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II

(Non-legislative acts)

# REGULATIONS

# **COMMISSION REGULATION (EU) 2022/1264**

of 20 July 2022

amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for fludioxonil in or on certain products

(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 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (1), and in particular Article 14(1)(a) thereof,

Whereas:

- (1) For fludioxonil maximum residue levels ('MRLs') were set in Annex II to Regulation (EC) No 396/2005.
- (2) An application for import tolerances pursuant to Article 6(2) and (4) of Regulation (EC) No 396/2005 for fludioxonil used in the United States on sugar beet roots, and in Guatemala, Honduras and Colombia on bananas was submitted. The applicant states that the authorised uses of that substance on such crops in those countries lead to residues exceeding the MRLs provided for in Regulation (EC) No 396/2005 and that higher MRLs are necessary to avoid trade barriers for the importation of those crops.
- (3) In accordance with Article 8 of Regulation (EC) No 396/2005, the application was evaluated by the Member State concerned and the evaluation report was forwarded to the Commission.
- (4) The European Food Safety Authority ('the Authority') assessed the application and the evaluation report, examining in particular the risks to consumers and, where relevant, to animals, and gave a reasoned opinion on the proposed MRLs (2). It forwarded that opinion to the applicant, the Commission and the Member States and made it available to the public.

<sup>(1)</sup> OJ L 70, 16.3.2005, p. 1.

<sup>(2)</sup> Reasoned opinion on the setting of import tolerances for fludioxonil in sugar beet roots and bananas. EFSA Journal 2021;19 (11):6919. EFSA scientific reports available online: http://www.efsa.europa.eu.

- (5) The Authority concluded that all requirements with respect to completeness of data submission were met and that the modifications to the MRLs requested by the applicant were acceptable with regard to consumer safety on the basis of a consumer exposure assessment for 27 specific European consumer groups. In so concluding, the Authority took into account the most recent information on the toxicological properties of the substance. The lifetime exposure to the substance via consumption of all food products that may contain it showed that there is no risk that the acceptable daily intake is exceeded. Moreover, the Authority concluded that the establishment of an acute reference dose is not necessary on the basis of the low acute toxicity profile of the active substance.
- (6) Based on the reasoned opinion of the Authority and taking into account the factors relevant to the matter under consideration, the proposed modifications to the MRLs fulfil the requirements of Article 14(2) of Regulation (EC) No 396/2005.
- (7) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

#### Article 1

Annex II to Regulation (EC) No 396/2005 is amended in accordance with the Annex to this Regulation.

#### Article 2

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, 20 July 2022.

For the Commission
The President
Ursula VON DER LEYEN

# ANNEX

In Annex II to Regulation (EC) No 396/2005, the column for fludioxonil is replaced by the following:

# 'Pesticide residues and maximum residue levels (mg/kg)

Code number	Groups and examples of individual products to which the MRLs apply (a)	Fludioxonil (R) (F)
0100000	FRUITS, FRESH or FROZEN; TREE NUTS	
0110000	Citrus fruits	10
0110010	Grapefruits	
0110020	Oranges	
0110030	Lemons	
0110040	Limes	
0110050	Mandarins	
0110990	Others (2)	
0120000	Tree nuts	
0120010	Almonds	0,01 (*)
0120020	Brazil nuts	0,01 (*)
0120030	Cashew nuts	0,01 (*)
0120040	Chestnuts	0,01 (*)
0120050	Coconuts	0,01 (*)
0120060	Hazelnuts/cobnuts	0,01 (*)
0120070	Macadamias	0,01 (*)
0120080	Pecans	0,01 (*)
0120090	Pine nut kernels	0,01 (*)
0120100	Pistachios	0,2
0120110	Walnuts	0,01 (*)
0120990	Others (2)	0,01 (*)
0130000	Pome fruits	5
0130010	Apples	
0130020	Pears	
0130030	Quinces	
0130040	Medlars	
0130050	Loquats/Japanese medlars	
0130990	Others (2)	
0140000	Stone fruits	



0140010	Apricots	5
0140020	Cherries (sweet)	5
0140030	Peaches	10
0140040	Plums	5
0140990	Others (2)	0,01 (*)
0150000	Berries and small fruits	, ,
0151000	(a) grapes	
0151010	Table grapes	5
0151020	Wine grapes	4
0152000	(b) strawberries	4
0153000	(c) cane fruits	5
0153010	Blackberries	
0153020	Dewberries	
0153030	Raspberries (red and yellow)	
0153990	Others (2)	
0154000	(d) other small fruits and berries	
0154010	Blueberries	4
0154020	Cranberries	4
0154030	Currants (black, red and white)	4
0154040	Gooseberries (green, red and yellow)	4
0154050	Rose hips	0,01 (*)
0154060	Mulberries (black and white)	0,01 (*)
0154070	Azaroles/Mediterranean medlars	0,01 (*)
0154080	Elderberries	4
0154990	Others (2)	0,01 (*)
0160000	Miscellaneous fruitswith	
0161000	(a) edible peel	0,01 (*)
0161010	Dates	
0161020	Figs	
0161030	Table olives	
0161040	Kumquats	
0161050	Carambolas	
0161060	Kaki/Japanese persimmons	
0161070	Jambuls/jambolans	
0161990	Others (2)	
0162000	(b) inedible peel, small	
0162010	Kiwi fruits (green, red, yellow)	15
0162020	Litchis/lychees	0,01 (*)

0162030	Passionfruits/maracujas	0,01 (*)
0162040	Prickly pears/cactus fruits	0,01 (*)
0162050	Star apples/cainitos	0,01 (*)
0162060	American persimmons/Virginia kaki	0,01 (*)
0162990	Others (2)	0,01 (*)
0163000	(c) inedible peel, large	
0163010	Avocados	1,5
0163020	Bananas	2
0163030	Mangoes	2
0163040	Papayas	0,01 (*)
0163050	Granate apples/pomegranates	3
0163060	Cherimoyas	0,01 (*)
0163070	Guavas	0,5
0163080	Pineapples	7
0163090	Breadfruits	0,01 (*)
0163100	Durians	0,01 (*)
0163110	Soursops/guanabanas	0,01 (*)
0163990	Others (2)	0,01 (*)
0200000	VEGETABLES, FRESH or FROZEN	
0210000	Root and tuber vegetables	
0211000	(a) potatoes	5
0212000	(b) tropical root and tuber vegetables	
0212010	Cassava roots/manioc	0,01 (*)
0212020	Sweet potatoes	10
0212030	Yams	10
0212040	Arrowroots	0,01 (*)
0212990	Others (2)	0,01 (*)
0213000	(c) other root and tuber vegetables except sugar beets	
0213010	Beetroots	1
0213020	Carrots	1
0213030	Celeriacs/turnip rooted celeries	0,2
0213040	Horseradishes	1
0213050	Jerusalem artichokes	0,01 (*)
0213060	Parsnips	1
0213070	Parsley roots/Hamburg roots parsley	1
0213080	Radishes	0,3

0213100	Swedes/rutabagas	0,01 (*)
0213110	Turnips	0,01 (*)
0213990	Others (2)	0,01 (*)
0220000	Bulb vegetables	
0220010	Garlic	0,5
0220020	Onions	0,5
0220030	Shallots	0,5
0220040	Spring onions/green onions and Welsh onions	5
0220990	Others (2)	0,5
0230000	Fruiting vegetables	
0231000	(a) Solanaceae and Malvaceae	
0231010	Tomatoes	3
0231020	Sweet peppers/bell peppers	1
0231030	Aubergines/eggplants	0,4
0231040	Okra/lady's fingers	0,01 (*)
0231990	Others (2)	0,01 (*)
0232000	(b) cucurbits with edible peel	0,4
0232010	Cucumbers	
0232020	Gherkins	
0232030	Courgettes	
0232990	Others (2)	
0233000	(c) cucurbits with inedible peel	0,3
0233010	Melons	
0233020	Pumpkins	
0233030	Watermelons	
0233990	Others (2)	
0234000	(d) sweet corn	0,01 (*)
0239000	(e) other fruiting vegetables	0,01 (*)
0240000	Brassica vegetables(excluding brassica roots and brassica baby leaf crops)	
0241000	(a) flowering brassica	
0241010	Broccoli	0,7
0241020	Cauliflowers	0,01 (*)
0241990	Others (2)	0,01 (*)
0242000	(b) head brassica	
0242010	Brussels sprouts	0,01 (*)
0242020	Head cabbages	2
0242990	Others (2)	0,01 (*)

0243000	(c) leafy brassica	
0243010	Chinese cabbages/pe-tsai	10
0243020	Kales	0,01 (*)
0243990	Others (2)	0,01 (*)
0244000	(d) kohlrabies	0,01 (*)
0250000	Leaf vegetables, herbs and edible flowers	
0251000	(a) lettuces and salad plants	
0251010	Lamb's lettuces/corn salads	20
0251020	Lettuces	40
0251030	Escaroles/broad-leaved endives	20
0251040	Cresses and other sprouts and shoots	20
0251050	Land cresses	20
0251060	Roman rocket/rucola	20
0251070	Red mustards	20
0251080	Baby leaf crops (including brassica species)	20
0251990	Others (2)	20
0252000	(b) spinaches and similar leaves	
0252010	Spinaches	30
0252020	Purslanes	20
0252030	Chards/beet leaves	20
0252990	Others (2)	20
0253000	(c) grape leaves and similar species	0,01 (*)
0254000	(d) watercresses	10
0255000	(e) witloofs/Belgian endives	0,02
0256000	(f) herbs and edible flowers	20
0256010	Chervil	
0256020	Chives	
0256030	Celery leaves	
0256040	Parsley	
0256050	Sage	
0256060	Rosemary	
0256070	Thyme	
0256080	Basil and edible flowers	
0256090	Laurel/bay leaves	
0256100	Tarragon	
0256990	Others (2)	
0260000	Legume vegetables	



0260010	Beans (with pods)	1
0260020	Beans (without pods)	0,4
0260030	Peas (with pods)	1
0260040	Peas (without pods)	0,3
0260050	Lentils	0,05
0260990	Others (2)	0,01 (*)
0270000	Stem vegetables	
0270010	Asparagus	0,01 (*)
0270020	Cardoons	0,01 (*)
0270030	Celeries	1,5
0270040	Florence fennels	1,5
0270050	Globe artichokes	0,01 (*)
0270060	Leeks	0,01 (*)
0270070	Rhubarbs	0,7
0270080	Bamboo shoots	0,01 (*)
0270090	Palm hearts	0,01 (*)
0270990	Others (2)	0,01 (*)
0280000	Fungi, mosses and lichens	0,01 (*)
0280010	Cultivated fungi	
0280020	Wild fungi	
0280990	Mosses and lichens	
0290000	Algae and prokaryotes organisms	0,01 (*)
0300000	PULSES	
0300010	Beans	0,5
0300020	Lentils	0,4
0300030	Peas	0,4
0300040	Lupins/lupini beans	0,4
0300990	Others (2)	0,4
0400000	OILSEEDS AND OIL FRUITS	
0401000	Oilseeds	
0401010	Linseeds	0,3
0401020	Peanuts/groundnuts	0,01 (*)
0401030	Poppy seeds	0,01 (*)
0401040	Sesame seeds	0,3
0401050	Sunflower seeds	0,01 (*)
0401060	Rapeseeds/canola seeds	0,3

	T	
0401070	Soyabeans	0,2
0401080	Mustard seeds	0,3
0401090	Cotton seeds	0,01 (*)
0401100	Pumpkin seeds	0,01 (*)
0401110	Safflower seeds	0,01 (*)
0401120	Borage seeds	0,3
0401130	Gold of pleasure seeds	0,3
0401140	Hemp seeds	0,3
0401150	Castor beans	0,01 (*)
0401990	Others (2)	0,01 (*)
0402000	Oil fruits	0,01 (*)
0402010	Olives for oil production	
0402020	Oil palms kernels	
0402030	Oil palms fruits	
0402040	Kapok	
0402990	Others (2)	
0500000	CEREALS	0,01 (*)
0500010	Barley	
0500020	Buckwheat and other pseudocereals	
0500030	Maize/corn	
0500040	Common millet/proso millet	
0500050	Oat	
0500060	Rice	
0500070	Rye	
0500080	Sorghum	
0500090	Wheat	
0500990	Others (2)	
0600000	TEAS, COFFEE, HERBAL INFUSIONS, COCOA AND CAROBS	
0610000	Teas	0,05 (*)
0620000	Coffee beans	0,05 (*)
0630000	Herbal infusions from	
0631000	(a) flowers	0,05 (*)
0631010	Chamomile	
0631020	Hibiscus/roselle	
0631030	Rose	
0631040	Jasmine	
0631050	Lime/linden	

0631990	Others (2)	
0632000	(b) leaves and herbs	0,05 (*)
0632010	Strawberry	
0632020	Rooibos	
0632030	Mate/maté	
0632990	Others (2)	
0633000	(c) roots	
0633010	Valerian	1
0633020	Ginseng	4
0633990	Others (2)	1
0639000	(d) any other parts of the plant	0,05 (*)
0640000	Cocoa beans	0,05 (*)
0650000	Carobs/Saint John's breads	0,05 (*)
0700000	HOPS	0,05 (*)
0800000	SPICES	
0810000	Seed spices	0,05 (*)
0810010	Anise/aniseed	
0810020	Black caraway/black cumin	
0810030	Celery	
0810040	Coriander	
0810050	Cumin	
0810060	Dill	
0810070	Fennel	
0810080	Fenugreek	
0810090	Nutmeg	
0810990	Others (2)	
0820000	Fruit spices	0,05 (*)
0820010	Allspice/pimento	
0820020	Sichuan pepper	
0820030	Caraway	
0820040	Cardamom	
0820050	Juniper berry	
0820060	Peppercorn (black, green and white)	
0820070	Vanilla	
0820080	Tamarind	
0820990	Others (2)	
0830000	Bark spices	0,05 (*)



0830010	Cinnamon	
0830990	Others (2)	
0840000	Root and rhizome spices	
0840010	Liquorice	1
0840020	Ginger (10)	
0840030	Turmeric/curcuma	1
0840040	Horseradish (11)	
0840990	Others (2)	1
0850000	Bud spices	0,05 (*
0850010	Cloves	
0850020	Capers	
0850990	Others (2)	
0860000	Flower pistil spices	0,05 (*
0860010	Saffron	
0860990	Others (2)	
0870000	Aril spices	0,05 (*
0870010	Mace	
0870990	Others (2)	
0900000	SUGAR PLANTS	
0900010	Sugar beet roots	4
0900020	Sugar canes	0,01 (*)
0900030	Chicory roots	0,01 (*
0900990	Others (2)	0,01 (*
1000000	PRODUCTS OF ANIMAL ORIGIN -TERRESTRIAL ANIMALS	
1010000	Commodities from	
1011000	(a) swine	
1011010	Muscle	0,02
1011020	Fat	0,02
1011030	Liver	0,1
1011040	Kidney	0,1
1011050	Edible offals (other than liver and kidney)	0,1
1011990	Others (2)	0,02
1012000	(b) bovine	
1012010	Muscle	0,02
1012020	Fat	0,02
1012030	Liver	0,1
	Kidney	0,1

1012050	Edible offals (other than liver and kidney)	0,1
1012990	Others (2)	0,02
1013000	(c) sheep	
1013010	Muscle	0,02
1013020	Fat	0,02
1013030	Liver	0,1
1013040	Kidney	0,1
1013050	Edible offals (other than liver and kidney)	0,1
1013990	Others (2)	0,02
1014000	(d) goat	
1014010	Muscle	0,02
1014020	Fat	0,02
1014030	Liver	0,1
1014040	Kidney	0,1
1014050	Edible offals (other than liver and kidney)	0,1
1014990	Others (2)	0,02
1015000	(e) equine	
1015010	Muscle	0,02
1015020	Fat	0,02
1015030	Liver	0,1
1015040	Kidney	0,1
1015050	Edible offals (other than liver and kidney)	0,1
1015990	Others (2)	0,02
1016000	(f) poultry	
1016010	Muscle	0,01 (*)
1016020	Fat	0,01 (*)
1016030	Liver	0,1
1016040	Kidney	0,1
1016050	Edible offals (other than liver and kidney)	0,1
1016990	Others (2)	0,01 (*)
1017000	(g) other farmed terrestrial animals	
1017010	Muscle	0,02
1017020	Fat	0,02
1017030	Liver	0,1
1017040	Kidney	0,1
1017050	Edible offals (other than liver and kidney)	0,1
1017990	Others (2)	0,02

1020000	Milk	0,04
	· ·	0,04
1020010	Cattle	
1020020	Sheep	
1020030	Goat	
1020040	Horse	
1020990	Others (2)	
1030000	Birds eggs	0,02
1030010	Chicken	
1030020	Duck	
1030030	Geese	
1030040	Quail	
1030990	Others (2)	
1040000	Honey and other apiculture products (7)	0,05 (*)
1050000	Amphibians and Reptiles	0,01 (*)
1060000	Terrestrial invertebrate animals	0,01 (*)
1070000	Wild terrestrial vertebrate animals	0,02
1100000	PRODUCTS OF ANIMAL ORIGIN - FISH, FISHPRODUCTS AND ANY OTHER MARINE AND FRESHWATER FOOD PRODUCTS (8)	
1200000	PRODUCTS OR PART OF PRODUCTS EXCLUSIVELY USED FOR ANIMAL FEED PRODUCTION (8)	
1300000	PROCESSED FOOD PRODUCTS (9)	

# Fludioxonil (R) (F)

- (R) The residue definition differs for the following combinations pesticide-code number: Fludioxonil code 1000000 except 1040000: sum of fludioxonil and its metabolites oxidized to metabolite 2,2-difluoro-benzo[1,3]dioxole-4 carboxylic acid, expressed as fludioxonil
- (F) Fat soluble'

<sup>(\*)</sup> Indicates lower limit of analytical determination
(\*) For the complete list of products of plant and animal origin to which MRL's apply, reference should be made to Annex I

### **COMMISSION IMPLEMENTING REGULATION (EU) 2022/1265**

#### of 20 July 2022

# establishing measures to prevent the introduction into and the spread within the Union territory of Rose Rosette Virus

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2016/2031 of the European Parliament and of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) No 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC (¹), and in particular Article 30(1),

#### Whereas:

- (1) Rose Rosette virus ('the specified pest') and its vector *Phyllocoptes fructiphilus* are currently not listed as Union quarantine pests in Annex II, nor as Union regulated non-quarantine pests in Annex IV to Commission Implementing Regulation (EU) 2019/2072 (2). The specified pest and its vector are not known to be present in the Union territory.
- (2) A pest risk analysis carried out by the European and Mediterranean Plant Protection Organization (EPPO) (3) in 2018 has demonstrated that the specified pest and its damaging effects could be of significant plant health concern to the Union territory, in particular for the production of all types of roses.
- (3) Because of the significant plant health concern posed by the specified pest to the Union territory, Commission Implementing Decision (EU) 2019/1739 (4) was adopted, laying down requirements for the introduction into the Union of plants, other than seeds, of *Rosa* spp. (4 the specified plants) originating in third countries, where the specified pest is known to occur (Canada, India and the United States), as well as for official checks to be conducted at their introduction into the Union. That Implementing Decision provides for a prohibition for the introduction of the specified pest in the Union territory, for an immediate submission of information on the suspected presence of the specified pest and of its specified vector in the Union and for rules for surveys for its presence in the Union territory.
- (4) Since the adoption of that Implementing Decision, no interceptions of infected specified plants, during their introduction into, or movement within, the Union territory, have been reported. However, the specified pest has continued to spread in Canada, India and the United States.
- (5) The conclusions of the EPPO's analysis remain valid today. That analysis indicated that the likelihood of entry and establishment of the specified pest, of the magnitude of its spread and impact into the Union, and of the phytosanitary risk for the Union territory is considered high.
- (6) Moreover, the plant health concerns indicated in the EPPO's analysis have increased since the adoption of Implementing Decision (EU) 2019/1739, because the specified plants are imported into the Union in increasingly high volumes from third countries where the presence of the specified pest is expanding.

<sup>(1)</sup> OJ L 317, 23.11.2016, p. 4.

<sup>(\*)</sup> Commission Implementing Regulation (EU) 2019/2072 of 28 November 2019 establishing uniform conditions for the implementation of Regulation (EU) 2016/2031 of the European Parliament and the Council, as regards protective measures against pests of plants, and repealing Commission Regulation (EC) No 690/2008 and amending Commission Implementing Regulation (EU) 2018/2019 (OJ L 319, 10.12.2019, p. 1).

<sup>(3)</sup> EPPO (2018) Pest risk analysis for Rose rosette virus and its vector Phyllocoptes fructiphilus. EPPO, Paris. Available at https://gd.eppo.int/taxon/RRV000/documents

<sup>(\*)</sup> Commission Implementing Decision (EU) 2019/1739 of 16 October 2019 establishing emergency measures to prevent the introduction into and the spread within the Union of Rose Rosette Virus (OJ L 265, 18.10.2019, p. 12).

- (7) The Commission concludes that the specified pest fulfils the criteria set out in Subsection 2 of Section 3 of Annex I to Regulation (EU) 2016/2031.
- (8) On the basis of those facts, it is estimated that there is an imminent danger for the entry into, and the spread within, the Union territory of the specified pest, unless the measures provided for in Implementing Decision (EU) 2019/1739, which apply until 31 July 2022 and have proven effective in preventing the entry of the specified pest into the Union territory, are maintained.
- (9) Therefore it is appropriate to provide for those measures in this Regulation which should apply from 1 August 2022 to ensure continued protection of the Union territory from the specified pest.
- (10) This Regulation should apply until 31 July 2024. Such application period is necessary for a full risk assessment in order to determine the status of the specified pest.
- (11) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

#### Article 1

#### **Definitions**

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

- (a) 'specified pest' means Rose Rosette Virus;
- (b) 'specified plants' means plants, other than seeds, of Rosa spp. originating in Canada, India or the United States;
- (c) 'specified vector' means Phyllocoptes fructiphilus.

### Article 2

# Prohibition concerning the specified pest

The specified pest shall not be introduced into, moved, held, multiplied or released in the Union territory.

#### Article 3

# Information on the suspected presence of the specified pest or of its specified vector

Member States shall ensure that any person in the Union territory in possession of plants which may be infected with the specified pest or its specified vector, is immediately informed of the presence or the suspected presence of the specified pest or of its specified vector, of the possible consequences and risks, and of the respective measures to be taken.

#### Article 4

# Surveys

The competent authorities shall conduct annual surveys for the presence of the specified pest and the specified vector on host plants in their territory.

Those surveys shall include sampling and testing, and shall be based on sound scientific and technical principles with regard to the possibility to detect the specified pest and the specified vector.

By 30 April of each year, Member States shall notify to the Commission and the other Member States the results of the surveys carried out in the previous calendar year.

#### Article 5

# Requirements for the introduction into the Union territory of the specified plants

- 1. The specified plants shall only be introduced into the Union territory if they are accompanied by a phytosanitary certificate which includes, under the heading 'Additional declaration', an official statement containing one of the following declarations:
- (a) that the specified plants have been produced in an area free from the specified pest, registered and supervised by the National Plant Protection Organisation of the third country of origin, with the indication of the name of the area under the heading 'Place of origin';
- (b) in the case of specified plants for planting, that:
  - (i) they have been produced in a place of production where neither symptoms of the specified pest nor of the specified vector have been observed during official inspections, since the start of the last growing season; and
  - (ii) they have been sampled and tested for the specified pest before introduction in the Union territory, and found, on the basis of those tests, to be free from it;
- (c) in the case of the specified plants, other than plants for planting, that:
  - (i) they have been produced in a place of production where neither symptoms of the specified pest nor of the specified vector have been observed during official inspections, since the start of the last growing season; and
  - (ii) they have been inspected and, in case of presence of the specified vector or symptoms of the specified pest, they have been sampled and tested before introduction in the Union territory, and found, on the basis of those tests, to be free from the specified pest;
- (d) in the case of specified plants in tissue culture, which do not originate in an area free from the specified pest, that they have been produced from mother plants tested and found free from the specified pest.
- 2. The specified plants shall only be introduced into the Union territory if they are handled, packaged and transported in a manner to prevent infestation by the specified vector.

# Article 6

#### Entry into force and application

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 1 August 2022 until 31 July 2024.

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

Done at Brussels, 20 July 2022.

For the Commission
The President
Ursula VON DER LEYEN

# **COMMISSION IMPLEMENTING REGULATION (EU) 2022/1266**

#### of 20 July 2022

concerning the authorisation of monosodium glutamate produced by fermentation with Corynebacterium glutamicum KCCM 80187 as a feed additive for all animal species

(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 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (1), and in particular Article 9(2) thereof,

#### Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation.
- (2) In accordance with Article 7(1) of Regulation (EC) No 1831/2003 an application was submitted for the authorisation of monosodium glutamate produced by fermentation with Corynebacterium glutamicum KCCM 80187. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) The application concerns the authorisation of monosodium glutamate as a feed additive for all animal species, to be classified in the category 'sensory additives' and in the functional group 'flavouring compounds'.
- (4) The applicant requested the additive to be authorised also for use in water for drinking. However, Regulation (EC) No 1831/2003 does not allow the authorisation of 'flavouring compounds' for use in water for drinking. Therefore, the use of monosodium glutamate produced by fermentation with *Corynebacterium glutamicum* KCCM 80187 in water for drinking should not be allowed.
- (5) The European Food Safety Authority ('the Authority') concluded in its opinion of 10 November 2021 (²) that, under the proposed conditions of use, monosodium glutamate produced by fermentation with *Corynebacterium glutamicum* KCCM 80187 does not have adverse effects on animal health, human health or the environment. The Authority concluded in the opinion that the additive is not toxic by inhalation, is not irritant to skin or eyes and is not a dermal sensitiser. The Authority further concluded, that monosodium glutamate is efficacious for contributing to the flavour of feed. The Authority also verified the report on the methods of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (6) The assessment of monosodium glutamate produced by fermentation with *Corynebacterium glutamicum KCCM* 80187 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that substance should be authorised as specified in the Annex to this Regulation.
- (7) Certain conditions should be provided for to allow better control. In particular, a recommended content should be indicated on the label of the feed additives. Where such content is exceeded, certain information should be indicated on the label of premixtures.
- (8) The fact that monosodium glutamate produced by fermentation with Corynebacterium glutamicum KCCM 80187 is not authorised for use as a flavouring in water for drinking, does not preclude its use in compound feed which is administered via water.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

<sup>(1)</sup> OJ L 268, 18.10.2003, p. 29.

<sup>(2)</sup> EFSA Journal 2021;19(12):6982.

# HAS ADOPTED THIS REGULATION:

# Article 1

The substance specified in the Annex, belonging to the additive category 'sensory additives' and to the functional group 'flavouring compounds', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

#### Article 2

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, 20 July 2022.

For the Commission The President Ursula VON DER LEYEN

21.7.2022

Identification number of the additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maxi- mum age	substan compl with a	Maximum content active acte feed moisture of 12 %	Other provisions	End of period of authorisation
2b621i	Monosodium glutamate	Additive composition:  Monosodium glutamate  Characterisation of the active substance: Monosodium L-glutamate produced by fermentation with Corynebacterium glutamicum KCCM 80187  Purity: ≥ 99 %  Chemical formula: C₅HଃNaNO₄ •H₂O  CAS number: 6106-04-03 Einecs number: 205-538-1  Analytical method (¹):  For the identification of monosodium L-glutamate in the feed additive:  — Food Chemical Codex 'Monosodium L-glutamate monograph'  For the quantification of monosodium L-glutamate in the feed additive:  — ion-exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS)	All animal species				<ol> <li>The additive shall be incorporated into the feed in the form of a premixture.</li> <li>In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</li> <li>On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance per kg of complete feeding stuff with a moisture content of 12 %: 25 mg.'</li> <li>The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixture where the use level on the label of the premixture would result in exceeding the level referred to in point 3.</li> </ol>	10.8.2032

For the quantification of monosodium L-glutamate in premixtures:  — ion-exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS), Commission Regulation (EC) No 152/2009 (Annex III, F) (²)					
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<sup>(1)</sup> Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports\_en

<sup>(2)</sup> Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed (OJ L 54, 26.2.2009, p. 1).

### COMMISSION IMPLEMENTING REGULATION (EU) 2022/1267

#### of 20 July 2022

specifying the procedures for the designation of Union testing facilities for the purposes of market surveillance and verification of product compliance in accordance with Regulation (EU) 2019/1020 of the European Parliament and of the Council

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011 (1), and in particular Article 21(9) thereof,

#### Whereas:

- (1) One of the objectives of Union testing facilities is to assist the national market surveillance authorities in their activities by contributing to enhancing laboratory capacity for specific categories of products or for specific risks related to a category of products. The procedures for the designation of Union testing facilities should ensure in particular that Union testing facilities are designated where there is a shortage of laboratory testing capacity.
- (2) In order to prevent a shortage of laboratory capacity, wide access to designation should be given. With a view to providing such access and in order to ensure transparency in the process leading to designation, it should be determined which public testing facilities of Member States are to be designated as Union testing facilities following calls for expression of interest.
- (3) The designation of Commission testing facilities as Union testing facilities should be done by means of direct appointment by the Commission.
- (4) Due to the high number of categories of products and of specific risks related to a category of products, the Union Product Compliance Network established under Article 29 of Regulation (EU) 2019/1020 should be consulted in order to ensure the correct prioritisation of such categories and specific risks.
- (5) The designation of Union testing facilities should be reviewed on a regular basis in order to verify that they ensure a consistently high level of products testing, and that they provide technical and scientific advice of high quality.
- (6) The measures provided for in this Regulation are in accordance with the opinion of the committee established by Article 43(1) of Regulation (EU) 2019/1020,

HAS ADOPTED THIS REGULATION:

#### Article 1

# Procedures for the designation of the Union testing facilities

- 1. Public testing facilities of Member States shall be designated as Union testing facilities following a call for expression of interest, setting out the conditions for their designation.
- 2. Commission testing facilities shall be designated as Union testing facilities following a direct appointment from the Commission, setting out the conditions for their designation.

- 3. Prior to designation, the Union Product Compliance Network established under Article 29 of Regulation (EU) 2019/1020 (the 'Network') shall be consulted on both of the following:
- (a) the specific categories of products and specific risks related to a category of products for which the Union testing facilities need to be designated;
- (b) the conditions for the designation of the Union testing facilities, to ensure a consistently high level of product testing and high quality of technical and scientific advice.

#### Article 2

# Review of the designation

- 1. The Commission, in consultation with the Network, shall review the designation of Union testing facilities on a regular basis in order to ascertain that Union testing facilities fulfil the conditions for their designation and the requirements set out in Articles 21(3), 21(5) and 21(6) of Regulation (EU) 2019/1020.
- 2. A time-limit for review of the designation of the Union testing facility shall be set out in the decision to designate the testing facility.
- 3. Where a Union testing facility fails to comply with the conditions for its designation and the requirements set out in Articles 21(3), 21(5) and 21(6) of Regulation (EU) 2019/1020, the Commission, after consultation with the Network, shall, where appropriate, withdraw the designation.

#### Article 3

#### **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, 20 July 2022.

For the Commission
The President
Ursula VON DER LEYEN

#### III

(Other acts)

# EUROPEAN ECONOMIC AREA

EFTA Surveillance Authority Decision No 051/22/COL

of 16 February 2022

on the Icelandic regional aid map 2022–2027 (Iceland) [2022/1268]

#### 1. SUMMARY

- (1) The EFTA Surveillance Authority (ESA') wishes to inform Iceland that, having assessed the Icelandic regional aid map 2022–2027, ESA finds it compliant with the principles set out in the Guidelines on regional State aid ('the RAG') (').
- (2) This decision represents ESA's assessment of the regional aid map under paragraph 190 of the RAG. The approved map constitutes an integral part of the RAG (²). It does not involve any State aid, and it does not constitute an authorisation to grant such aid.
- (3) ESA has based its decision on the following considerations.

#### 2. PROCEDURE

- (4) On 1 December 2021, ESA adopted its new RAG. The RAG set out conditions under which notifiable regional aid may be considered compatible with the functioning of the EEA Agreement (3). They also set out criteria for identifying the areas that fulfil the compatibility conditions under Article 61(3)(a) and Article 61(3)(c) of the EEA Agreement (4), the so-called 'a' and 'c' areas.
- (5) According to paragraph 150 of the RAG, the areas which EEA EFTA States wish to designate as 'a' or 'c' areas must be identified in a regional aid map.
- (6) Pursuant to paragraph 189 of the RAG, each EEA EFTA State should notify to ESA a single regional aid map applicable until 31 December 2027. The Icelandic authorities notified the Icelandic regional aid map 2022–2027 on 27 January 2022 (5).

<sup>(</sup>¹) EFTA Surveillance Authority Decision No 269/21/COL of 1 December 2021 introducing revised Guidelines on Regional State aid for 2022-2027 [2022/1047] (OJ L 173, 30.6.2022, p. 79).

<sup>(2)</sup> The RAG, paragraph 190.

<sup>(3)</sup> The RAG, paragraph 2.

<sup>(4)</sup> Ibid.

<sup>(5)</sup> The notification is filed as Document No 1265806. Its two Annexes are filed as Document Nos 1265808 and 1265810.

# 3. ELIGIBLE AREAS DESIGNATED BY THE ICELANDIC AUTHORITIES

- (7) A common classification of territorial units for statistics has been established in the EU. This classification is called NUTS. The NUTS classification operates with three hierarchical levels numbered from 1 to 3. NUTS 1 comprises the largest units, whereas NUTS 3 covers the smallest units (6).
- (8) As noted in footnote 30 to the RAG, statistical regions similar to the NUTS classification have been defined in the EEA EFTA States. Accordingly, while the Commission regional aid guidelines (7) refer to the NUTS classification, the RAG make use of the term statistical regions. The NUTS classification and the statistical regions in the EEA EFTA States are available on Eurostat's web-pages (8).
- (9) The whole of Iceland falls within one statistical region at level 2 (*Ísland*). At level 3, Iceland is further divided into two statistical regions. These are respectively the capital region (*Höfuðborgarsvæði*) and Iceland outside of the capital region (*Landsbyggð*) (9).
- (10) The areas designated in the Icelandic regional aid map 2022–2027 are those comprising the level 3-region of Landsbyggð (10).
- (11) Based on population data from 1 January 2018, the population density of Iceland is 3,48 inhabitants per km². Landsbyggð is significantly less densely populated than Höfuðborgarsvæði. The population densities in Landsbyggð and Höfuðborgarsvæði are respectively 1,27 and 225,87 inhabitants per km² based on the population data from 1 January 2018 (11).
- (12) Landsbyggð covers areas of 99 258 km². Based on the most recent data from Statistics Iceland (Hagstofan), the resident population was 132 264 inhabitants on 1 January 2021. This equates to a population density of 1,33 inhabitants per km² (1²).
- (13) The graphical illustration attached as Annex I to this decision depicts *Landsbyggð*. Annex II further contains a list of those smaller units that make up this level 3-region (13).

#### 4. ASSESSMENT

- (14) The regional aid coverage available for 2022–2027 is set out for each EEA EFTA State in Annex I to the RAG. The whole of Iceland is identified in Annex I as predefined 'c' areas.
- (15) The Icelandic authorities may use this allocation to designate 'c' areas in their regional aid map. The rules governing this designation are found in paragraphs 168 and 169 of the RAG.
- (16) According to paragraph 168 of the RAG, EEA EFTA States may designate as 'c' areas the predefined 'c' areas. Paragraph 169 additionally allows for a flexible approach where under other areas are included. Since the whole of Iceland is allocated in Annex I as predefined 'c' area, the Icelandic authorities could have designated the whole of Iceland as 'c' area in their regional aid map.
- (6) Regulation (EC) No 1059/2003 of the European Parliament and of the Council of 26 May 2003 on the establishment of a common classification of territorial units for statistics (NUTS) (OJ L 154, 21.6.2003, p. 1) as amended by Commission Delegated Regulation (EU) 2019/1755 of 8 August 2019 amending the Annexes to Regulation (EC) No 1059/2003 of the European Parliament and of the Council on the establishment of a common classification of territorial units for statistics (NUTS) (OJ L 270, 24.10.2019, p. 1).
- (7) Guidelines on regional State aid (OJ C 153, 29.4.2021, p. 1).
- (8) https://ec.europa.eu/eurostat/web/nuts/nuts-maps. This web-link was inserted, and last checked, on 8 February 2022.
- (9) Document No 1265806, p. 2.
- (10) Ibid.
- (11) Ibid.
- (12) Document No 1265806, p. 3 and 4.
- (13) The Annexes are based on Document Nos 1265808 and 1265810.

- (17) As set out in paragraph (9) above, Iceland falls within one statistical region at level 2 (*Ísland*). At level 3, Iceland is further divided into two statistical regions. These are respectively the capital region (*Höfuðborgarsvæði*) and Iceland outside of the capital region (*Landsbyggð*).
- (18) When designating the eligible areas in the Icelandic regional aid map 2022–2027, the Icelandic authorities have included the level 3-region of Landsbyggð and excluded the level 3-region of Höfuðborgarsvæði. Since the included level 3-region of Landsbyggð falls within those predefined 'c' areas set out in Annex I to the RAG, ESA finds that the designation of Landsbyggð as 'c' areas in the Icelandic regional aid map 2022–2027 is compliant with the RAG.
- (19) According to footnote 65 of the RAG, sparsely populated and very sparsely populated areas should be identified on the regional aid map. 'Very sparsely populated areas' are defined in paragraph 19(32) as 'statistical regions at level 2 with fewer than eight inhabitants per km² or parts of such statistical regions designated by the EEA EFTA State concerned in line with paragraph 169'. *Landsbyggð* therefore qualifies as very sparsely populated.

#### 5. AID INTENSITIES

- (20) Pursuant to paragraph 151 of the RAG, the regional aid map must specify the maximum aid intensities applicable in the eligible areas during the period of validity of the approved map.
- (21) The maximum aid intensities apply to regional investment aid. The maximum aid intensities allowed for such aid under the RAG, are set out in its Section 7.4.
- (22) Paragraph 182(1) of the RAG stipulates that the aid intensity for large enterprises must not exceed 20 % in sparsely populated areas. It further follows from paragraph 186 that the aid intensity may be increased by up to 20 percentage points for small enterprises or up to 10 percentage points for medium-sized enterprises. As specified in footnote 85 of the RAG, however, the increased aid intensities for small and medium-sized enterprises will not apply to aid awarded for large investment projects (14).
- (23) The Icelandic authorities have notified a maximum aid intensity for large enterprises of 20 %. This maximum intensity is increased by 20 percentage points for small enterprises and 10 percentage points for medium-sized enterprises. These increased aid intensities do, however, not apply to aid awarded for large investment projects (15).
- (24) The limits in aid intensities defined by the Icelandic authorities, as described in paragraph (23), are in line with the provisions described in paragraph (22). They are therefore compliant with the RAG.

#### 6. DURATION AND REVIEW

- (25) In accordance with paragraph 189 of the RAG, the Icelandic authorities have notified a single regional aid map applicable to 31 December 2027.
- (26) It follows from paragraph 194 of the RAG that a mid-term review of regional aid maps will be carried out in 2023. ESA will communicate the details on this review by June 2023.

# 7. CONCLUSION

(27) On the basis of the foregoing assessment, ESA finds that the Icelandic regional aid map 2022–2027 is compliant with the principles set out in the RAG. The approved map constitutes an integral part of the RAG.

<sup>(14)</sup> The term 'large investment project' is defined in the RAG paragraph 19(18) as an initial investment with eligible costs exceeding EUR 50 million.

<sup>(15)</sup> Document No 1265806, p. 3.

(28) Annexes I and II form an integral part of this decision.

For the EFTA Surveillance Authority,

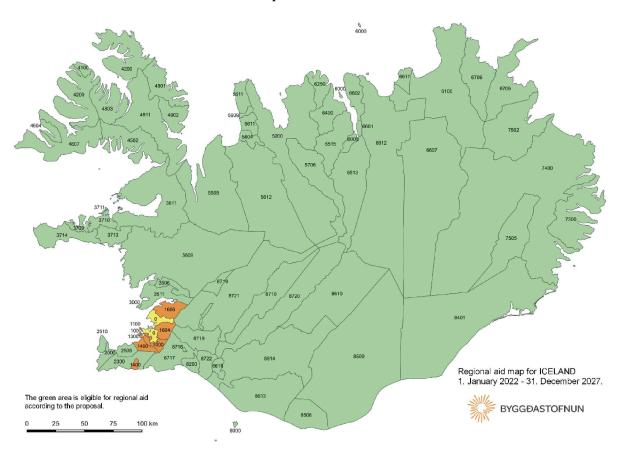
Arne RØKSUND President Responsible College Member Stefan BARRIGA College Member

Árni PÁLL ÁRNASON College Member

Melpo-Menie JOSÉPHIDÈS Countersigning as Director, Legal and Executive Affairs

# ANNEX I

# **Graphical illustration**



# ANNEX II

# List of smaller units

Akrahreppur	5 706		
Akraneskaupstaður	3 000		
Akureyrarbær	6 000		
Árneshreppur	4 901		
Ásahreppur	8 610		
Bláskógabyggð	8 721		
Blönduósbær	5 604		
Bolungarvíkurkaupstaður	4 100		
Borgarbyggð	3 609		
Dalabyggð	3 811		
Dalvíkurbyggð	6 400		
Eyja- og Miklaholtshreppur	3 713		
Eyjafjarðarsveit	6 513		
Fjallabyggð	6 250		
Fjarðabyggð	7 300		
Fljótsdalshreppur	7 505		
Flóahreppur	8 722		
Grindavíkurbær	2 300		
Grímsnes- og Grafningshreppur	8 719		
Grundarfjarðarbær	3 709		
Grýtubakkahreppur	6 602		
Helgafellssveit	3 710		
Hrunamannahreppur	8 710		
Húnavatnshreppur	5 612		
Húnaþing vestra	5 508		
Hvalfjarðarsveit	3 511		
Hveragerðisbær	8 716		
Hörgársveit	6 515		
Ísafjarðarbær	4 200		
Kaldrananeshreppur	4 902		
Kjósarhreppur	1 606		
Langanesbyggð	6 709		
Múlaþing	7 400		
Mýrdalshreppur	8 508		
Norðurþing	6 100		
Rangárþing eystra	8 613		

Rangárþing ytra	8 614
Reykhólahreppur	4 502
Reykjanesbær	2 000
Skaftárhreppur	8 509
Skagabyggð	5 611
Skeiða- og Gnúpverjahreppur	8 7 2 0
Skorradalshreppur	3 506
Skútustaðahreppur	6 607
Snæfellsbær	3 714
Strandabyggð	4 911
Stykkishólmsbær	3 711
Suðurnesjabær	2 510
Súðavíkurhreppur	4 803
Svalbarðshreppur	6 706
Svalbarðsstrandarhreppur	6 601
Sveitarfélagið Árborg	8 200
Sveitarfélagið Hornafjörður	8 401
Sveitarfélagið Skagafjörður	5 200
Sveitarfélagið Skagaströnd	5 609
Sveitarfélagið Vogar	2 506
Sveitarfélagið Ölfus	8 717
Tálknafjarðarhreppur	4 604
Tjörneshreppur	6 611
Vestmannaeyjabær	8 000
Vesturbyggð	4 607
Vopnafjarðarhreppur	7 502
Þingeyjarsveit	6 612

# **CORRIGENDA**

Corrigendum to Commission Implementing Regulation (EU) 2022/892 of 1 April 2022 amending Implementing Regulation (EU) No 668/2014 laying down rules for the application of Regulation (EU) No 1151/2012 of the European Parliament and of the Council on quality schemes for agricultural products and foodstuffs

(Official Journal of the European Union L 155 of 8 June 2022)

On page 12, in	n Article 10a(4):
for:	'Annex VI',
read:	'Annex VII'.
On page 13, in	1 Article 10b(4):
for:	'Annex VII',
read:	'Annex VIII'.

Corrigendum to Commission Implementing Decision (EU) 2022/716 of 6 May 2022 on the approval of a Smart Diesel Fuel Heater for use in conventional combustion engine and certain hybrid electric passenger cars and light commercial vehicles as an innovative technology pursuant to Regulation (EU) 2019/631 of the European Parliament and of the Council

(Official Journal of the European Union L 133 of 10 May 2022)

On page 35, in Article 4:

for: 'eco-innovation code 37'

read: 'eco-innovation code 38'.

On page 39, in the Annex, in point 3 in Formula 5:

$$\textit{for:} \quad \text{`$C_{Co_2} = (\overline{P_{base}} - \ P_{eco})$} \bullet \frac{V_{Pe_D} \bullet CF_D}{\eta_A \bullet v} \bullet UF"}$$

$$\textit{read:} \quad \text{`$C_{CO_2} = (\overline{P_{base}} - \ P_{eco})$} \bullet \frac{V_{Pe_D} \bullet CF_D}{\eta_A \bullet v} \bullet UF \bullet \frac{1}{1000}$},$$

On page 40, in the Annex, in point 4 in Formula 6:

for: 
$$(S_{\overline{base}}) = \sqrt{\sum_{i=1}^{n} (P_{basei} - \overline{P_{base}})^2},$$

read: 
$$s_{\overline{P_{base}}} = \sqrt{\frac{\sum_{i=1}^{n} (P_{base_i} - \overline{P_{base}})^2}{n(n-1)}}$$

On page 40, in the Annex, in point 4 in Formula 7:

$$\textit{for:} \quad \text{`$s_{C_{cO_2}} = \frac{V_{Pe\_D} \bullet CF_D}{\eta_A \bullet v} \bullet UF \bullet s_{\overline{P_{base}}}$'}$$

$$\textit{Read:} \quad \text{`$s_{C_{cO_2}} = \frac{V_{Pe\_D} \bullet CF_D}{\eta_A \bullet v} \bullet UF \bullet s_{\overline{P_{base}}} \bullet \frac{1}{1000}$'}$$

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