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Contents

[1] Text with EEA relevance

EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.

II

(Non-legislative acts)

REGULATIONS

COMMISSION DELEGATED REGULATION (EU) No 1252/2014

of 28 May 2014

supplementing Directive 2001/83/EC of the European Parliament and of the Council with regard to principles and guidelines of good manufacturing practice for active substances for medicinal products for human use

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [1], and in particular the third paragraph of Article 47 thereof,

Whereas:

(1) All active substances manufactured in the Union, including active substances intended for export, should be manufactured in accordance with the principles and guidelines of good manufacturing practice for active substances which at present are set out in the technical guidelines on manufacturing of active substances published by the Commission. It is necessary to lay down principles and guidelines of good manufacturing practice for active substances in a legally binding act.

(2) In order to promote the use of harmonised standards at global level, principles and guidelines of good manufacturing practice for active substances should be laid down in line with the guidelines for active substances established by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use.

(3) Principles and guidelines of good manufacturing practice should be set out in relation to all issues, operations and processes that are key to determining the quality of active substances, such as quality management, personnel, premises and equipment, documentation, material management, production, in-process quality controls, packaging, labelling, laboratory controls, returns, complaints and recalls, contracting out and repackaging. In order to ensure compliance with those principles and guidelines, the manufacturers of active substances should be required to establish and implement an effective system for managing the quality of those substances.

(4) Personnel in unsanitary conditions, wearing unsuitable clothing or practicing potentially contaminating activities in the manufacturing area may compromise the quality of the active substance. This should be prevented by practicing sanitation and health habits that are appropriate to the manufacturing operations performed. Those practices should be provided for in the quality management system established by the manufacturer of the active substance.

(5) In order to ensure an adequate quality of the active substance, it is necessary to minimise potential contamination and cross-contamination by requiring the use of facilities, production processes and containers designed for this purpose, as well as appropriate contamination controls.

[1] OJ L 311, 28.11.2001, p. 67.

(6) It is of particular importance to prevent cross-contamination when producing active substances harmful to human health. Contamination of other products with highly sensitising active substances could pose a serious threat to public health since exposure to these substances very often results in the development of hypersensitivity and allergic reactions. For that reason, manufacturing of those active substances should only be allowed to take place in separate production areas. The use of separate production areas may also be necessary for the production of active substances with the potential to be harmful to human health because of their potency or their infective or toxic nature. For those substances, the manufacturer should perform an assessment of the risks to human health and the need for separate production areas.

(7) In order to facilitate the tracing, identification and solving of potential quality problems as well as to verify compliance with good manufacturing practice, the manufacturer should keep detailed written records of all processes he performs that relate to the manufacturing of active substances, including of deviations from those processes.

(8) In order to ensure that medicinal products have the appropriate standards of quality, safety and efficacy and to protect public health, manufacturers of an active substance should communicate without delay any changes which may affect the quality of the active substance to manufacturers of medicinal products using the active substance.

(9) It is necessary to have in place appropriate procedures to record and investigate quality-related complaints and perform product recalls in order to rapidly address quality concerns and remove from the market active substances that do not meet quality standards or pose a serious threat to public health.

(10) When the manufacturer of the active substance entrusts any part of the manufacturing to another party, it is important to clarify in writing the responsibilities of that other party with regard to compliance with good manufacturing practices and quality measures.

(11) The application of good manufacturing practices to the process of repackaging and relabelling is necessary to avoid that active substances are wrongly labelled or become contaminated in the process,

HAS ADOPTED THIS REGULATION:

Article 1

Scope

This Regulation lays down the principles and guidelines of good manufacturing practice for active substances for medicinal products for human use, including active substances intended for export.

Article 2

Definitions

For the purposes of this Regulation, the following definitions shall apply:

(1) 'manufacturing' means any total or partial operation of receipt of materials, production, packaging, repackaging, labelling, relabelling, quality control or release of active substances, and the related controls;

(2) 'active substance starting material' means any substance from which an active substance is manufactured or extracted;

(3) 'active substance intermediate' means a substance which is obtained during the production of an active substance and which is intended for further processing;

(4) 'raw material' means any substance, reagent or solvent which is intended for use in the production of an active substance and from which the active substance is not directly manufactured or extracted.

Article 3

Quality management

1. Manufacturers of active substances ('the manufacturer') shall establish, document and implement an effective system for managing the quality of those substances during the manufacturing operations performed by them (the 'manufacturing process'). The system shall provide for the active participation of the management and manufacturing personnel.

The system shall ensure that the active substances meet the specifications for their quality and purity established in accordance with Article 12(1).

The system shall incorporate quality risk management.

2. The manufacturer shall appoint a quality unit that is independent of the production unit to be responsible for quality assurance and quality control.

3. The manufacturer shall conduct regular internal audits and follow-up on the findings.

Article 4

Personnel

1. The manufacturer shall ensure an adequate number of personnel having the necessary qualifications acquired through education, training or experience to carry out and supervise the manufacturing of active substances.

2. Personnel shall practice good sanitation and hygiene in the manufacturing area. Personnel shall not access the manufacturing area if they:

(a) suffer from an infectious disease or have open lesions or other dermatological conditions on the exposed surface of the body that could negatively affect the quality and purity of the active substance;

(b) wear clothing which is visibly dirty, or does not protect the active substance from potential contamination coming from personnel, or does not protect personnel from exposure to active substances potentially harmful to human health;

(c) at the moment of entering the manufacturing area, are performing activities that could contaminate or otherwise compromise the quality of the active substance.

Article 5

Buildings and facilities

1. Buildings and facilities used in the manufacturing of active substances shall be located, designed and constructed to suit the intended operations and to facilitate cleaning and maintenance having regard to the type and stage of manufacturing which the buildings and facilities are used for.

Facilities and the flow of material and personnel through the facilities shall be designed to ensure that different substances and materials are kept separate and do not contaminate each other.

2. Buildings shall be properly maintained and repaired and kept in a clean condition.

3. Highly sensitising active substances shall be produced in separate production areas.

When carrying out production operations, the manufacturer shall assess the need for separate production areas for other active substances with the potential to be harmful to human health because of their potency or their infective or toxic nature. The assessment shall evaluate the risk to human health posed by those active substances by taking account of the active substance potency, toxicity, infectivity and the risk minimisation procedures in place. The assessment shall be documented in writing.

Where the assessment shows a risk of harm to human health, the active substance shall be produced in separate production areas.

Article 6

Equipment

1. Equipment used in the manufacturing of active substances shall be appropriately designed, sized and located for its intended use, cleaning, maintenance and, where appropriate, sanitisation.

Equipment shall be constructed and operated so that surfaces that come into contact with raw materials, active substance starting materials, active substance intermediates or active substances do not alter the quality of the raw materials, the active substance starting materials, the active substance intermediates or the active substances to the extent that they no longer comply with the specifications established in accordance with Article 12(1).

2. The manufacturer shall establish written procedures for the cleaning of equipment and the subsequent verification of its suitability for use in the manufacturing process.

3. Control, weighing, measuring, monitoring and test equipment that is critical for assuring the quality of the active substance shall be calibrated in accordance with written procedures and an established schedule.

Article 7

Documentation and records

1. The manufacturer shall establish and maintain a documentation system and written procedures covering the manufacturing process.

All documents in relation to the manufacturing process shall be prepared, reviewed, approved and distributed in accordance with written procedures.

The manufacturer shall maintain records of at least the following elements in relation to the manufacturing process:

(1) equipment cleaning and use;

(2) origins of raw materials, active substance starting materials and active substance intermediates;

(3) controls in relation to raw materials, active substance starting materials and active substance intermediates;

(4) use of raw materials, active substance starting materials and active substance intermediates;

(5) labelling of the active substances and of the packaging materials;

(6) master production instructions;

(7) batch production and control;

(8) laboratory controls.

The issuance, revision, replacement and withdrawal of documents related to the manufacturing process shall be controlled, and records of their revision, replacement and withdrawal shall be kept.

2. All quality related activities carried out during the manufacturing process shall be recorded at the time they are performed. Any deviation from the written procedures referred to in Article 7(1) shall be documented and explained. Deviations affecting the quality of the active substance or preventing the active substance from meeting the specifications referred to in Article 12(1) shall be investigated, and the investigation and its conclusions shall be documented.

3. After carrying out production and control operations, the manufacturer shall retain all production and control records for at least one year after the expiry date of the batch. For an active substance with retest dates, the manufacturer shall retain records for at least three years after the complete batch has been placed on the market.

Article 8

Material management

1. The manufacturer shall have written procedures in place for ensuring the quality of incoming material covering the following elements:

(1) receipt;

(2) identification;

(3) quarantine;

(4) storage;

(5) handling;

(6) sampling;

(7) testing;

(8) approving;

(9) rejection.

2. The manufacturer shall have a system in place for evaluating suppliers of critical materials.

Article 9

Production and in-process control

1. Production operations shall be subject to controls in order to monitor and adjust the production process or verify that the active substance conforms to the specifications of quality and purity pursuant to Article 12(1). Production operations which are critical to ensure that the active substance meets the quality specifications referred to in Article 12(1) shall be carried out under the visual supervision of qualified personnel or subjected to an equivalent control.

2. Weighing and measuring of raw materials and active substance starting materials shall be accurate and shall be conducted in a manner which does not affect their suitability for use.

3. Production operations, including any operation after purification of the active substance intermediates or the active substance, shall be conducted in a manner that prevents raw materials, active substance starting materials, active substance intermediates and active substances from being contaminated by other materials.

Article 10

Packaging and labelling

1. Containers shall provide adequate protection against deterioration or contamination of the active substance from the moment the active substance is packaged to the moment it is used in the manufacturing of medicinal products.

2. Storage, print and use of labels on the packaging of active substances shall be controlled. Labels shall contain the information necessary to assure the quality of the active substance.

Article 11

Placing on the market

An active substance shall only be placed on the market after it has been released for sale by the quality unit.

Article 12

Laboratory controls

1. The manufacturer shall establish specifications for the quality and purity of the active substances he manufactures and for the raw materials, active substance starting materials and active substance intermediates used in that process.

2. Laboratory tests shall be conducted to verify compliance with the specifications referred to in paragraph 1.

The manufacturer shall issue certificates of analysis for each batch of active substance upon the request of:

(a) the competent authorities of a Member State;

(b) manufacturers of active substances supplied directly or indirectly with the active substance for the purpose of further processing, packing, repacking, labelling or relabelling the active substance;

(c) distributors and brokers of active substances;

(d) manufacturers of medicinal products supplied directly or indirectly with the active substance.

3. The manufacturer shall monitor the stability of the active substance through stability studies. Dates for the expiry or retest of active substances shall be set on the basis of an evaluation of data derived from the stability studies. Appropriately identified samples of the active substance shall be retained in accordance with a sampling plan established on the basis of the shelf-life of the active substance.

Article 13

Validation

The manufacturer shall set up and implement a validation policy for those processes and procedures that are critical to ensure that the active substance meets the quality and purity specifications established in accordance with Article 12(1).

Article 14

Change control

1. The manufacturer shall evaluate the potential impact on the quality of the active substance of any changes to the manufacturing process that may affect the production and control of the active substance before implementing those changes.

2. Changes to the manufacturing process that negatively affect the quality of the active substance shall be not be implemented.

3. The manufacturer of an active substance shall notify without delay the manufacturers of medicinal products which he supplies with the active substance of any changes to the manufacturing process that may impact the quality of the active substance.

Article 15

Rejection and returns

1. Batches of active substances and active substance intermediates failing to conform to the specifications established in accordance with Article 12(1) shall be rejected, labelled as such and quarantined.

2. The manufacturer who reprocesses or reworks rejected batches of an active substance that do not conform to specifications, or recovers raw materials and solvents for re-use in the manufacturing process, shall follow the procedures established in accordance with Article 7(1) and shall perform appropriate controls to ensure that:

(a) the reprocessed or reworked active substance meets the quality specifications established in accordance with Article 12(1);

(b) the recovered raw materials and solvents are suitable for their intended use in the manufacturing process.

3. Returned active substances shall be identified as such and quarantined.

Article 16

Complaints and recalls

1. The manufacturer shall record and investigate all quality related complaints.

2. The manufacturer shall establish procedures for the recall of active substances from the market.

3. In the event of the recalled active substance posing a serious threat to public health, the manufacturer shall inform the competent authorities without delay.

Article 17

Contract manufacturing

1. A manufacturing operation or an operation linked thereto which is to be carried out on behalf of the manufacturer of the active substance by another party ('the contract manufacturer') shall be the subject of a written contract.

The contract shall clearly define the responsibilities of the contract manufacturer with regards to good manufacturing practice.

2. The manufacturer of the active substance shall control that operations carried out by a contract manufacturer comply with good manufacturing practice.

3. A manufacturing operation or an operation linked thereto which has been entrusted to a contract manufacturer shall not be subcontracted to a third party without the written consent of the manufacturer of the active substance.

Article 18

Repackaging

Where the active substance is repackaged by a manufacturer in a container which differs from the original container with regard to its volume, or the material it is made of, or its opaqueness to light, he shall conduct stability studies on the active substance and assign an expiration or retest date for it on the basis of those studies.

Article 19

Entry into force

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

It shall apply from 25 May 2015.

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

Done at Brussels, 28 May 2014.

For the Commission
The President
José Manuel BARROSO

COMMISSION REGULATION (EU) No 1253/2014

of 7 July 2014

implementing Directive 2009/125/EC of the European Parliament and of the Council with regard to ecodesign requirements for ventilation units

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products [1], and in particular Article 15(1) thereof,

Whereas:

(1) Under Directive 2009/125/EC energy-related products representing significant volumes of sales and trade, having significant environmental impact within the Union and presenting significant potential for improvement in terms of their environmental impact, without entailing excessive costs, are to be covered by an implementing measure or a self-regulation measure regarding ecodesign requirements.

(2) The Commission has assessed the technical, environmental and economic aspects of ventilation units. The assessment showed that ventilation units are placed on the Union market in large quantities. The energy consumption in the use phase is the most significant environmental aspect of ventilation units, presenting significant potential for cost-effective energy savings and greenhouse gas emission reduction.

(3) Fans are an important part of ventilation units. Generic minimum energy efficiency requirements for fans have been established in Commission Regulation (EU) No 327/2011 [2]. The power consumption of the ventilation functions of fans which are part of ventilation units is covered by the minimum energy performance requirements of that Regulation, but many ventilation units use fans not covered by it. It is therefore necessary to introduce implementing measures for ventilation units.

(4) A distinction should be made between measures applying to residential ventilation units and those applying to non-residential ventilation units on the basis of their individual air flow rate because two different sets of measurement standards are used in practice.

(5) Small ventilation units with an electric power input of less than 30 W per air stream should be exempted from the requirements of this Regulation, except for information requirements. Those units are designed for many different applications, predominantly working intermittently and with supplementary functions only, for example in bathrooms. Including those would represent a considerable administrative burden in terms of market surveillance because of large sales numbers, while contributing only to a small share of the energy saving potential. However, considering that they offer similar functionalities to other ventilation units, their possible inclusion should similarly be addressed in the review of this Regulation. Furthermore, ventilation units specifically designed to operate exclusively for emergency purposes or in exceptional or hazardous environments should also be exempted, as they are used rarely and for a short time. The exemptions also clarify that multifunctional units which predominantly heat or cool and kitchen range hoods are excluded. The Commission has carried out preparatory studies to analyse the technical, environmental and economic aspects of residential and non-residential ventilation units. The studies have been developed together with stakeholders and interested parties from the Union and third countries, and the results have been made publicly available.

[1] OJ L 285, 31.10.2009, p. 10.

[2] Commission Regulation (EU) No 327/2011 of 30 March 2011 implementing Directive 2009/125/EC of the European Parliament and of the Council with regard to ecodesign requirements for fans driven by motors with an electric input power between 125 W and 500 kW (OJ L 90, 6.4.2011, p. 8).

(6) The environmental parameter of the products covered which has been identified as the most significant for the purposes of this Regulation is energy consumption in the use phase. The annual electricity consumption of products subject to this Regulation was estimated at 77,6 TWh in the Union in 2010. At the same time, these products save 2 570 PJ on energy for heating space. In aggregate, using a primary energy conversion coefficient of 2,5 for electricity, the energy balance is 1 872 PJ primary energy of annual saving in 2010. Without specific measures, the aggregate saving is projected to grow to 2 829 PJ in 2025.

(7) The preparatory studies show that the energy consumption of products subject to this Regulation can be significantly reduced. The combined effect of the ecodesign requirements set out in this Regulation and in Commission Delegated Regulation (EU) No 1254/2014 ([1]) is expected to result in an aggregate increase in savings by 1 300 PJ (45 %) to a level of 4 130 PJ in 2025.

(8) The preparatory studies show that requirements regarding the other ecodesign parameters referred to in Part 1 of Annex I to Directive 2009/125/EC are not necessary for ventilation units as energy consumption in the use phase is by far the most important environmental parameter.

(9) The ecodesign requirements should be introduced gradually in order to provide a sufficient timeframe for manufacturers to re-design products subject to this Regulation. The timing should take into account the impact on costs for end-users and manufacturers, in particular small and medium-sized enterprises, while ensuring that the environmental performance of ventilation units is improved without unnecessary delay.

(10) Product parameters should be measured and calculated using reliable, accurate and reproducible methods which take into account recognised state-of-the-art measurement and calculation methods, including, where available, harmonised standards adopted by the European standardisation bodies following a request by the Commission, in accordance with the procedures laid down in Regulation (EU) No 1025/2012 of the European Parliament and of the Council ([2]).

(11) Benchmarks for currently available ventilation unit types with high energy efficiency should be identified in the implementing measure on the basis of information gathered during the preparation of the measure, in order that manufacturers can make use of this assessment to evaluate alternative design solutions and the achieved environmental performance of the product against benchmarks. This will help to ensure a wide availability and easy accessibility of information, in particular for small and medium-sized enterprises and very small firms, which will further facilitate the integration of best design technologies and facilitate the development of more efficient products for reducing energy consumption.

(12) The Consultation Forum referred to in Article 18 of Directive 2009/125/EC has been consulted.

(13) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 19(1) of Directive 2009/125/EC,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter and scope

1. This Regulation applies to ventilation units and establishes ecodesign requirements for their placing on the market or putting into service.

2. This Regulation shall not apply to ventilation units which:

(a) are unidirectional (exhaust or supply) with an electric power input of less than 30 W, except for information requirements;

([1]) Commission Delegated Regulation (EU) No 1254/2014 of 11 July 2014 supplementing Directive 2010/30/EU of the European Parliament and of the Council with regard to energy labelling of residential ventilation units (see page 27 of this Official Journal).

([2]) Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation (OJ L 316, 14.11.2012, p. 12).

(b) are bidirectional, with a total electric power input for the fans of less than 30 W per air stream, except for information requirements;

(c) are axial or centrifugal fans only equipped with a housing in terms of Regulation (EU) No 327/2011;

(d) are exclusively specified as operating in a potentially explosive atmosphere as defined in Directive 94/9/EC of the European Parliament and of the Council ([1]);

(e) are exclusively specified as operating for emergency use, for short periods of time, and which comply with the basic requirements for construction works with regard to safety in case of fire as set out in Regulation (EU) No 305/2011 of the European Parliament and of the Council ([2]);

(f) are exclusively specified as operating:

(i) where operating temperatures of the air being moved exceed 100 °C;

(ii) where the operating ambient temperature for the motor, if located outside the air stream, driving the fan exceeds 65 °C;

(iii) where the temperature of the air being moved or the operating ambient temperature for the motor, if located outside the air stream, are lower than – 40 °C;

(iv) where the supply voltage exceeds 1 000 V AC or 1 500 V DC;

(v) in toxic, highly corrosive or flammable environments or in environments with abrasive substances;

(g) include a heat exchanger and a heat pump for heat recovery or allowing heat transfer or extraction being additional to that of the heat recovery system, except heat transfer for frost protection or defrosting;

(h) are classified as range hoods covered by Commission Regulation (EU) No 66/2014 ([3]) on kitchen appliances.

Article 2

Definitions

For the purposes of this Regulation the following definitions shall apply:

(1) 'ventilation unit (VU)' means an electricity driven appliance equipped with at least one impeller, one motor and a casing and intended to replace utilised air by outdoor air in a building or a part of a building;

(2) 'residential ventilation unit' (RVU) means a ventilation unit where:

(a) the maximum flow rate does not exceed 250 m^3/h;

(b) the maximum flow rate is between 250 and 1 000 m^3/h, and the manufacturer declares its intended use as being exclusively for a residential ventilation application;

(3) 'non-residential ventilation unit' (NRVU) means a ventilation unit where the maximum flow rate of the ventilation unit exceeds 250 m^3/h, and, where the maximum flow rate is between 250 and 1 000 m^3/h, the manufacturer has not declared its intended use as being exclusively for a residential ventilation application;

(4) 'maximum flow rate' is the declared maximum air volume flow rate of a ventilation unit that can be achieved with integrated or separately co-supplied controls at standard air conditions (20 °C) and 101 325 Pa, where the unit is installed complete (e.g. including clean filters) and according to the manufacturer's instructions, for ducted RVUs the maximum flow is related to the air flow at 100 Pa of external static pressure difference, and for non-ducted RVUs to the air flow at the lowest achievable total pressure difference to be chosen from a set of values of 10 (minimum)-20-50-100-150-200-250 Pa, whichever is equal or just below the measured pressure difference value;

([1]) Directive 94/9/EC of the European Parliament and the Council of 23 March 1994 on the approximation of the laws of the Member States concerning equipment and protective systems intended for use in potentially explosive atmospheres (OJ L 100, 19.4.1994, p. 1).
([2]) Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC (OJ L 88, 4.4.2011, p. 5).
([3]) Commission Regulation (EU) No 66/2014 of 14 January 2014 implementing Directive 2009/125/EC of the European Parliament and of the Council with regard to ecodesign requirements for domestic ovens, hobs and range hoods (OJ L 29, 31.1.2014, p. 33).

(5) 'unidirectional ventilation unit' (UVU) means a ventilation unit producing an air flow in one direction only, either from indoors to outdoors (exhaust) or from outdoors to indoors (supply), where the mechanically produced air flow is balanced by natural air supply or exhaust;

(6) 'bidirectional ventilation unit' (BVU) means a ventilation unit which produces an air flow between indoors and outdoors and is equipped with both exhaust and supply fans;

(7) 'equivalent ventilation unit model' means a ventilation unit with the same technical characteristics according to the applicable product information requirements, but placed on the market as a different ventilation unit model by the same manufacturer, authorised representative or importer.

For the purposes of Annexes II to IX, additional definitions are set out in Annex I.

Article 3

Ecodesign requirements

1. From 1 January 2016 RVUs shall comply with the specific ecodesign requirements set out in Annex II, point 1.

2. From 1 January 2016 NRVUs shall comply with the specific ecodesign requirements set out in Annex III, point 1.

3. From 1 January 2018 RVUs shall comply with the specific ecodesign requirements set out in Annex II, point 2.

4. From 1 January 2018 NRVUs shall comply with the specific ecodesign requirements set out in Annex III, point 2.

Article 4

Information requirements

1. From 1 January 2016 manufacturers, their authorised representatives and importers of RVUs shall comply with the information requirements set out in Annex IV.

2. From 1 January 2016 manufacturers, their authorised representatives and importers of NRVUs shall comply with the information requirements set out in Annex V.

Article 5

Conformity assessment

1. Manufacturers of ventilation units shall carry out the conformity assessment laid down in Article 8 of Directive 2009/125/EC using the internal design control system set out in Annex IV to that Directive or the management system set out in Annex V to that Directive.

For the purposes of the conformity assessment of RVUs, calculation of the specific energy consumption requirement shall be carried out in accordance with Annex VIII to this Regulation.

For the purposes of the conformity assessment of NRVUs, measurements and calculations for the specific ecodesign requirements shall be carried out in accordance with Annex IX to this Regulation.

2. The technical documentation file compiled in accordance with Annex IV to Directive 2009/125/EC shall contain a copy of the product information set out in Annexes IV and V to this Regulation.

Where the information included in the technical documentation for a particular ventilation unit model has been obtained by calculation on the basis of design, or extrapolation from other ventilation units, or both, the technical documentation shall include the following information:

(a) details of such calculations or extrapolations, or both;

(b) details of tests undertaken by manufacturers to verify the accuracy of the calculations and extrapolations;

(c) a list of any other ventilation unit models where the information included in the technical documentation was obtained on the same basis;

(d) a list of equivalent ventilation unit models.

Article 6

Verification procedure for market surveillance purposes

The authorities of the Member States shall apply the verification procedure set out in Annex VI when performing the market surveillance referred to in Article 3(2) of Directive 2009/125/EC to ensure compliance with the requirements set out for RVUs in Annex II to this Regulation and for NRVUs in Annex III to this Regulation.

Article 7

Benchmarks

The benchmarks referred to in point (2) of Part 3 of Annex I to Directive 2009/125/EC, which are to be applied to ventilation units, are set out in Annex VII to this Regulation.

Article 8

Review

The Commission shall assess the need to set requirements on air leakage rates in the light of technological progress and present the results of this assessment to the Consultation Forum no later than 1 January 2017.

The Commission shall review this Regulation in the light of technological progress and present the results of this review to the Consultation Forum no later than 1 January 2020.

The review shall include an assessment of the following:

(a) the possible extension of the scope of this Regulation to cover unidirectional units with an electric power input of less than 30 W, and bidirectional units, with a total electric power input for the fans of less than 30 W per air stream;

(b) the verification tolerances set out in Annex VI;

(c) the appropriateness of taking into account the effects of low-energy consuming filters on the energy efficiency;

(d) the need to set a further tier with tightened ecodesign requirements.

Article 9

Entry into force

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, 7 July 2014.

For the Commission

The President

José Manuel BARROSO

ANNEX I

Definitions

Definitions applicable for the purposes of Annexes II to IX to this Regulation:

1. **Definitions:**

(1) 'specific energy consumption (SEC)' (expressed in kWh/(m².a)) means a coefficient to express the energy consumed for ventilation per m² heated floor area of a dwelling or building, calculated for RVUs in accordance with Annex VIII;

(2) 'sound power level (L_{WA})' means the casing-radiated A-weighted sound power level expressed in decibels (dB) with reference to the sound power of one picowatt (1pW), transmitted by the air at reference airflow;

(3) 'multi-speed drive' means a fan motor that can be operated at three or more fixed speeds plus zero ('off');

(4) 'variable speed drive (VSD)' means an electronic controller, integrated or functioning as one system or as a separate delivery with the motor and the fan, which continuously adapts the electrical power supplied to the motor in order to control the flow rate;

(5) 'heat recovery system (HRS)' means the part of a bidirectional ventilation unit equipped with a heat exchanger designed to transfer the heat contained in the (contaminated) exhaust air to the (fresh) supply air;

(6) 'thermal efficiency of a residential HRS (η_t)' means the ratio between supply air temperature gain and exhaust air temperature loss, both relative to the outdoor temperature, measured under dry conditions of the HRS, and standard air conditions, with balanced mass flow, at reference flow rate, an indoor-outdoor temperature difference of 13 K, no correction for thermal heat gain from fan motors;

(7) 'internal leakage rate' means the fraction of extract air present in the supply air of ventilation units with HRS as a result of leakage between extract and supply airflows inside the casing when the unit is operated at reference air volume flow, measured at the ducts; the test shall be performed for RVUs at 100 Pa, and for NRVUs at 250 Pa;

(8) 'carry over' means the percentage of the exhaust air which is returned to the supply air for a regenerative heat exchanger according to the reference flow;

(9) 'external leakage rate' means the leakage fraction of the reference air volume flow to or from the inside of the casing of a unit to or from the surrounding air when it is subjected to a pressure test; the test shall be performed at 250 Pa for RVUs and at 400 Pa for NRVUs, for both under and over pressure;

(10) 'mixing' means the immediate recirculation or short-circuiting of airflows between discharge and intake ports at both the indoor and outdoor terminals so that they do not contribute to the effective ventilation of a building space, when the unit is operated at reference air volume rate;

(11) 'mixing rate' means the fraction of extract airflow, as part of the total reference air volume, that recirculates between discharge and intake ports at both the indoor and outdoor terminals and thus does not contribute to the effective ventilation of a building space, when the unit is operated at reference air volume (measured at 1 m distance from the indoor supply duct), less the internal leakage rate;

(12) 'effective power input' (expressed in W) means the electric power input at reference flow rate and corresponding external total pressure difference and includes the electrical demand for fans, controls (including remote controls) and the heat pump (if integrated);

(13) 'specific power input (SPI)' (expressed in W/(m³/h)) means the ratio between the effective power input (in W) and the reference flow rate (in m³/h);

(14) 'flow rate/pressure diagram' means a set of curves for flow rate (horizontal axis) and pressure difference of a unidirectional RVU or the supply side of a bidirectional RVU, where each curve represents one fan speed with at least eight equidistant test-points and the number of curves is given by the number of discrete fan speed options (one, two or three) or, in the case of a variable fan speed drive, includes at least a minimum, maximum and appropriate intermediate curve close to the reference air volume and pressure difference for SPI testing;

(15) 'reference flow rate' (expressed in m^3/s) is the abscissa value to a point on a curve in the flow rate/pressure diagram which is on or closest to a reference point at 70 % at least of the maximum flow rate and 50 Pa for ducted units and at a minimum pressure for non-ducted units. For bidirectional ventilation units, the reference air volume flow rate applies to the air supply outlet;

(16) 'control factor (CTRL)' means a correction factor for the SEC calculation depending on the type of control that is part of the ventilation unit, according to the description in Annex VIII Table 1;

(17) 'control parameter' means a measurable parameter or set of measurable parameters that are assumed to be representative of the ventilation demand, e.g. the level of relative humidity (RH), carbon dioxide (CO_2), volatile organic compounds (VOC) or other gases, presence, motion or occupancy detection from infrared body heat or from reflection of ultrasonic waves, electrical signals from human operation of lights or equipment;

(18) 'manual control' means any control type that does not use demand control;

(19) 'demand control' means a device or set of devices, integrated or as a separate delivery, that measures a control parameter and uses the result to regulate automatically the flow rate of the unit and/or the flow rates of the ducts;

(20) 'clock control' means a clocked (daytime-controlled) human interface to control the fan speed/flow rate of the ventilation unit, with at least seven weekday manual settings of the adjustable flow rate for at least two setback periods, i.e. periods in which a reduced or no flow rate applies;

(21) 'demand controlled ventilation (DCV)' means a ventilation unit that uses demand control;

(22) 'ducted unit' means a ventilation unit intended to ventilate one or more rooms or enclosed space in a building through the use of air ducts, intended to be equipped with duct connections;

(23) 'non-ducted unit' means a single room ventilation unit intended to ventilate a single room or enclosed space in a building, and not intended to be equipped with duct connections;

(24) 'central demand control' means a demand control of a ducted ventilation unit that continuously regulates the fan speed(s) and flow rate based on one sensor for the whole ventilated building or part of the building at central level;

(25) 'local demand control' means a demand control for a ventilation unit that continuously regulates the fan speed(s) and flow rates based on more than one sensor for a ducted ventilation unit or one sensor for a non-ducted unit;

(26) 'static pressure (p_{sf})' means the total pressure minus the fan dynamic pressure;

(27) 'total pressure (p_f)' means the difference between the stagnation pressure at the fan outlet and that at the fan inlet;

(28) 'stagnation pressure' means the pressure measured at a point in a flowing gas if it were to be brought to rest by means of an isentropic process;

(29) 'dynamic pressure' means the pressure calculated from the mass flow rate and the average gas density at the outlet and the unit outlet area;

(30) 'recuperative heat exchanger' means a heat exchanger intended to transfer thermal energy from one air stream to another without moving parts, such as a plate or tubular heat exchanger with parallel flow, cross flow or counter flow, or a combination of these, or a plate or tubular heat exchanger with vapour diffusion;

(31) 'regenerative heat exchanger' means a rotary heat exchanger incorporating a rotating wheel for the purpose of transferring thermal energy from one air stream to the other, including material allowing latent heat transfer, a drive mechanism, a casing or frame, and seals to reduce bypassing and leakage of air from one stream or another; such heat exchangers have varying degrees of moisture recovery depending on the material used;

(32) 'airflow sensitivity to pressure variations' of a non-ducted RVU is the ratio between the maximum deviation from the maximum RVU flow rate at + 20 Pa and that at – 20 Pa external total pressure difference;

(33) 'indoor/outdoor air tightness' of a non-ducted RVU is the flow rate (expressed in m^3/h) between indoors and outdoors when the fan(s) is(are) switched off;

(34) 'dual use unit' means a ventilation unit designed for ventilation purposes as well as fire or smoke extraction, complying with the basic requirements for construction works with regard to safety in case of fire as set out in Regulation (EU) No 305/2011;

(35) 'thermal by-pass facility' means any solution that circumvents the heat exchanger or controls automatically or manually its heat recovery performance, without necessarily requiring a physical airflow bypass (for example: summer box, rotor speed control, control of air flow);

2. **Definitions for NRVU, in addition to the definitions in Annex I Part 1:**

(1) 'nominal electric power input (P)' (expressed in kW) means the effective electric power input of the fan drives, including any motor control equipment, at the nominal external pressure and the nominal airflow;

(2) 'fan efficiency (η_{fan})' means the static efficiency including motor and drive efficiency of the individual fan(s) in the ventilation unit (reference configuration) determined at nominal air flow and nominal external pressure drop;

(3) 'reference configuration of a BVU' means a product configured with a casing, at least two fans with variable speed or multi-speed drives, a HRS, a clean fine filter on the inlet-side and a clean medium filter on the exhaust-side;

(4) 'reference configuration of an UVU' means a product configured with a casing and at least one fan with variable speed or multi-speed drive, and — in case the product is intended to be equipped with a filter on the inlet-side — this filter shall be a clean fine filter;

(5) 'minimum fan efficiency (ηv_u)' is the specific minimum efficiency requirement for VUs within the scope of this Regulation;

(6) 'nominal flow rate (q_{nom})' (expressed in m^3/s) means the declared design flow rate of an NRVU at standard air conditions 20 °C and 101 325 Pa, whereby the unit is installed complete (for example, including filters) and according to the manufacturer instructions;

(7) 'nominal external pressure ($\Delta p_{s,\ ext}$)' in (expressed in Pa) means the declared design external static pressure difference at nominal flow rate;

(8) 'maximum rated fan speed (v_{fan_rated})' (expressed in rounds per minute — rpm) is the fan speed at nominal flow rate and nominal external pressure;

(9) 'internal pressure drop of ventilation components ($\Delta p_{s,int}$)' (expressed in Pa) means the sum of the static pressure drops of a reference configuration of a BVU or an UVU at nominal flow rate;

(10) 'internal pressure drop of additional non-ventilation components ($\Delta p_{s,add}$)' (expressed in Pa) means the remainder of the sum of all internal static pressure drops at nominal flow rate and nominal external pressure after subtraction of the internal pressure drop of ventilation components ($\Delta p_{s,int}$);

(11) 'thermal efficiency of a non-residential HRS (η_{t_nrvu})' means the ratio between supply air temperature gain and the exhaust air temperature loss, both relative to the outdoor temperature, measured under dry reference conditions, with balanced mass flow, an indoor-outdoor air temperature difference of 20 K, excluding thermal heat gain from fan motors and from internal leakages;

(12) 'internal specific fan power of ventilation components (SFP_{int})' (expressed in $W/(m^3/s)$) is the ratio between the internal pressure drop of ventilation components and the fan efficiency, determined for the reference configuration;

(13) 'maximum internal specific fan power of ventilation components (SFP_{int_limit})' (expressed in $W/(m^3/s)$) is the specific efficiency requirement for SFP_{int} for VUs within the scope of this Regulation;

(14) 'run-around HRS' is a heat recovery system where the heat recovery device on the exhaust side and the device supplying the recovered heat to the air stream on the supply side of a ventilated space are connected through a heat transfer system where the two sides of the HRS can be freely positioned in different parts of a building;

(15) 'face velocity' (expressed in m/s) is the larger of supply and extract air velocity. The velocities are the air velocities in the VU based on the inside unit area for supply respectively extract air flow of the VU. The velocity is based on the area of the filter section of the respective unit, or if no filter is installed, based on the area of the fan section;

(16) 'efficiency bonus (E)' is a correction factor taking account of the fact that more efficient heat recovery causes more pressure drops requiring more specific fan power;

(17) 'filter correction (F)' (expressed in Pa) is a correction value to be applied if a unit deviates from the reference configuration of a BVU;

(18) 'fine filter' means a filter that meets the relevant conditions described in Annex IX;

(19) 'medium filter' means a filter that meets the relevant conditions described in Annex IX;

(20) 'filter efficiency' means the average ratio between the dust fraction captured and the amount fed into the filter, under the conditions described for fine and medium filters in Annex IX.

ANNEX II

Specific ecodesign requirements for RVUs, as referred to in Article 3(1) and 3(3)

1. From 1 January 2016:
   - SEC, calculated for average climate, shall be no more than 0 kWh/(m².a).
   - Non-ducted units including ventilation units intended to be equipped with one duct connection on either supply or extract air side shall have a maximum L_{WA} of 45 dB.
   - All VUs, except dual use units, shall be equipped with a multi-speed drive or variable speed drive.
   - All BVUs shall have a thermal by-pass facility.
2. From 1 January 2018:
   - SEC, calculated for average climate, shall be no more than – 20 kWh/(m².a).
   - Non-ducted units including ventilation units intended to be equipped with one duct connection on either supply or extract air side shall have a maximum L_{WA} of 40 dB.
   - All VUs, except dual use units, shall be equipped with a multi-speed drive or variable speed drive.
   - All BVUs shall have a thermal by-pass facility.
   - Ventilation units with a filter shall be equipped with a visual filter change warning signal.

ANNEX III

Specific ecodesign requirements for NRVUs, as referred to in Article 3(2) and 3(4)

1. From 1 January 2016:

— All ventilation units, except dual use units, shall be equipped with a multi-speed drive or a variable speed drive.

— All BVUs shall have a HRS.

— The HRS shall have a thermal by-pass facility.

— The minimum thermal efficiency η_{t_nrvu} of all HRS except run-around HRS in BVUs shall be 67 % and the efficiency bonus E = (η_{t_nrvu} – 0,67) * 3 000 if the thermal efficiency η_{t_nrvu} is at least 67 %, otherwise E = 0.

— The minimum thermal efficiency η_{t_nrvu} of run-around HRS in BVUs shall be 63 % and the efficiency bonus E = (η_{t_nrvu} – 0,63) * 3 000 if the thermal efficiency η_{t_nrvu} is at least 63 %, otherwise E = 0.

— The minimum fan efficiency for UVUs (ηv_u) is

— 6,2 % * ln(P) + 35,0 % if P ≤ 30 kW and

— 56,1 % if P > 30 kW.

— The maximum internal specific fan power of ventilation components (SFP_{int_limit}) in W/(m³/s) is

— for a BVU with run-around HRS

1 700 + E – 300 * q_{nom}/2 – F if q_{nom} < 2 m³/s and

1 400 + E – F if q_{nom} ≥ 2 m³/s;

— for a BVU with other HRS

1 200 + E – 300 * q_{nom}/2 – F if q_{nom} < 2 m³/s and

900 + E – F if q_{nom} ≥ 2 m³/s;

— 250 for an UVU intended to be used with a filter.

2. From 1 January 2018:

— All ventilation units, except dual use units, shall be equipped with a multi-speed drive or a variable speed drive.

All BVUs shall have a HRS.

The HRS shall have a thermal by-pass facility.

— The minimum thermal efficiency η_{t_nrvu} of all HRS except run-around HRS in BVUs shall be 73 % and the efficiency bonus E = (η_{t_nrvu} – 0,73) * 3 000 if the thermal efficiency η_{t_nrvu} is at least 73 %, otherwise E = 0.

— The minimum thermal efficiency η_{t_nrvu} of run-around HRS in BVUs shall be 68 % and the efficiency bonus E = (η_{t_nrvu} – 0,68) * 3 000 if the thermal efficiency η_{t_nrvu} is at least 68 %, otherwise E = 0.

— The minimum fan efficiency for UVUs (ηv_u) is

— 6,2 % * ln(P) + 42,0 % if P ≤ 30 kW and

— 63,1 % if P > 30 kW.

— The maximum internal specific fan power of ventilation components (SFP_{int_limit}) in W/(m³/s) is

— for a BVU with run-around HRS

1 600 + E – 300 * q_{nom}/2 – F if q_{nom} < 2 m³/s and

1 300 + E – F if q_{nom} ≥ 2 m³/s;

— for a BVU with other HRS

1 100 + E – 300 * q_{nom}/2 – F if q_{nom} < 2 m³/s and

800 + E – F if q_{nom} ≥ 2 m³/s;

— 230 for an UVU intended to be used with a filter.

— If a filter unit is part of the configuration the product shall be equipped with a visual signalling or an alarm in the control system which shall be activated if the filter pressure drop exceeds the maximum allowable final pressure drop.

ANNEX IV

Information requirements for RVUs as referred to in Article 4(1)

1. From 1 January 2016, the following product information shall be provided:
   (a) supplier's name or trade mark;
   (b) supplier's model identifier i.e. the code, usually alphanumeric, used to distinguish a specific residential ventilation unit model from other models with the same trade mark or supplier's name;
   (c) specific energy consumption (SEC) in kWh/(m^2.a) for each applicable climate zone; and SEC class;
   (d) declared typology in accordance with Article 2 of this Regulation (RVU or NRVU, unidirectional or bidirectional);
   (e) type of drive installed or intended to be installed (multi-speed drive or variable speed drive);
   (f) type of heat recovery system (recuperative, regenerative, none);
   (g) thermal efficiency of heat recovery (in % or 'not applicable' if the product has no heat recovery system);
   (h) maximum flow rate in m^3/h;
   (i) electric power input of the fan drive, including any motor control equipment, at maximum flow rate (W);
   (j) sound power level (L_{WA}), rounded to the nearest integer;
   (k) reference flow rate in m^3/s;
   (l) reference pressure difference in Pa;
   (m) SPI in W/(m^3/h);
   (n) control factor and control typology in accordance with the relevant definitions and classification in Annex VIII, Table 1;
   (o) declared maximum internal and external leakage rates (%) for bidirectional ventilation units or carry over (for regenerative heat exchangers only), and external leakage rates (%) for ducted unidirectional ventilation units;
   (p) mixing rate of non-ducted bidirectional ventilation units not intended to be equipped with one duct connection on either supply or extract air side;
   (q) position and description of visual filter warning for RVUs intended for use with filters, including text pointing out the importance of regular filter changes for performance and energy efficiency of the unit;
   (r) for unidirectional ventilation systems, instructions to install regulated supply/exhaust grilles in the façade for natural air supply/extraction;
   (s) internet address for disassembly instructions as referred to in point 3;
   (t) for non-ducted units only: the airflow sensitivity to pressure variations at + 20Pa and − 20 Pa;
   (u) for non-ducted units only: the indoor/outdoor air tightness in m^3/h.
2. The information listed in point 1 shall be available:
   — in the technical documentation of RVUs; and
   — on free access websites of manufacturers, their authorised representatives, and importers.
3. The manufacturer's free access website shall make available detailed instructions, inter alia, identifying the required tools for the manual disassembly of permanent magnet motors, and of electronics parts (printed wiring boards/printed circuit boards and displays > 10 g or > 10 cm^2), batteries and larger plastic parts (> 100 g) for the purpose of efficient materials recycling, except for models of which less than 5 units per year are produced.

ANNEX V

Information requirements for NRVUs as referred to in Article 4(2)

1. From 1 January 2016, the following product information shall be provided:
   (a) manufacturer's name or trade mark;
   (b) manufacturer's model identifier, i.e. the code, usually alphanumeric, used to distinguish a specific non-residential ventilation unit model from other models with the same trade mark or supplier's name;
   (c) declared typology in accordance with Article 2 (RVU or NRVU, UVU or BVU);
   (d) type of drive installed or intended to be installed (multi-speed drive or variable speed drive);
   (e) type of HRS (run-around, other, none);
   (f) thermal efficiency of heat recovery (in % or 'not applicable' if the product has no heat recovery system);
   (g) nominal NRVU flow rate in m^3/s;
   (h) effective electric power input (kW);
   (i) SFP_{int} in $W/(m^3/s)$;
   (j) face velocity in m/s at design flow rate;
   (k) nominal external pressure ($\Delta p_{s,\,ext}$) in Pa;
   (l) internal pressure drop of ventilation components ($\Delta p_{s,int}$) in Pa;
   (m) optional: internal pressure drop of non-ventilation components ($\Delta p_{s,add}$) in Pa;
   (n) static efficiency of fans used in accordance with Regulation (EU) No 327/2011;
   (o) declared maximum external leakage rate (%) of the casing of ventilation units; and declared maximum internal leakage rate (%) of bidirectional ventilation units or carry over (for regenerative heat exchangers only); both measured or calculated according to the pressurisation test method or tracer gas test method at declared system pressure;
   (p) energy performance, preferably energy classification, of the filters (declared information about the calculated annual energy consumption);
   (q) description of visual filter warning for NRVUs intended for use with filters, including text pointing out the importance of regular filter changes for performance and energy efficiency of the unit;
   (r) in the case of NRVUs specified for use indoors, the casing sound power level (L_{WA}), rounded to the nearest integer;
   (s) internet address for disassembly instructions as referred to in point 3.
2. The information listed in point 1(a) to (s) shall be available:
   — in the technical documentation of NRVUs; and
   — on free access websites of manufacturers, their authorised representatives, and importers.
3. The manufacturer's free access website shall make available detailed instructions, inter alia, identifying the required tools for the manual pre-/dis-assembly of permanent magnet motors, and of electronics parts (printed wiring boards/printed circuit boards and displays > 10 g or > 10 cm^2), batteries and larger plastic parts (> 100 g) for the purpose of efficient materials recycling, except for models of which less than 5 units per year are produced.

ANNEX VI

Verification procedure for market surveillance purposes

For the purposes of checking conformity with the requirements laid down in Annexes II to V, Member State authorities shall test a single ventilation unit. If the measured values or values calculated on the basis of measured values do not match the manufacturer's declared values within the meaning of Article 5, subject to the tolerances in Table 1:

— for models that are produced in lower quantities than 5 per year, the model shall be considered not to comply with this Regulation,

— for models that are produced in quantities of 5 or more per year, the market surveillance authority shall randomly test 3 additional units.

If the arithmetic mean of the measured values for these units does not meet the requirements, subject to the tolerances in Table 1, the model and all other equivalent models shall be considered not to comply with the requirements of Annexes II to V.

The Member State authorities shall provide the test results and other relevant information to the authorities of the other Member States and to the Commission within one month of the decision being taken on the non-compliance of the model.

Member State authorities shall use the measurement and calculation methods set out in Annexes VIII and IX and apply only those tolerances that are set out in Table 1.

Table 1

Parameter	Verification tolerances
SPI	The measured value shall be no more than 1,07 times the maximum declared value.
Thermal efficiency RVU and NRVU	The measured value shall be no less than 0,93 times the minimum declared value.
SFP_{int}	The measured value shall be no more than 1,07 times the maximum declared value.
Fan efficiency UVU, non-residential	The measured value shall be no less than 0,93 times the minimum declared value.
Sound power level RVU	The measured value shall be no more than the maximum declared value plus 2 dB.
Sound power level NRVU	The measured value shall be no more than the maximum declared value plus 5 dB.

The verification tolerances shall not be used by the manufacturer or importer in establishing the values in the technical documentation or in interpreting these values with a view to achieving compliance.

ANNEX VII

Benchmarks

Residential ventilation units:

(a) SEC: – 42 kWh/(m².a) for BVUs, and – 27 kWh/(m².a) for UVUs.

(b) Heat recovery η_t: 90 % for BVUs.

Non-residential ventilation units:

(a) SFP_{int}: 150 W/(m³/s) below the Tier 2 limit for NRVUs with flow rate ≥ 2 m³/s, and 250 W/(m³/s) below the Tier 2 limit for NRVUs with flow rate < 2 m³/s

(b) Heat recovery η_{t_nrvu}: 85 %, and with run-around heat recovery systems 80 %.

ANNEX VIII

Calculation of the specific energy consumption requirement

The specific energy consumption SEC is calculated with the following equation:

$$SEC = t_a \cdot pef \cdot q_{net} \cdot MISC \cdot CTRL^x \cdot SPI - t_h \cdot \Delta T_h \cdot \eta_h^{-1} \cdot c_{air} \cdot (q_{ref} - q_{net} \cdot CTRL \cdot MISC \cdot (1 - \eta_t)) + Q_{defr}$$

where:

— *SEC* is Specific Energy Consumption for ventilation per m² heated floor area of a dwelling or building [kWh/(m².a)];

— t_a is annual operating hours [h/a];

— *pef* is primary energy factor for electric power generation and distribution [-];

— q_{net} is net ventilation rate demand per m² heated floor area [m³/h.m²];

— *MISC* is an aggregated general typology factor, incorporating factors for ventilation effectiveness, duct leakage and extra infiltration [-];

— *CTRL* is ventilation control factor [-];

— *x* is an exponent that takes into account non-linearity between thermal energy and electricity saving, depending on motor and drive characteristics [-];

— *SPI* is Specific Power Input [kW/(m³/h)];

— t_h is total hours heating season [h];

— ΔT_h is the average difference in indoor (19 °C) and outdoor temperature over a heating season, minus 3K correction for solar and internal gains [K];

— η_h is the average space heating efficiency [-];

— c_{air} is the specific heat capacity of air at constant pressure and density [kWh/(m³ K)];

— q_{ref} is the reference natural ventilation rate per m² heated floor area [m³/h.m²];

— η_t is the thermal efficiency of heat recovery [-];

— Q_{defr} is the annual heating energy per m² heated floor area [kWh/m².a] for defrosting, based on a variable electric resistance heating.

$$Q_{defr} = t_{defr} \cdot \Delta T_{defr} \cdot c_{air} \cdot q_{net} \cdot pef,$$

where

— t_{defr} is the duration of defrosting period, i.e. when the outdoor temperature is below – 4 °C [h/a], and

— ΔT_{defr} is the average difference in K between the outdoor temperature and – 4 °C during the defrosting period.

Q_{defr} applies only to bidirectional units with recuperative heat exchanger; for unidirectional units or units with regenerative heat exchanger is $Q_{defr} = 0$.

SPI and η_t are values derived from tests and calculation methods.

Other parameters and their defaults are given in Table 1.

Table 1

SEC calculation parameters

general typology	**MISC**
Ducted units	**1,1**
Non-ducted units	**1,21**
ventilation control	**CTRL**
Manual control (no DCV)	**1**
Clock control (no DCV)	**0,95**
Central demand control	**0,85**
Local demand control	**0,65**
motor & drive	**x-value**
on/off & single speed	**1**
2-speed	**1,2**
multi-speed	**1,5**
variable speed	**2**

Climate	t_h in h	ΔT_h in K	t_{defr} in h	ΔT_{defr} in K	Q_{defr} (*) in kWh/a.m²
Cold	**6 552**	**14,5**	1 003	5,2	**5,82**
Average	**5 112**	**9,5**	168	2,4	**0,45**
Warm	**4 392**	**5**	—	—	—

(*) Defrosting applies only to bidirectional units with recuperative heat exchanger and is calculated as $Q_{defr} = t_{defr} * \Delta t_{defr} * c_{air} * q_{net} * pef$. For unidirectional units or unit with regenerative heat exchanger is $Q_{defr} = 0$

Defaults	**value**
specific heat capacity of air, c_{air} in kWh/(m³K)	**0,000344**
net ventilation requirement per m² heated floor area, q_{net} in m³/h.m²	**1,3**
reference natural ventilation rate per m² heated floor area, q_{ref} in m³/h.m²	**2,2**
annual operating hours, t_a in h	**8760**
primary energy factor electric power generation & distribution, *pef*	**2,5**
space heating efficiency, η_h	**75 %**

ANNEX IX

Measurements and calculations for NRVUs

NRVUs shall be tested and calculated using a 'reference configuration' of the product.

Dual use units shall be tested and calculated in the ventilation mode.

1. THERMAL EFFICIENCY OF A NON-RESIDENTIAL HEAT RECOVERY SYSTEM

The thermal efficiency of a non-residential heat recovery system is defined as

$$\eta_{t\_nrvu} = (t_2'' - t_2') / (t_1' - t_2')$$

where:

— η_t is the thermal efficiency of the HRS [-];

— t_2'' is temperature of the supply air leaving the HRS and entering the room [°C];

— t_2' is temperature of the outside air [°C];

— t_1' is temperature of the exhaust air, leaving the room and entering the HRS [°C].

2. FILTER CORRECTIONS

In case one or both filters are missing in comparison to reference configuration, the following filter correction shall be used:

From 1 January 2016:

F = 0 in case the reference configuration is complete;

F = 160 if the medium filter is missing;

F = 200 if the fine filter is missing;

F = 360 if both the medium and the fine filters are missing.

From 1 January 2018

F = 150 if the medium filter is missing;

F = 190 if the fine filter is missing;

F = 340 if both the medium and the fine filters are missing.

'fine filter' means a filter that meets the conditions for filter efficiency in the following test and calculation methods, to be declared by the filter supplier. Fine filters are tested at air flow of 0,944 m^3/s and filter face 592 × 592 mm (installation frame 610 × 610 mm) (face velocity 2,7 m/s). After proper preparation, calibration and checking the airstream for uniformity, initial filter efficiency and pressure drop of the clean filter are measured. The filter is progressively loaded with appropriate dust up to a final filter pressure drop of 450 Pa. At first 30 g is loaded in the dust generator subsequently there must be at least 4 equidistant dust loading steps before reaching the final pressure. The dust is fed to the filter at a concentration of 70 mg/m^3. Filter efficiency is measured with droplets in the size range 0,2 to 3 µm of a test aerosol (DEHS DiEthylHexylSebacate) at a rate of about 0,39 dm^3/s (1,4 m^3/h), Particles are counted 13 times, successively upstream and downstream of the filter at minimum 20 seconds with an optical particle counter (OPC). Incremental filter efficiency and pressure drop values are established. Average filter efficiency over the test for the various particle size classes is calculated. To qualify as a 'fine filter' the average efficiency for particle size 0,4 µm should be more than 80 % and the minimum efficiency should be more than 35 %. The minimum efficiency is the lowest efficiency among the discharged efficiency, initial efficiency and the lowest efficiency throughout the loading procedure of the test. The discharge efficiency test is largely identical to the average efficiency test above, except that the flat sheet of filter media sample is electrostatically discharged with isopropanol (IPA) before testing.

'medium filter' means a filter that meets the following conditions for filter efficiency: A 'medium filter' is an air filter for a ventilation unit with performance tested and calculated as for the fine filter, but meeting the conditions that the average efficiency for particle size 0,4 µm should be more than 40 %, to be declared by the filter supplier.

COMMISSION DELEGATED REGULATION (EU) No 1254/2014

of 11 July 2014

supplementing Directive 2010/30/EU of the European Parliament and of the Council with regard to energy labelling of residential ventilation units

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2010/30/EU of the European Parliament and of the Council of 19 May 2010 on the indication by labelling and standard product information of the consumption of energy and other resources by energy related products ([1]), and in particular Article 10 thereof,

Whereas:

(1) Directive 2010/30/EU requires the Commission to adopt delegated acts for the labelling of energy-related products. The delegated acts are to be adopted where products represent a significant potential for energy savings and present a wide disparity in performance levels although having an equivalent functionality and no other Union legislation or self-regulation is expected to achieve the policy objectives more quickly or at lesser expense than mandatory requirements.

(2) The Commission has assessed the technical, environmental and economic aspects of residential ventilation units. The assessment showed that the energy used by residential ventilation units accounts for a significant part of total household energy demand in the Union. Improvements have already been achieved in the energy efficiency of those products, but there is substantial scope for further reducing the energy consumption of such units. The assessment also confirmed a wide disparity in performance levels, and found no self-regulation or voluntary agreements which could achieve the policy objectives.

(3) Small ventilation units with an electric power input of less than 30 W per air stream should be exempted from the scope of this Regulation. Those units are designed for many different applications, predominantly working intermittently and with supplementary functions only, for example in bathrooms. Including those ventilation units would represent a considerable administrative burden in terms of market surveillance due to large sales numbers, while contributing only to a small share of the energy saving potential. However, considering that they offer similar functionalities to other ventilation units, their possible inclusion should be similarly addressed in the review of this Regulation. Non-residential ventilation units (NRVUs) should be excluded from labelling as these products are chosen by planners and architects and largely independent from consumer and market behaviour. Ventilation units specifically designed to operate exclusively for emergency purposes or in exceptional or hazardous environments should also be exempted, as they are used rarely and for a short time. The exemptions also clarify that multifunctional units which predominantly heat or cool and kitchen range hoods are excluded. Harmonised provisions on labelling and standard product information regarding the specific energy consumption of residential ventilation units should be laid down in order to provide incentives for manufacturers to improve the energy efficiency of these units, encourage end-users to purchase energy-efficient products and contribute to the functioning of the internal market.

(4) As the sound power level of a residential ventilation unit can be an important consideration for consumers, information on this should be included on the label.

(5) The combined effect of this Regulation and Commission Regulation (EU) No 1253/2014 ([2]) is expected to raise the aggregated saving by 1 300 PJ (45 %) to 4 130 PJ in 2025.

([1]) OJ L 153, 18.6.2010, p. 1.

([2]) Commission Regulation (EU) No 1253/2014 of 7 July 2014 implementing Directive 2009/125/EC of the European Parliament and of the Council with regard to ecodesign requirements for ventilation units (see page 8 of this Official Journal).

(6) The information provided on the label should be obtained through reliable, accurate and reproducible methods which take into account recognised 'state of the art' measurement and calculation methods, including, where available, harmonised standards adopted by the European standardisation bodies in accordance with the procedures laid down in Regulation (EU) No 1025/2012 of the European Parliament and of the Council ([1]).

(7) This Regulation should specify requirements as to the uniform design and content for the label, the technical documentation and the fiche. Requirements should also be laid down as regards the information to be provided in the case of any form of distance selling, advertisements and technical promotional materials for ventilation units, as the importance of information displayed to end-users via the internet is increasing,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter and scope

1. This Regulation establishes energy labelling requirements for residential ventilation units.

2. This Regulation shall not apply to residential ventilation units which:

(a) are unidirectional (exhaust or supply) with an electric power input of less than 30 W;

(b) are exclusively specified as operating in a potentially explosive atmosphere as defined in Directive 94/9/EC of the European Parliament and of the Council ([2]);

(c) are exclusively specified as operating for emergency use, for short periods of time, and which comply with the basic requirements for construction works with regard to safety in case of fire as set out in Regulation (EU) No 305/2011 of the European Parliament and of the Council ([3]);

(d) are exclusively specified as operating:

(i) where operating temperatures of the air being moved exceed 100 °C;

(ii) where the operating ambient temperature for the motor, if located outside the air stream, driving the fan exceeds 65 °C;

(iii) where the temperature of the air being moved or the operating ambient temperature for the motor, if located outside the air stream, are lower than – 40 °C;

(iv) where the supply voltage exceeds 1 000 V AC or 1 500 V DC;

(v) in toxic, highly corrosive or flammable environments or in environments with abrasive substances;

(e) include a heat exchanger and a heat pump for heat recovery, or allowing heat transfer or extraction being additional to that of the heat recovery system, except heat transfer for frost protection or defrosting;

(f) are classified as range hoods covered by Commission Delegated Regulation (EU) No 65/2014 ([4]).

Article 2

Definitions

For the purposes of this Regulation the following definitions shall apply:

(1) 'ventilation unit' (VU) means an electricity driven appliance equipped with at least one impeller, one motor and a casing and intended to replace utilised air by outdoor air in a building or a part of a building;

([1]) Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation (OJ L 316, 14.11.2012, p. 12).
([2]) Directive 94/9/EC of the European Parliament and of the Council of 23 March 1994 on the approximation of the laws of the Member States concerning equipment and protective systems intended for use in potentially explosive atmospheres (OJ L 100, 19.4.1994, p. 1).
([3]) Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC (OJ L 88, 4.4.2011, p. 5).
([4]) Commission Delegated Regulation (EU) No 65/2014 of 1 October 2013 supplementing Directive 2010/30/EU of the European Parliament and of the Council with regard to the energy labelling of domestic ovens and range hoods (OJ L 29, 31.1.2014, p. 1).

(2) 'residential ventilation unit' (RVU) means a ventilation unit where:

(a) the maximum flow rate does not exceed 250 m^3/h;

(b) the maximum flow rate is between 250 and 1 000 m^3/h, and the manufacturer declares its intended use as being exclusively for a residential ventilation application;

(3) 'maximum flow rate' is the declared maximum air volume flow rate of a ventilation unit that can be achieved with integrated or separately co-supplied controls at standard air conditions (20 °C) and 101 325 Pa, where the unit is installed complete (e.g. including clean filters) and according to the manufacturer's instructions, for ducted RVUs the maximum flow is related to the air flow at 100 Pa of external static pressure difference, and for non-ducted RVUs to the air flow at the lowest achievable total pressure difference to be chosen from a set of values of 10 (minimum)-20-50-100-150-200-250 Pa, whichever is equal or just below the measured pressure difference value;

(4) 'unidirectional ventilation unit' (UVU) means a ventilation unit producing an air flow in one direction only, either from indoors to outdoors (exhaust) or from outdoors to indoors (supply), where the mechanically produced air flow is balanced by natural air supply or exhaust;

(5) 'bidirectional ventilation unit' (BVU) means a ventilation unit producing an air flow between indoors and outdoors and which is equipped with both exhaust and supply fans;

(6) 'equivalent ventilation unit model' means a ventilation unit with the same technical characteristics according to the applicable product information requirements, but placed on the market as a different ventilation unit model by the same manufacturer, authorised representative or importer.

For the purposes of Annexes II to IX, additional definitions are set out in Annex I.

Article 3

Responsibilities of suppliers

1. Suppliers placing residential ventilation units on the market shall ensure that from 1 January 2016 the following requirements are fulfilled:

(a) each residential ventilation unit is accompanied by a printed label in the format and containing the information set out in Annex III, the label must be provided at least in the packaging of the unit. For each model of residential ventilation units an electronic label in the format and containing the information set out in Annex III shall be made available to dealers;

(b) a product fiche, as set out in Annex IV, is made available. The fiche must be provided at least in the packaging of the unit. For each model of residential ventilation units an electronic product fiche, as set out in Annex IV, shall be made available to dealers, and on free access websites;

(c) technical documentation, as set out in Annex V, is made available on request to the Member State authorities and the Commission;

(d) instructions for use are made available;

(e) any advertisement for a specific model of residential ventilation units that discloses energy-related or price information contains the specific energy consumption class of that model;

(f) any technical promotional material concerning a specific model of residential ventilation unit which describes its specific technical parameters states the specific energy consumption class of that model.

2. From 1 January 2016 residential ventilation units placed on the market shall be provided with a label in the format set out in Annex III, point 1, if they are unidirectional residential ventilation units, and with a label in the format set out in Annex III, point 2, if they are bidirectional ventilation units.

Article 4

Responsibilities of dealers

Dealers shall ensure that:

(a) each residential ventilation unit, at the point of sale, bears the label provided by suppliers in accordance with Article 3(1)(a) on the outside of the front or top of the appliance in such a way as to be clearly visible;

(b) residential ventilation units offered for sale, hire or hire-purchase, where the end-user cannot be expected to see the product displayed, are marketed with the information provided by suppliers in accordance with Annex VI, except where the offer is made on the internet, in which case the provisions of Annex VII shall apply;

(c) any advertisement for a specific model of residential ventilation unit that discloses energy-related or price information contains a reference to the specific energy consumption class of the unit;

(d) any technical promotional material concerning a specific model which describes the technical parameters of a residential ventilation unit includes the specific energy consumption class of the model and the instructions for use provided by the supplier.

Article 5

Measurement methods

For the purposes of information to be provided under Articles 3 and 4, the specific energy consumption class shall be determined in accordance with the table set out in Annex II. The specific energy consumption, the annual electricity consumption, the annual heating saved, the maximum flow rate and the sound power level shall be determined in accordance with measurement and calculation methods as set out in Annex VIII, and take into account recognised state-of-the-art measurement and calculation methods.

Article 6

Verification procedure for market surveillance purposes

When assessing the conformity of the ventilation unit, Member States shall apply the procedure laid down in Annex IX.

Article 7

Review

The Commission shall review this Regulation in the light of technological progress and present the results of this review to the Consultation Forum no later than 1 January 2020.

The review shall assess in particular the possible inclusion of other ventilation units, notably of non-residential units, units with a total electric power input smaller than 30 W, and the specific energy consumption calculation and classes for demand controlled unidirectional and bidirectional ventilation units.

Article 8

Entry into force

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, 11 July 2014.

For the Commission

The President

José Manuel BARROSO

ANNEX I

Definitions applicable for Annexes II to IX

(1) 'specific energy consumption (SEC)' (expressed in kWh/(m².a)) means a coefficient to express the energy consumed for ventilation per m² heated floor area of a dwelling or building, calculated for RVUs in accordance with Annex VIII;

(2) 'sound power level (L_{WA})' means the casing-radiated A-weighted sound power level expressed in decibels (dB) with reference to the sound power of one picowatt (1 pW), transmitted by the air at reference airflow;

(3) 'multi-speed drive' means a fan motor that can be operated at three or more fixed speeds plus zero ('off');

(4) 'variable speed drive (VSD)' means an electronic controller, integrated or functioning as one system or as a separate delivery with the motor and the fan, which continuously adapts the electrical power supplied to the motor in order to control the flow rate;

(5) 'heat recovery system (HRS)' means the part of a bidirectional ventilation unit equipped with a heat exchanger designed to transfer the heat contained in the (contaminated) exhaust air to the (fresh) supply air;

(6) 'thermal efficiency of a residential HRS (η_t)' means the ratio between supply air temperature gain and exhaust air temperature loss, both relative to the outdoor temperature, measured under dry conditions of the HRS, and standard air conditions, with balanced mass flow at reference flow rate, an indoor-outdoor temperature difference of 13 K, no correction for thermal heat gain from fan motors;

(7) 'internal leakage rate' means the fraction of extract air present in the supply air of ventilation units with HRS as a result of leakage between extract and supply airflows inside the casing when the unit is operated at reference air volume flow, measured at the ducts, the test shall be performed at 100 Pa;

(8) 'carry over' means the percentage of the exhaust air which is returned to the supply air for a regenerative heat exchanger according to the reference flow;

(9) 'external leakage rate' means the fraction of reference air volume flow escaping from the casing of a unit when it is subjected to a pressure test, the test shall be performed at 250 Pa for both under and over pressure;

(10) 'mixing' means the immediate recirculation or short-circuiting of airflows between discharge and intake ports at both the indoor and outdoor terminals so that they do not contribute to the effective ventilation of a building space, when the unit is operated at reference air volume rate;

(11) 'mixing rate' means the fraction of extract airflow, as part of the total reference air volume, that recirculates between discharge and intake ports at both the indoor and outdoor terminals and thus does not contribute to the effective ventilation of a building space, when the unit is operated at reference air volume (measured at 1 m distance from the indoor supply duct), less the internal leakage rate;

(12) 'effective power input' (expressed in W) means the electric power input at reference flow rate and corresponding external total pressure difference and includes the electrical demand for fans, controls (including remote controls) and the heat pump (if integrated);

(13) 'specific power input (SPI)' (expressed in W/(m³/h)) means the ratio between the effective power input (in W) and the reference flow rate (in m³/h);

(14) 'flow rate/pressure diagram' means a set of curves for flow rate (horizontal axis) and pressure difference of a unidirectional RVU or the supply side of a bidirectional RVU, where each curve represents one fan speed with at least eight equidistant test-points and the number of curves is given by the number of discrete fan speed options (one, two or three) or, in the case of a variable fan speed drive, includes at least a minimum, maximum and appropriate intermediate curve close to the reference air volume and pressure difference for SPI testing;

(15) 'reference flow rate' (expressed in m^3/s) is the abscissa value to a point on a curve in the flow rate/pressure diagram which is on or closest to a reference point at 70 % at least of the maximum flow rate and 50 Pa for ducted units and at a minimum pressure for non-ducted units. For bidirectional ventilation units, the reference air volume flow rate applies to the air supply outlet;

(16) 'control factor (CTRL)' means a correction factor for the SEC calculation depending on the type of control that is part of the ventilation unit, according to the description in Annex VIII Table 1;

(17) 'control parameter' means a measurable parameter or set of measurable parameters that are assumed to be representative of the ventilation demand, e.g. the level of relative humidity (RH), carbon dioxide (CO_2), volatile organic compounds (VOC) or other gases, presence, motion or occupancy detection from infrared body heat or from reflection of ultrasonic waves, electrical signals from human operation of lights or equipment;

(18) 'manual control' means any control type that does not use demand control;

(19) 'demand control' means a device or set of devices, integrated or as a separate delivery, that measures a control parameter and uses the result to regulate automatically the flow rate of the unit and/or the flow rates of the ducts;

(20) 'clock control' means a clocked (daytime-controlled) human interface to control the fan speed/flow rate of the ventilation unit, with at least seven weekday manual settings of the adjustable flow rate for at least two setback periods, i.e. periods in which a reduced or no flow rate applies;

(21) 'demand controlled ventilation (DCV)' means a ventilation unit that uses demand control;

(22) 'ducted unit' means a ventilation unit intended to ventilate one or more rooms or enclosed space in a building through the use of air ducts, intended to be equipped with duct connections;

(23) 'non-ducted unit' means a single room ventilation unit intended to ventilate a single room or enclosed space in a building, and not intended to be equipped with duct connections;

(24) 'central demand control' means a demand control of a ducted ventilation unit that continuously regulates the fan speed(s) and flow rate based on one sensor for the whole ventilated building or part of the building at central level;

(25) 'local demand control' means a demand control for a ventilation unit that continuously regulates the fan speed(s) and flow rates based on more than one sensor for a ducted ventilation unit or one sensor for a non-ducted unit;

(26) 'static pressure (p_{sf})' means the total pressure minus the fan dynamic pressure;

(27) 'total pressure (p_f)' means the difference between the stagnation pressure at the fan outlet and that at the fan inlet;

(28) 'stagnation pressure' means the pressure measured at a point in a flowing gas if it were to be brought to rest by means of an isentropic process;

(29) 'dynamic pressure' means the pressure calculated from the mass flow rate and the average gas density at the outlet and the unit outlet area;

(30) 'recuperative heat exchanger' means a heat exchanger intended to transfer thermal energy from one air stream to another without moving parts, such as a plate or tubular heat exchanger with parallel flow, cross flow or counter flow, or a combination of these, or a plate or tubular heat exchanger with vapour diffusion;

(31) 'regenerative heat exchanger' means a rotary heat exchanger incorporating a rotating wheel for the purpose of transferring thermal energy from one air stream to the other, including material allowing latent heat transfer, a drive mechanism, a casing or frame, and seals to reduce bypassing and leakage of air from one stream or another; such heat exchangers have varying degrees of moisture recovery depending on the material used;

(32) 'airflow sensitivity to pressure variations' of a non-ducted RVU is the ratio between the maximum deviation from the maximum RVU flow rate at + 20 Pa and that at – 20 Pa external total pressure difference;

(33) 'indoor/outdoor air tightness' of a non-ducted RVU is the flow rate (expressed in m^3/h) between indoors and outdoors when the fan(s) is(are) switched off.

ANNEX II

Specific energy consumption classes

Specific energy consumption (SEC) classes of residential ventilation units calculated for average climate:

Table 1

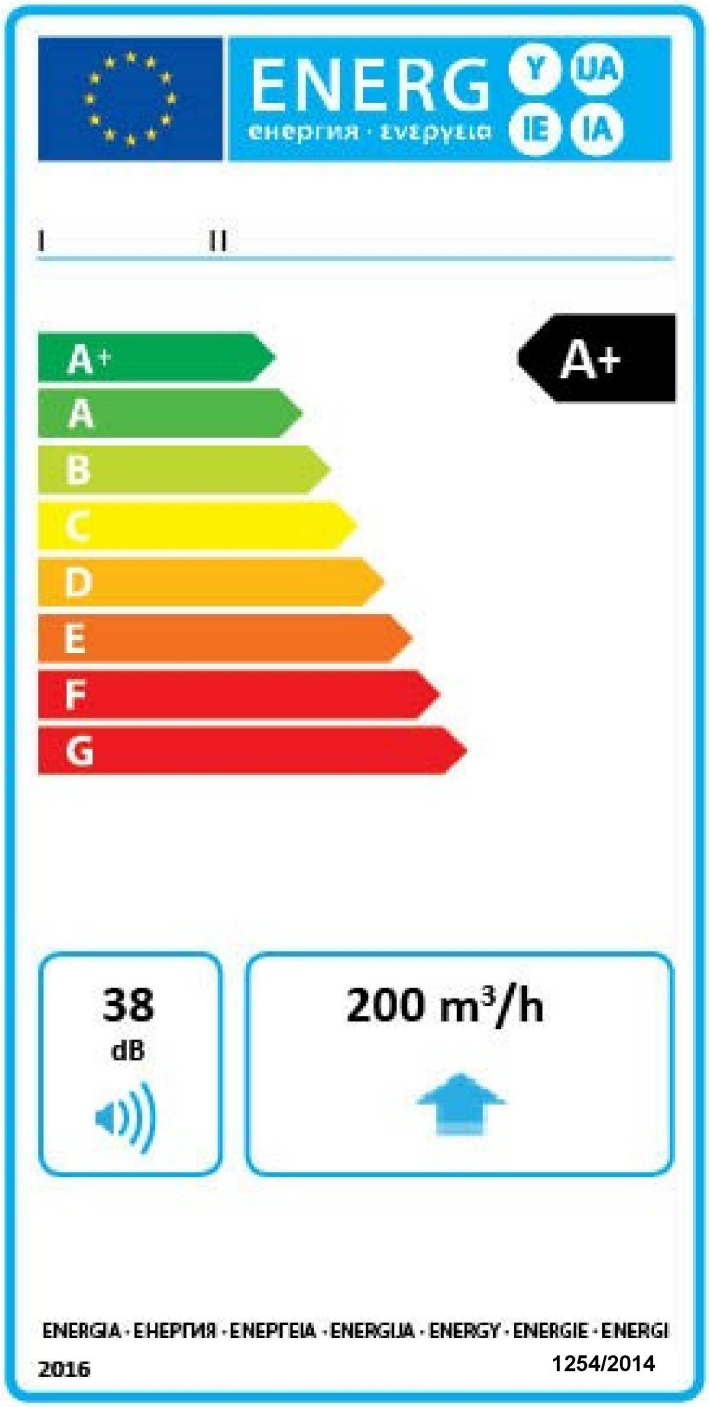
Classification from 1 January 2016

SEC class	SEC in $kWh/a.m^2$
A+ (most efficient)	SEC < – 42
A	– 42 ≤ SEC < – 34
B	– 34 ≤ SEC < – 26
C	– 26 ≤ SEC < – 23
D	– 23 ≤ SEC < – 20
E	– 20 ≤ SEC < – 10
F	– 10 ≤ SEC < 0
G (least efficient)	0 ≤ SEC

ANNEX III

The label

1. Label for UVUs marketed after 1 January 2016:



I, II

III

IV, V

The label shall provide the following information:

I. supplier's name or trade mark;

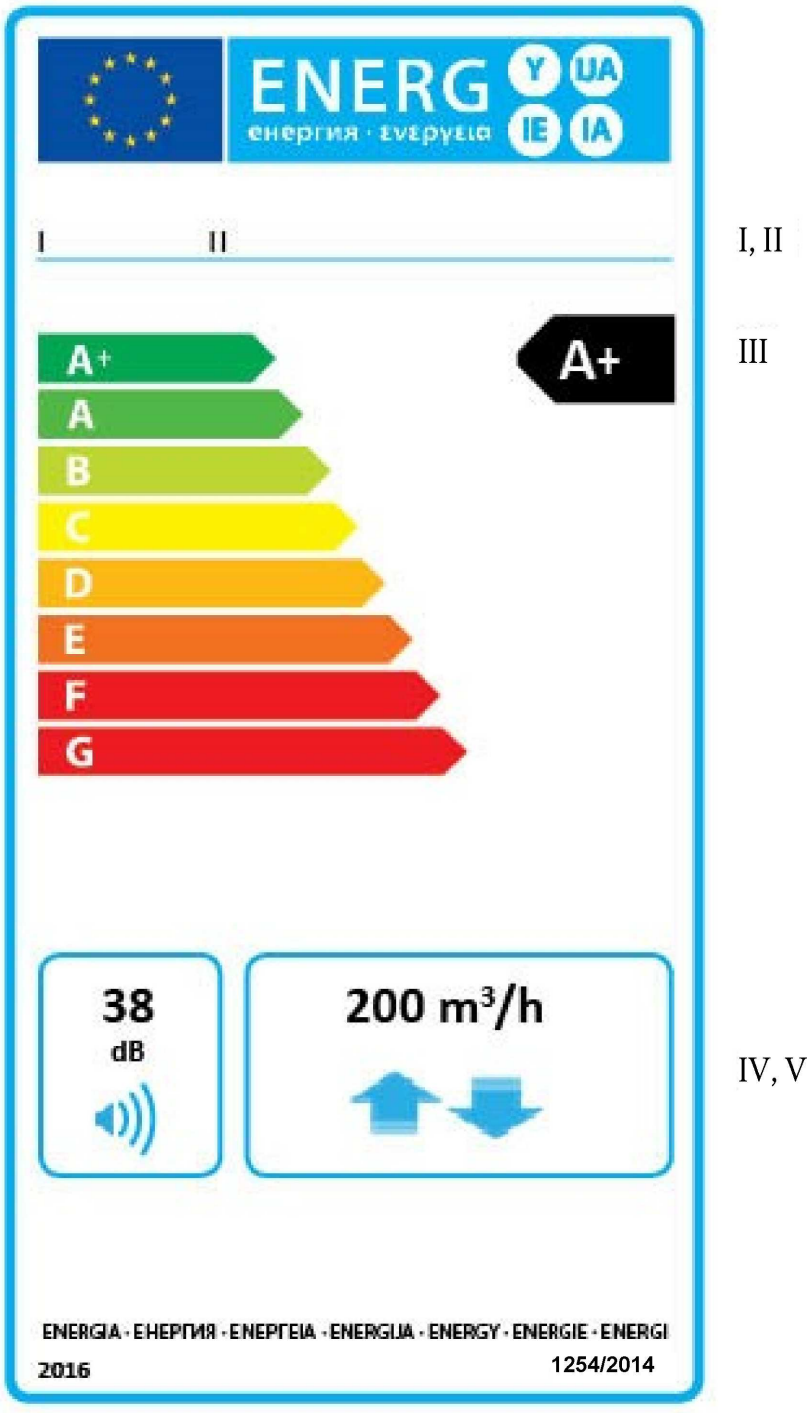
II. supplier's model identifier;

III. energy efficiency; the head of the arrow containing the energy efficiency class of the appliance shall be placed at the same height as the head of the arrow of the relevant energy efficiency class. Energy efficiency is indicated for an 'average' climate;

IV. sound power level (L_{WA}) in dB rounded to the nearest integer;

V. maximum flow rate in m^3/h rounded to the nearest integer, accompanied by one arrow representing UVUs.

2. Label for BVUs marketed after 1 January 2016:



The label shall provide the following information:

I. supplier's name or trade mark;

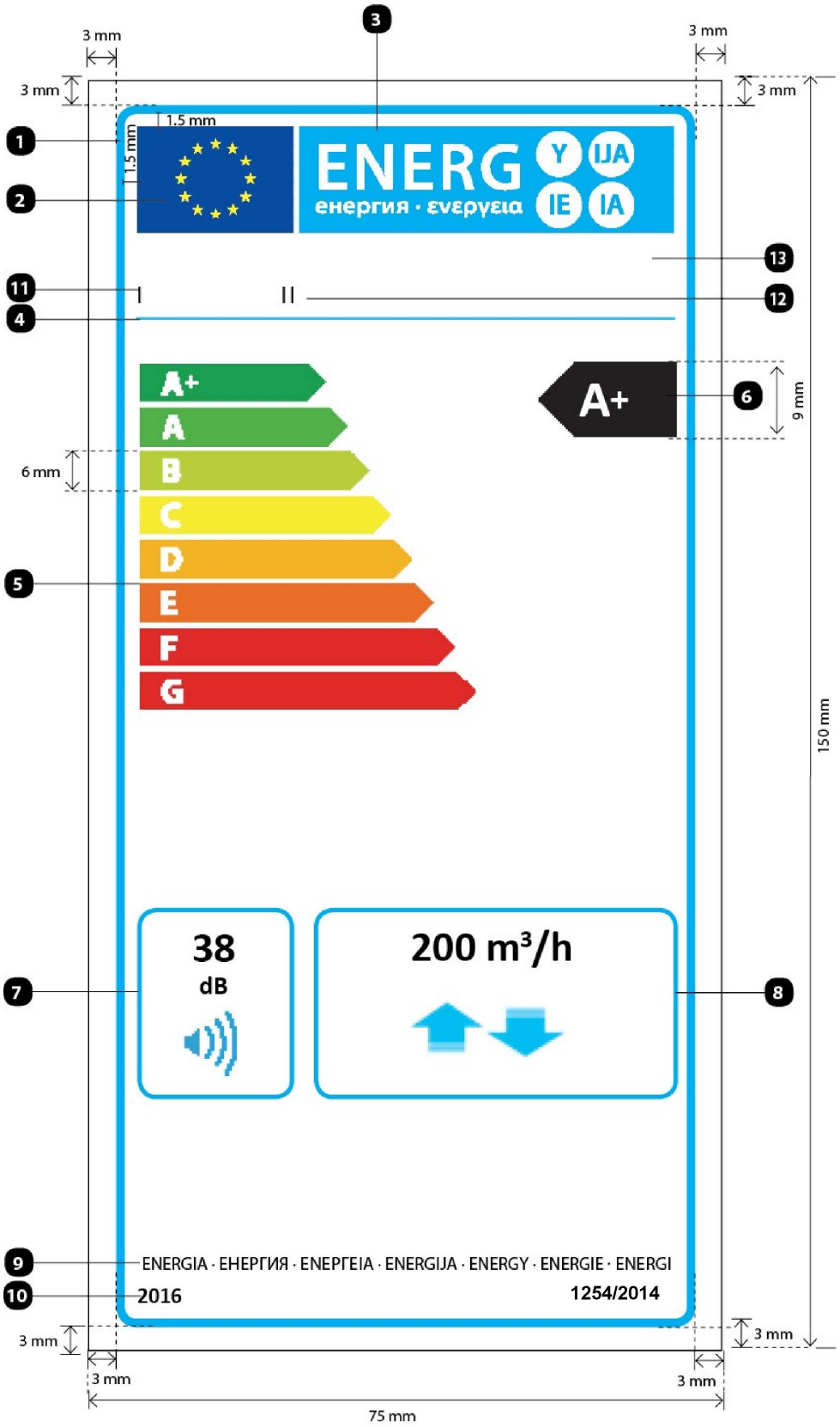
II. supplier's model identifier;

III. energy efficiency; the head of the arrow containing the energy efficiency class of the appliance shall be placed at the same height as the head of the arrow of the relevant energy efficiency class. Energy efficiency is indicated for an 'average' climate;

IV. sound power level (L_{WA}) in dB rounded to the nearest integer;

V. maximum flow rate in m^3/h rounded to the nearest integer, accompanied by two arrows in opposite directions representing BVUs.

3. The design of the labels for residential ventilation units set out in points 1 to 2 shall be the following:



Whereby:

The label shall be at least 75 mm wide and 150 mm high. Where the label is printed in a larger format, its content shall nevertheless remain proportionate to the specifications above.

The background shall be white.

Colours are coded as CMYK — cyan, magenta, yellow and black, following this example: 00-70-X-00: 0 % cyan, 70 % magenta, 100 % yellow, 0 % black.

The label shall fulfil all of the following requirements (numbers refer to the figure above):

❶ **EU label border stroke:** 3,5 pt — colour: Cyan 100 % — round corners: 2,5 mm.

❷ **EU logo:** Colours: X-80-00-00 and 00-00-X-00.

❸ **Energy logo:** Colour: X-00-00-00.

Pictogram as depicted: EU logo + energy logo: width: 62 mm, height: 12 mm.

❹ **Sub-logos border:** 1 pt — colour: cyan 100 % — length: 62 mm.

❺ **A+–G scales:**

— Arrow: height: 6 mm, gap: 1 mm — colours:

— Highest class: X-00-X-00,

— Second class: 70-00-X-00,

— Third class: 30-00-X-00,

— Fourth class: 00-00-X-00,

— Fifth class: 00-30-X-00,

— Sixth class: 00-70-X-00,

— Seventh class 00-X-X-00,

— Last class: 00-X-X-00,

— Text: Calibri bold 13 pt, capitals, white.

❻ **Specific energy consumption class**

— Arrow: width: 17 mm, height: 9 mm, 100 % black;

— Text: Calibri bold 18,5 pt, capitals, white; '+' symbols: Calibri bold 11 pt, white aligned on a single row.

❼ **Sound power level in dB:**

— Border: 1,5 pt — colour: cyan 100 % — round corners: 2,5 mm;

— Value: Calibri bold 16 pt, 100 % black;

— 'dB': Calibri regular 10 pt, 100 % black.

❽ **Maximum flow rate in m^3/h:**

— Border: 1,5 pt — colour: cyan 100 % — round corners: 2,5 mm;

— Value: Calibri bold 16 pt, 100 % black;

— 'm^3/h': Calibri bold 16 pt, 100 % black;

— One or two arrows

— each width: 10 mm, each height: 10 mm.

— Colour: cyan 100 %.

❾ **Energy:**

— Text: Calibri regular 6 pt, capitals, black.

❿ **Reference period:**

— Text: Calibri bold 8 pt.

⓫ **Supplier's name or trademark**

⓬ **Supplier's model identifier**

⓭ The suppliers' name or trade mark and model identifier shall fit in a space of 62 × 10 mm.

ANNEX IV

Product fiche

The information in the product fiche of the residential ventilation unit referred to in Article 3(1)(b) shall be given in the following order and shall be included in the product brochure or other literature provided with the product:

(a) supplier's name or trade mark;

(b) supplier's model identifier i.e. the code, usually alphanumeric, used to distinguish a specific residential ventilation unit model from other models with the same trade mark or supplier's name;

(c) specific energy consumption (SEC) in kWh/(m^2.a) for each applicable climate zone and SEC class;

(d) declared typology in accordance with Article 2 of this Regulation (, unidirectional or bidirectional);

(e) type of drive installed or intended to be installed (multi-speed drive or variable speed drive);

(f) type of heat recovery system (recuperative, regenerative, none);

(g) thermal efficiency of heat recovery (in % or 'not applicable' if the product has no heat recovery system);

(h) maximum flow rate in m^3/h;

(i) electric power input of the fan drive, including any motor control equipment, at maximum flow rate (W);

(j) sound power level (L_{WA}), rounded to the nearest integer;

(k) reference flow rate in m^3/s;

(l) reference pressure difference in Pa;

(m) SPI in W/(m^3/h);

(n) control factor and control typology in accordance with the relevant definitions and classification in Annex VIII Table 1;

(o) declared maximum internal and external leakage rates (%) for bidirectional ventilation units or carry over (for regenerative heat exchangers only), and external leakage rates (%) for ducted unidirectional ventilation units;

(p) mixing rate of non-ducted bidirectional ventilation units not intended to be equipped with one duct connection on either supply or extract air side;

(q) position and description of visual filter warning for RVUs intended for use with filters, including text pointing out the importance of regular filter changes for performance and energy efficiency of the unit;

(r) for unidirectional ventilation systems, instructions to install regulated supply/exhaust grilles in the façade for natural air supply/extraction;

(s) internet address for pre-/dis-assembly instructions;

(t) for non-ducted units only: the airflow sensitivity to pressure variations at + 20 Pa and − 20 Pa;

(u) for non-ducted units only: the indoor/outdoor air tightness in m^3/h;

(v) the annual electricity consumption (AEC) (in kWh electricity/a);

(w) the annual heating saved (AHS) (in kWh primary energy/a) for each type of climate ('average', 'warm', 'cold').

ANNEX V

Technical documentation

The technical documentation referred to in Article 3(1)(c) shall include at least the following:

(a) the name and address of the supplier;

(b) supplier's model identifier i.e. the code, usually alphanumeric, used to distinguish a specific residential ventilation unit model from other models with the same trade mark or supplier's name;

(c) where appropriate, the references of the harmonised standards applied;

(d) where appropriate, the other calculation methods, measurement standards and specifications used;

(e) identification and signature of the person empowered to bind the supplier;

(f) where appropriate, the technical parameters for measurements, established in accordance with Annex VIII;

(g) overall dimensions;

(h) specification of the type of RVU;

(i) the specific energy consumption class of the model as defined in Annex II;

(j) the specific energy consumption (SEC) for each applicable climate zone;

(k) sound power level (L_{WA});

(l) the results of calculations carried out in accordance with Annex VIII.

Suppliers may include additional information at the end of the above list.

ANNEX VI

Information to be provided where end-users cannot be expected to see the product displayed, except on the internet

1. Where end-users cannot be expected to see the product displayed, except on the internet, the information shall be provided in the following order:

   (a) the specific energy consumption class of the model as defined in Annex II;

   (b) the specific energy consumption (SEC) in kWh/(m^2.a) for each applicable climate zone;

   (c) the maximum flow rate (in m^3/h);

   (d) sound power level (L_{WA}) in dB(A) rounded to the nearest integer.

2. Where other information contained in the product information fiche is provided, it shall be in the form and order specified in Annex IV.

3. The size and font in which the information referred in this Annex is printed or shown shall be such that it is legible.

ANNEX VII

Information to be provided in the case of sale, hire or hire-purchase through the internet

1. For the purpose of points 2 to 5 of this Annex, the following definitions shall apply:

   (a) 'display mechanism' means any screen, including tactile screen, or other visual technology used for displaying internet content to users;

   (b) 'nested display' means a visual interface where an image or data set is accessed by a mouse click, mouse roll-over or tactile screen expansion of another image or data set;

   (c) 'tactile screen' means a screen responding to touch, such as that of a tablet computer, slate computer or smartphone;

   (d) 'alternative text' means text provided as an alternative to a graphic, allowing information to be presented in non-graphical form where display devices cannot render the graphic or as an aid to accessibility such as input to voice synthesis applications.

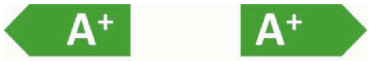
2. The appropriate label made available by suppliers in accordance with Article 3(1)(a) shall be shown on the display mechanism near the price of the product in accordance with the timelines indicated in Article 3(2) and (3). The size of the label shall be such that it is clearly visible and legible and shall be proportionate to the size specified in Annex III. The label may be displayed using a nested display, in which case the image used for accessing it shall comply with the specifications in point 3 of this Annex. If nested display is applied, the label shall appear on the first mouse click, mouse roll-over or tactile screen expansion on the image.

3. The image used for accessing the label in the case of nested display shall:

   (a) be an arrow in the colour corresponding to the energy efficiency class of the product on the label;

   (b) indicate the energy efficiency class of the product in white in the same font size as that used for the price; and

   (c) be in one of the following two formats:



4. In the case of nested display, the sequence of display of the label shall be as follows:

   a) the image referred to in point 3 of this Annex is shown on the display mechanism in proximity to the price of the product;

   b) the image links to the label;

   c) the label is displayed after a mouse click, mouse roll-over or tactile screen expansion on the image;

   d) the label is displayed by pop-up, new tab, new page or inset screen display;

   e) for magnification of the label on tactile screens, the device conventions for tactile magnification apply;

   f) display of the label is closed by means of a close option or other standard closing mechanism;

   g) the alternative text for the graphic, to be displayed on failure to display the label, is the energy efficiency class of the product in the same font size as that used for the price.

5. The appropriate product fiche made available by suppliers in accordance with Article 3(1)(b) shall be shown on the display mechanism near the price of the product. The size shall be such that the product fiche is clearly visible and legible. The product fiche may be displayed using a nested display, in which case the link used for accessing it shall clearly and legibly indicate 'Product fiche'. If nested display is used, the fiche shall appear on the first mouse click, mouse roll-over or tactile screen expansion on the link.

ANNEX VIII

Measurements and calculations

1. The specific energy consumption (SEC) is calculated using the following equation:

$$SEC = t_a \cdot pef \cdot q_{net} \cdot MISC \cdot CTRL^x \cdot SPI - t_h \cdot \Delta T_h \cdot \eta_h^{-1} \cdot c_{air} \cdot (q_{ref} - q_{net} \cdot CTRL \cdot MISC \cdot (1 - \eta_t)) + Q_{defr}$$

where:

— *SEC* is the specific energy consumption for ventilation per m² heated floor area of a dwelling or building [kWh/m².a];

— t_a is annual operating hours [h/a];

— *pef* is the primary energy factor for electric power generation and distribution [-];

— q_{net} is net ventilation rate demand per m² heated floor area [m³/h.m²];

— *MISC* is an aggregated general typology factor, incorporating factors for ventilation effectiveness, duct leakage and extra infiltration [-];

— *CTRL* is the ventilation control factor [-];

— *x* is an exponent that takes into account non-linearity between thermal energy and electricity saving, depending on motor and drive characteristics [-];

— *SPI* is specific power input [kW/(m³/h)];

— t_h is total hours heating season [h];

— ΔT_h is the average difference in indoor (19 °C) and outdoor temperature over a heating season, minus 3 K correction for solar and internal gains [K];

— η_h is the average space heating efficiency [-];

— c_{air} is the specific heat capacity of air at constant pressure and density [kWh/(m³ K)];

— q_{ref} is the reference natural ventilation rate per m² heated floor area [m³/h.m²];

— η_t is the thermal efficiency of heat recovery [-];

— Q_{defr} is the annual heating energy per m² heated floor area [kWh/m².a] for defrosting, based on a variable electric resistance heating.

$$Q_{defr} = t_{defr} \cdot \Delta T_{defr} \cdot c_{air} \cdot q_{net} \cdot pef,$$

where:

— t_{defr} is the duration of the defrosting period, i.e. when the outdoor temperature is below – 4 °C [h/a]; and

— ΔT_{defr} is the average difference in K between the outdoor temperature and – 4 °C during the defrosting period.

Q_{defr} applies only to bidirectional units with recuperative heat exchanger; for unidirectional units or units with regenerative heat exchangers, $Q_{defr} = 0$.

SPI and η_t are values derived from tests and calculation methods.

Other parameters and their defaults are given in Table 1. The SEC for label classification is based on the 'average' climate.

2. The annual electricity consumption per 100 m² floor area (AEC) (in kWh/a electric per year); and the annual heating saved ((AHS), which means the annual saving in consumption of energy for heating (in kWh fuel gross calorific value per year) are calculated as follows, using the definitions in point 1, and the default values given in Table 1, for each type of climate (average, warm and cold):

$$AEC = t_a \cdot q_{net} \cdot MISC \cdot CTRL^x \cdot SPI + Q_{defr};$$

$$AHS = t_h \cdot \Delta T_h \cdot \eta_h^{-1} \cdot c_{air} \cdot (q_{ref} - q_{net} \cdot CTRL \cdot MISC \cdot (1 - \eta_t)).$$

Table 1

SEC calculation parameters

general typology					**MISC**
Ducted ventilation units					**1,1**
Non-ducted ventilation units					**1,21**
ventilation control					**CTRL**
Manual control (no DCV)					**1**
Clock control (no DCV)					**0,95**
Central demand control					**0,85**
Local demand control					**0,65**
motor & drive					**x-value**
on/off & single speed					**1**
2-speed					**1,2**
3-speed					**1,5**
variable speed					**2**
Climate	t_h in h	ΔT_h in K	t_{defr} in h	ΔT_{defr} in K	Q_{defr} (*) in kWh/a.m²
Cold	**6 552**	**14,5**	1 003	5,2	**5,82**
Average	**5 112**	**9,5**	168	2,4	**0,45**
Warm	**4 392**	**5**	—	—	—

(*) Defrosting applies only to bidirectional units with recuperative heat exchanger and is calculated as $Q_{defr} = t_{defr}*\Delta t_{defr}*c_{air}*q_{net}*pef$. For unidirectional units or units with regenerative heat exchangers, $Q_{defr} = 0$

Defaults	**value**
specific heat capacity of air, c_{air} in kWh/(m³K)	**0,000344**
net ventilation requirement per m² heated floor area, q_{net} in m³/h.m²	**1,3**
reference natural ventilation rate per m² heated floor area, q_{ref} in m³/h.m²	**2,2**
annual operating hours, t_a in h	**8 760**
primary energy factor electric power generation & distribution, *pef*	**2,5**
space heating efficiency, η_h	**75 %**

ANNEX IX

Verification procedure for market surveillance purposes

For the purposes of checking conformity with the requirements laid down in Annex II, Member State authorities shall test a single RVU. If the measured values or values calculated on the basis of measured values do not match the manufacturer's declared values within the meaning of Article 3, subject to the tolerances in Table 1, measurements shall be carried out on three other units.

If the arithmetic mean of the measured values for these units does not meet the requirements, subject to the tolerances in Table 1, the model and all other equivalent models shall be considered not to comply with the requirements of Annex II.

The Member State authorities shall provide the test results and other relevant information to the authorities of the other Member States and to the Commission within one month of the decision being taken on the non-compliance of the model.

Member State authorities shall use the measurement and calculation methods in Annex VIII.

Table 1

Parameter	Verification tolerances
SPI	The measured value shall be no more than 1,07 times the maximum declared value.
Thermal efficiency RVU	The measured value shall be no less than 0,93 times the minimum declared value.
Sound power level	The measured value shall be no more than the maximum declared value plus 2 dB.

The verification tolerances defined in this Annex relate only to the verification of the measured parameters by Member State authorities and shall not be used by the supplier as an allowed tolerance to establish values in the technical documentation. The values and classes on the label or in the (electronic) product fiche shall not be more favourable for the supplier than the values reported in the technical documentation.

COMMISSION DELEGATED REGULATION (EU) No 1255/2014

of 17 July 2014

supplementing Regulation (EU) No 223/2014 of the European Parliament and of the Council on the Fund for European Aid to the Most Deprived by laying down the content of the annual and final implementation reports, including the list of common indicators

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 223/2014 of the European Parliament and of the Council of 11 March 2014 on the Fund for European Aid to the Most Deprived ([1]) and in particular Article 13(6) thereof,

Whereas:

(1) Regulation (EU) No 223/2014 requires the Commission to adopt delegated acts supplementing non-essential elements with regard to the Fund for European Aid to the Most Deprived (FEAD)

(2) Regulation (EU) No 223/2014 requires the Member States to submit to the Commission annual and final reports containing information regarding the implementation of operational programmes (OPs), including the data relating to the common and, where applicable, specific programme indicators.

(3) In order to ensure an appropriate monitoring of the implementation of the OPs and their contribution to the FEAD specific objectives, provisions should be established regarding the content of the annual and final implementation reports, as well as the list of common indicators which need to be reported.

(4) The requirements set out in this Regulation should be limited to the necessary taking into account of the provisions set out under the Regulation (EU) No 223/2014, as well as applicable Union law concerning the protection of individuals with regard to the processing of personal data and on the free movement of such data, in particular Directive 95/46/EC of the European Parliament and of the Council ([2]).

(5) To take account of the different nature of operations supported by OP I and OP II and in accordance with the different provisions that apply to each OP as set out in the Regulation (EU) No 223/2014, different requirements should apply with regard to the content of the annual and final implementation reports, as well as to the list of common indicators which should be reported for each OP. To take account of the specific need to protect the dignity of the individuals supported by the FEAD and with a view to reducing the administrative burden for beneficiaries to the minimum necessary in accordance with the requirements set out in the Regulation (EU) No 223/2014, the values of certain indicators shall be determined based on the informed estimation of the partner organisations rather than information provided by end-recipients.

In order to allow for the prompt application of the measures provided for in this Regulation, this Regulation shall enter into force on the day following that of its publication in the *Official Journal of the European Union*,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter

This Regulation lays down the provisions supplementing Regulation (EU) No 223/2014 with regard to the content of the annual and final implementation reports, including the list of common indicators.

([1]) OJ L 72, 12.3.2014, p. 1.
([2]) Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ L 281, 23.11.1995, p. 31).

Article 2

Content of the annual and final implementation reports and list of indicators

(Article 13(6) of Regulation (EU) No 223/2014)

1. The annual and final implementation reports shall set out the following elements:

(a) information on implementation of the programme by reference to the common indicators for the partially or fully completed operations;

(b) information on and assessment of the actions which take into account the principles set out in Articles 5(6), 5(11) and, where appropriate, Article 5(13) of Regulation (EU) No 223/2014.

In addition to the information referred to in the first subparagraph, the annual and final implementation reports on OP II shall provide information on the data regarding to the programme specific indicators and quantified target values, and on the changes in the result indicators, as well as information on and assessessment of the progress towards achieving the specific objectives of the operational programme.

2. The indicators referred to in point (a) of paragraph 1 are listed in the Annex.

3. In addition to the information referred to in paragraph 1, the final implementation report and, in 2017 and 2022, the annual implementation report shall set out information on and assessment of the contribution to achieving the specific and global objectives of the FEAD, specified in Article 3 of Regulation (EU) No 223/2014.

Article 3

This Regulation shall enter into force on the 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, 17 July 2014.

For the Commission

The President

José Manuel BARROSO

ANNEX

COMMON INDICATORS FOR OP I AND OP II

Input indicators

(1) Total amount of eligible public expenditure approved in the documents setting out the conditions for support of operations.

(2) Total amount of eligible public expenditure incurred by beneficiaries and paid in implementing operations.

Thereof, where relevant:

(a) total amount of eligible public expenditure incurred by beneficiaries and paid in implementing operations relating to provision of food support;

(b) total amount of eligible public expenditure incurred by beneficiaries and paid in implementing operations relating to provision of basic material assistance.

(3) Total amount of eligible public expenditure declared to the Commission.

These data shall be expressed in euro.

COMMON INDICATORS FOR OP I

Output indicators on food support distributed ([1])

(4) Quantity of fruits and vegetables.

(5) Quantity of meat, eggs, fish, seafood.

(6) Quantity of flour, bread, potatoes, rice and other starchy products.

(7) Quantity of sugar.

(8) Quantity of milk products.

(9) Quantity of fats, oil.

(10) Quantity of convenience food, other foodstuff (not falling under the aforementioned categories).

(11) Total quantity of food support distributed.

Thereof:

(a) share of food for which only transport, distribution and storage were paid for by the OP (in %);

(b) proportion of FEAD co-financed food products in the total volume of food distributed by the partner organisations (in %) ([2]).

(12) Total number of meals distributed partly or totally financed by the OP ([3]).

(13) Total number of food packages distributed partly or totally financed by the OP ([4]).

([1]) The indicators (4) to (11) include any form of these products, e.g. fresh, canned and frozen foodstuff and should be expressed in tons.
([2]) Values for this indicator shall be established by an informed estimation of the partner organisations.
([3]) The definition of what is to be understood as a meal can be provided at the level of the partner organisation/operation/managing authority. Values for this indicator shall be established by an assessment by the partner organisations.
([4]) The definition of what is to be understood as a food package can be provided at the level of the partner organisation/operation/managing authority. Packages do not need to be standardised in size or content. Values for this indicator shall be established by an assessment by the partner organisations.

Result indicators on food support distributed ([5])

(14) Total number of persons receiving food support.

Thereof:

(a) number of children aged 15 years or below;

(b) number of persons aged 65 years or above;

(c) number of women;

(d) number of migrants, participants with a foreign background, minorities (including marginalised communities such as the Roma);

(e) number of persons with disabilities;

(f) number of homeless.

Output indicators on basic material assistance distributed

(15) Total monetary value of goods distributed.

Thereof:

(a) total monetary value of goods for children;

(b) total monetary value of goods for the homeless;

(c) total monetary value of goods for other target groups.

(16) List of most relevant categories of goods distributed to children ([6]):

(a) layette;

(b) school bags;

(c) stationery, exercise books, pens, painting equipment and other equipment required in school (non-clothes);

(d) sports equipment (sport shoes, leotard, swimsuit, etc.);

(e) clothes (winter coat, footwear, school uniform, etc.);

(f) other category — to be specified

(17) List of most relevant categories of goods distributed to the homeless ([6]):

(a) sleeping bags/blankets;

(b) kitchen equipment (pots, pans, cutlery, etc.);

(c) clothes (winter coat, footwear, etc.);

(d) household linen (towels, bedclothes);

(e) hygiene articles (first aid kit, soap, toothbrush, disposable razor, etc.);

(f) other category —to be specified.

(18) List of most relevant categories of goods distributed to other target groups ([6]):

(a) categories to be specified.

Result indicators on basic material assistance distributed ([5])

(19) Total number of persons receiving basic material assistance.

Thereof:

(a) number of children aged 15 years or below;

(b) number of persons aged 65 years or above;

([5]) Values for these indicators shall be determined based on the informed estimation of the partner organisations. It is neither expected nor required that they are based on information provided by end-recipients.

([6]) The list shall include all relevant categories covering at least 75 % of the goods distributed.

(c) number of women;

(d) number of migrants, participants with a foreign background, minorities including marginalised communities such as the Roma;

(e) number of persons with disabilities;

(f) number of homeless.

COMMON INDICATORS FOR OP II

Output indicators on social inclusion assistance

(20) Total number of persons receiving social inclusion assistance.

Thereof:

(a) number of children aged 15 years or below;

(b) number of persons aged 65 years or above;

(c) number of women;

(d) number of migrants, participants with a foreign background, minorities (including marginalised communities such as the Roma);

(e) number of persons with disabilities;

(f) number of homeless.

These data for OP II are personal data according to Article 7 of Directive 95/46/EC. Their processing is necessary for compliance with the legal obligation to which the controller is subject (Article 7(c) of Directive 95/46/EC). For the definition of controller, see Article 2 of Directive 95/46/EC.

COMMISSION REGULATION (EU) No 1256/2014

of 21 November 2014

establishing a prohibition of fishing for skates and rays in Union waters of IIa and IV by vessels flying the flag of The Netherlands

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 1224/2009 of 20 November 2009 establishing a Community control system for ensuring compliance with the rules of the common fisheries policy [1], and in particular Article 36(2) thereof,

Whereas:

(1) Council Regulation (EU) No 43/2014 [2], lays down quotas for 2014.

(2) According to the information received by the Commission, catches of the stock referred to in the Annex to this Regulation by vessels flying the flag of or registered in the Member State referred to therein have exhausted the quota allocated for 2014.

(3) It is therefore necessary to prohibit fishing activities for that stock,

HAS ADOPTED THIS REGULATION:

Article 1

Quota exhaustion

The fishing quota allocated to the Member State referred to in the Annex to this Regulation for the stock referred to therein for 2014 shall be deemed to be exhausted from the date set out in that Annex.

Article 2

Prohibitions

Fishing activities for the stock referred to in the Annex to this Regulation by vessels flying the flag of or registered in the Member State referred to therein shall be prohibited from the date set out in that Annex. In particular it shall be prohibited to retain on board, relocate, tranship or land fish from that stock caught by those vessels after that date.

Article 3

Entry into force

This Regulation shall enter into force on the 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, 21 November 2014.

For the Commission,
On behalf of the President,
Lowri EVANS
Director-General for Maritime Affairs and Fisheries

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[1] OJ L 343, 22.12.2009, p. 1.
[2] Council Regulation (EU) No 43/2014 of 20 January 2014 fixing for 2014 the fishing opportunities for certain fish stocks and groups of fish stocks, applicable in Union waters and, to Union vessels, in certain non-Union waters (OJ L 24, 28.1.2014, p. 1).

ANNEX

No	74/TQ43
Member State	The Netherlands
Stock	SRX/2AC4-C
Species	Skates and rays (*Rajiformes)*
Zone	Union waters of IIa and IV
Closing date	10.11.2014

COMMISSION REGULATION (EU) No 1257/2014

of 24 November 2014

amending Regulation (EC) No 2003/2003 of the European Parliament and of the Council relating to fertilisers for the purposes of adapting Annexes I and IV

(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 2003/2003 of the European Parliament and of the Council of 13 October 2003 relating to fertilisers ([1]), and in particular Article 31(1) and (3) thereof,

Whereas:

(1) Crude potassium salts are materials obtained from natural resources through mining. For such natural products, the minimum nutrient content requirements set out in entry 1 of Table A.3 of Annex I to Regulation (EC) No 2003/2003 were laid down in accordance with sound industrial practice. However, when the potassium grade in the ore is naturally declining, producers encounter increasing difficulties to comply with the current limits, which jeopardies the continuous supply of fertilisers obtained from crude potassium salts to professional farmers. Therefore, these limits should be slightly reduced by amending entry 1 of Table A.3 of that Annex to allow producers to continue marketing their product as 'EC fertiliser'. This amendment takes into account that the revised, slightly lower limit values also allow for efficient fertilisation and can therefore be considered as technical progress in accordance with Article 31(3) of Regulation (EC) No 2003/2003.

(2) 3,4–dimethyl-1H-pyrazole phosphate (hereinafter 'DMPP') is a nitrification inhibitor that is suitable for use with common nitrogen fertilisers (solid or fluid). DMPP reduces the risks of nitrogen losses into the soil and in the atmosphere and therefore enhances nitrogen use efficiency.

(3) The reaction mixture between N-butyl-thiophosphoric-triamide and N-propyl-thiophosphoric-triamide (hereinafter 'NBPT/NPPT') is a urease inhibitor. NBPT/NPPT reduces the risk of nitrogen losses in the form of ammonia emissions after the application of urea-containing fertilisers and therefore enhances the nitrogen use efficiency.

(4) In order to make them more widely available to farmers throughout the Union, DMPP and NBPT/NPPT should be added to the lists of authorised nitrification and urease inhibitors in Annex I to Regulation (EC) No 2003/2003 in accordance with Article 31(1) of Regulation (EC) No 2003/2003.

(5) Solid or fluid straight urea formaldehyde fertilisers as well as solid NPK, NP and NK fertilisers containing urea formaldehyde are listed as fertiliser types in Annex I to Regulation (EC) No 2003/2003. Although urea formaldehyde condensates are stable in solution and in suspension, fluid NPK, NP and NK fertilisers containing urea formaldehyde are not yet listed in Annex I to Regulation (EC) No 2003/2003 as an individual product type. As there is a growing interest in marketing fluid NPK, NP and NK fertilisers containing a certain amount of urea formaldehyde as source of nitrogen, urea formaldehyde should be allowed in the preparation of fluid NPK, NP and NK fertilisers. Six new type designations should therefore be included in Table C.2 of Annex I to that Regulation.

(6) Further to the inclusion of DMPP and NBPT/NPPT in Annex I to Regulation (EC) No 2003/2003, analytical methods to be applied for the official control of those fertilisers should be added to Annex IV to that Regulation.

(7) Regulation (EC) No 2003/2003 should therefore be amended accordingly.

(8) In order to ensure that the method for the analysis of NBPT/NPPT, which is currently under validation, is published by the European Committee for Standardisation before the addition of NBPT/NPPT in Annex I to Regulation (EC) No 2003/2003 and the new analytical method for that fertiliser type in its Annex IV, the application should be deferred as regards those amendments.

(9) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 32 of Regulation (EC) No 2003/2003,

([1]) OJ L 304, 21.11.2003, p. 1.

HAS ADOPTED THIS REGULATION:

Article 1

Amendments

Regulation (EC) No 2003/2003 is amended as follows:

(1) Annex I is amended in accordance with Annex I to this Regulation;

(2) Annex IV is amended in accordance with Annex II to this Regulation.

Article 2

Entry into force

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

Annex I, point (4), and Annex II, point (2), shall apply from 1 January 2016.

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

Done at Brussels, 24 November 2014.

For the Commission

The President

Jean-Claude JUNCKER

ANNEX I

Annex I to Regulation (EC) No 2003/2003 is amended as follows:

(1) in Table A.3, entry 1 in the table is replaced by the following:

'1	Crude potassium salt	Product obtained from crude potassium salts	9 % K_2O Potassium expressed as water-soluble K_2O 2 % MgO Magnesium in the form of water-soluble salts, expressed as magnesium oxide	Usual trade names may be added	Water-soluble potassium oxide Water-soluble magnesium oxide Total sodium oxide Chloride content must be declared'

(2) Table C.2 is amended as follows:

(a) entries C.2.2 to C.2.8 are replaced by the following:

'C.2.2	Type designation:	NPK-fertiliser solution containing urea formaldehyde
	Data on method of production:	Product obtained chemically and by dissolution in water, in a form stable at atmospheric pressure, without addition of organic nutrients of animal or vegetable origin and containing urea formaldehyde
	Minimum content of nutrients (percentage by weight) and other requirements:	— Total 15 % (N + P_2O_5 + K_2O) — For each of the nutrients: — 5 % N, at least 25 % of the declared content of total nitrogen must derive from nitrogen form (5) — 3 % P_2O_5 — 3 % K_2O Maximum biuret content: (ureic N + urea formaldehyde N) × 0,026

Forms, solubilities and nutrient content to be declared as specified in columns 4, 5 and 6 — Particle size			Data for identification of the fertilisers — Other requirements		
N	P_2O_5	K_2O	N	P_2O_5	K_2O
1	2	3	4	5	6
(1) Total nitrogen (2) Nitric nitrogen (3) Ammoniacal nitrogen (4) Ureic nitrogen (5) Nitrogen from urea formaldehyde	Water-soluble P_2O_5	Water-soluble K_2O	(1) Total nitrogen (2) If any of the forms of nitrogen (2), (3) and (4) amounts to not less than 1 % by weight, it must be declared (3) Nitrogen from urea formaldehyde (4) If the biuret content is less than 0,2 %, the words "low in biuret" may be added	Water-soluble P_2O_5	(1) Water-soluble potassium oxide (2) The words "low in chloride" may be used only where the Cl content does not exceed 2 % (3) The chloride content may be declared

C.2.3	Type designation:	NPK-fertiliser suspension
	Data on method of production:	Product in liquid form, in which the nutrients are derived from substances both in suspension in the water and in solution without addition of organic nutrients of animal or vegetable origin
	Minimum content of nutrients (percentage by weight) and other requirements:	— Total: 20 %, ($N + P_2O_5 + K_2O$) — For each of the nutrients: 3 % N, 4 % P_2O_5, 4 % K_2O — Maximum biuret content: ureic N × 0,026

Forms, solubilities and nutrient content to be declared as specified in columns 4, 5 and 6 — Particle size			Data for identification of the fertilisers — Other requirements		
N	P_2O_5	K_2O	N	P_2O_5	K_2O
1	2	3	4	5	6
(1) Total nitrogen (2) Nitric nitrogen (3) Ammoniacal nitrogen (4) Ureic nitrogen	(1) Water-soluble P_2O_5 (2) P_2O_5 soluble in neutral ammonium citrate (3) P_2O_5 soluble in neutral ammonium citrate and water	Water-soluble K_2O	(1) Total nitrogen (2) If any of the forms of nitrogen (2), (3) and (4) amounts to not less than 1 % by weight, it must be declared (3) If the biuret content is less than 0,2 %, the words “low in biuret” may be added	The fertilisers must not contain Thomas slag, aluminium calcium phosphate, calcined phosphates, partially solubilised phosphates or rock phosphates (1) If the water-soluble P_2O_5 is less than 2 %, only solubility 2 shall be declared (2) If the water-soluble P_2O_5 is at least 2 %, solubility 3 and the water-soluble P_2O_5 content shall be declared	(1) Water-soluble potassium oxide (2) The words “low in chloride” may be used only where the Cl content does not exceed 2 % (3) The chloride content may be declared

C.2.4	Type designation:	NPK-fertiliser suspension containing urea formaldehyde
	Data on method of production:	Product in liquid form, in which the nutrients are derived from substances both in solution and in suspension in water, without addition of organic nutrients of animal or vegetable origin and containing urea formaldehyde

	Minimum content of nutrients (percentage by weight) and other requirements:	— Total 20 % (N +P_2O_5 +K_2O) — For each of the nutrients: — 5 % N, at least 25 % of the declared content of total nitrogen must derive from nitrogen form (5) At least 3/5 of the declared nitrogen content (5) must be soluble in hot water — 4 % P_2O_5 — 4 % K_2O Maximum biuret content: (ureic N + urea formaldehyde N) × 0,026

Forms, solubilities and nutrient content to be declared as specified in columns 4, 5 and 6 — Particle size			Data for identification of the fertilisers — Other requirements		
N	P_2O_5	K_2O	N	P_2O_5	K_2O
1	2	3	4	5	6
(1) Total nitrogen (2) Nitric nitrogen (3) Ammoniacal nitrogen (4) Ureic nitrogen (5) Nitrogen from urea formaldehyde	(1) Water-soluble P_2O_5 (2) P_2O_5 soluble in neutral ammonium citrate (3) P_2O_5 soluble in neutral ammonium citrate and in water	Water-soluble K_2O	(1) Total nitrogen (2) If any of the forms of nitrogen (2), (3) and (4) amounts to not less than 1 % by weight, it must be declared (3) Nitrogen from urea formaldehyde (4) If the biuret content is less than 0,2 %, the words "low in biuret" may be added	The fertilisers must not contain Thomas slag, aluminium calcium phosphate, calcined phosphates, partially solubilised phosphates or rock phosphates (1) If the water-soluble P_2O_5 is less than 2 %, only solubility (2) shall be declared (2) If the water-soluble P_2O_5 is at least 2 %, solubility (3) and the water-soluble P_2O_5 content shall be declared	(1) Water-soluble potassium oxide (2) The words "low in chloride" may be used only where the Cl content does not exceed 2 % (3) The chloride content may be declared

C.2.5	Type designation:	NP-fertiliser solution
	Data on method of production:	Product obtained chemically and by dissolution in water, in a form stable at atmospheric pressure, without addition of organic nutrients of animal or vegetable origin
	Minimum content of nutrients (percentage by weight) and other requirements:	— Total: 18 %, (N + P_2O_5) — For each of the nutrients: 3 % N, 5 % P_2O_5 — Maximum biuret content: ureic N × 0,026

Forms, solubilities and nutrient content to be declared as specified in columns 4, 5 and 6 — Particle size			Data for identification of the fertilisers — Other requirements		
N	P_2O_5	K_2O	N	P_2O_5	K_2O
1	2	3	4	5	6
(1) Total nitrogen (2) Nitric nitrogen (3) Ammoniacal nitrogen (4) Ureic nitrogen	Water-soluble P_2O_5		(1) Total nitrogen (2) If any of the forms of nitrogen (2), (3) and (4) amounts to not less than 1 % by weight, it must be declared (3) If the biuret content is less than 0,2 %, the words "low in biuret" may be added	Water-soluble P_2O_5	

C.2.6	Type designation:	NP-fertiliser solution containing urea formaldehyde
	Data on method of production:	Product obtained chemically and by dissolution in water, in a form stable at atmospheric pressure, without addition of organic nutrients of animal or vegetable origin and containing urea formaldehyde
	Minimum content of nutrients (percentage by weight) and other requirements:	— Total 18 % (N +P_2O_5) — For each of the nutrients: — 5 % N, at least 25 % of the declared content of total nitrogen must derive from nitrogen form (5) — 5 % P_2O_5 Maximum biuret content: (ureic N + urea formaldehyde N) × 0,026

Forms, solubilities and nutrient content to be declared as specified in columns 4, 5 and 6 — Particle size			Data for identification of the fertilisers — Other requirements		
N	P_2O_5	K_2O	N	P_2O_5	K_2O
1	2	3	4	5	6
(1) Total nitrogen (2) Nitric nitrogen (3) Ammoniacal nitrogen (4) Ureic nitrogen (5) Nitrogen from urea formaldehyde	Water-soluble P_2O_5		(1) Total nitrogen (2) If any of the forms of nitrogen (2), (3) and (4) amounts to not less than 1 % by weight, it must be declared (3) Nitrogen from urea formaldehyde (4) If the biuret content is less than 0,2 %, the words "low in biuret" may be added	Water-soluble P_2O_5	

C.2.7	Type designation:	NP-fertiliser suspension
	Data on method of production:	Product in liquid form, in which the nutrients are derived from substances both in solution and in suspension in the water, without addition of organic nutrients of animal or vegetable origin
	Minimum content of nutrients (percentage by weight) and other requirements:	— Total: 18 %, (N + P_2O_5) — For each of the nutrients: 3 % N, 5 % P_2O_5 — Maximum biuret content: ureic N × 0,026

Forms, solubilities and nutrient content to be declared as specified in columns 4, 5 and 6 — Particle size			Data for identification of the fertilisers. Other requirements		
N	P_2O_5	K_2O	N	P_2O_5	K_2O
1	2	3	4	5	6
(1) Total nitrogen (2) Nitric nitrogen (3) Ammoniacal nitrogen (4) Ureic nitrogen	(1) Water-soluble P_2O_5 (2) P_2O_5 soluble in neutral ammonium citrate (3) P_2O_5 soluble in neutral ammonium citrate and water		(1) Total nitrogen (2) If any of the forms of nitrogen (2), (3) and (4) amounts to not less than 1 % by weight, it must be declared (3) If the biuret content is less than 0,2 %, the words “low in biuret” may be added	The fertilisers may not contain Thomas slag, aluminium calcium phosphate, calcined phosphates, partially solubilised phosphate or rock phosphates (1) If the water-soluble P_2O_5 is less than 2 % only solubility 2 shall be declared (2) If the water-soluble P_2O_5 is at least 2 %, solubility 3 will be declared and the water-soluble P_2O_5 content must be stated	

C.2.8	Type designation:	NP-fertiliser suspension containing urea formaldehyde
	Data on method of production:	Product in liquid form, in which the nutrients are derived from substances both in solution and in suspension in water, without addition of organic nutrients of animal or vegetable origin and containing urea formaldehyde
	Minimum content of nutrients (percentage by weight) and other requirements:	— Total 18 % (N +P_2O_5) — For each of the nutrients: — 5 % N, at least 25 % of the declared content of total nitrogen must derive from nitrogen form (5) At least 3/5 of the declared nitrogen content (5) must be soluble in hot water — 5 % P_2O_5 Maximum biuret content: (ureic N + urea formaldehyde N) × 0,026

Forms, solubilities and nutrient content to be declared as specified in columns 4, 5 and 6 — Particle size			Data for identification of the fertilisers — Other requirements		
N	P_2O_5	K_2O	N	P_2O_5	K_2O
1	2	3	4	5	6
(1) Total nitrogen (2) Nitric nitrogen (3) Ammoniacal nitrogen (4) Ureic nitrogen (5) Nitrogen from urea formaldehyde	(1) Water-soluble P_2O_5 (2) P_2O_5 soluble in neutral ammonium citrate (3) P_2O_5 soluble in neutral ammonium citrate and in water		(1) Total nitrogen (2) If any of the forms of nitrogen (2), (3) (4) amounts to not less than 1 % by weight, it must be declared (3) Nitrogen from urea formaldehyde (4) If the biuret content is less than 0,2 %, the words "low in biuret" may be added	The fertilisers must not contain Thomas slag, aluminium calcium phosphate, calcined phosphates, partially solubilised phosphates or rock phosphates (1) If the water-soluble P_2O_5 is less than 2 %, only solubility (2) shall be declared (2) If the water-soluble P_2O_5 is at least 2 %, solubility (3) and the water-soluble P_2O_5 content shall be declared'	

(b) the following entries C.2.9 to C.2.14 are added:

'C.2.9	Type designation:	NK-fertiliser solution
	Data on method of production:	Product obtained chemically and by dissolution in water, in a form stable at atmospheric pressure, without addition of organic nutrients of animal or vegetable origin
	Minimum content of nutrients (percentage by weight) and other requirements:	— Total: 15 % (N + K_2O) — For each of the nutrients: 3 % N, 5 % K_2O — Maximum biuret content: ureic N × 0,026

Forms, solubilities and nutrient content to be declared as specified in columns 4, 5 and 6 — Particle size			Data for identification of the fertilisers — Other requirements		
N	P_2O_5	K_2O	N	P_2O_5	K_2O
1	2	3	4	5	6
(1) Total nitrogen (2) Nitric nitrogen (3) Ammoniacal nitrogen (4) Ureic nitrogen		Water-soluble K_2O	(1) Total nitrogen (2) If any of the forms of nitrogen (2), (3) and (4) amounts to not less than 1 % by weight, it must be declared (3) If the biuret content is less than 0,2 %, the words "low in biuret" may be added		(1) Water-soluble potassium oxide (2) The words "low in chloride" may be used only where the Cl content does not exceed 2 % (3) The chloride content may be declared

C.2.10	Type designation:	NK-fertiliser solution containing urea formaldehyde
	Data on method of production:	Product obtained chemically and by dissolution in water, in a form stable at atmospheric pressure, without addition of organic nutrients of animal or vegetable origin and containing urea formaldehyde
	Minimum content of nutrients (percentage by weight) and other requirements:	— Total 15 % ($N + K_2O$) — For each of the nutrients: — 5 % N, at least 25 % of the declared content of total nitrogen must derive from nitrogen form (5) — 5 % K_2O Maximum biuret content: (ureic N + urea formaldehyde N) × 0,026

Forms, solubilities and nutrient content to be declared as specified in columns 4, 5 and 6 — Particle size			Data for identification of the fertilisers — Other requirements		
N	P_2O_5	K_2O	N	P_2O_5	K_2O
1	2	3	4	5	6
(1) Total nitrogen (2) Nitric nitrogen (3) Ammoniacal nitrogen (4) Ureic nitrogen (5) Nitrogen from urea formaldehyde		Water-soluble K_2O	(1) Total nitrogen (2) If any of the forms of nitrogen (2), (3) and (4) amounts to not less than 1 % by weight, it must be declared (3) Nitrogen from urea formaldehyde (4) If the biuret content is less than 0,2 %, the words "low in biuret" may be added		(1) Water-soluble potassium oxide (2) The words "low in chloride" may be used only where the Cl content does not exceed 2 % (3) The chloride content may be declared

C.2.11	Type designation:	NK-fertiliser suspension
	Data on method of production:	Product in liquid form, in which the nutrients are derived from substances both in solution and in suspension in the water, without addition of organic nutrients of animal or vegetable origin
	Minimum content of nutrients (percentage by weight) and other requirements:	— Total: 18 % ($N + K_2O$) — For each of the nutrients: 3 % N, 5 % K_2O — Maximum biuret content: ureic N × 0,026

Forms, solubilities and nutrient content to be declared as specified in columns 4, 5 and 6 — Particle size			Data for identification of the fertilisers — Other requirements		
N	P_2O_5	K_2O	N	P_2O_5	K_2O
1	2	3	4	5	6
(1) Total nitrogen (2) Nitric nitrogen (3) Ammoniacal nitrogen (4) Ureic nitrogen		Water-soluble K_2O	(1) Total nitrogen (2) If any of the forms of nitrogen (2), (3) and (4) amounts to not less than 1 % by weight, it must be declared (3) If the biuret content is less than 0,2 %, the words "low in biuret" may be added		(1) Water-soluble potassium oxide (2) The words "low in chloride" may be used only where the Cl content does not exceed 2 % (3) The chloride content may be declared

C.2.12	Type designation:	NK-fertiliser suspension containing urea formaldehyde
	Data on method of production:	Product in liquid form, in which the nutrients are derived from substances both in solution and in suspension in water, without addition of organic nutrients of animal or vegetable origin and containing urea formaldehyde
	Minimum content of nutrients (percentage by weight) and other requirements:	— Total 18 %(N +K_2O) — For each of the nutrients: — 5 % N, at least 25 % of the declared content of total nitrogen must derive from nitrogen form (5) At least 3/5 of the declared nitrogen content (5) must be soluble in hot water — 5 % K_2O Maximum biuret content: (ureic N + urea formaldehyde N) × 0,026

Forms, solubilities and nutrient content to be declared as specified in columns 4, 5 and 6 — Particle size			Data for identification of the fertilisers — Other requirements		
N	P_2O_5	K_2O	N	P_2O_5	K_2O
1	2	3	4	5	6
(1) Total nitrogen (2) Nitric nitrogen (3) Ammoniacal nitrogen (4) Ureic nitrogen (5) Nitrogen from urea formaldehyde		Water-soluble K_2O	(1) Total nitrogen (2) If any of the forms of nitrogen (2), (3) and (4) amounts to not less than 1 % by weight, it must be declared (3) Nitrogen from urea formaldehyde (4) If the biuret content is less than 0,2 %, the words "low in biuret" may be added		(1) Water-soluble potassium oxide (2) The words "low in chloride" may be used only where the Cl content does not exceed 2 % (3) The chloride content may be declared

C.2.13	Type designation:	PK-fertiliser solution
	Data on method of production:	Product obtained chemically and by dissolution in water, without addition of organic nutrients of animal or vegetable origin
	Minimum content of nutrients (percentage by weight) and other requirements:	— Total: 18 % (P_2O_5 + K_2O) — For each of the nutrients: 5 % P_2O_5, 5 % K_2O

Forms, solubilities and nutrient content to be declared as specified in columns 4, 5 and 6 — Particle size			Data for identification of the fertilisers — Other requirements		
N	P_2O_5	K_2O	N	P_2O_5	K_2O
1	2	3	4	5	6
	Water-soluble P_2O_5	Water-soluble K_2O		Water-soluble P_2O_5	(1) Water-soluble potassium oxide (2) The words “low in chloride” may be used only where the Cl content does not exceed 2 % (3) The chloride content may be declared

C.2.14	Type designation:	PK-fertiliser suspension
	Data on method of production:	Product in liquid form, in which the nutrients are derived from substances both in solution and in suspension in water, without addition of organic nutrients of animal or vegetable origin
	Minimum content of nutrients (percentage by weight) and other requirements:	— Total: 18 % (P_2O_5 + K_2O) — For each of the nutrients: 5 % P_2O_5, 5 % K_2O

Forms, solubilities and nutrient content to be declared as specified in columns 4, 5 and 6 — Particle size			Data for identification of the fertilisers — Other requirements		
N	P_2O_5	K_2O	N	P_2O_5	K_2O
1	2	3	4	5	6
	(1) Water-soluble P_2O_5 (2) P_2O_5 soluble in neutral ammonium citrate (3) P_2O_5 soluble in neutral ammonium citrate and water	Water-soluble K_2O		The fertilisers must not contain Thomas slag, aluminium calcium phosphate, calcined phosphates, partially solubilised phosphates or rock phosphates (1) If the water-soluble P_2O_5 is less than 2 % only solubility 2 will be declared (2) If the water-soluble P_2O_5 is at least 2 % solubility 3 and the water-soluble P_2O_5 content shall be declared	(1) Water-soluble potassium oxide (2) The words “low in chloride” may be used only where the Cl content does not exceed 2 % (3) The chloride content may be declared’

(3) in Table F.1, the following entry 4 is added:

‘4	3,4-dimethyl-1H-pyrazole phosphate (DMPP) EC No 424-640-9	Minimum: 0,8 Maximum: 1,6’		

(4) in Table F.2, the following entry 3 is added:

‘3	Reaction mixture of N-butyl-thiophosphoric-triamide (NBPT) and N-propyl- thiosphosphoric- triamide (NPPT) (ratio 3:1 ([1])) EC No 700-457-2	Minimum: 0,02 Maximum: 0,3’		

([1]) Tolerance on the portion of N-propyl-thiophosphoric-triamide (NPPT): 20 %.

ANNEX II

In Annex IV, Section B, to Regulation (EC) No 2003/2003, the following methods are added:

'Method 12.6

Determination of DMPP

EN 16328: Fertilizers — Determination of 3, 4-dimethyl-1H-pyrazole phosphate (DMPP) — Method using high-performance liquid chromatography (HPLC)

This method of analysis has been ring-tested.

Method 12.7

Determination of NBPT/NPPT

EN 16651: Fertilizers — Determination of N-(n-Butyl)thiophosphoric acid triamide (NBPT) and N-(n-Propyl)thiophosphoric acid triamide (NPPT) — Method using high-performance liquid chromatography (HPLC)

This method of analysis has been ring-tested.'

COMMISSION IMPLEMENTING REGULATION (EU) No 1258/2014

of 24 November 2014

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 Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 ([1]),

Having regard to Commission Implementing Regulation (EU) No 543/2011 of 7 June 2011 laying down detailed rules for the application of Council Regulation (EC) No 1234/2007 in respect of the fruit and vegetables and processed fruit and vegetables sectors ([2]), and in particular Article 136(1) thereof,

Whereas:

(1) Implementing Regulation (EU) No 543/2011 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 XVI, Part A thereto.

(2) The standard import value is calculated each working day, in accordance with Article 136(1) of Implementing Regulation (EU) No 543/2011, taking into account variable daily data. Therefore this Regulation should enter into force on the day of its publication in the *Official Journal of the European Union*,

HAS ADOPTED THIS REGULATION:

Article 1

The standard import values referred to in Article 136 of Implementing Regulation (EU) No 543/2011 are fixed in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the day 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, 24 November 2014.

For the Commission,
On behalf of the President,
Jerzy PLEWA
Director-General for Agriculture and Rural Development

([1]) OJ L 347, 20.12.2013, p. 671.
([2]) OJ L 157, 15.6.2011, 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	66,6
	IL	45,2
	MA	77,1
	ZZ	63,0
0707 00 05	AL	91,9
	JO	203,0
	TR	135,5
	ZZ	143,5
0709 93 10	MA	35,1
	TR	125,7
	ZZ	80,4
0805 20 10	MA	76,2
	ZZ	76,2
0805 20 30, 0805 20 50, 0805 20 70, 0805 20 90	CN	59,1
	PE	74,4
	TR	72,6
	ZZ	68,7
0805 50 10	TR	77,9
	ZZ	77,9
0808 10 80	AU	203,7
	BR	51,7
	CA	133,4
	CL	82,8
	NZ	96,9
	US	93,2
	ZA	147,3
	ZZ	115,6
0808 30 90	CN	82,7
	US	201,1
	ZZ	141,9

(1) Nomenclature of countries laid down by Commission Regulation (EU) No 1106/2012 of 27 November 2012 implementing Regulation (EC) No 471/2009 of the European Parliament and of the Council on Community statistics relating to external trade with non-member countries, as regards the update of the nomenclature of countries and territories (OJ L 328, 28.11.2012, p. 7). Code 'ZZ' stands for 'of other origin'.

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