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Delegations will find attached document D036035 ANNEX.

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ANNEX 1

ANNEX

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COMMISSION REGULATION (EU) No …/..

amending Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards requirements for the placing on the market and conditions of use of additives consisting of preparations

ANNEX

Annexes III and IV to Regulation (EC) 1831/2003 are amended as follows:

(1) Annex III is replaced by the following text:

"**ANNEX III**

1. SPECIFIC LABELLING REQUIREMENTS FOR CERTAIN ADDITIVES AND FOR PREMIXTURES.

(a) Zootechnical additives, coccidiostats and histomonostats:

– the expiry date of the guarantee or the storage life from the date of manufacture,

– the directions for use, and

– the concentration.

(b) Enzymes, in addition to the abovementioned indications:

– the specific name of the active component or components in accordance with their enzyme activities, in conformity with the authorisation given;

– the International Union of Biochemistry identification number, and

– instead of concentration: units of activity (units of activity per gram or units of activity per millilitre).

(c) Micro-organisms:

– the expiry date of the guarantee or the storage life from the date of manufacture,

– the directions for use,

– the strain identification number, and

– the number of colony-forming units per gram.

(d) Nutritional additives:

– the active-substance level, and

– the expiry date of the guarantee of that level or storage life from the date of manufacture.

(e) Technological and sensory additives with the exception of flavouring compounds:

– the active substance level.

(f) Flavouring compounds:

– the incorporation rate in premixtures.

2. ADDITIONAL LABELLING AND INFORMATION REQUIREMENTS FOR CERTAIN ADDITIVES CONSISTING OF PREPARATIONS AND PREMIXTURES CONTAINING SUCH PREPARATIONS.

(a) Additives belonging to the categories referred to in Article 6(1)(a), (b) and (c) and consisting of preparations:

(i) the indication on the packaging or container of the specific name, the identification number and the level of any technological additive contained in the preparation for which maximum levels are set in the corresponding authorisation;

(ii) the following information via any written medium or accompanying the preparation:

– the specific name and the identification number of any technological additive contained in the preparation, and

– the name of any other substance or product contained in the preparation, indicated in descending order by weight.

(b) Premixtures containing additives belonging to the categories referred to in Article 6(1) (a), (b) and (c) and consisting of preparations:

(i) if appropriate, the indication on the packaging or container that the premixture contains technological additives included in additive preparations, for which maximum levels are set in the corresponding authorisation;

(ii) upon request from the purchaser or the user, information on the specific name, the identification number and an indication of the level of technological additives referred to in point (i) of this paragraph included in the additive preparations."

(2) In Annex IV, the following point 5 is added:

"5. Technological additives or other substances or products contained in additives consisting of preparations shall only modify the physico-chemical characteristics of the active substance of the preparation and shall be used in accordance with their conditions of authorisation where such provisions are provided for.

Physico-chemical and biological compatibility between the components of the preparation shall be ensured in relation to the effects desired."