the assay endpoints. It also ensures that the assay conditions do not inappropriately result in an irritant response.
35. When testing a diluted liquid, surfactant, or solid, a concurrent solvent/vehicle control group is included in the BCOP test method so that nonspecific changes in the test system can be detected and to provide a baseline for the assay endpoints. Only a solvent/vehicle that has been demonstrated to have no adverse effects on the test system can be used.
36. A known ocular irritant is included as a concurrent positive control in each experiment to verify that an appropriate response is induced. As the BCOP assay is being used in this test method to identify corrosive or severe irritants, ideally the positive control should be a reference substance that induces a severe response in this test method. However, to ensure that variability in the positive control response across time can be assessed, the magnitude of irritant response should not be excessive.
37. Examples of positive controls for liquid test substances are dimethylformamide or 1 % sodium hydroxide. An example of a positive control for solid test substances is 20 % (weight to volume) imidazole in 0,9 % sodium chloride solution.

38. Benchmark substances are useful for evaluating the ocular irritancy potential of unknown chemicals of a specific chemical or product class, or for evaluating the relative irritancy potential of an ocular irritant within a specific range of irritant responses.

Endpoints Measured

39. Opacity is determined by the amount of light transmission through the cornea. Corneal opacity is measured quantitatively with the aid of an opacitometer, resulting in opacity values measured on a continuous scale.
40. Permeability is determined by the amount of sodium fluorescein dye that penetrates all corneal cell layers (*i.e.*, the epithelium on the outer cornea surface through the endothelium on the inner cornea surface). 1 mL sodium fluorescein solution (4 or 5 mg/mL when testing liquids and surfactants or non-surfactant solids, respectively) is added to the anterior chamber of the corneal holder, which interfaces with the epithelial side of the cornea, while the posterior chamber, which interfaces with the endothelial side of the cornea, is filled with fresh EMEM. The holder is then incubated in a horizontal position for 90 ± 5 min at 32 ± 1 °C. The amount of sodium fluorescein that crosses into the posterior chamber is quantitatively measured with the aid of UV/VIS spectrophotometry. Spectrophotometric measurements evaluated at 490 nm are recorded as optical density (OD₄₉₀) or absorbance values, which are measured on a continuous scale. The fluorescein permeability values are determined using OD₄₉₀ values based upon a visible light spectrophotometer using a standard 1 cm path length.
41. Alternatively, a 96-well microtiter plate reader may be used provided that; (i) the linear range of the plate reader for determining fluorescein OD₄₉₀ values can be established; and (ii), the correct volume of fluorescein samples are used in the 96-well plate to result in OD₄₉₀ values equivalent to the standard 1 cm path length (this could require a completely full well [usually 360 µL]).

DATA AND REPORTING

Data Evaluation

42. Once the opacity and mean permeability (OD₄₉₀) values have been corrected for background opacity and the negative control permeability OD₄₉₀ values, the mean opacity and permeability OD₄₉₀ values for each treatment group should be combined in an empirically-derived formula to calculate an *in vitro* irritancy score (IVIS) for each treatment group as follows:

$$\text{IVIS} = \text{mean opacity value} + (15 \times \text{mean permeability OD}_{490} \text{ value})$$

Sina *et al.* (16) reported that this formula was derived during in-house and inter-laboratory studies. The data generated for a series of 36 compounds in a multi-laboratory study were subjected to a multivariate analysis to determine the equation of best fit between *in vivo* and *in vitro* data. This analysis was performed by scientists at two separate companies, who derived nearly identical equations.

43. The opacity and permeability values should also be evaluated independently to determine whether a test substance induced corrosivity or severe irritation through only one of the two endpoints (see Decision Criteria).

Decision Criteria

44. A substance that induces an IVIS $\geq 55,1$ is defined as a corrosive or severe irritant. As stated in paragraph 1, if the test substance is not identified as an ocular corrosive or severe irritant, additional testing should be conducted for classification and labelling purposes. The BCOP test method has an overall accuracy of 79 % (113/143) to 81 % (119/147), a false positive rate of 19 % (20/103) to 21 % (22/103), and a false negative rate of 16 % (7/43) to 25 % (10/40), when compared to *in vivo* rabbit eye test method data classified according to the EPA (1), EU (2), or GHS (3) classification systems. When substances within certain chemical (*i.e.*, alcohols, ketones) or physical (*i.e.*, solids) classes are excluded from the database, the accuracy of BCOP across the EU, EPA, and GHS classification systems ranges from 87 % (72/83) to 92 % (78/85), the false positive rates range from 12 % (7/58) to 16 % (9/56), and the false negative rates range from 0 % (0/27) to 12 % (3/26).
45. Even if an ocular corrosive or severe irritant classification is not obtained for a test substance, BCOP data can be useful, in conjunction with test data from the *in vivo* rabbit eye test or from an adequately validated *in vitro* test, to further evaluate the usefulness and limitations of the BCOP test method for identifying non-severe irritants and non-irritants (a Guidance Document on the use of *in vitro* ocular toxicity test methods is under development).

Study Acceptance Criteria

46. A test is considered acceptable if the positive control gives an IVIS that falls within two standard deviations of the current historical mean, which is to be updated at least every three months, or each time an acceptable test is conducted in laboratories where tests are conducted infrequently (*i.e.*, less than once a month). The negative or solvent/vehicle control responses should result in opacity and permeability values that are less than the established upper limits for background opacity and permeability values for bovine corneas treated with the respective negative or solvent/vehicle control.

Test Report

47. The test report should include the following information, if relevant to the conduct of the study:

Test and Control Substances

Chemical name(s) such as the structural name used by the Chemical Abstracts Service (CAS), followed by other names, if known;

The CAS Registry Number (RN), if known;

Purity and composition of the substance or mixture (in percentage(s) by weight), to the extent this information is available;

Physicochemical properties such as physical state, volatility, pH, stability, chemical class, water solubility relevant to the conduct of the study;

Treatment of the test/control substances prior to testing, if applicable (*e.g.*, warming, grinding);

Stability, if known.

Information Concerning the Sponsor and the Test Facility

Name and address of the sponsor, test facility and study director;

Identification of the source of the eyes (*i.e.*, the facility from which they were collected);

Storage and transport conditions of eyes (*e.g.*, date and time of eye collection, time interval prior to initiating testing, transport media and temperature conditions, any antibiotics used);

If available, specific characteristics of the animals from which the eyes were collected (*e.g.*, age, sex, weight of the donor animal).

*Justification of the Test Method and Protocol Used**Test Method Integrity*

The procedure used to ensure the integrity (*i.e.*, accuracy and reliability) of the test method over time (*e.g.*, periodic testing of proficiency substances, use of historical negative and positive control data).

Criteria for an Acceptable Test

Acceptable concurrent positive and negative control ranges based on historical data;

If applicable, acceptable concurrent benchmark control ranges based on historical data.

Test Conditions

Description of test system used;

Type of corneal holder used;

Calibration information for devices used for measuring opacity and permeability (*e.g.*, opacitometer and spectrophotometer);

Information on the bovine corneas used, including statements regarding their quality;

Details of test procedure used;

Test substance concentration(s) used;

Description of any modifications of the test procedure;

Reference to historical data of the model (e.g., negative and positive controls, proficiency substances, benchmark substances);

Description of evaluation criteria used.

Results

Tabulation of data from individual test samples (e.g., opacity and OD₄₉₀ values and calculated IVIS for the test substance and the positive, negative, and benchmark controls [if included], reported in tabular form, including data from replicate repeat experiments as appropriate, and means $\pm$ the standard deviation for each experiment);

Description of other effects observed.

Discussion of the Results

Conclusion

LITERATURE

- (1) U.S. EPA (1996). Label Review Manual: 2nd Edition. EPA737-B-96-001. Washington, DC: U.S. Environmental Protection Agency.

- (2) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directive 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, p. 1.

- (3) UN (2007). Globally Harmonized System of Classification and Labelling of Chemicals (GHS). Second revised edition, New York & Geneva: United Nations Publications, 2007. Available:

[http://www.unece.org/trans/danger/publi/ghs/ghs_rev02/02files_e.html]

- (4) ESAC (2007). Statement on the conclusion of the ICCVAM retrospective study on organotypic *in vitro* assays as screening tests to identify potential ocular corrosives and severe eye irritants. Available:

[<http://ecvam.jrc.it/index.htm>]

- (5) ICCVAM (2007). Test Method Evaluation Report - *In Vitro* Ocular Toxicity Test Methods for Identifying Ocular Severe Irritants and Corrosives. Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) and the National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM). NIH Publication No: 07-4517. Available:

[http://iccvam.niehs.nih.gov/methods/ocutox/ivocutox/ocu_tmter.htm]

- (6) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC. OJ L 396, 30.12.2006, p. 1.

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Appendix 1

DEFINITIONS

Accuracy: The closeness of agreement between test method results and accepted reference values. It is a measure of test method performance and one aspect of 'relevance'. The term is often used interchangeably with 'concordance', to mean the proportion of correct outcomes of a test method.

Benchmark substance: A substance used as a standard for comparison to a test substance. A benchmark substance should have the following properties; (i) a consistent and reliable source(s); (ii) structural and functional similarity to the class of substances being tested; (iii) known physical/chemical characteristics; (iv) supporting data on known effects, and (v) known potency in the range of the desired response.

Cornea: The transparent part of the front of the eyeball that covers the iris and pupil and admits light to the interior.

Corneal opacity: Measurement of the extent of opaqueness of the cornea following exposure to a test substance. Increased corneal opacity is indicative of damage to the cornea. Opacity can be evaluated subjectively as done in the Draize rabbit eye test, or objectively with an instrument such as an 'opacitometer'.

Corneal permeability: Quantitative measurement of damage to the corneal epithelium by a determination of the amount of sodium fluorescein dye that passes through all corneal cell layers.

EPA Category 1: Corrosive (irreversible destruction of ocular tissue) or corneal involvement or irritation persisting for more than 21 days (1).

EU Category R41: Production of tissue damage in the eye, or serious physical decay of vision, following application of a test substance to the anterior surface of the eye, which is not fully reversible within 21 days of application (2).

False negative rate: The proportion of all positive substances falsely identified by a test method as negative. It is one indicator of test method performance.

False positive rate: The proportion of all negative substances that are falsely identified by a test method as positive. It is one indicator of test method performance.

GHS (Globally Harmonized System of Classification and Labelling of Chemicals): A system proposing the classification of chemicals (substances and mixtures) according to standardized types and levels of physical, health and environmental hazards, and addressing corresponding communication elements, such as pictograms, signal words, hazard statements, precautionary statements and safety data sheets, so that to convey information on their adverse effects with a view to protect people (including employers, workers, transporters, consumers and emergency responders) and the environment (3).

GHS Category 1: Production of tissue damage in the eye, or serious physical decay of vision, following application of a test substance to the anterior surface of the eye, which is not fully reversible within 21 days of application (3).

Hazard: Inherent property of an agent or situation having the potential to cause adverse effects when an organism, system or (sub) population is exposed to that agent.

In Vitro Irritancy Score (IVIS): An empirically-derived formula used in the BCOP assay whereby the mean opacity and mean permeability values for each treatment group are combined into a single *in vitro* score for each treatment group. The IVIS = mean opacity value + (15 × mean permeability value).

Negative control: An untreated replicate containing all components of a test system. This sample is processed with test substance-treated samples and other control samples to determine whether the solvent interacts with the test system.

Non-irritant: Substances that are not classified as EPA Category I, II, or III; EU Category R41 or R36; or GHS Category 1, 2A, or 2B ocular irritants.

Ocular corrosive: (a) A substance that causes irreversible tissue damage to the eye; (b) Substances that are classified as GHS Category 1, EPA Category I, or EU Category R41 ocular irritants (1) (2) (3).

Ocular irritant: (a) A substance that produces a reversible change in the eye following application to the anterior surface of the eye; (b) Substances that are classified as EPA Category II or III, EU Category R36, or GHS Category 2A or 2B ocular irritants (1) (2) (3).

Ocular severe irritant: (a) A substance that causes tissue damage in the eye following application to the anterior surface of the eye that does not resolve within 21 days of application or causes serious physical decay of vision; (b) Substances that are classified as GHS Category 1, EPA Category I, or EU Category R41 ocular irritants (1) (2) (3).

Opacitometer: An instrument used to measure 'corneal opacity' by quantitatively evaluating light transmission through the cornea. The typical instrument has two compartments, each with its own light source and photocell. One compartment is used for the treated cornea, while the other is used to calibrate and zero the instrument. Light from a halogen lamp is sent through a control compartment (empty chamber without windows or liquid) to a photocell and compared to the light sent through the experimental compartment, which houses the chamber containing the cornea, to a photocell. The difference in light transmission from the photocells is compared and a numeric opacity value is presented on a digital display.

Positive control: A replicate containing all components of a test system and treated with a substance known to induce a positive response. To ensure that variability in the positive control response across time can be assessed, the magnitude of the severe response should not be excessive.

Reliability: Measures of the extent that a test method can be performed reproducibly within and between laboratories over time, when performed using the same protocol. It is assessed by calculating intra- and inter-laboratory reproducibility and intra-laboratory repeatability.

Solvent/vehicle control: An untreated sample containing all components of a test system, including the solvent or vehicle that is processed with the test substance-treated and other control samples to establish the baseline response for the samples treated with the test substance dissolved in the same solvent or vehicle. When tested with a concurrent negative control, this sample also demonstrates whether the solvent or vehicle interacts with the test system.

Tiered testing: A stepwise testing strategy where all existing information on a test substance is reviewed, in a specified order, using a weight of evidence process at each tier to determine if sufficient information is available for a hazard classification decision, prior to progression to the next tier. If the irritancy potential of a test substance can be assigned based on the existing information, no additional testing is required. If the irritancy potential of a test substance cannot be assigned based on the existing information, a step-wise sequential animal testing procedure is performed until an unequivocal classification can be made.

Validated test method: A test method for which validation studies have been completed to determine the relevance (including accuracy) and reliability for a specific purpose. It is important to note that a validated test method may not have sufficient performance in terms of accuracy and reliability to be found acceptable for the proposed purpose.

Weight-of-evidence: The process of considering the strengths and weaknesses of various pieces of information in reaching and supporting a conclusion concerning the hazard potential of a substance.

Appendix 2

Proficiency substances for the BCOP test method

Prior to routine use of a test method that adheres to this test method, laboratories may wish to demonstrate technical proficiency by correctly identifying the ocular corrosivity classification of the 10 substances recommended in Table 1. These substances were selected to represent the range of responses for local eye irritation/corrosion, which is based on results in the *in vivo* rabbit eye test (TG 405) (*i.e.*, Categories 1, 2A, 2B, or Not Classified and Labelled according to the UN GHS (3) (7)). However, considering the validated usefulness of these assays (*i.e.*, to identify ocular corrosives/severe irritants only), there are only two test outcomes for classification purposes (corrosive/severe irritant or non-corrosive/non-severe irritant) to demonstrate proficiency. Other selection criteria were that substances are commercially available, there are high quality *in vivo* reference data available, and there are high quality data from the two *in vitro* methods for which Test Guidelines are being developed. For this reason, irritant substances were selected from the ICCVAM recommended list of 122 reference substances for the validation of *in vitro* ocular toxicity test methods (see Appendix H: ICCVAM Recommended Reference Substances) (5). Reference data are available in the ICCVAM Background Review Documents for BCOP and Isolated Chicken Eye (ICE) test method (17) (18).

Table 1

Recommended substances for demonstrating technical proficiency with BCOP

Substance	CASRN	Chemical Class ⁽¹⁾	Physical Form	<i>In Vivo</i> Classification ⁽²⁾	<i>In Vitro</i> Classification ⁽³⁾
Benzalkonium chloride (5 %)	8001-54-5	Onium compound	Liquid	Category 1	Corrosive/Severe Irritant
Chlorhexidine	55-56-1	Amine, Amidine	Solid	Category 1	Corrosive/Severe Irritant
Dibenzoyl-L-tartaric acid	2743-38-6	Carboxylic acid, Ester	Solid	Category 1	Corrosive/Severe Irritant
Imidazole	288-32-4	Heterocyclic	Solid	Category 1	Corrosive/Severe Irritant
Trichloroacetic acid (30 %)	76-03-9	Carboxylic Acid	Liquid	Category 1	Corrosive/Severe Irritant
2,6-Dichlorobenzoyl chloride	4659-45-4	Acyl halide	Liquid	Category 2A	Non corrosive/Non severe irritant
Ethyl-2-methylacetoacetate	609-14-3	Ketone, Ester	Liquid	Category 2B	Non corrosive/Non severe irritant
Ammonium nitrate	6484-52-2	Inorganic salt	Solid	Category 2A	Non corrosive/Non severe irritant
Glycerol	56-81-5	Alcohol	Liquid	Not Labelled	Non corrosive/Non severe irritant
n-Hexane	110-54-3	Hydrocarbon (acyclic)	Liquid	Not Labeled	Noncorrosive/Non severe irritant

Abbreviations: CASRN = Chemical Abstracts Service Registry Number

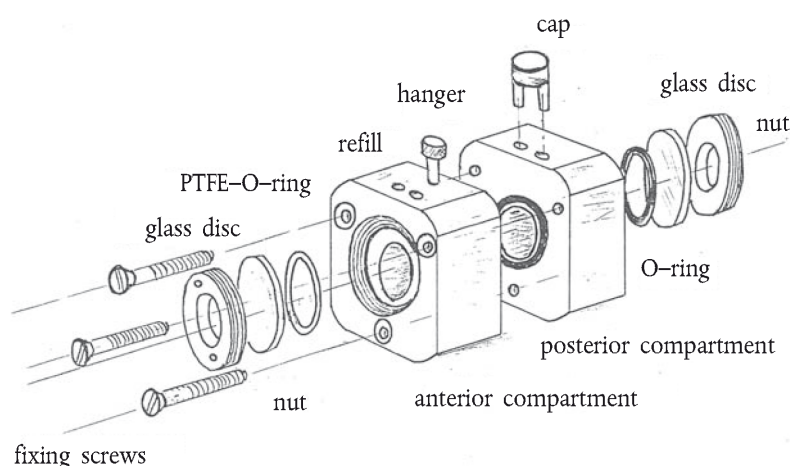
⁽¹⁾ Chemical classes were assigned to each test substance using a standard classification scheme, based on the National Library of Medicine Medical Subject Headings (MeSH) classification system (available at <http://www.nlm.nih.gov/mesh>).⁽²⁾ Based on results from the *in vivo* rabbit eye test (OECD TG 405) and using the UN GHS (3)(7).⁽³⁾ Based on results in BCOP and ICE.

Appendix 3

THE BCOP CORNEAL HOLDER

1. The BCOP corneal holders are made of an inert material (e.g., polypropylene). The holders are comprised of two halves (an anterior and posterior chamber), and have two similar cylindrical internal chambers. Each chamber holds a volume of 5 mL and terminates in a glass window, through which opacity measurements are recorded. Each of the inner chambers is 1,7 cm in diameter and 2,2 cm in depth ⁽¹⁾. An o-ring located on the posterior chamber is used to prevent leaks. The corneas are placed endothelial side down on the o-ring of the posterior chambers and the anterior chambers are placed on the epithelial side of the corneas. The chambers are maintained in place by three stainless screws located on the outer edges of the chamber. The end of each chamber houses a glass window which can be removed for easy access to the cornea. An o-ring is also located between the glass window and the chamber to prevent leaks. Two holes on the top of each chamber permit introduction and removal of medium and test compounds. They are closed with rubber caps during the treatment and incubation periods.

⁽¹⁾ The dimensions provided are based on a corneal holder that is used for cows ranging in age from 12 to 60 months old. In the event that animals 6 to 12 months are being used, the holder would instead need to be designed such that each chamber holds a volume of 4 mL, and each of the inner chambers is 1,5 cm in diameter and 2,2 cm in depth. With any newly designed corneal holder, it is very important that the ratio of exposed corneal surface area to posterior chamber volume should be the same as the ratio in the traditional corneal holder. This is necessary to assure that permeability values are correctly determined for the calculation of the IVIS by the proposed formula.



Glossary

Glass disc:

PTFE-O-ring:

Refill:

Hanger:

Cap:

Nut:

O-ring:

Posterior compartment:

Anterior compartment:

Fixing screws:

THE OPACITOMETER

2. The opacitometer is a light transmission measuring device. Light from a halogen lamp is sent through a control compartment (empty chamber without windows or liquid) to a photocell and compared to the light sent through the experimental compartment, which houses the chamber containing the cornea, to a photocell. The difference in light transmission from the photocells is compared and a numeric opacity value is presented on a digital display. The opacity units are established.
3. The opacitometer should provide a linear response through a range of opacity readings covering the cut-offs used for the different classifications described by the Prediction Model (*i.e.*, up to the cut-off determining corrosiveness/severe irritancy). To ensure linear and accurate readings up to 75-80 opacity units, it is necessary to calibrate the opacitometer using a series of calibrators. Calibrators (opaque sheets of polyester) are placed into the calibration chamber (a corneal chamber designed to hold the calibrators) and read on the opacitometer. The calibration chamber is designed to hold the calibrators at approximately the same distance between the light and photocell that the corneas would be placed during the opacity measurements. The opacitometer is first calibrated to 0 opacity units using the calibration chamber without a calibrator. Three different calibrators are then placed into the calibration chamber one by one and the opacities are measured. Calibrators 1, 2 and 3 should result in opacity readings equal to their set values of 75, 150, and 225 opacity units, respectively, $\pm 5\%$.

B. 48. ISOLATED CHICKEN EYE TEST METHOD FOR IDENTIFYING OCULAR CORROSIVES AND SEVERE IRRITANTS**INTRODUCTION**

1. The Isolated Chicken Eye (ICE) test method is an *in vitro* test method that can be used, under certain circumstances and with specific limitations, to classify substances and mixtures as ocular corrosives and severe irritants, (1) (2) (3). For the purpose of this test method, severe irritants are defined as those that induce ocular lesions that persist in the rabbit for at least 21 days after administration. While it is not considered valid as a complete replacement for the *in vivo* rabbit eye test, the ICE is recommended for use as part of a tiered testing strategy for regulatory classification and labelling within a specific applicability domain (4) (5). Test substances and mixtures (6) that are positive in this assay can be classified as ocular corrosives or severe irritants without further testing in rabbits. A substance that tests negative would need to be tested in rabbits using a sequential testing strategy, as outlined in OECD Test Guideline 405 (7) (chapter B. 5 of this Annex).
2. The purpose of this test method is to describe the procedures used to evaluate the potential ocular corrosivity or severe irritancy of a test substance as measured by its ability to induce toxicity in an enucleated chicken eye. Toxic effects to the cornea are measured by (i) a qualitative assessment of opacity, (ii) a qualitative assessment of damage to epithelium based on application of fluorescein to the eye (fluorescein retention), (iii) a quantitative measurement of increased thickness (swelling), and (iv) a qualitative evaluation of macroscopic morphological damage to the surface. The corneal opacity, swelling, and damage assessments following exposure to a test substance are assessed individually and then combined to derive an Eye Irritation Classification.
3. Ocular irritants that induce lesions that resolve in less than 21 days and non-irritants have also been tested using the ICE test method. However, the accuracy and reliability of the ICE test method for substances in these categories have not been formally evaluated.
4. Definitions are provided in Appendix 1.

INITIAL CONSIDERATIONS AND LIMITATIONS

5. This test method is based on the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) ICE test method protocol (8), which was developed following an international validation study (4) (5) (9), with contributions from the European Centre for the Validation of Alternative Methods, the Japanese Center for the Validation of Alternative Methods, and TNO Quality of Life Department of Toxicology and Applied Pharmacology (Netherlands). The protocol is based on information obtained from published protocols, as well as the current protocol used by TNO (10) (11) (12) (13) (14).
6. The identified limitations for this method are based upon the false positive rate for alcohols and the false negative rates for solids and surfactants (see paragraph 47) (4). When substances within these chemical and physical classes are excluded from the database, the accuracy of ICE across the EU, EPA, and GHS classification systems is substantially improved (4). Based on the purpose of this assay (*i.e.*, to identify ocular corrosives/severe irritants only), false negative rates are not critical since such substances would be subsequently tested in rabbits or with other adequately validated *in vitro* tests, depending on regulatory requirements, using a sequential testing strategy in a weight of evidence approach. Furthermore, the current validation database did not allow for an adequate evaluation of some chemical or product classes (*e.g.*, mixtures). However, investigators could consider using this test method for testing all types of material (including mixtures), whereby a positive result could be accepted as indicative of an ocular corrosive or severe irritant response. However, positive results obtained with alcohols should be interpreted cautiously due to risk of over-prediction.
7. All procedures with chicken eyes should follow the test facility's applicable regulations and procedures for handling of human or animal-derived materials, which include, but are not limited to, tissues and tissue fluids. Universal laboratory precautions are recommended (15).
8. A limitation of the test method is that, although it takes into account some of the ocular effects evaluated in the rabbit ocular irritancy test method and to some degree their severity, it does not consider conjunctival and iridal injuries. Also, although the reversibility of corneal lesions cannot be evaluated *per se* in the ICE test method, it has been proposed, based on rabbit eye studies, that an assessment of the initial depth of corneal injury can be used to distinguish between irreversible and reversible effects (16). Finally, the ICE test method does not allow for an assessment of the potential for systemic toxicity associated with ocular exposure.
9. Efforts are ongoing to further characterize the usefulness and limitations of the ICE test method for identifying non-severe irritants and non-irritants (see also paragraph 48). Users are also encouraged to provide specimens and/or data to validation organizations for a formal evaluation of possible future uses of the ICE test method, including for the identification of non-severe ocular irritants and non-irritants.

10. For any laboratory initially establishing this assay, the proficiency chemicals provided in Appendix 2 should be used. A laboratory can use these chemicals to demonstrate their technical competence in performing the ICE test method prior to submitting ICE data for regulatory hazard classification purposes.

PRINCIPLE OF THE TEST

11. The ICE test method is an organotypic model that provides short-term maintenance of the chicken eye *in vitro*. In this test method, damage by the test substance is assessed by determination of corneal swelling, opacity, and fluorescein retention. While the latter two parameters involve a qualitative assessment, analysis of corneal swelling provides for a quantitative assessment. Each measurement is either converted into a quantitative score used to calculate an overall Irritation Index, or assigned a qualitative categorization that is used to assign an *in vitro* ocular corrosivity and severe irritancy classification. Either of these outcomes can then be used to predict the *in vivo* ocular corrosivity and severe irritation potential of a test substance (see Decision Criteria).

Source and Age of Chicken Eyes

12. Historically, eyes collected from chickens obtained from a slaughterhouse where they are killed for human consumption have been used for this assay, eliminating the need for laboratory animals. Only the eyes of healthy animals considered suitable for entry into the human food chain are used.
13. Although a controlled study to evaluate the optimum chicken age has not been conducted, the age and weight of the chickens used historically in this test method are that of spring chickens traditionally processed by a poultry slaughterhouse (*i.e.*, approximately 7 weeks old, 1,5-2,5 kg).

Collection and Transport of Eyes to the Laboratory

14. Heads should be removed immediately after sedation of the chickens, usually by electric shock, and incision of the neck for bleeding. A local source of chickens close to the laboratory should be located so that their heads can be transferred from the slaughterhouse to the laboratory quickly enough to minimize deterioration and/or bacterial contamination. The time interval between collection of the chicken heads and use of eyes in the ICE test method should be minimized (typically within two hours) and should be demonstrated to not compromise the assay results. These results are based on the selection criteria for the eyes, as well as the positive and negative control responses. All eyes used in the assay should be from the same group of eyes collected on a specific day.
15. Because eyes are dissected in the laboratory, the intact heads are transported from the slaughterhouse at ambient temperature in plastic boxes humidified with towels moistened with isotonic saline.

Selection Criteria for Eyes Used in the ICE

16. Eyes that have high baseline fluorescein staining (*i.e.*, > 0,5) or corneal opacity score (*i.e.*, > 0,5) after they are enucleated are rejected.
17. Each treatment group and concurrent positive control consists of at least three eyes. The negative control group or the solvent control (if using a solvent other than saline) consists of at least one eye.

PROCEDURE

Preparation of the Eyes

18. The eyelids are carefully excised, taking care not to damage the cornea. Corneal integrity is quickly assessed with a drop of 2 % (w/v) sodium fluorescein applied to the corneal surface for a few seconds, and then rinsed with isotonic saline. Fluorescein-treated eyes are then examined with a slit-lamp microscope to ensure that the cornea is undamaged (*i.e.*, fluorescein retention and corneal opacity scores $\leq 0,5$).
19. If undamaged, the eye is further dissected from the skull, taking care not to damage the cornea. The eyeball is pulled from the orbit by holding the nictitating membrane firmly with surgical forceps, and the eye muscles are cut with a bent, blunt-tipped scissor. It is important to avoid causing corneal damage due to excessive pressure (*i.e.*, compression artifacts).
20. When the eye is removed from the orbit, a visible portion of the optic nerve should be left attached. Once removed from the orbit, the eye is placed on an absorbent pad and the nictitating membrane and other connective tissue are cut away.

21. The enucleated eye is mounted in a stainless steel clamp with the cornea positioned vertically. The clamp is then transferred to a chamber of the superfusion apparatus (16). The clamps should be positioned in the superfusion apparatus such that the entire cornea is supplied with the isotonic saline drip. The chambers of the superfusion apparatus should be temperature controlled at $32 \pm 1,5$ °C. Appendix 3 provides a diagram of a typical superfusion apparatus and the eye clamps, which can be obtained commercially or constructed. The apparatus can be modified to meet the needs of an individual laboratory (e.g., to accommodate a different number of eyes).
22. After being placed in the superfusion apparatus, the eyes are again examined with a slit-lamp microscope to ensure that they have not been damaged during the dissection procedure. Corneal thickness should also be measured at this time at the corneal apex using the depth measuring device on the slit-lamp microscope. Eyes with; (i), a fluorescein retention score of $> 0,5$; (ii) corneal opacity $> 0,5$; or, (iii), any additional signs of damage should be replaced. For eyes that are not rejected based on any of these criteria, individual eyes with a corneal thickness deviating more than 10 % from the mean value for all eyes are to be rejected. Users should be aware that slit-lamp microscopes could yield different corneal thickness measurements if the slit-width setting is different. The slit-width should be set at 0,095 mm.
23. Once all eyes have been examined and approved, the eyes are incubated for approximately 45 to 60 minutes to equilibrate them to the test system prior to dosing. Following the equilibration period, a zero reference measurement is recorded for corneal thickness and opacity to serve as a baseline (i.e., time = 0). The fluorescein score determined at dissection is used as the baseline measurement for that endpoint.

Application of the Test Substance

24. Immediately following the zero reference measurements, the eye (in its holder) is removed from the superfusion apparatus, placed in a horizontal position, and the test substance is applied to the cornea.
25. Liquid test substances are typically tested undiluted, but may be diluted if deemed necessary (e.g., as part of the study design). The preferred solvent for diluted substances is physiological saline. However, alternative solvents may also be used under controlled conditions, but the appropriateness of solvents other than physiological saline should be demonstrated.
26. Liquid test substances are applied to the cornea such that the entire surface of the cornea is evenly covered with the test substance; the standard volume is 0,03 mL.
27. If possible, solid substances should be ground as finely as possible in a mortar and pestle, or comparable grinding tool. The powder is applied to the cornea such that the surface is uniformly covered with the test substance; the standard amount is 0,03 g.
28. The test substance (liquid or solid) is applied for 10 seconds and then rinsed from the eye with isotonic saline (approximately 20 mL) at ambient temperature. The eye (in its holder) is subsequently returned to the superfusion apparatus in the original upright position.

Control Substances

29. Concurrent negative or solvent/vehicle controls and positive controls should be included in each experiment.
30. When testing liquids at 100 % or solids, physiological saline is used as the concurrent negative control in the ICE test method to detect non-specific changes in the test system, and to ensure that the assay conditions do not inappropriately result in an irritant response.
31. When testing diluted liquids, a concurrent solvent/vehicle control group is included in the test method to detect non-specific changes in the test system, and to ensure that the assay conditions do not inappropriately result in an irritant response. As stated in paragraph 25, only a solvent/vehicle that has been demonstrated to have no adverse effects on the test system can be used.

32. A known ocular irritant is included as a concurrent positive control in each experiment to verify that an appropriate response is induced. As the ICE assay is being used in this test method to identify corrosive or severe irritants, the positive control should be a reference substance that induces a severe response in this test method. However, to ensure that variability in the positive control response across time can be assessed, the magnitude of the severe response should not be excessive. Sufficient *in vitro* data for the positive control should be generated such that a statistically defined acceptable range for the positive control can be calculated. If adequate historical ICE test method data are not available for a particular positive control, studies may need to be conducted to provide this information.
33. Examples of positive controls for liquid test substances are 10 % acetic acid or 5 % benzalkonium chloride, while examples of positive controls for solid test substances are sodium hydroxide or imidazole.
34. Benchmark substances are useful for evaluating the ocular irritancy potential of unknown chemicals of a specific chemical or product class, or for evaluating the relative irritancy potential of an ocular irritant within a specific range of irritant responses.

Endpoints Measured

35. Treated corneas are evaluated pretreatment and starting at 30, 75, 120, 180, and 240 minutes ($\pm$ 5 minutes) after the post-treatment rinse. These time points provide an adequate number of measurements over the four-hour treatment period, while leaving sufficient time between measurements for the requisite observations to be made for all eyes.
36. The endpoints evaluated are corneal opacity, swelling, fluorescein retention, and morphological effects (e.g., pitting or loosening of the epithelium). All of the endpoints, with the exception of fluorescein retention (which is determined only at pretreatment and 30 minutes after test substance exposure) are determined at each of the above time points.
37. Photographs are advisable to document corneal opacity, fluorescein retention, morphological effects and, if conducted, histopathology
38. After the final examination at four hours, users are encouraged to preserve eyes in an appropriate fixative (e.g., neutral buffered formalin) for possible histopathological examination.
39. Corneal swelling is determined from corneal thickness measurements made with an optical pachymeter on a slit-lamp microscope. It is expressed as a percentage and is calculated from corneal thickness measurements according to the following formula:

$$\left(\frac{\text{corneal thickness at time } t - \text{corneal thickness at time } = 0}{\text{corneal thickness at time } = 0} \right) \times 100$$

40. The mean percentage of corneal swelling for all test eyes is calculated for all observation time points. Based on the highest mean score for corneal swelling, as observed at any time point, an overall category score is then given for each test substance.
41. Corneal opacity is calculated by using the area of the cornea that is most densely opacified for scoring. The mean corneal opacity value for all test eyes is calculated for all observation time points. Based on the highest mean score for corneal opacity, as observed at any time point, an overall category score is then given for each test substance (Table 1).

Table 1
Corneal opacity scores

Score	Observation
0	No opacity
0,5	Very faint opacity

Score	Observation
1	Scattered or diffuse areas; details of the iris are clearly visible
2	Easily discernible translucent area; details of the iris are slightly obscured
3	Severe corneal opacity; no specific details of the iris are visible; size of the pupil is barely discernible
4	Complete corneal opacity; iris invisible

42. The mean fluorescein retention value for all test eyes is calculated for the 30-minute observation time point only, which is used for the overall category score given for each test substance (Table 2).

Table 2
Fluorescein retention scores

Score	Observation
0	No fluorescein retention
0,5	Very minor single cell staining
1	Single cell staining scattered throughout the treated area of the cornea
2	Focal or confluent dense single cell staining
3	Confluent large areas of the cornea retaining fluorescein

43. Morphological effects include “pitting” of corneal epithelial cells, “loosening” of epithelium, “roughening” of the corneal surface and “sticking” of the test substance to the cornea. These findings can vary in severity and may occur simultaneously. The classification of these findings is subjective according to the interpretation of the investigator.

DATA AND REPORTING

Data Evaluation

44. Results from corneal opacity, swelling, and fluorescein retention should be evaluated separately to generate an ICE class for each endpoint. The ICE classes for each endpoint are then combined to generate an Irritancy Classification for each test substance.

Decision Criteria

45. Once each endpoint has been evaluated, ICE classes can be assigned based on a predetermined range. Interpretation of corneal thickness (Table 3), opacity (Table 4), and fluorescein retention (Table 5) using four ICE classes is done according to the following scales:

Table 3
ICE classification criteria for corneal thickness

Mean Corneal Swelling (%) (*)	ICE Class
0 to 5	I
> 5 to 12	II
> 12 to 18 (> 75 min after treatment)	II
> 12 to 18 (≤ 75 min after treatment)	III
> 18 to 26	III

Mean Corneal Swelling (%) (*)	ICE Class
> 26 to 32 (> 75 min after treatment)	III
> 26 to 32 (≤ 75 min after treatment)	IV
> 32	IV

(*) Corneal swelling scores only applicable if thickness is measured with a Haag-Streit BP900 slit-lamp microscope with depth-measuring device No I and slit-width setting at 9½, equaling 0,095 mm. Users should be aware that slit-lamp microscopes could yield different corneal thickness measurements if the slit-width setting is different.

Table 4

ICE classification criteria for opacity

Mean Maximum Opacity Score (*)	ICE Class
0,0-0,5	I
0,6-1,5	II
1,6-2,5	III
2,6-4,0	IV

(*) See Table 1.

Table 5

ICE classification criteria for mean fluorescein retention

Mean Fluorescein Retention Score at 30 minutes post-treatment (*)	ICE Class
0,0-0,5	I
0,6-1,5	II
1,6-2,5	III
2,6-3,0	IV

(*) See Table 2.

46. The overall *in vitro* irritancy classification for a test substance is assessed by reading the irritancy classification that corresponds to the combination of categories obtained for corneal swelling, corneal opacity, and fluorescein retention and applying the scheme presented in Table 6.

Table 6

Overall *in vitro* irritancy classifications

Classification	Combinations of the 3 Endpoints
Corrosive/Severe Irritant	3 × IV 2 × IV, 1 × III 2 × IV, 1 × II (*) 2 × IV, 1 × I (*) Corneal opacity ≥ 3 at 30 min (in at least 2 eyes) Corneal opacity = 4 at any time point (in at least 2 eyes) Severe loosening of the epithelium (in at least 1 eye)

(*) Combinations less likely to occur.

47. As stated in paragraph 1, if the test substance is not identified as an ocular corrosive or severe irritant, additional testing should be conducted for classification and labelling purposes. The ICE test method has an overall accuracy of 83 % (120/144) to 87 % (134/154), a false positive rate of 6 % (7/122) to 8 % (9/116), and a false negative rate of 41 % (13/32) to 50 % (15/30) for the identification of ocular corrosives and severe irritants, when compared to *in vivo* rabbit eye test method data classified according to the EPA (1), EU (2), or GHS (3) classification systems. When substances within certain chemical (*i.e.*, alcohols and surfactants) and physical (*i.e.*, solids) classes are excluded from the database, the accuracy of ICE across the EU, EPA, and GHS classification systems ranges from 91 % (75/82) to 92 % (69/75), the false positive rates range from 5 % (4/73) to 6 % (4/70), and the false negative rates range from 29 % (2/7) to 33 % (3/9) (4).
48. Even if an ocular corrosive or severe irritant classification is not obtained for a test substance, ICE data can be useful in conjunction with test data from the *in vivo* rabbit eye test or from an adequately validated *in vitro* test to further evaluate the usefulness and limitations of the ICE test method for identifying non-severe irritants and non-irritants (a Guidance Document on the use of *in vitro* ocular toxicity test methods is under development).

Study Acceptance Criteria

49. A test is considered acceptable if the concurrent negative or vehicle/solvent controls and the concurrent positive controls give an Irritancy Classification that falls within nonirritant and severe irritant/corrosive classes, respectively.

Test Report

50. The test report should include the following information, if relevant to the conduct of the study:

Test and Control Substances

Chemical name(s) such as the structural name used by the Chemical Abstracts Service (CAS), followed by other names, if known;

The CAS Registry Number (RN), if known;

Purity and composition of the substance or mixture (in percentage(s) by weight), to the extent this information is available;

Physicochemical properties such as physical state, volatility, pH, stability, chemical class water solubility relevant to the conduct of the study;

Treatment of the test/control substances prior to testing, if applicable (*e.g.*, warming, grinding);

Stability, if known;

Information Concerning the Sponsor and the Test Facility

Name and address of the sponsor, test facility and study director;

Identification on the source of the eyes (*e.g.*, the facility from which they were collected);

Storage and transport conditions of eyes (*e.g.*, date and time of eye collection, time interval prior to initiating testing);

If available, specific characteristics of the animals from which the eyes were collected (*e.g.*, age, sex, weight of the donor animal);

Justification of the Test Method and Protocol Used

Test Method Integrity

The procedure used to ensure the integrity (*i.e.*, accuracy and reliability) of the test method over time (*e.g.*, periodic testing of proficiency substances, use of historical negative and positive control data).

Criteria for an Acceptable Test

If applicable, acceptable concurrent benchmark control ranges based on historical data;

Test Conditions

Description of test system used;

Slit-lamp microscope used (e.g., model);

Instrument settings for the slit-lamp microscope used;

Information for the chicken eyes used, including statements regarding their quality;

Details of test procedure used;

Test substance concentration(s) used;

Description of any modifications of the test procedure;

Reference to historical data of the model (e.g., negative and positive controls, proficiency substances, benchmark substances);

Description of evaluation criteria used;

Results

Description of other effects observed;

If appropriate, photographs of the eye;

*Discussion of the Results**Conclusion*

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Appendix 1

DEFINITIONS

Accuracy: The closeness of agreement between test method results and accepted reference values. It is a measure of test method performance and one aspect of 'relevance'. The term is often used interchangeably with 'concordance', to mean the proportion of correct outcomes of a test method.

Benchmark substance: A substance used as a standard for comparison to a test substance. A benchmark substance should have the following properties; (i), a consistent and reliable source(s); (ii), structural and functional similarity to the class of substances being tested; (iii), known physical/chemical characteristics; (iv), supporting data on known effects; and (v), known potency in the range of the desired response

Cornea: The transparent part of the front of the eyeball that covers the iris and pupil and admits light to the interior.

Corneal opacity: Measurement of the extent of opaqueness of the cornea following exposure to a test substance. Increased corneal opacity is indicative of damage to the cornea.

Corneal swelling: An objective measurement in the ICE test of the extent of distention of the cornea following exposure to a test substance. It is expressed as a percentage and is calculated from baseline (pre-dose) corneal thickness measurements and the thickness recorded at regular intervals after exposure to the test material in the ICE test. The degree of corneal swelling is indicative of damage to the cornea.

EPA Category 1: Corrosive (irreversible destruction of ocular tissue) or corneal involvement or irritation persisting for more than 21 days (1).

EU Category R41: Production of tissue damage in the eye, or serious physical decay of vision, following application of a test substance to the anterior surface of the eye, which is not fully reversible within 21 days of application (2).

False negative rate: The proportion of all positive substances falsely identified by a test method as negative. It is one indicator of test method performance.

False positive rate: The proportion of all negative substances that are falsely identified by a test method as positive. It is one indicator of test method performance.

Fluorescein retention: A subjective measurement in the ICE test of the extent of fluorescein sodium that is retained by epithelial cells in the cornea following exposure to a test substance. The degree of fluorescein retention is indicative of damage to the corneal epithelium.

GHS (Globally Harmonized System of Classification and Labelling of Chemicals): A system proposing the classification of chemicals (substances and mixtures) according to standardized types and levels of physical, health and environmental hazards, and addressing corresponding communication elements, such as pictograms, signal words, hazard statements, precautionary statements and safety data sheets, so that to convey information on their adverse effects with a view to protect people (including employers, workers, transporters, consumers and emergency responders) and the environment (3).

GHS Category 1: Production of tissue damage in the eye, or serious physical decay of vision, following application of a test substance to the anterior surface of the eye, which is not fully reversible within 21 days of application (3).

Hazard: Inherent property of an agent or situation having the potential to cause adverse effects when an organism, system or (sub) population is exposed to that agent.

Negative control: An untreated replicate containing all components of a test system. This sample is processed with test substance-treated samples and other control samples to determine whether the solvent interacts with the test system.

Non-irritant: Substances that are not classified as EPA Category I, II, or III; EU Category R41 or R36; or GHS Category 1, 2A, or 2B ocular irritants (1)(2)(3).

Ocular corrosive: (a) A substance that causes irreversible tissue damage to the eye. (b) Substances that are classified as GHS Category 1, EPA Category I, or EU Category R41 ocular irritants (1)(2)(3).

Ocular irritant: (a) A substance that produces a reversible change in the eye following application to the anterior surface of the eye; (b) Substances that are classified as EPA Category II or III; EU Category R36; or GHS Category 2A, or 2B ocular irritants (1)(2)(3).

Ocular severe irritant: (a) A substance that causes tissue damage in the eye following application to the anterior surface of the eye that is not reversible within 21 days of application or causes serious physical decay of vision. (b) Substances that are classified as GHS Category 1, EPA Category I, or EU Category R41 ocular irritants (1)(2)(3).

Positive control: A replicate containing all components of a test system and treated with a substance known to induce a positive response. To ensure that variability in the positive control response across time can be assessed, the magnitude of the severe response should not be excessive.

Reliability: Measures of the extent that a test method can be performed reproducibly within and between laboratories over time, when performed using the same protocol. It is assessed by calculating intra- and inter-laboratory reproducibility and intra-laboratory repeatability.

Slit-lamp microscope: An instrument used to directly examine the eye under the magnification of a binocular microscope by creating a stereoscopic, erect image. In the ICE test method, this instrument is used to view the anterior structures of the chicken eye as well as to objectively measure corneal thickness with a depth-measuring device attachment.

Solvent/vehicle control: An untreated sample containing all components of a test system, including the solvent or vehicle that is processed with the test substance-treated and other control samples to establish the baseline response for the samples treated with the test substance dissolved in the same solvent or vehicle. When tested with a concurrent negative control, this sample also demonstrates whether the solvent or vehicle interacts with the test system.

Tiered testing: A stepwise testing strategy where all existing information on a test substance is reviewed, in a specified order, using a weight of evidence process at each tier to determine if sufficient information is available for a hazard classification decision, prior to progression to the next tier. If the irritancy potential of a test substance can be assigned based on the existing information, no additional testing is required. If the irritancy potential of a test substance cannot be assigned based on the existing information, a step-wise sequential animal testing procedure is performed until an unequivocal classification can be made.

Validated test method: A test method for which validation studies have been completed to determine the relevance (including accuracy) and reliability for a specific purpose. It is important to note that a validated test method may not have sufficient performance in terms of accuracy and reliability to be found acceptable for the proposed purpose.

Weight-of-evidence: The process of considering the strengths and weaknesses of various pieces of information in reaching and supporting a conclusion concerning the hazard potential of a substance.

Appendix 2

PROFICIENCY CHEMICALS FOR THE ICE TEST METHOD

Prior to routine use of a test method that adheres to this test method, laboratories may wish to demonstrate technical proficiency by correctly identifying the ocular corrosivity classification of the 10 substances recommended in Table 1. These substances were selected to represent the range of responses for local eye irritation/corrosion, which is based on results in the *in vivo* rabbit eye test (TG 405) (i.e., Categories 1, 2A, 2B, or Not Classified or Labeled according to the UN GHS)(3)(7). However, considering the validated usefulness of these assays (i.e., to identify ocular corrosives/severe irritants only), there are only two test outcomes for classification purposes (corrosive/severe irritant or non-corrosive/non-severe irritant) to demonstrate proficiency. Other selection criteria were that substances are commercially available, there are high quality *in vivo* reference data available, and there are high quality data from the two *in vitro* methods for which Test Guidelines are being developed. For this reason, irritant substances were selected from the ICCVAM recommended list of 122 reference substances for the validation of *in vitro* ocular toxicity test methods (see Appendix H, ICCVAM Recommended Reference Substances List)(4). Reference data are available in the ICCVAM Background Review Documents for the Bovine Corneal Opacity and Permeability (BCOP) and the ICE test methods (18) (19).

Table 1

Recommended substances for demonstrating technical proficiency with ICE

Chemical	CASRN	Chemical Class ⁽¹⁾	Physical Form	<i>In Vivo</i> Classification ⁽²⁾	<i>In Vitro</i> Classification ⁽³⁾
Benzalkonium chloride (5 %)	8001-54-5	Onium compound	Liquid	Category 1	Corrosive/Severe Irritant
Chlorhexidine	55-56-1	Amine, Amidine	Solid	Category 1	Corrosive/Severe Irritant
Dibenzoyl-L-tartaric acid	2743-38-6	Carboxylic acid, Ester	Solid	Category 1	Corrosive/Severe Irritant
Imidazole	288-32-4	Heterocyclic	Solid	Category 1	Corrosive/Severe Irritant
Trichloroacetic acid (30 %)	76-03-9	Carboxylic Acid	Liquid	Category 1	Corrosive/Severe Irritant
2,6-Dichlorobenzoyl chloride	4659-45-4	Acyl halide	Liquid	Category 2A	Non-corrosive/Non-severe irritant
Ethyl-2-methylacetoacetate	609-14-3	Ketone, Ester	Liquid	Category 2B	Non-corrosive/Non-severe irritant
Ammonium nitrate	6484-52-2	Inorganic salt	Solid	Category 2A	Non-corrosive/Non-severe irritant
Glycerol	56-81-5	Alcohol	Liquid	Not Labeled	Non-corrosive/Non-severe irritant
n-Hexane	110-54-3	Hydrocarbon (acyclic)	Liquid	Not Labeled	Non-corrosive/Non-severe irritant

Abbreviations: CASRN = Chemical Abstracts Service Registry Number

⁽¹⁾ Chemical classes were assigned to each test substance using a standard classification scheme, based on the National Library of Medicine Medical Subject Headings (MeSH) classification system (available at <http://www.nlm.nih.gov/mesh>).

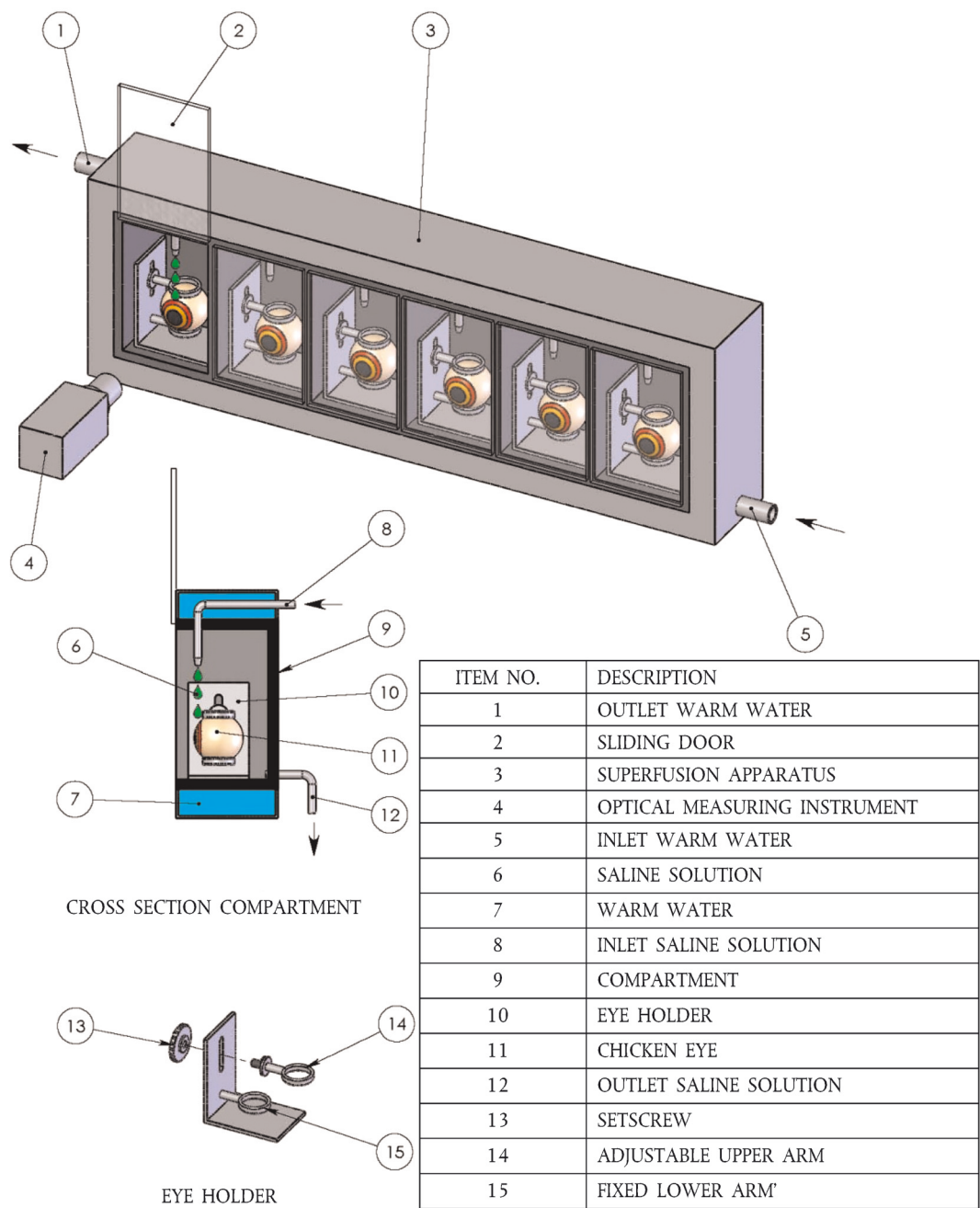
⁽²⁾ Based on results from the *in vivo* rabbit eye test (OECD TG 405) and using the UN GHS (3)(7).

⁽³⁾ Based on results in BCOP and ICE.

Appendix 3

Diagrams of the ICE superfusion apparatus and eye clamps

(See Burton et al. (17) for additional generic descriptions of the superfusion apparatus and eye clamp)



COMMISSION REGULATION (EU) No 1153/2010

of 8 December 2010

amending Regulation (EU) No 175/2010 by prolonging the period of application of measures to control increased mortality in Pacific oysters (*Crassostrea gigas*)

(Text with EEA relevance)

THE EUROPEAN COMMISSION

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

Having regard to Council Directive 2006/88/EC of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals ⁽¹⁾, and in particular Articles 41(3) and 61(3) thereof,

Whereas:

- (1) Commission Regulation (EU) No 175/2010 of 2 March 2010 implementing Council Directive 2006/88/EC as regards measures to control increased mortality in oysters of the species *Crassostrea gigas* in connection with the detection of Ostreid herpesvirus-1 μ var (OsHV-1 μ var) ⁽²⁾ was adopted to contain the spread of a disease potentially caused by a viral infection in Pacific oysters (*Crassostrea gigas*) in France, Ireland and the Channel Islands.
- (2) As it was unclear whether that virus really caused increased mortality in Pacific oysters (*Crassostrea gigas*), those measures were adopted on a temporary basis until 31 December 2010.
- (3) Increased mortality in Pacific oysters (*Crassostrea gigas*) in connection with the detection of OsHV-1 μ var has continued to occur in 2010.

(4) Reports on experience gained by the Member States with programmes for the early detection of OsHV-1 μ var, as well as an opinion of the European Food Safety Authority on the causes will only become available in autumn 2010 and they will need to be evaluated before the measures adopted pursuant to Regulation (EU) No 175/2010 can be reconsidered.

(5) Consequently, the period of application of Regulation (EU) No 175/2010 should be extended until 30 April 2011. That Regulation should therefore be amended accordingly.

(6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

In the second paragraph of Article 8 of Regulation (EU) No 175/2010, the date '31 December 2010' is replaced by '30 April 2011'.

Article 2

This Regulation shall enter into force on the third day following that of its publication in the *Official journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 8 December 2010.

For the Commission

The President

José Manuel BARROSO

⁽¹⁾ OJ L 328, 24.11.2006, p. 14.

⁽²⁾ OJ L 52, 3.3.2010, p. 1.

COMMISSION REGULATION (EU) No 1154/2010**of 8 December 2010****amending Regulation (EC) No 1580/2007 as regards the trigger levels for additional duties for pears, lemons, apples and courgettes**

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation) ⁽¹⁾, and in particular Article 143(b) in conjunction with Article 4 thereof,

Whereas:

- (1) Commission Regulation (EC) No 1580/2007 of 21 December 2007 laying down implementing rules of Council Regulations (EC) No 2200/96, (EC) No 2201/96 and (EC) No 1182/2007 in the fruit and vegetable sector ⁽²⁾ provides for surveillance of imports of the products listed in Annex XVII thereto. That surveillance is to be carried out in accordance with the rules laid down in Article 308d of Commission Regulation (EEC) No 2454/93 of 2 July 1993 laying down provisions for the implementation of Council Regulation (EEC) No 2913/92 establishing the Community Customs Code ⁽³⁾.

- (2) For the purposes of applying Article 5(4) of the Agreement on Agriculture ⁽⁴⁾ concluded as part of the Uruguay Round of multilateral trade negotiations and in the light of the latest data available for 2007, 2008 and 2009, the trigger levels for additional duties on pears, lemons, apples and courgettes should be adjusted.

- (3) Regulation (EC) No 1580/2007 should therefore be amended accordingly.

- (4) The measures provided for in this Regulation are in accordance with the opinion of the Management Committee for the Common Organisation of Agricultural Markets,

HAS ADOPTED THIS REGULATION:

Article 1

Annex XVII to Regulation (EC) No 1580/2007 is replaced by the text set out in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the day following its publication in the *Official Journal of the European Union*.

It shall apply from 1 January 2011.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 8 December 2010.

For the Commission

The President

José Manuel BARROSO

⁽¹⁾ OJ L 299, 16.11.2007, p. 1.

⁽²⁾ OJ L 350, 31.12.2007, p. 1.

⁽³⁾ OJ L 253, 11.10.1993, p. 1.

⁽⁴⁾ OJ L 336, 23.12.1994, p. 22.

ANNEX

‘ANNEX XVII

ADDITIONAL IMPORT DUTIES: TITLE IV, CHAPTER II, SECTION 2

Without prejudice to the rules governing the interpretation of the Combined Nomenclature, the description of the products is deemed to be indicative only. The scope of the additional duties for the purposes of this Annex is determined by the scope of the CN codes as they stand at the time of the adoption of this Regulation.

Order number	CN Code	Description	Period of application	Trigger level (tonnes)
78.0015	0702 00 00	Tomatoes	From 1 October to 31 May	1 215 717
78.0020			From 1 June to 30 September	966 474
78.0065	0707 00 05	Cucumbers	From 1 May to 31 October	12 303
78.0075			From 1 November to 30 April	33 447
78.0085	0709 90 80	Artichokes	From 1 November to 30 June	17 258
78.0100	0709 90 70	Courgettes	From 1 January to 31 December	57 955
78.0110	0805 10 20	Oranges	From 1 December to 31 May	368 535
78.0120	0805 20 10	Clementines	From 1 November to end of February	175 110
78.0130	0805 20 30 0805 20 50 0805 20 70 0805 20 90	Mandarins (including tangerines and satsumas); wilkings and similar citrus hybrids	From 1 November to end of February	115 625
78.0155	0805 50 10	Lemons	From 1 June to 31 December	329 872
78.0160			From 1 January to 31 May	120 619
78.0170	0806 10 10	Table grapes	From 21 July to 20 November	146 510
78.0175	0808 10 80	Apples	From 1 January to 31 August	916 384
78.0180			From 1 September to 31 December	95 396
78.0220	0808 20 50	Pears	From 1 January to 30 April	291 094
78.0235			From 1 July to 31 December	93 666
78.0250	0809 10 00	Apricots	From 1 June to 31 July	49 314
78.0265	0809 20 95	Cherries, other than sour cherries	From 21 May to 10 August	90 511
78.0270	0809 30	Peaches, including nectarines	From 11 June to 30 September	6 867
78.0280	0809 40 05	Plums	From 11 June to 30 September	57 764

COMMISSION REGULATION (EU) No 1155/2010**of 1 December 2010****concerning the classification of certain goods in the Combined Nomenclature**

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff⁽¹⁾, and in particular Article 9(1)(a) thereof,

Whereas:

- (1) In order to ensure uniform application of the Combined Nomenclature annexed to Regulation (EEC) No 2658/87, it is necessary to adopt measures concerning the classification of the goods referred to in the Annex to this Regulation.
- (2) Regulation (EEC) No 2658/87 has laid down the general rules for the interpretation of the Combined Nomenclature. Those rules apply also to any other nomenclature which is wholly or partly based on it or which adds any additional subdivision to it and which is established by specific provisions of the Union, with a view to the application of tariff and other measures relating to trade in goods.
- (3) Pursuant to those general rules, the goods described in column (1) of the table set out in the Annex should be classified under the CN code indicated in column (2), by virtue of the reasons set out in column (3) of that table.
- (4) It is appropriate to provide that binding tariff information which has been issued by the customs

authorities of Member States in respect of the classification of goods in the Combined Nomenclature but which is not in accordance with this Regulation can, for a period of three months, continue to be invoked by the holder, under Article 12(6) of Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code⁽²⁾.

- (5) The measures provided for in this Regulation are in accordance with the opinion of the Customs Code Committee,

HAS ADOPTED THIS REGULATION:

Article 1

The goods described in column (1) of the table set out in the Annex shall be classified within the Combined Nomenclature under the CN code indicated in column (2) of that table.

Article 2

Binding tariff information issued by the customs authorities of Member States, which is not in accordance with this Regulation, can continue to be invoked for a period of three months under Article 12(6) of Regulation (EEC) No 2913/92.

Article 3

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 1 December 2010.

*For the Commission,
On behalf of the President,
Algirdas ŠEMETA
Member of the Commission*

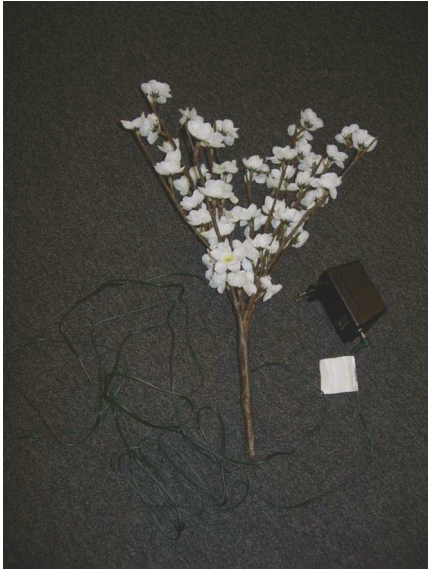
⁽¹⁾ OJ L 256, 7.9.1987, p. 1.

⁽²⁾ OJ L 302, 19.10.1992, p. 1.

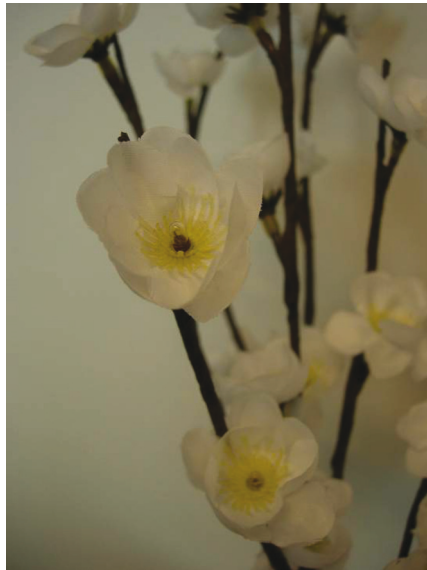
ANNEX

Description of the goods	Classification (CN code)	Reasons
(1)	(2)	(3)
Composite goods made up of an artificial cherry tree branch and an electric lighting fitting with an electrical transformer. These components are attached to each other to form a practically inseparable whole. The artificial branch resembles the natural product (a cherry tree branch with blossoms), made by assembling various parts (brown paper to imitate the twigs, wires to support them, adhesive bands to hold them together, white textile fabric imitating the petals of the blossoms and small plastic parts sustaining the blossoms). The parts are bound, glued and fitted together. An electric light chain holding 60 micro electric bulbs is integrated into the artificial branch. The light bulbs represent the pistils of the blossoms. Due to their size the light bulbs give little illumination effect. The electric wire of the light chain holding the micro light bulbs is completely covered by the branch. The remaining, several metre long, electric wire leaves the main branch and ends in an electrical transformer. The article is neither self-standing nor does it have any means by which it can be hung. It is designed to be placed in a vase. (artificial cherry tree branch) (See photographs no. 654 A, B and C) (*)	6702 90 00	Classification is determined by General Rules (GIR) 1, 3(b) and 6 for the interpretation of the Combined Nomenclature and the wording of CN codes 6702 and 6702 90 00. The article consists of composite goods within the meaning of GIR3(b). It is made up of artificial flowers of heading 6702, an electric lighting fitting of heading 9405 and an electrical transformer of heading 8504. The electric lighting fitting is integrated into the artificial flower branch to form an inseparable whole (See also the HS EN (Harmonised System Explanatory Notes) to GIR 3(b), (IX)). Due to the objective characteristics of the article (it looks like a typical artificial flower; the light bulbs are tiny and give little illumination effect), the article is mainly designed to be placed in a vase and decorate the room as an imitation of flowers. The illumination is only an additional effect enhancing the decorative effect. Consequently, the artificial flower branch is the component that gives the article its essential character (i.e. as a decorative article) within the meaning of GIR 3(b). The article cannot be classified as a lamp of heading 9405, because it is not primarily designed to illuminate for example a room, nor is it a specialised lamp (see also the HS EN to heading 9405, (I), (1) and (3)). The artificial flower branch resembles the natural product (see also the HS EN to heading 6702, (1)). The article is therefore to be classified under heading 6702 as 'artificial flowers'.

(*) The image is purely for information.



654 A



654 B



654 C

COMMISSION REGULATION (EU) No 1156/2010**of 8 December 2010****establishing the standard import values for determining the entry price of certain fruit and vegetables**

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation) ⁽¹⁾,Having regard to Commission Regulation (EC) No 1580/2007 of 21 December 2007 laying down implementing rules for Council Regulations (EC) No 2200/96, (EC) No 2201/96 and (EC) No 1182/2007 in the fruit and vegetable sector ⁽²⁾, and in particular Article 138(1) thereof,

Whereas:

Regulation (EC) No 1580/2007 lays down, pursuant to the outcome of the Uruguay Round multilateral trade negotiations, the criteria whereby the Commission fixes the standard values for imports from third countries, in respect of the products and periods stipulated in Annex XV, Part A thereto,

HAS ADOPTED THIS REGULATION:

Article 1

The standard import values referred to in Article 138 of Regulation (EC) No 1580/2007 are fixed in the Annex hereto.

Article 2

This Regulation shall enter into force on 9 December 2010.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 8 December 2010.

*For the Commission,
On behalf of the President,**Jean-Luc DEMARTY
Director-General for Agriculture and
Rural Development*⁽¹⁾ OJ L 299, 16.11.2007, p. 1.⁽²⁾ OJ L 350, 31.12.2007, p. 1.

ANNEX

Standard import values for determining the entry price of certain fruit and vegetables

(EUR/100 kg)

CN code	Third country code ⁽¹⁾	Standard import value
0702 00 00	AL	62,5
	MA	84,4
	MK	66,1
	TR	141,6
	ZZ	88,7
0707 00 05	EG	145,5
	TR	75,2
	ZZ	110,4
0709 90 70	MA	100,7
	TR	112,6
	ZZ	106,7
0805 10 20	AR	50,8
	BR	57,8
	CL	87,6
	MA	57,1
	PE	58,9
	SZ	46,6
	TR	58,3
	ZA	50,9
	ZW	48,4
0805 20 10	ZZ	57,4
	MA	79,6
0805 20 30, 0805 20 50, 0805 20 70, 0805 20 90	ZZ	79,6
	IL	72,3
	TR	67,4
0805 50 10	ZZ	69,9
	TR	58,4
0808 10 80	ZZ	58,4
	AU	187,9
	CA	100,0
	CN	95,3
	MK	26,7
	NZ	99,2
	US	106,8
	ZA	113,7
0808 20 50	ZZ	104,2
	CN	77,6
	US	112,9
	ZA	143,3
	ZZ	111,3

⁽¹⁾ Nomenclature of countries laid down by Commission Regulation (EC) No 1833/2006 (OJ L 354, 14.12.2006, p. 19). Code 'ZZ' stands for 'of other origin'.

DECISIONS

DECISION OF THE REPRESENTATIVES OF THE GOVERNMENTS OF THE MEMBER STATES, MEETING WITHIN THE COUNCIL

of 25 February 2010

determining the seat of the European Asylum Support Office

(2010/762/EU)

THE REPRESENTATIVES OF THE GOVERNMENTS OF THE MEMBER STATES OF THE EUROPEAN UNION, MEETING WITHIN THE COUNCIL,

Article 2

This Decision shall enter into force on 18 June 2010.

Whereas:

Article 3

(1) Regulation (EU) No 439/2010 ⁽¹⁾ of the European Parliament and of the Council establishes a European Asylum Support Office.

This Decision shall be published in the *Official Journal of the European Union*.

(2) It is necessary to determine the seat of the European Asylum Support Office,

Done at Brussels, 25 February 2010.

HAVE ADOPTED THIS DECISION:

Article 1

The European Asylum Support Office shall have its seat at Valletta Harbour.

For the Council

The President

A. PÉREZ RUBALCABA

⁽¹⁾ OJ L 132, 29.5.2010, p. 11.

COUNCIL DECISION**of 6 December 2010****on the conclusion of a Fisheries Partnership Agreement between the European Union and Solomon Islands**

(2010/763/EU)

THE COUNCIL OF THE EUROPEAN UNION,

(4) The Agreement should be concluded,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 43(2) in conjunction with Article 218(6)(a) thereof,

HAS ADOPTED THIS DECISION:

Having regard to the proposal from the Commission,

Article 1

The Fisheries Partnership Agreement between the European Union and Solomon Islands is hereby approved ⁽²⁾.

Having regard to the consent of the European Parliament,

Whereas:

Article 2

(1) On the basis of the Council Decision of 22 September 2009 authorising the Commission to open negotiations on behalf of the Community with a view to concluding a Fisheries Partnership Agreement with Solomon Islands, the Community has negotiated with Solomon Islands a Fisheries Partnership Agreement providing EU vessels with fishing opportunities in the waters over which Solomon Islands has sovereignty or jurisdiction in respect of fisheries.

The President of the Council shall designate the person(s) empowered to proceed, on behalf of the Union, to the notification provided for in Article 18 of the Agreement, in order to express the consent of the Union to be bound by the Agreement ⁽³⁾.

(2) As a result of those negotiations, a new Fisheries Partnership Agreement was initialled on 26 September 2009.

Article 3

This Decision shall enter into force on the day of its adoption.

(3) By Council Decision No 2010/397/EU of 3 June 2010 ⁽¹⁾, the Fisheries Partnership Agreement between the European Union and Solomon Islands has been signed and provisionally applied since 9 October 2009.

Done at Brussels, 6 December 2010.

For the Council

The President

J. MILQUET

⁽¹⁾ OJ L 190, 22.7.2010, p. 1.

⁽²⁾ The text of the Agreement has been published in OJ L 190, 22.7.2010, p. 3, together with the decision on signature.

⁽³⁾ The date of entry into force of the Agreement will be published in the *Official Journal of the European Union* by the General Secretariat of the Council.

COMMISSION DECISION

of 8 December 2010

concerning the adoption of a financing decision for 2010 in the framework of food safety

(notified under document C(2010) 8620)

(2010/764/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities ⁽¹⁾ (hereinafter referred to as the 'Financial Regulation'), and in particular Article 75 thereof,

Having regard to Commission Regulation (EC, Euratom) No 2342/2002 of 23 December 2002 laying down detailed rules for the implementation of Council Regulation (EC, Euratom) No 1605/2002 on the Financial Regulation applicable to the general budget of the European Communities ⁽²⁾ (hereinafter referred to as the 'Implementing Rules'), and in particular Article 90 thereof,

Having regard to Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules ⁽³⁾, and in particular Article 66(1)(c) thereof,

Whereas:

- (1) In accordance with Article 75 of the Financial Regulation and Article 90(1) of the Implementing Rules, the commitment of expenditure from the Union budget shall be preceded by a financing decision setting out the essential elements of the action involving expenditure and adopted by the institution or the authorities to which powers have been delegated by the institution.
- (2) Different actions are foreseen to amend Regulation (EC) No 882/2004 as outlined in the report from the Commission to the European Parliament and to the Council on the application of said Regulation ⁽⁴⁾, in particular those related to the amendment of Council Directive 96/23/EC ⁽⁵⁾ on measures to monitor certain substances and residues thereof in live animals and animal products and on the review of the rules on the financing of official controls (inspection fees – Articles 26 to 29 of Regulation (EC) No 882/2004).

- (3) Studies to evaluate the possible impacts of the different options of the revision of the current European legislation on inspection fees and on the control of residues of veterinary medicines in food of animal origin are foreseen to be carried out in 2010.
- (4) Article 66 of Regulation (EC) No 882/2004 empowers the Commission to finance measures necessary to ensure the application of Regulation (EC) No 882/2004 including the organisation of studies.
- (5) It is appropriate to commit adequate financial resources for the organisation of studies related to a possible revision of the current rules on residue controls and inspection fees.
- (6) The present financing decision may also cover the payment of interest due for late payment on the basis of Article 83 of the Financial Regulation and Article 106(5) of the Implementing Rules.
- (7) It is appropriate to define the terms 'substantial change' within the meaning of Article 90(4) of the Implementing Rules for the application of this decision,

HAS ADOPTED THIS DECISION:

Article 1

The organisation of studies to support the revision of the current rules on residue controls and inspection fees is hereby adopted. It constitutes a financing decision in the meaning of Article 75 of the Financial Regulation.

Article 2

The maximum contribution authorised by this Decision for the implementation of the studies is set at EUR 70 000 for the inspections fees and at EUR 30 000 for the residue control, to be financed from the following Budgetary Line of the General Budget of the European Union for 2010:

— Budgetary Line No 17 04 07 01,

These appropriations may also cover interest due for late payment.

⁽¹⁾ OJ L 248, 16.9.2002, p. 1.

⁽²⁾ OJ L 357, 31.12.2002, p. 1.

⁽³⁾ OJ L 165, 30.4.2004, p. 1.

⁽⁴⁾ COM(2009) 334 final.

⁽⁵⁾ OJ L 125, 23.5.1996, p. 10.

Article 3

Cumulated changes of the allocations to the specific actions not exceeding 20 % of the maximum contribution authorised by this Decision are not considered to be substantial provided that they do not significantly affect the nature and objective of the work programme.

The authorising officer may adopt such changes in accordance with the principles of sound financial management and of proportionality.

Article 4

This Decision is addressed to the authorising officers by delegation.

Done at Brussels, 8 December 2010.

For the Commission

John DALLI

Member of the Commission

ANNEX

Inspection fees and residue controls: in the context of the on-going review, specific information and analysis are needed with reference to the possible impacts of the different options for change which have been identified by the Commission. For this part of the exercise, the external consultant to be contracted will be tasked with gathering the necessary data and information. It is foreseen to receive the results of this work by the second quarter of 2011.

RULES OF PROCEDURE

CONSOLIDATED VERSION OF THE RULES OF PROCEDURE OF THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE

On 14 July 2010, the European Economic and Social Committee adopted the consolidated version of its Rules of Procedure

This edition combines:

The Rules of Procedure of the European Economic and Social Committee adopted at the plenary session of 17 and 18 July 2002 (OJ No L 268 of 4 October 2002), which entered into force on 1 August 2002, in accordance with Rule 78;

the changes resulting from the following:

1. amendments of 27 February 2003 to the Rules of Procedure of the European Economic and Social Committee (OJ L 258 of 10 October 2003);
2. amendments of 31 March 2004 to the Rules of Procedure of the European Economic and Social Committee (OJ L 310 of 7 October 2004);
3. amendments of 5 July 2006 to the Rules of Procedure of the European Economic and Social Committee (OJ L 93 of 3 April 2007);
4. amendments of 12 March 2008 to the Rules of Procedure of the European Economic and Social Committee (OJ L 159 of 20 June 2009);
5. amendments of 14 July 2010 to the Rules of Procedure of the European Economic and Social Committee.

This edition has been produced by the general secretariat of the European Economic and Social Committee and groups together the different amendments approved by the Committee assembly.

The implementing provisions for the Rules of Procedure, which have been adopted by the Committee bureau in accordance with Rule 77(2a), are presented separately.

PREAMBLE

1. The European Economic and Social Committee represents the various economic and social components of organised civil society. It is an institutional consultative body established by the 1957 Treaty of Rome.
2. The Committee's consultative role enables its members, and hence the organisations they represent, to participate in the European Union decision-making process. With views occasionally being diametrically opposed, the Committee's discussions often require real negotiations involving not only the usual social partners, i.e. employers (group I) and wage-earners (group II) but also all the other socio-occupational interests represented (group III). This expertise, these discussions and negotiations and the search for convergence may improve the quality and credibility of the European Union decision-making process, inasmuch as they make it more comprehensible and acceptable for Europe's citizens and increase the transparency which is so vital for democracy.

3. Within the European institutional set-up, the EESC fulfils a specific role: it is the prime forum in which the organisations of civil society in the European Union can have their views represented and discussed, and it is especially well placed to act as an intermediary between organised civil society and the European Union institutions.
4. As a chamber for debating and for drawing up opinions, the EESC helps to strengthen the democratic credentials of the process of building the European Union, including the promotion of relations between the EU and socio-economic groupings in third countries. In so doing it helps to promote a genuine identification with Europe.
5. To carry out its missions successfully, on 17 July 2002, the EESC adopted its Rules of Procedure ⁽¹⁾, in accordance with the second paragraph of Article 260 of the Treaty establishing the European Community.
6. On 14 July 2010, the EESC's plenary assembly adopted the latest codified version of these Rules of Procedure.

TITLE I

ORGANISATION OF THE COMMITTEE

Chapter I

INSTALLATION OF THE COMMITTEE IN OFFICE

Rule 1

1. The Committee shall hold office for terms of five years.

2. The first meeting of the Committee following each five-yearly renewal shall be convened by the oldest member, if possible not later than one month after the members of the Committee have been notified of their appointment by the Council.

Rule 2

1. The Committee shall consist of the following bodies: the assembly, the bureau, the president and the sections.

2. The Committee shall be divided into three groups, the composition and role of which are set out in Rule 27.

3. The members of the Committee may not be bound by any mandatory instructions. They shall be completely independent in the performance of their duties, in the general interest of the Union. During the performance of their duties and on journeys to and from the place of meetings, members

shall enjoy the privileges and immunities established in the Protocol on the privileges and immunities of the European Union. Specifically, they shall enjoy freedom of movement, personal inviolability and immunity.

Rule 2a

1. The Committee recognises and adopts the following European Union symbols:

a) the flag representing a circle of twelve gold stars on a blue background;

b) the anthem taken from the 'Ode to Joy' from Beethoven's Ninth Symphony;

c) the motto 'United in diversity'.

2. The Committee shall celebrate Europe Day on 9 May.

3. The flag shall be displayed in the buildings of the Committee and to mark official occasions.

4. The anthem shall be played at the opening of every inaugural session at the beginning of a term of office and at other formal sessions, e.g. when welcoming heads of state or government, or new members following an enlargement.

⁽¹⁾ These rules were subsequently amended on 27 February 2003, 31 March 2004, 5 July 2006 and 12 March 2008.

Chapter II

BUREAU

Rule 3

1. The election of the bureau members shall comply with the principle of observing an overall and geographical balance between the groups, with at least one, and a maximum of three, representatives from each Member State. The groups shall negotiate and draft a proposal for bureau membership which shall be submitted to the assembly.

The bureau of the Committee shall comprise:

- a) the president, the two vice-presidents;
- b) the three group presidents, elected as provided for in Rule 27;
- c) the section presidents.
- d) a variable number of members, totalling no more than the number of Member States.

2. The president shall be elected in turn from among the members of the three groups.

3. The president and vice-presidents may not be re-elected. For the two and a half years immediately following the expiry of his term of office the president may not be a member of the bureau as a vice-president or as the president of a group or section.

4. The vice-presidents shall be elected from among the members of the two groups to which the president does not belong.

Rule 4

1. At its first meeting, held in pursuance of Rule 1, the Committee, with the interim president in the chair, shall elect from among its members a president, two vice-presidents, the presidents of the sections and the other members of the bureau other than the group presidents for a term of two and a half years, commencing on the date of the installation of the Committee in office.

2. Only matters pertaining to these elections may be discussed under the chairmanship of the interim president.

Rule 5

The meeting at which the bureau of the Committee is elected for the last two and a half years of a five-year period shall be convened by the outgoing president. It shall be held at the

beginning of the session of the month in which the term of office of the first bureau expires. The chair shall be taken by the outgoing president.

Rule 6

1. The Committee may set up an election panel, drawn from its members and consisting of one representative per Member State, to receive candidatures and to submit a list of candidates to the assembly, taking due account of the provisions of Rule 3.

2. The Committee, acting in accordance with the provisions of this Rule, shall decide on the list or lists of candidates for the bureau and the presidency.

3. The Committee shall elect the members of the bureau other than the presidents of the groups, holding more than one ballot if necessary, according to the procedure for voting by list.

4. Only complete lists of candidates conforming to the provisions of Rule 3 and accompanied by a declaration of acceptance from each candidate may be admitted to the vote.

5. Those candidates on the list which obtains the highest number and at least one-quarter of the valid votes cast shall be declared elected as members of the bureau.

6. The assembly shall then elect the president and the vice-presidents of the Committee by a simple majority.

7. The Committee shall then elect the presidents of the sections by a simple majority.

8. Finally, the Committee shall vote on the bureau as a whole. At least two-thirds of the total number of valid votes must be cast in favour.

Rule 7

If a bureau member is unable to discharge the duties attaching to his post or in the cases provided for in Rule 70(2), such a member shall be replaced for the remainder of his term of office in accordance with Rule 6. Replacement shall be subject to a vote by the assembly on the basis of a proposal from the group concerned.

Rule 8

1. Meetings of the bureau shall be convened by the president, acting either *ex officio* or at the request of ten members.

2. Minutes of each bureau meeting shall be drawn up. These minutes shall be submitted to the bureau for approval.

3. The bureau shall lay down its own procedural rules.

4. It shall lay down the organisation and working procedures of the Committee. It shall adopt provisions for implementing the Rules of Procedure after consulting the groups.

5. The bureau and the president shall exercise the budgetary and financial powers provided for in the Financial Regulation and the Committee's Rules of Procedure.

6. The bureau shall determine the implementing arrangements regarding the travel and subsistence expenses of members, their alternates, appointed in accordance with Rule 18, delegates and their alternates appointed in accordance with Rule 24, and of the experts appointed in accordance with Rule 23, in compliance with the budget and financial procedures.

7. The bureau shall have political responsibility for the general management of the Committee. In particular, it shall ensure that the activities of the Committee, its bodies and its staff are in keeping with its institutional aims.

8. The bureau shall be responsible for ensuring that in carrying out the tasks entrusted to it by the Treaty, the Committee makes good use of the human, budgetary and technical resources available to it. The bureau shall, for instance, take part in the budgetary procedure and in the organisation of the secretariat.

9. The bureau may set up ad hoc groups, drawn from among its members, to examine any questions falling within its competence. Other members may also be involved in the work of these groups, except when issues concerning the appointment of permanent staff are discussed.

10. Every six months the bureau shall examine, on the basis of a report drawn up for this purpose, the action taken on opinions delivered by the Committee.

11. At the request of a member or of the secretary-general, the bureau shall clarify the interpretation of the Rules of Procedure and its Implementing Provisions. Its findings shall be binding subject to the right of appeal to the assembly to make a final decision.

12. At the time of the Committee's five-yearly renewal, the outgoing bureau shall discharge current business until the first meeting of the new Committee. In exceptional cases, it may make an outgoing member responsible for the implementation of specific tasks, or tasks subject to time limits, that require a particular level of expertise.

Rule 9

Within the framework of interinstitutional cooperation, the bureau may instruct the president to conclude cooperation

agreements with the institutions and other bodies of the European Union.

Rule 10

1. A 'budget group' shall be set up to prepare all draft decisions of a financial or budgetary nature to be adopted by the bureau.

2. The budget group shall be chaired by one of the two vice-presidents under the authority of the president. It shall have nine members, appointed by the bureau on the proposal of the groups.

2a. The budget group shall participate in the drawing-up of the Committee budget, issue an opinion on it for the approval of the bureau and ensure that the budget is properly implemented and accounted for.

3. For specified additional matters the bureau may delegate its decision-making power to the budget group.

4. The budget group's decisions shall be governed by the principles of unity and budgetary accuracy, annuality, equilibrium, unit of account, universality, specification, sound financial management and transparency. Its decisions shall be adopted by the following procedure:

a) proposals adopted unanimously by the budget group shall be submitted to the bureau for approval without debate,

b) proposals adopted by simple majority or refusals of such proposals shall be justified in order that they may be examined subsequently by the Committee bureau.

5. The budget group may distribute tasks among its members; however, it shall adopt its decisions by consensus.

6. The president of the budget group shall chair the delegation responsible for negotiations with the budgetary authorities and shall report thereon to the bureau.

7. The budget group's duties shall include advising the president, the bureau and the Committee and exercising control over the various services.

Rule 10a

1. A communication group shall be set up, responsible for guiding and monitoring the Committee's communication strategy. Each year it shall draw up for the Committee a report on the implementation of this strategy and a programme for the year ahead.

2. The communication group shall be chaired by one of the two vice-presidents under the authority of the president. It shall have nine members, appointed by the bureau on the proposal of the groups.

3. The communication group shall coordinate the activities of the structures responsible for communication and relations with the press and media, and ensure that such activities are consistent with the approved strategy and programmes.

Chapter III

PRESIDENCY AND THE PRESIDENT

Rule 11

1. The presidency shall comprise the president and the two vice-presidents.

2. The Committee presidency shall meet with the group presidents to prepare the work of the bureau and the assembly. The section presidents may be invited to take part in these meetings.

3. In order to define the Committee's programme of work and assess its progress, the presidency shall meet at least twice a year with the presidents of the groups and sections.

Rule 12

1. The president shall direct all the work of the Committee and its internal bodies, in accordance with the Treaty and with these Rules. He shall have all the powers necessary to direct the deliberations of the Committee and ensure that they proceed smoothly.

2. The president shall involve the vice-presidents in his activities on a permanent basis; he may delegate to them specific tasks or responsibilities falling within his remit.

3. The president may entrust specific tasks to the secretary-general for a limited period.

4. The president shall represent the Committee. He may delegate this authority of representation to a vice-president or, if appropriate, to a member.

5. The president shall report to the Committee on action and measures taken on its behalf between plenary sessions. These reports shall not be followed by a debate.

6. After his election, the president shall present his work programme for his term of office to the plenary session. He shall also present a review of achievements at the end of his term.

These two presentations may be debated by the assembly.

Rule 13

The two vice-presidents shall be respectively president of the budget group and president of the communication group and shall perform these tasks under the authority of the president.

Rule 13a

1. The enlarged presidency shall comprise the president of the Committee, the two vice-presidents and the group presidents.

2. The enlarged presidency shall have the role of preparing and facilitating the work of the bureau.

Chapter IV

SECTIONS

Rule 14

1. The Committee shall comprise six sections. Other sections may be set up by the plenary assembly on a proposal from the bureau, in the fields covered by the Treaties.

2. The Committee shall set up its sections at the inaugural session following each five-yearly renewal.

3. The list of sections and their terms of reference may be re-examined at the time of each five-yearly renewal.

Rule 15

1. The number of members of the sections shall be decided by the Committee on a proposal from its bureau.

2. Apart from the president, every member of the Committee must be a member of at least one section.

3. No member may belong to more than two sections, except if he comes from a Member State where the number of members is nine or less. However, no member may belong to more than three sections.

4. The members of the sections shall be appointed by the Committee. Appointments shall be for two and a half years and shall be renewable.

5. The procedure laid down for the appointment of section members shall also be followed for the replacement of such members.

Rule 16

1. The bureau of a section, elected for a term of two and a half years, shall comprise twelve members including a president and three vice-presidents, one from each group.
2. Elections of section presidents and of other members of section bureaux shall be conducted by the Committee.
3. Section presidents and other members of section bureaux may be re-elected.
4. The presidency of three sections shall be rotated between the groups every two and a half years. The same group may not hold the presidency of any section for a period exceeding five consecutive years.

Rule 17

1. It shall be the task of the sections to adopt opinions or information reports on questions referred to them in accordance with Rule 32.
2. The sections may set up from among their members a study group or drafting group or appoint a rapporteur working alone to deal with the questions referred to them.
3. The appointment of rapporteurs and, where appropriate, co-rapporteurs, and the composition of study and drafting groups shall be decided on the basis of proposals from the groups.
- 3a. In order that study groups may be set up quickly and in the event of agreement between the three group presidents on the proposed appointment of rapporteurs and, where appropriate, co-rapporteurs, and on the composition of study or drafting groups, the section presidents shall take the steps required to ensure that work can begin.
4. The rapporteur, with the help of his expert, where appropriate, shall be responsible for monitoring action taken on an opinion after its adoption at the plenary session. He shall be assisted in this task by the secretariat of the section concerned. The section shall be informed of the findings of such monitoring.
5. Study groups may not become permanent bodies, save in exceptional cases for which the Committee bureau's prior authorisation is required for the same two-and-a-half-year period.

Rule 18

1. Any member of the Committee unable to attend a preparatory meeting may arrange to be represented by his alternate.
- 1a. Alternates shall have no voting rights.

1b. However, should a member be president of a section or study group, member of the section bureau or rapporteur, he may not be represented by his alternate in the performance of these duties.

2. The name and capacity of the alternate selected shall be communicated to the bureau of the Committee for its approval.
3. During the preparatory work the alternate shall carry out the same duties as the member whom he replaces and shall be subject to the same rules as regards travel and subsistence expenses.

Chapter V*SUBCOMMITTEES AND RAPPOREUR-GENERAL**Rule 19*

1. On the initiative of the bureau, the Committee may, in exceptional cases, set up subcommittees drawn from its members to produce, for submission initially to the bureau and then to the assembly, draft opinions or information reports on strictly horizontal general matters.
2. In the periods between plenary sessions the bureau may set up subcommittees, subject to subsequent confirmation by the Committee. In no case may a subcommittee be set up for more than one issue. A subcommittee shall be automatically dissolved as soon as the draft opinion or information report which it has prepared is voted on by the Committee.
3. Subcommittees set up for questions coming within the purview of two or more sections shall be made up of members of those sections.
4. The rules governing sections shall be applicable, *mutatis mutandis*, to subcommittees.

Rule 20

In the event of referrals covering topics of secondary interest or of an urgent nature, the Committee may appoint a rapporteur-general, who shall address the plenary assembly alone and without first addressing the section.

Chapter VI*OBSERVATORIES, HEARINGS, EXPERTS**Rule 21*

1. The Committee may set up observatories when the nature, extent and complexity of the subject to be dealt with calls for particular flexibility in the working methods, procedures and instruments to be used.

2. An observatory shall be set up by a decision of the plenary assembly, ratifying a decision taken earlier by the bureau on a proposal from a group or from a section.

3. The decision to set up an observatory shall define the object, structure, composition and duration in each case.

4. The observatories may draw up an annual information document on the application of the horizontal clauses in the Treaty (the social clause, environmental clause and consumer protection clause) and their impact on the policies of the European Union. This report may be forwarded to the European Parliament, the Council and the Commission, if the assembly so decides.

5. Each observatory shall work under the oversight and supervision of a section.

Rule 22

If an issue under discussion is of sufficient importance, the various bodies and working units of the Committee may invite guest speakers from outside the Committee to a hearing. If the use of guest speakers involves additional costs, the body or unit concerned must seek prior authorisation from the Committee bureau and submit a programme giving reasons why it considers that certain aspects call for outside assistance.

Rule 23

Insofar as such action is essential for preparing certain tasks, the president may, on his own initiative, or on a proposal from the groups, sections, rapporteurs or co-rapporteurs, appoint experts under the terms laid down by the bureau in line with the provisions of Rule 8(6). Experts taking part in preparatory work shall be subject to the same conditions as those laid down for members as regards travel and subsistence expenses.

Chapter VII

CONSULTATIVE COMMISSIONS

Rule 24

1. The Committee shall have the option of setting up consultative commissions. These shall be made up of members of the Committee and of delegates from areas of civil society that the Committee wishes to involve in its work.

2. Such commissions shall be set up by a decision of the plenary assembly which shall confirm a decision taken by the bureau. The decision setting up such commissions shall define their object, their structure, their composition, their duration and their rules.

3. In accordance with Rule 24(1) and (2), a 'consultative commission on industrial change' (CCMI) may be set up, made up of members of the European Economic and Social Committee and delegates from organisations representing the various economic and social sectors as well as civil society

organisations concerned by industrial change. The president of the commission shall be a member of the Committee bureau, to which he shall report every two and a half years on the activity of the CCMI. He shall be chosen from among the members of the bureau referred to in Rule 3(1)(d) of these Rules of Procedure. Delegates and alternates participating in preparatory work shall be subject to the same rules as members as regards travel and subsistence expenses.

Chapter VIII

DIALOGUE WITH ECONOMIC AND SOCIAL ORGANISATIONS IN EU AND NON-EU STATES

Rule 25

1. The Committee, on the initiative of the bureau, may maintain structured relations with economic and social councils and similar institutions and with civil society organisations of an economic and social nature in the European Union and non-EU countries.

2. In the same way, it shall undertake actions designed to foster the establishment of economic and social councils or similar institutions in countries which do not yet have them.

Rule 26

1. The Committee, on a proposal from the bureau, may appoint delegations to maintain relations with the various economic and social components of organised civil society in states or associations of states outside the European Union.

2. Cooperation between the Committee and partners from organised civil society in the candidate countries shall take the form of joint consultative committees if these have been formed by the Association Councils. Otherwise it shall take place in contact groups.

3. The joint consultative committees and contact groups shall draw up joint information reports and declarations, which may be forwarded by the Committee to the relevant institutions and to the actors concerned.

Chapter IX

GROUPS AND CATEGORIES

Rule 27

1. The Committee shall be made up of three groups of members representing respectively employers, employees and the various other economic and social components of organised civil society.

2. The groups shall elect their presidents and vice-presidents. These groups shall participate in the preparation, organisation and coordination of the business of the Committee and its constituent bodies, and help supply them with information. Each group shall be provided with a secretariat.

2a. The groups shall propose to the assembly candidates for election as president and vice-presidents, in accordance with Rule 6(6) and respecting the principle of equality between men and women as defined by the institutions of the European Union.

3. The group presidents shall be members of the bureau in accordance with Rule 3(1)(b).

4. The group presidents shall assist the Committee presidency in the formulation of policy and, where appropriate, in the monitoring of expenditure.

5. The group presidents shall meet with the Committee presidency to assist in preparing the work of the bureau and the assembly.

6. The groups shall make proposals to the assembly for the election of section presidents under Rule 6(7) and of section bureaux under Rule 16.

7. The groups shall make proposals for membership of the budget group to be set up by the bureau under Rule 10(1).

8. The groups shall make proposals for the membership of observatories and consultative commissions to be set up by the assembly under Rules 21 and 24 respectively.

9. The groups shall make proposals for the membership of delegations and joint consultative committees to be set up in accordance with Rules 26(1) and (2) respectively.

10. The groups shall make proposals for rapporteurs and for the composition of study and drafting groups to be appointed/set up by the sections under Rule 17(3).

11. In applying Rules 27(6) to 27(10), the groups shall take account of the representation within the Committee of the Member States, the various components of economic and social activity, terms of reference and the criteria of good management.

12. Members may, on a voluntary basis, join one of the groups subject to the approval of their eligibility by the members of that group. No member shall belong to more than one group at the same time.

13. The general secretariat shall provide members not belonging to a group with the material and technical support required for the performance of their duties. Their participation in study groups and other internal bodies shall be the subject of a decision by the Committee president after consultation of the groups.

Rule 28

1. Members of the Committee may, on a voluntary basis, form categories representing the various economic and social interests of organised civil society in the European Union.

2. A category may be made up of members from the three groups within the Committee. No member shall belong to more than one category at the same time.

3. The creation of a category shall be subject to approval being granted by the bureau, who shall inform the assembly.

TITLE II

PROCEDURE OF THE COMMITTEE

Chapter I

CONSULTATION OF THE COMMITTEE

Rule 29

1. The Committee shall be convened by its president to adopt opinions requested by the Council, the Commission or the European Parliament.

2. It shall be convened by its president, on a proposal from its bureau and with the agreement of the majority of its members, to deliver, on its own initiative, opinions on any question pertaining to the European Union, its policies and their possible developments.

Rule 30

1. Requests for opinions referred to in Rule 29(1) shall be addressed to the president of the Committee. The president, in consultation with the bureau, shall organise the work of the Committee, taking account as far as possible of the time limits set in the request for an opinion.

2. The bureau shall determine the order of priority of opinions allocating them among categories.

3. The sections shall draw up a proposal for allocating opinions among the three categories below. They shall give a provisional indication of the size of the study group. After discussions between the Committee presidency and the group presidents, the proposal shall be submitted to the bureau for a decision. In special cases, the presidents of the groups may propose that the size of the study group be modified. At its next meeting the bureau shall confirm this new proposal and lay down the final size of the study group.

The three categories shall be defined according to the following criteria:

Category A (referrals on topics identified as a priority). This category includes:

- all requests for exploratory opinions (Commission, European Parliament, future Council presidencies);
- all adopted proposals for own-initiative opinions;
- certain mandatory or optional referrals.

Such referrals shall be handled by study groups of various sizes (6, 9, 12, 15, 18, 21 or 24 members) and possessing appropriate resources.

Category B (mandatory or optional referrals covering topics of secondary interest or of an urgent nature).

Such referrals shall normally be handled by a rapporteur working alone or a rapporteur-general. In exceptional cases, following a decision by the bureau, a category B referral may be handled by a three-member drafting group (category 'B +'). The number of meetings and working languages shall be decided by the bureau.

Category C (mandatory or optional referrals of a purely technical nature).

Such referrals shall be dealt with in a standard opinion, which the bureau shall submit to the assembly. This procedure shall not involve either the appointment of a rapporteur or examination by a section, but simply the adoption or rejection of the opinion at the plenary session. When such items come up at the plenary session, the assembly shall first of all be asked whether it is in favour of or against them being handled according to the above-mentioned procedure, and then to vote for or against the adoption of the standard opinion.

4. For urgent matters, the provisions of Rule 59 of these Rules shall apply.

Rule 31

The Committee may, on a proposal from the bureau, decide to prepare an information report with a view to examining any question pertaining to the policies of the European Union and their possible developments.

Rule 31a

The Committee may, following a proposal from a section, a group or a third of its members, issue resolutions on a current topic, which shall be adopted by the assembly in accordance with Rule 56(2). Draft resolutions shall be given priority on the agenda for the plenary session.

Chapter II

ORGANISATION OF WORK

A. *Work of the sections*

Rule 32

1. When an opinion or information report is to be produced, the bureau, in accordance with Rule 8(4), shall designate the section which is to be responsible for preparing the work in question. Where the matter for consideration is clearly within the purview of a given section, the president shall designate that section and inform the bureau of his decision.

2. Where a section that has been designated to prepare an opinion wishes to hear the views of the Consultative Commission on Industrial Change (CCMI) or where the CCMI wishes to set out its views on an opinion allocated to a section, the bureau may authorise the CCMI to draw up a supplementary opinion on one or more of the issues covered by the referral. The bureau may also take this decision on its own initiative. The bureau shall organise the Committee's work in such a way that the CCMI is able to prepare its opinion in good time to be taken into consideration by the section.

The section alone shall be responsible for reporting to the Committee. It shall however append to its opinion the supplementary opinion drawn up by the Consultative Commission on Industrial Change.

3. The president of the section concerned shall be notified by the Committee president of the decision and of the time limit for the completion of the section's work.

4. The Committee president shall inform the members of the Committee of the referral to the section and of the date on which the subject is to be dealt with by the plenary session.

Rule 33

(deleted)

Rule 34

The Committee president, in agreement with the bureau, may authorise a section to hold a joint meeting with a European Parliament committee, or a Committee of the Regions commission.

Rule 35

Sections to which a question has been referred in accordance with these Rules shall be convened by their president.

Rule 36

1. Meetings of the sections shall be prepared by the section presidents in consultation with the section bureau.

2. Meetings shall be chaired by the section president or, in his absence, by one of the vice-presidents.

Rule 37

1. A quorum shall exist at section meetings if over half of the full members are present or represented.

2. If there is not a quorum, the president shall close the meeting and convene a further meeting to be held at a time and in a manner which he considers appropriate, but during the course of the same day; at that further meeting a quorum shall exist irrespective of the number of members present or represented.

Rule 38

The sections shall adopt opinions with reference to the draft opinion submitted by the rapporteur and, where appropriate, the co-rapporteur.

Rule 39

1. Section opinions shall contain only texts adopted by the section in accordance with the procedure laid down in Rule 56.

2. The text of proposed amendments which have been rejected, together with the result of the voting thereon, shall be appended to the opinion if the amendments received at least one-quarter of the votes cast.

Rule 40

Section opinions, together with all the documents appended thereto in accordance with Rule 39, shall be sent by the president of the section to the president of the Committee

and shall be laid before the Committee by its bureau as soon as possible. These documents shall be made available to the members of the Committee in good time.

Rule 41

Concise minutes of each section meeting shall be drawn up and submitted to the section for approval.

Rule 42

The president, in agreement with the bureau or where appropriate the assembly, may refer a question back to a section if he considers that the procedure laid down in these Rules for drawing up opinions has not been adhered to or that further study is necessary.

Rule 43

1. Without prejudice to Rule 17(2), the preparatory work of the sections shall be carried out, in principle, within a study group.

2. The rapporteur, assisted by his expert and, where appropriate, by one or more co-rapporteurs, shall study the question referred, take account of the views expressed and, on this basis, draw up the draft opinion, which shall be sent to the president of the section.

3. There shall be no voting at study group meetings.

B. Proceedings of the plenary sessions*Rule 44*

The assembly, comprising all the members of the Committee, shall meet in plenary session.

Rule 45

1. Sessions shall be prepared by the president in consultation with the bureau. The bureau shall meet before each session, and where appropriate during a session, to organise the proceedings.

2. The bureau may set a time limit for the general discussion of each opinion at the session.

Rule 46

1. The draft agenda drawn up by the bureau on a proposal from the Committee presidency in collaboration with the group presidents shall be sent by the Committee president to all Committee members and to the Council, the Commission and the European Parliament at least fifteen days before the opening of the relevant session.

2. The draft agenda shall be submitted to the assembly for approval at the opening of each session. Once the agenda has been adopted, the items must be examined during the sitting for which they are scheduled. The documents necessary for the Committee's deliberations shall be made available to the members in accordance with Rule 40.

Rule 47

1. A quorum shall exist at session sittings if more than half of the members of the Committee are present or represented.

2. If there is not a quorum, the president shall close the sitting and convene a further sitting to be held at a time he considers appropriate but during the same session; at that further sitting there shall be a quorum whatever the number of members present or represented.

Rule 48

When the agenda is submitted for adoption, the inclusion of any topical item shall be announced, where appropriate, by the president.

Rule 49

The Committee may amend the draft agenda for the purpose of examining draft resolutions submitted in accordance with the procedure referred to in Rule 31a.

Rule 50

1. The president shall open session sittings, preside over discussions and ensure that these Rules are observed. The president shall be assisted by the vice-presidents.

2. If the president is absent, the vice-presidents shall deputise. If the vice-presidents are absent, the oldest member of the bureau shall deputise.

3. The Committee shall base its deliberations on the work of the section competent to report to the assembly on the questions concerned.

4. Where a text has been adopted by a section with less than five votes against, the bureau may propose that it be included on the plenary session agenda among the items to be voted on without a discussion.

This procedure shall not apply if:

— at least twenty-five members signify their objection,

— an amendment is tabled for discussion during the plenary session or

— a section decides that the text should be discussed at the plenary session.

5. If a text fails to secure a majority of votes in the assembly, the president of the Committee may, with the consent of the assembly, refer the text back to the competent section for re-examination or appoint a rapporteur-general, who shall submit a new draft text at the same or another session.

Rule 51

1. Proposals for amendments must be drawn up in writing, signed by the proposers and lodged with the secretariat before the opening of the relevant session.

2. In the interests of efficient organisation of the proceedings of the assembly, the bureau shall fix the arrangements for the lodging of proposals for amendments.

3. The Committee shall, however, allow proposals for amendments to be lodged up to the opening of the relevant session sitting, provided such proposals are signed by at least twenty-five members.

4. Proposals for amendments must specify the part of the text to which they refer and be supported by a brief explanatory statement. Amendments that are repetitive in their form and content shall be examined together.

5. As a general rule, for each amendment the assembly shall hear only the proposer, a member who is against the proposed amendment and the rapporteur.

6. When a proposal for an amendment is examined, the rapporteur may put forward compromise proposals orally with the agreement of the proposer of the amendment. In such cases the Committee shall only vote on these compromise proposals.

7. Any amendment or amendments which aim to set out a generally divergent view to the section opinion shall be described as a counter-opinion.

The bureau shall be the body with the authority to decide on such a description. It shall take its decision after consulting the president of the section concerned.

The bureau may decide, after this consultation, to refer the draft opinion, together with the counter-opinion, back to the section for further study. In urgent circumstances, the Committee president shall have authority to do this.

8. Where appropriate, the president of the Committee, in consultation with the president and the rapporteur of the competent section, may propose to the Committee that any amendments be dealt with in such a way as to ensure that the final text is consistent.

Rule 52

1. The president, either on his own initiative or at the request of a member, may invite the Committee to decide on a limitation of speaking time or the number of speakers, the adjournment of a sitting or the closure of a discussion. Once a discussion has been declared closed, no member may speak except to explain his vote; such explanations of voting shall be made after the relevant vote has been taken and shall not exceed the speaking time allotted by the president.

2. A member may at any time request and be given precedence to speak during a discussion for the purpose of submitting a procedural motion.

Rule 53

1. Minutes of each plenary session shall be drawn up and submitted to the Committee for its approval.

2. The final version of such minutes shall be signed by the president and the secretary-general of the Committee.

Rule 54

1. Opinions of the Committee shall consist of, in addition to the legal basis of the opinion, an explanatory statement and the views of the Committee on the question as a whole.

2. The result of the voting on the opinion as a whole shall be set out in a preamble to the text of the opinion. Where a recorded vote is held, the names of the voters shall be given.

3. If proposed amendments are rejected by the plenary session but receive at least one-quarter of the votes cast, their texts and explanatory statements shall be appended to the relevant Committee opinions, together with the results of the voting. This requirement shall also apply to counter-opinions.

4. Section opinion texts that are rejected in favour of amendments adopted by the assembly shall also be appended to Committee opinions together with the results of the voting, provided that at least one-quarter of the votes cast were in favour of retention of the section opinion texts.

5. When one of the groups formed within the Committee under Rule 27 or one of the categories of economic and social activity formed under Rule 28 adopts a divergent but uniform standpoint on a matter submitted to the assembly for examination, its position may be summarised in a brief statement to be appended to the opinion, where the debate on that matter has been concluded by a recorded vote.

Rule 55

1. Opinions adopted by the Committee and minutes of Committee sessions shall be sent to the European Parliament, the Council and the Commission.

2. Opinions adopted by the Committee may be forwarded to any other institution or concerned entity.

TITLE III

GENERAL PROVISIONS

Chapter I

METHODS OF VOTING

Rule 56

1. The valid forms of votes shall be votes for, votes against and abstentions.

2. Except where otherwise provided in these Rules, adoption of the texts and decisions of the Committee and its constituent bodies shall be by a majority of the votes cast for and against.

3. Voting shall be by open ballot, by recorded vote, or by secret ballot.

4. Voting on a resolution, a proposed amendment, a counter-opinion, an opinion or any other text shall be by recorded vote if one-quarter of the members present or represented so request.

5. Election to the various representative posts shall always be by secret ballot. Other votes may be taken by secret ballot if a majority of the members present or represented so request.

6. If the vote is a tie (an equal number of votes for and against), the chairman of the meeting shall have a casting vote.

7. The acceptance by the rapporteur of an amendment shall not constitute a reason for not voting on that amendment.

Chapter II

URGENCY PROCEDURE

Rule 57

1. Where the urgency results from a deadline for the submission of its opinion imposed on the Committee by the Council, by the European Parliament or by the Commission, the urgency procedure may be applied if the president finds that this is necessary to enable the Committee to adopt its opinion in good time.

2. In cases of urgency at Committee level the president may, immediately and without consulting the bureau beforehand, take all requisite steps to enable the Committee to carry out its work. He shall inform the members of the bureau of the steps which he takes.

3. Arrangements made by the president under the urgency procedure shall be submitted to the following session of the Committee for confirmation.

Rule 58

(deleted)

Rule 59

1. Where the urgency results from the deadlines imposed on a section for issuing an opinion, the president of that section may, with the agreement of the three group presidents, organise the work of the section otherwise than as provided in these Rules.

2. Arrangements made by the president of a section under the urgency procedure shall be submitted to the following meeting of that section for confirmation.

Chapter III

ABSENCE AND REPRESENTATION

Rule 60

1. Any member of the Committee who is unable to attend a meeting to which he has been duly invited must give the president concerned advance notice of his absence.

2. Where a member of the Committee fails to attend more than three consecutive plenary sessions of the Committee without appointing a member to represent him and without providing a reason recognised as valid, the president may, after consulting the bureau and inviting the member

concerned to explain his absence, call upon the Council to remove that member from office.

3. Where a member of a section fails to attend more than three consecutive meetings of the section without appointing a member to represent him and without providing a reason recognised as valid, the president of that section may, after inviting the member concerned to explain his absence, call upon him to yield his seat on the section to another member and shall inform the bureau of this fact.

Rule 61

1. Any member of the Committee who is unable to attend a Committee session or a section meeting may, after notifying the president concerned, delegate his voting right, in writing, to another member of the Committee or section.

2. No member may hold more than one delegated voting right at a plenary session or section meeting.

Rule 62

1. Any member who is unable to attend a meeting to which he has been duly invited may, after giving written notice to the president concerned directly or through his group secretariat, arrange for another member of the Committee to represent him at the relevant meeting. This possibility does not apply for meetings of the bureau or budget group.

2. Such proxies shall be valid solely for the meeting in respect of which they are issued.

3. At the time of the constitution of a study group, any member designated as a member of that study group may ask to be replaced by another member of the Committee. Such replacement shall apply for a specific question and for the duration of the work of the section on that question. It may not be revoked. However, should the work of the study group continue beyond the end of a two-and-a-half or five-year term, the replacement shall only remain valid until the end of the term during which it was decided.

Chapter IV

PUBLICATION AND DISTRIBUTION OF COMMITTEE TEXTS – ADMISSION OF THE PUBLIC

Rule 63

1. The Committee shall publish its opinions in the *Official Journal of the European Union* in accordance with the procedure laid down by the Council and the Commission after consultation of the Committee bureau.

2. The names of the members of the Committee, its bureau and its sections, and all changes in the membership thereof, shall be published in the *Official Journal of the European Union* and on the Committee's website.

Rule 64

1. The Committee shall ensure the transparency of its decisions, in accordance with the second paragraph of Article 1 of the Treaty on European Union.

2. The secretary-general shall be responsible for taking the measures necessary to guarantee the public's right of access to the corresponding documents.

3. Any citizen of the European Union may write to the Committee in one of the official languages and receive a reply written in the same language (in accordance with the fourth paragraph of Article 24 of the Treaty on the Functioning of the European Union).

Rule 65

1. Plenary sessions of the Committee and meetings of the sections shall be public.

2. Certain debates that do not concern consultative work may be declared confidential by the Committee, acting on a request from a concerned institution or body or on a proposal from the bureau.

3. Other meetings shall not be public. However, in duly justified cases at the discretion of the chairman of the meeting other persons may attend as observers.

Rule 66

1. Members of the European institutions may attend and address meetings of the Committee and its constituent bodies.

2. Members of other bodies and duly authorised officials of the institutions and these other bodies may be invited to attend, address or answer questions at meetings, under the direction of the president of the meeting.

Chapter V

TITLES, PRIVILEGES, IMMUNITIES AND STATUTE OF MEMBERS, QUAESTORS

Rule 67

1. Members of the Committee shall have the title 'member of the European Economic and Social Committee'.

2. The provisions of Article 10, Chapter IV of Protocol No 7 on the privileges and immunities of the European Union,

annexed to the Treaties, shall apply to the members of the European Economic and Social Committee.

Rule 68

1. The members' statute shall contain the rights and duties of Committee members, as well as the rules governing their activity and their relations with the institution and its services.

2. It shall also determine the measures that may be taken in the event of violations of the Rules of Procedure or of the statute.

Rule 69

On a proposal from the bureau, the assembly shall elect, for each two-and-a-half-year period, three members, who have no other permanent responsibilities within the Committee structure, to form the quaestors' group with the following functions:

- a) to monitor and ensure the proper implementation of the members' statute;
- b) to draw up appropriate proposals for perfecting and improving the members' statute;
- c) to endeavour, by taking appropriate steps, to resolve any cases of doubt or dispute arising from application of the members' statute;
- d) to be responsible for relations between the members of the Committee and the general secretariat as regards application of the members' statute.

Chapter VI

TERMINATION OF MEMBERS' TENURE OF OFFICE, INCOMPATIBILITIES

Rule 70

1. Membership of the Committee shall expire at the end of the five-year term laid down by the Council at the time of the Committee's renewal.

2. Individual membership shall cease on resignation, on removal from office, through death, in the case of force majeure or in the event of an incompatibility of functions arising.

3. The functions of a member of the Committee shall be incompatible with those of a member of a government, a parliament, an institution of the European Union, the Committee of the Regions or the board of directors of the European Investment Bank, and with the post of official or other servant of the European Union in active employment.

4. Resignations shall be in writing and shall be addressed to the president of the Committee.

5. The circumstances in which members may be removed from office are laid down in Rule 60(2). In such cases the Council shall initiate the replacement procedure, if it decides to terminate membership.

6. In the case of resignation, death, force majeure or incompatibility of functions, the president of the Committee shall notify the Council, which shall verify the vacancy and initiate the replacement procedure. In the case of resignation, however, the resigning member shall remain in office until the date on which the appointment of his replacement takes effect, unless the resigning member indicates otherwise.

7. In all the cases referred to in the second paragraph of this Rule, the replacement shall be appointed for the remainder of the current term of office.

Chapter VII

ADMINISTRATION OF THE COMMITTEE

Rule 71

1. The Committee shall be assisted by a secretariat headed by a secretary-general, who shall discharge his duties under the direction of the president, representing the bureau.

2. The secretary-general shall attend the meetings of the bureau in an advisory capacity and shall keep the minutes of those meetings.

3. He shall give a solemn undertaking, before the bureau, to discharge his duties conscientiously and with complete impartiality.

4. The secretary-general shall be responsible for giving effect to decisions taken by the assembly, the bureau and the president pursuant to the Rules of Procedure; he shall report in writing every three months to the president on the criteria and implementing provisions which have been adopted or are envisaged for handling administrative or organisational problems and staff matters.

5. The secretary-general may delegate his powers within the limits decided by the president.

6. The bureau, acting on a proposal from the secretary-general, shall draw up the establishment plan for the general secretariat in such a way that it can ensure the efficient functioning of the Committee and its constituent bodies and help the members in the performance of their duties, in particular in the organisation of meetings and the preparation of opinions.

Rule 72

1. All the powers which the Staff Regulations of Officials of the Communities confer on the appointing authority and which the Conditions of Employment of Other Servants of the Communities confer on the authority competent to conclude contracts of service shall be exercised, with respect to the secretary-general of the Committee, by the bureau.

2. The powers which the Staff Regulations of Officials of the Communities confer on the appointing authority shall be exercised as follows:

— with respect to deputy secretaries-general and directors, by the bureau, acting on a proposal from the secretary-general, as regards application of Articles 29, 30, 31, 40, 41, 49, 50, 51, 78 and 90(1) of the Staff Regulations; by the president, acting on a proposal from the secretary-general, as regards application of the other provisions of the Staff Regulations, including Article 90(2);

— with respect to:

— deputy directors (in grade AD13),

— heads of unit (in grades AD9 to AD 13), and

— other officials in grade AD14;

by the president, acting on a proposal from the secretary-general;

— with respect to officials in grades AD5 to AD13 who do not have a management post at the level of head of unit or above and all grades of the assistants function group, by the secretary-general.

3. The powers which the Conditions of Employment of Other Servants of the Communities (CEOS) confer on the authority competent to conclude contracts of service shall be exercised as follows:

— with respect to temporary staff appointed to the post of deputy secretary-general or director, by the bureau, acting on a proposal by the secretary-general, as regards application of Articles 11, 17, 33 and 48 of the CEOS; as regards the other provisions of the CEOS, by the president, acting on a proposal from the secretary-general;

— with respect to temporary staff appointed to the post of deputy director or head of unit and temporary staff of grade AD14, by the president, acting on a proposal from the secretary-general;

— with respect to temporary staff in grades AD5 to AD13 who do not have a management post at the level of head of unit or above and all grades of the assistants' function group, by the secretary-general;

— with respect to special advisers, and contract staff, by the secretary-general.

4. The president shall exercise the powers conferred on the institution by Article 110 of the Staff Regulations with a view to implementing the general provisions for giving effect to the Staff Regulations and the rules adopted by agreement between the institutions.

5. The bureau, the president and the secretary-general may delegate the powers vested in them by this Rule.

6. Decisions to delegate adopted in accordance with Rule 72(5) above shall specify the scope of the powers delegated, their limits and period of validity, as well as stating whether they may be subdelegated.

Rule 72a

1. The groups shall each have a secretariat which reports directly to the group president.

2. The powers of the appointing authority shall be exercised, with respect to officials seconded to the groups in accordance with the second indent of Article 37(a) of the Staff Regulations,

on a proposal from the group president concerned, as regards the application of Article 38 of the Staff Regulations, including decisions relating to their career development within the group.

When an official seconded to a group rejoins the Committee secretariat, he shall be classified in the grade to which he would have been entitled as an official.

3. The powers of the authority empowered to conclude contracts of employment shall be exercised, with respect to temporary staff seconded to the groups in accordance with Article 2(c) of the CEOS, on a proposal from the group president concerned, as regards the application of the third paragraph of Article 8, Article 9 and the third paragraph of Article 10 of the CEOS.

Rule 73

1. The president shall have a private secretariat.

2. The staff of the secretariat shall be engaged under the budget as temporary staff, the powers of the authority competent to conclude contracts of service being exercised by the president.

Rule 74

1. Before 1 June of each year the secretary-general shall submit to the bureau the draft estimates of the expenditure and revenue of the Committee for the next financial year. The budget group shall examine the draft before the bureau discussion and, where appropriate, make remarks or propose modifications. The bureau shall draw up the estimates of the expenditure and revenue of the Committee. It shall forward these in accordance with the procedure and within the time limits laid down in the Financial Regulation of the European Communities.

2. The president of the Committee, acting in accordance with the Financial Regulation, shall implement or cause to be implemented the statement of expenditure and revenue.

Rule 75

Correspondence to the Committee shall be addressed to the president or the secretary-general.

Chapter VIII*GENERAL PROVISIONS**Rule 76*

The terms used in these Rules of Procedure for the various offices are not gender-specific.

Rule 77

1. The Committee may decide by an absolute majority of its members that these Rules of Procedure should be revised.

2. If such a decision is taken, the Committee shall set up a panel, which shall be known as the Rules of Procedure Panel. The Committee shall appoint a rapporteur-general to produce a draft text of the new Rules of Procedure.

2a. After the adoption of the amended Rules of Procedure by an absolute majority, the assembly shall renew the mandate of the Rules of Procedure Panel for a maximum period of sixty days so that, if necessary, it may draw up a draft amendment of the implementing provisions and submit it to the bureau, who will take a decision after receiving the views of the groups.

3. The date on which the new Rules of Procedure and the changes to the implementing provisions shall enter into force shall be decided at the time of their adoption by the Committee.

Rule 78

These Rules of Procedure shall enter into force on 21 September 2010.

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