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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.

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II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) 2020/770

of 8 June 2020

amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for myclobutanil, napropamide and sintofen 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) and Article 49(2) thereof,

Whereas:

- (1) For myclobutanil maximum residue levels (MRLs) were set in Annex II and Part B of Annex III to Regulation (EC) No 396/2005. For napropamide MRLs were set in Part A of Annex III to Regulation (EC) No 396/2005. For sintofen no MRLs were set in Regulation (EC) No 396/2005, and as this active substance is not included in Annex IV to that Regulation, the default value of 0,01 mg/kg laid down in Article 18(1)(b) of Regulation (EC) No 396/2005 applies.
- (2) For myclobutanil the European Food Safety Authority ('the Authority'), submitted a reasoned opinion on the review of the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005 ⁽²⁾. It proposed to change the residue definition. It recommended raising or keeping the existing MRLs for apples, pears, quinces, medlars, loquats/Japanese medlars, apricots, cherries (sweet), peaches, plums, table grapes and wines grapes. The Authority concluded that concerning the MRLs for strawberries, blackberries, gooseberries (green, red and yellow), bananas, tomatoes, aubergines/eggplants, melons, pumpkins, watermelons, lamb's lettuces/corn salads, beans (with pods), globe artichokes, hops, sugar beet roots, swine (muscle, fat, liver, kidney), bovine (muscle, fat, liver, kidney), sheep (muscle, fat, liver, kidney), goat (muscle, fat, liver, kidney) equine (muscle, fat, liver, kidney), poultry (muscle, fat, liver), milk (cattle, sheep, goat, horse) and birds' eggs some information was not available and that further consideration by risk managers was required. As there is no risk for consumers, the MRLs for those products should be set in Annex II to Regulation (EC) No 396/2005 at the level identified by the Authority. These MRLs will be reviewed; the review will take into account the information available within two years from the publication of this Regulation.
- (3) For napropamide the Authority submitted a reasoned opinion on the review of the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005 ⁽³⁾. It proposed to change the residue definition. It recommended lowering the MRLs for almonds, chestnuts, hazelnuts/cobnuts, pecans, pine nut kernels, pistachios, walnuts, apples,

⁽¹⁾ OJ L 070, 16.3.2005, p. 1.

⁽²⁾ European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for myclobutanil according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2018;16(8):5392.

⁽³⁾ European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for napropamide according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2018;16(8):5394.

pears, quinces, medlars, loquats/Japanese medlars, apricots, cherries (sweet), peaches, plums, potatoes, celeriacs/turnip rooted celeries, horseradishes, radishes, swedes/rutabagas, turnips, tomatoes, aubergines/eggplants, broccoli, cauliflowers, Brussels sprouts, head cabbages, lamb's lettuces/corn salads, Roman rocket/rucola, beans (with pods), linseeds, poppy seeds, sesame seeds, sunflower seeds, rapeseeds/canola seeds, soyabeans, mustard seeds, cotton seeds, pumpkin seeds, safflower seeds, borage seeds, gold of pleasure seeds, hemp seeds and castor beans. The Authority concluded that concerning the MRLs for grapefruits, oranges, lemons, limes, mandarins, strawberries, blackberries, dewberries, raspberries (red and yellow), blueberries, cranberries, currants (black, red and white), gooseberries (green, red and yellow), rose hips, elderberries, herbs and edible flowers, herbal infusions (from flowers, leaves and herbs, roots and any other part of the plant) and fruit spices some information was not available and that further consideration by risk managers was required. As there is no risk for consumers, the MRLs for those products should be set in Annex II to Regulation (EC) No 396/2005 at the level identified by the Authority. These MRLs will be reviewed; the review will take into account the information available within two years from the publication of this Regulation.

- (4) For sintofen the European Food Safety Authority ('the Authority'), submitted a reasoned opinion on the review of the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005 ⁽⁴⁾. It concluded that concerning the MRL for wheat some information was not available and that further consideration by risk managers was required. No other authorisations exist for this substance. As there is no risk for consumers, this MRL should be set in Annex II to Regulation (EC) No 396/2005 at the level identified by the Authority. This MRL will be reviewed; the review will take into account the information available within two years from the publication of this Regulation.
- (5) As regards products on which the use of the plant protection product concerned is not authorised, and for which no import tolerances or Codex maximum residue limits (CXLs) exist, MRLs should be set at the specific limit of determination (LOD) or the default MRL should apply, as provided for in Article 18(1)(b) of Regulation (EC) No 396/2005.
- (6) The Commission consulted the European Union reference laboratories for residues of pesticides as regards the need to adapt certain limits of determination. As regards several substances, those laboratories concluded that for certain commodities technical development requires the setting of specific limits of determination.
- (7) Based on the reasoned opinions of the Authority and taking into account the factors relevant to the matter under consideration, the appropriate modifications to the MRLs fulfil the requirements of Article 14(2) of Regulation (EC) No 396/2005.
- (8) Through the World Trade Organisation, the trading partners of the Union were consulted on the new MRLs and their comments have been taken into account.
- (9) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (10) In order to allow for the normal marketing, processing and consumption of products, this Regulation should provide for a transitional arrangement for products which have been produced before the modification of the MRLs and for which information shows that a high level of consumer protection is maintained.
- (11) A reasonable period should be allowed to elapse before the modified MRLs become applicable in order to permit Member States, third countries and food business operators to prepare themselves to meet the new requirements which will result from the modification of the MRLs.
- (12) 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

Annexes II and III to Regulation (EC) No 396/2005 are amended in accordance with the Annex to this Regulation.

⁽⁴⁾ European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for sintofen according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2018;16(8):5406.

Article 2

Regulation (EC) No 396/2005 as it stood before being amended by this Regulation shall continue to apply to products which were produced in the Union or imported into the Union before 2 January 2021.

Article 3

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

It shall apply from 2 January 2021.

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

Done at Brussels, 8 June 2020.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Annexes II and III to Regulation (EC) No 396/2005 are amended as follows:

(1) In Annex II the column for myclobutamil is replaced and the columns for napropamide and sinterfen are added as follows:

Pesticide residues and maximum residue levels (mg/kg)

Code number	Groups and examples of individual products to which the MRLs apply (a)	Myclobutamil (sum of constituent isomers) (R)	Napropamide (sum of isomers)	Sinterfen
(1)	(2)	(3)	(4)	(5)
0100000	FRUITS, FRESH or FROZEN; TREE NUTS			0,01(*)
0110000	Citrus fruits	0,01(*)	0,01(*) (+)	
0110010	Grapefruits			
0110020	Oranges			
0110030	Lemons			
0110040	Limes			
0110050	Mandarins			
0110990	Others (2)			
0120000	Tree nuts	0,01(*)	0,01(*)	
0120010	Almonds			
0120020	Brazil nuts			
0120030	Cashew nuts			
0120040	Chestnuts			
0120050	Coconuts			
0120060	Hazelnuts/cobnuts			
0120070	Macadamias			
0120080	Pecans			
0120090	Pine nut kernels			
0120100	Pistachios			
0120110	Walnuts			
0120990	Others (2)			

(1)	(2)	(3)	(4)	(5)
0130000	Pome fruits	0,6 (+)	0,01(*)	
0130010	Apples			
0130020	Pears			
0130030	Quinces			
0130040	Medlars			
0130050	Loquats/Japanese medlars			
0130990	Others (2)			
0140000	Stone fruits		0,01(*)	
0140010	Apricots	3		
0140020	Cherries (sweet)	3		
0140030	Peaches	3		
0140040	Plums	2		
0140990	Others (2)	2		
0150000	Berries and small fruits			
0151000	(a) grapes	1,5 (+)	0,01(*)	
0151010	Table grapes			
0151020	Wine grapes			
0152000	(b) strawberries	1,5 (+)	0,01(*) (+)	
0153000	(c) cane fruits		0,01(*) (+)	
0153010	Blackberries	0,8 (+)		
0153020	Dewberries	0,01(*)		
0153030	Raspberries (red and yellow)	0,01(*)		
0153990	Others (2)	0,01(*)		
0154000	(d) other small fruits and berries			
0154010	Blueberries	0,01(*)	0,02(*) (+)	
0154020	Cranberries	0,01(*)	0,02(*) (+)	
0154030	Currants (black, red and white)	0,9	0,02(*) (+)	
0154040	Gooseberries (green, red and yellow)	0,8 (+)	0,02(*) (+)	
0154050	Rose hips	0,01(*)	0,02(*) (+)	
0154060	Mulberries (black and white)	0,01(*)	0,01(*)	
0154070	Azaroles/Mediterranean medlars	0,6 (+)	0,01(*)	

(1)	(2)	(3)	(4)	(5)
0154080	Elderberries	0,01(*)	0,02(*) (+)	
0154990	Others (2)	0,01(*)	0,01(*)	
0160000	Miscellaneous fruitswith		0,01(*)	
0161000	(a) edible peel			
0161010	Dates	0,01(*)		
0161020	Figs	0,01(*)		
0161030	Table olives	0,01(*)		
0161040	Kumquats	0,01(*)		
0161050	Carambolas	0,01(*)		
0161060	Kaki/Japanese persimmons	0,6 (+)		
0161070	Jambuls/jambolans	0,01(*)		
0161990	Others (2)	0,01(*)		
0162000	(b) inedible peel, small	0,01(*)		
0162010	Kiwi fruits (green, red, yellow)			
0162020	Litchis/lychees			
0162030	Passionfruits/maracujas			
0162040	Prickly pears/cactus fruits			
0162050	Star apples/cainitos			
0162060	American persimmons/Virginia kaki			
0162990	Others (2)			
0163000	(c) inedible peel, large			
0163010	Avocados	0,01(*)		
0163020	Bananas	3 (+)		
0163030	Mangoes	0,01(*)		
0163040	Papayas	0,01(*)		
0163050	Granate apples/pomegranates	0,01(*)		
0163060	Cherimoyas	0,01(*)		
0163070	Guavas	0,01(*)		
0163080	Pineapples	0,01(*)		
0163090	Breadfruits	0,01(*)		
0163100	Durians	0,01(*)		

(1)	(2)	(3)	(4)	(5)
0163110	Soursops/guanabanas	0,01(*)		
0163990	Others (2)	0,01(*)		
0200000	VEGETABLES, FRESH or FROZEN			
0210000	Root and tuber vegetables	0,06	0,01(*)	0,01(*)
0211000	(a) potatoes			
0212000	(b) tropical root and tuber vegetables			
0212010	Cassava roots/manioc			
0212020	Sweet potatoes			
0212030	Yams			
0212040	Arrowroots			
0212990	Others (2)			
0213000	(c) other root and tuber vegetables except sugar beets			
0213010	Beetroots			
0213020	Carrots			
0213030	Celeriacs/turnip rooted celeries			
0213040	Horseradishes			
0213050	Jerusalem artichokes			
0213060	Parsnips			
0213070	Parsley roots/Hamburg roots parsley			
0213080	Radishes			
0213090	Salsifies			
0213100	Swedes/rutabagas			
0213110	Turnips			
0213990	Others (2)			
0220000	Bulb vegetables	0,06	0,01(*)	0,01(*)
0220010	Garlic			
0220020	Onions			
0220030	Shallots			
0220040	Spring onions/green onions and Welsh onions			
0220990	Others (2)			

(1)	(2)	(3)	(4)	(5)
0230000	Fruiting vegetables		0,01(*)	0,01(*)
0231000	(a) Solanaceae and Malvaceae			
0231010	Tomatoes	0,6 (+)		
0231020	Sweet peppers/bell peppers	3		
0231030	Aubergines/eggplants	0,2 (+)		
0231040	Okra/lady's fingers	0,01(*)		
0231990	Others (2)	0,01(*)		
0232000	(b) cucurbits with edible peel	0,2		
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)	0,05		0,01(*)
0241000	(a) flowering brassica		0,01(*)	
0241010	Broccoli			
0241020	Cauliflowers			
0241990	Others (2)			
0242000	(b) head brassica		0,01(*)	
0242010	Brussels sprouts			
0242020	Head cabbages			
0242990	Others (2)			
0243000	(c) leafy brassica		0,05(*)	
0243010	Chinese cabbages/pe-tsai			

(1)	(2)	(3)	(4)	(5)
0243020	Kales			
0243990	Others (2)			
0244000	(d) kohlrabies		0,05(*)	
0250000	Leaf vegetables, herbs and edible flowers			
0251000	(a) lettuces and salad plants			0,01(*)
0251010	Lamb's lettuces/corn salads	9 (+)	0,05	
0251020	Lettuces	0,05	0,01(*)	
0251030	Escaroles/broad-leaved endives	0,05	0,01(*)	
0251040	Cresses and other sprouts and shoots	0,05	0,01(*)	
0251050	Land cresses	0,05	0,01(*)	
0251060	Roman rocket/rucola	0,05	0,05	
0251070	Red mustards	0,05	0,05	
0251080	Baby leaf crops (including brassica species)	0,05	0,05	
0251990	Others (2)	0,05	0,01(*)	
0252000	(b) spinaches and similar leaves	0,05	0,01(*)	0,01(*)
0252010	Spinaches			
0252020	Purslanes			
0252030	Chards/beet leaves			
0252990	Others (2)			
0253000	(c) grape leaves and similar species	0,05	0,01(*)	0,01(*)
0254000	(d) watercresses	0,05	0,01(*)	0,01(*)
0255000	(e) witloofs/Belgian endives	0,05	0,01(*)	0,01(*)
0256000	(f) herbs and edible flowers	0,05	0,05 (+)	0,02(*)
0256010	Chervil			
0256020	Chives			
0256030	Celery leaves			
0256040	Parsley			
0256050	Sage			
0256060	Rosemary			
0256070	Thyme			
0256080	Basil and edible flowers			

(1)	(2)	(3)	(4)	(5)
0256090	Laurel/bay leaves			
0256100	Tarragon			
0256990	Others (2)			
0260000	Legume vegetables		0,01(*)	0,01(*)
0260010	Beans (with pods)	0,8 (+)		
0260020	Beans (without pods)	0,01(*)		
0260030	Peas (with pods)	0,01(*)		
0260040	Peas (without pods)	0,01(*)		
0260050	Lentils	0,01(*)		
0260990	Others (2)	0,01(*)		
0270000	Stem vegetables		0,01(*)	0,01(*)
0270010	Asparagus	0,01(*)		
0270020	Cardoons	0,01(*)		
0270030	Celeries	0,01(*)		
0270040	Florence fennels	0,06		
0270050	Globe artichokes	0,8 (+)		
0270060	Leeks	0,06		
0270070	Rhubarbs	0,01(*)		
0270080	Bamboo shoots	0,01(*)		
0270090	Palm hearts	0,01(*)		
0270990	Others (2)	0,01(*)		
0280000	Fungi, mosses and lichens	0,01(*)	0,01(*)	0,01(*)
0280010	Cultivated fungi			
0280020	Wild fungi			
0280990	Mosses and lichens			
0290000	Algae and prokaryotes organisms	0,01(*)	0,01(*)	0,01(*)
0300000	PULSES	0,01(*)	0,01(*)	0,01(*)
0300010	Beans			
0300020	Lentils			
0300030	Peas			
0300040	Lupins/lupini beans			

(1)	(2)	(3)	(4)	(5)
0300990	Others (2)			
0400000	OILSEEDS AND OIL FRUITS	0,01(*)		0,01(*)
0401000	Oilseeds			
0401010	Linseeds		0,02	
0401020	Peanuts/groundnuts		0,01(*)	
0401030	Poppy seeds		0,02	
0401040	Sesame seeds		0,02	
0401050	Sunflower seeds		0,02	
0401060	Rapeseeds/canola seeds		0,02	
0401070	Soyabeans		0,02	
0401080	Mustard seeds		0,02	
0401090	Cotton seeds		0,02	
0401100	Pumpkin seeds		0,02	
0401110	Safflower seeds		0,02	
0401120	Borage seeds		0,02	
0401130	Gold of pleasure seeds		0,02	
0401140	Hemp seeds		0,02	
0401150	Castor beans		0,02	
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(*)	0,01(*)	0,01(*)
0500010	Barley			
0500020	Buckwheat and other pseudocereals			
0500030	Maize/corn			
0500040	Common millet/proso millet			
0500050	Oat			

(1)	(2)	(3)	(4)	(5)
0500060	Rice			
0500070	Rye			
0500080	Sorghum			
0500090	Wheat			(+)
0500990	Others (2)			
0600000	TEAS, COFFEE, HERBAL INFUSIONS, COCOA AND CAROBS	0,05(*)	0,05(*)	0,05(*)
0610000	Teas			
0620000	Coffee beans			
0630000	Herbal infusions from		(+)	
0631000	(a) flowers			
0631010	Chamomile			
0631020	Hibiscus/roselle			
0631030	Rose			
0631040	Jasmine			
0631050	Lime/linden			
0631990	Others (2)			
0632000	(b) leaves and herbs			
0632010	Strawberry			
0632020	Rooibos			
0632030	Mate/maté			
0632990	Others (2)			
0633000	(c) roots			
0633010	Valerian			
0633020	Ginseng			
0633990	Others (2)			
0639000	(d) any other parts of the plant			
0640000	Cocoa beans			
0650000	Carobs/Saint John's breads			
0700000	HOPS	6 (+)	0,05(*)	0,05(*)
0800000	SPICES			

(1)	(2)	(3)	(4)	(5)
0810000	Seed spices	0,05(*)	0,05(*)	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(*)	0,05(*) (+)	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(*)	0,05(*)	0,05(*)
0830010	Cinnamon			
0830990	Others (2)			
0840000	Root and rhizome spices			
0840010	Liquorice	0,05(*)	0,05(*)	0,05(*)
0840020	Ginger (10)			
0840030	Turmeric/curcuma	0,05(*)	0,05(*)	0,05(*)
0840040	Horseradish (11)			
0840990	Others (2)	0,05(*)	0,05(*)	0,05(*)

(1)	(2)	(3)	(4)	(5)
0850000	Bud spices	0,05(*)	0,05(*)	0,05(*)
0850010	Cloves			
0850020	Capers			
0850990	Others (2)			
0860000	Flower pistil spices	0,05(*)	0,05(*)	0,05(*)
0860010	Saffron			
0860990	Others (2)			
0870000	Aril spices	0,05(*)	0,05(*)	0,05(*)
0870010	Mace			
0870990	Others (2)			
0900000	SUGAR PLANTS	0,01(*)	0,01(*)	0,01(*)
0900010	Sugar beet roots	(+)		
0900020	Sugar canes			
0900030	Chicory roots			
0900990	Others (2)			
1000000	PRODUCTS OF ANIMAL ORIGIN -TERRESTRIAL ANIMALS			
1010000	Commodities from	0,01(*)	0,01(*)	0,01(*)
1011000	(a) swine	(+)		
1011010	Muscle			
1011020	Fat			
1011030	Liver			
1011040	Kidney			
1011050	Edible offals (other than liver and kidney)			
1011990	Others (2)			
1012000	(b) bovine	(+)		
1012010	Muscle			
1012020	Fat			
1012030	Liver			
1012040	Kidney			

(1)	(2)	(3)	(4)	(5)
1012050	Edible offals (other than liver and kidney)			
1012990	Others (2)			
1013000	(c) sheep	(+)		
1013010	Muscle			
1013020	Fat			
1013030	Liver			
1013040	Kidney			
1013050	Edible offals (other than liver and kidney)			
1013990	Others (2)			
1014000	d) goat	(+)		
1014010	Muscle			
1014020	Fat			
1014030	Liver			
1014040	Kidney			
1014050	Edible offals (other than liver and kidney)			
1014990	Others (2)			
1015000	(e) equine	(+)		
1015010	Muscle			
1015020	Fat			
1015030	Liver			
1015040	Kidney			
1015050	Edible offals (other than liver and kidney)			
1015990	Others (2)			
1016000	(f) poultry	(+)		
1016010	Muscle			
1016020	Fat			
1016030	Liver			
1016040	Kidney			

(1)	(2)	(3)	(4)	(5)
1016050	Edible offals (other than liver and kidney)			
1016990	Others (2)			
1017000	(g) other farmed terrestrial animals	(+)		
1017010	Muscle			
1017020	Fat			
1017030	Liver			
1017040	Kidney			
1017050	Edible offals (other than liver and kidney)			
1017990	Others (2)			
1020000	Milk	0,01(*) (+)	0,01(*)	0,01(*)
1020010	Cattle			
1020020	Sheep			
1020030	Goat			
1020040	Horse			
1020990	Others (2)			
1030000	Birds eggs	0,01(*) (+)	0,01(*)	0,01(*)
1030010	Chicken			
1030020	Duck			
1030030	Geese			
1030040	Quail			
1030990	Others (2)			
1040000	Honey and other apiculture products (7)	0,05(*)	0,05(*)	0,05(*)
1050000	Amphibians and Reptiles	0,01(*) (+)	0,01(*)	0,01(*)
1060000	Terrestrial invertebrate animals	0,01(*) (+)	0,01(*)	0,01(*)
1070000	Wild terrestrial vertebrate animals	0,01(*) (+)	0,01(*)	0,01(*)
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)			

(*) Limit of analytical determination

(a) For the complete list of products of plant and animal origin to which MRLs apply, reference should be made to Annex I,

Myclobutanil (sum of constituent isomers) (R)

(R) = The residue definition differs for the following combinations pesticide-code number:

Myclobutanil - code 1000000 except 1040000: free and conjugated forms of alpha-(3-hydroxybutyl) - alpha - (4-chloro-phenyl) - 1H - 1,2,4 - triazole -1-propanenitrile (RH9090), expressed as myclobutanil

(+) The European Food Safety Authority identified some information relating to triazole derivative metabolites (TDMs) as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 12 June 2022, or, if that information is not submitted by that date, the lack of it.

0130000 Pome fruits

0130010 Apples

0130020 Pear

0130030 Quinces

0130040 Medlars

0130050 Loquats/Japanese medlars

0130990 Others (2)

0151000 (a) grapes

0151010 Table grapes

0151020 Wine grapes

(+) The European Food Safety Authority identified some information on rotational crop field studies and relating to triazole derivative metabolites (TDMs) as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 12 June 2022, or, if that information is not submitted by that date, the lack of it.

0152000 (b) strawberries

0153010 Blackberries

0154040 Gooseberries (green, red and yellow)

(+) The European Food Safety Authority identified some information relating to triazole derivative metabolites (TDMs) as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 12 June 2022, or, if that information is not submitted by that date, the lack of it.

0154070 Azaroles/Mediterranean medlars

0161060 Kaki/Japanese persimmons

(+) The European Food Safety Authority identified some information on crop metabolism with post-harvest treatment as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 12 June 2022, or, if that information is not submitted by that date, the lack of it.

0163020 Bananas

(+) The European Food Safety Authority identified some information on rotational crop field studies and relating to triazole derivative metabolites (TDMs) as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 12 June 2022, or, if that information is not submitted by that date, the lack of it.

0231010 Tomatoes

0231030 Aubergines/eggplants**0233010 Melon****0233020 Pumpkins****0233030 Watermelons****0233990 Others (2)**

- (+) The European Food Safety Authority identified some information on crop metabolism with leafy vegetables and relating to triazole derivative metabolites (TDMs) as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 12 June 2022, or, if that information is not submitted by that date, the lack of it.

0251010 Lamb's lettuces/corn salads

- (+) The European Food Safety Authority identified some information on crop metabolism with pulses and oilseeds as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 12 June 2022, or, if that information is not submitted by that date, the lack of it.

0260010 Beans (with pods)

- (+) The European Food Safety Authority identified some information on crop metabolism with leafy vegetables as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 12 June 2022, or, if that information is not submitted by that date, the lack of it.

0270050 Globe artichokes

- (+) The European Food Safety Authority identified some information on residue trials, analytical methods and crop metabolism with leafy vegetables as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 12 June 2022, or, if that information is not submitted by that date, the lack of it.

0700000 HOPS

- (+) The European Food Safety Authority identified some information on rotational crop field studies and relating to triazole derivative metabolites (TDMs) as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 12 June 2022, or, if that information is not submitted by that date, the lack of it.

0900010 Sugar beet roots

- (+) The European Food Safety Authority identified some information on analytical methods as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 12 June 2022, or, if that information is not submitted by that date, the lack of it.

1011000 (a) swine**1011010 Muscle**

- (+) The European Food Safety Authority identified some information on analytical methods and storage stability as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 12 June 2022, or, if that information is not submitted by that date, the lack of it.

1011020 Fat

- (+) The European Food Safety Authority identified some information on analytical methods as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 12 June 2022, or, if that information is not submitted by that date, the lack of it.

1011030 Liver

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- (+) The European Food Safety Authority identified some information on analytical methods and storage stability as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 12 June 2022, or, if that information is not submitted by that date, the lack of it.

1011040 Kidney

- (+) The European Food Safety Authority identified some information on analytical methods as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 12 June 2022, or, if that information is not submitted by that date, the lack of it.

1011050 Edible offals (other than liver and kidney)

1011990 Others (2)

1012000 (b) bovine

1012010 Muscle

- (+) The European Food Safety Authority identified some information on analytical methods and storage stability as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 12 June 2022, or, if that information is not submitted by that date, the lack of it.

1012020 Fat

- (+) The European Food Safety Authority identified some information on analytical methods as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 12 June 2022, or, if that information is not submitted by that date, the lack of it.

1012030 Liver

- (+) The European Food Safety Authority identified some information on analytical methods and storage stability as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 12 June 2022, or, if that information is not submitted by that date, the lack of it.

1012040 Kidney

- (+) The European Food Safety Authority identified some information on analytical methods as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 12 June 2022, or, if that information is not submitted by that date, the lack of it.

1012050 Edible offals (other than liver and kidney)

1012990 Others (2)

1013000 (c) sheep

1013010 Muscle

- (+) The European Food Safety Authority identified some information on analytical methods and storage stability as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 12 June 2022, or, if that information is not submitted by that date, the lack of it.

1013020 Fat

- (+) The European Food Safety Authority identified some information on analytical methods as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 12 June 2022, or, if that information is not submitted by that date, the lack of it.

1013030 Liver

-
- (+) The European Food Safety Authority identified some information on analytical methods and storage stability as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 12 June 2022, or, if that information is not submitted by that date, the lack of it.

1013040 Kidney

- (+) The European Food Safety Authority identified some information on analytical methods as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 12 June 2022, or, if that information is not submitted by that date, the lack of it.

1013050 Edible offals (other than liver and kidney)

1013990 Others (2)

1014000 d) goat

1014010 Muscle

- (+) The European Food Safety Authority identified some information on analytical methods and storage stability as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 12 June 2022, or, if that information is not submitted by that date, the lack of it.

1014020 Fat

- (+) The European Food Safety Authority identified some information on analytical methods as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 12 June 2022, or, if that information is not submitted by that date, the lack of it.

1014030 Liver

- (+) The European Food Safety Authority identified some information on analytical methods and storage stability as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 12 June 2022, or, if that information is not submitted by that date, the lack of it.

1014040 Kidney

- (+) The European Food Safety Authority identified some information on analytical methods as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 12 June 2022, or, if that information is not submitted by that date, the lack of it.

1014050 Edible offals (other than liver and kidney)

1014990 Others (2)

1015000 (e) equine

1015010 Muscle

- (+) The European Food Safety Authority identified some information on analytical methods and storage stability as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 12 June 2022, or, if that information is not submitted by that date, the lack of it.

1015020 Fat

- (+) The European Food Safety Authority identified some information on analytical methods as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 12 June 2022, or, if that information is not submitted by that date, the lack of it.

1015030 Liver

-
- (+) The European Food Safety Authority identified some information on analytical methods and storage stability as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 12 June 2022, or, if that information is not submitted by that date, the lack of it.

1015040 Kidney

- (+) The European Food Safety Authority identified some information on analytical methods as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 12 June 2022, or, if that information is not submitted by that date, the lack of it.

1015050 Edible offals (other than liver and kidney)

1015990 Others (2)

1016000 (f) poultry

1016010 Muscle

- (+) The European Food Safety Authority identified some information on analytical methods and storage stability as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 12 June 2022, or, if that information is not submitted by that date, the lack of it.

1016020 Fat

- (+) The European Food Safety Authority identified some information on analytical methods as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 12 June 2022, or, if that information is not submitted by that date, the lack of it.

1016030 Liver

- (+) The European Food Safety Authority identified some information on analytical methods and storage stability as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 12 June 2022, or, if that information is not submitted by that date, the lack of it.

1016040 Kidney

- (+) The European Food Safety Authority identified some information on analytical methods as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 12 June 2022, or, if that information is not submitted by that date, the lack of it.

1016050 Edible offals (other than liver and kidney)

1016990 Others (2)

1017000 (g) other farmed terrestrial animals

1017010 Muscle

- (+) The European Food Safety Authority identified some information on analytical methods and storage stability as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 12 June 2022, or, if that information is not submitted by that date, the lack of it.

1017020 Fat

- (+) The European Food Safety Authority identified some information on analytical methods as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 12 June 2022, or, if that information is not submitted by that date, the lack of it.

1017030 Liver

-
- (+) The European Food Safety Authority identified some information on analytical methods and storage stability as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 12 June 2022, or, if that information is not submitted by that date, the lack of it.

1017040 Kidney

- (+) The European Food Safety Authority identified some information on analytical methods as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 12 June 2022, or, if that information is not submitted by that date, the lack of it.

1017050 Edible offals (other than liver and kidney)

1017990 Others (2)

- (+) The European Food Safety Authority identified some information on analytical methods and storage stability as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 12 June 2022, or, if that information is not submitted by that date, the lack of it.

1020000 Milk

1020010 Cattle

1020020 Sheep

1020030 Goat

1020040 Horse

1020990 Others (2)

- (+) The European Food Safety Authority identified some information on analytical methods as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 12 June 2022, or, if that information is not submitted by that date, the lack of it.

1030000 Birds eggs

1030010 Chicken

1030020 Duck

1030030 Geese

1030040 Quail

1030990 Others (2)

1050000 Amphibians and Reptiles

1060000 Terrestrial invertebrate animals

1070000 Wild terrestrial vertebrate animals

Napropamide (sum of isomers)

- (+) The European Food Safety Authority identified some information on storage stability as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 12 June 2022, or, if that information is not submitted by that date, the lack of it.

0110000 Citrus fruits

0110010 Grapefruits

0110020 Oranges

0110030 Lemons

0110040 Limes

0110050 Mandarins

0110990 Others (2)

0152000 (b) strawberries

0153000 (c) cane fruits

0153010 Blackberries

0153020 Dewberries

0153030 Raspberries (red and yellow)

0153990 Others (2)

- (+) The European Food Safety Authority identified some information on storage stability and crop metabolism as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 12 June 2022, or, if that information is not submitted by that date, the lack of it.

0154010 Blueberries

0154020 Cranberries

0154030 Currants (black, red and white)

0154040 Gooseberries (green, red and yellow)

0154050 Rose hips

0154080 Elderberries

- (+) The European Food Safety Authority identified some information on residue trials as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 12 June 2022, or, if that information is not submitted by that date, the lack of it.

0256000 (f) herbs and edible flowers

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

- (+) The European Food Safety Authority identified some information on analytical methods as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 12 June 2022, or, if that information is not submitted by that date, the lack of it.

0630000 Herbal infusions from

0631000 (a) flowers

0631010 Chamomile

0631020 Hibiscus/roselle

0631030 Rose

0631040 Jasmine

0631050 Lime/linden

0631990 Others (2)

0632000 (b) leaves and herbs

0632010 Strawberry

0632020 Rooibos

0632030 Mate/maté

0632990 Others (2)

0633000 (c) root

0633010 Valerian

0633020 Ginseng

0633990 Others (2)

0639000 (d) any other parts of the plant

0820000 Fruit spices

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)

Sintofen

- (+) The European Food Safety Authority identified some information on residue trials as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 12 June 2022, or, if that information is not submitted by that date, the lack of it.

0500090 Wheat'

- (2) Annex III is amended as follows:
- (a) in Part A, the column for napropamide is deleted.
 - (b) in Part B, the column for myclobutanil is deleted.
-

COMMISSION REGULATION (EU) 2020/771**of 11 June 2020****amending Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council and the Annex to Commission Regulation (EU) No 231/2012 as regards the use of Annatto, Bixin, Norbixin (E 160b)****(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 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives ⁽¹⁾, and in particular Article 10(3) and Article 14 thereof,

Whereas:

- (1) Annex II to Regulation (EC) No 1333/2008 lays down a Union list of food additives approved for use in foods and their conditions of use.
- (2) Annex III to Regulation (EC) No 1333/2008 lays down a Union list of food additives approved for use in food additives, food enzymes, food flavourings, nutrients and their conditions of use.
- (3) Commission Regulation (EU) No 231/2012 ⁽²⁾ lays down specifications for food additives that are listed in Annexes II and III to Regulation (EC) No 1333/2008.
- (4) The Union lists of food additives and the specifications may be updated in accordance with the common procedure referred to in Article 3(1) of Regulation (EC) No 1331/2008 of the European Parliament and of the Council ⁽³⁾, either on the initiative of the Commission or following an application.
- (5) Annatto, Bixin, Norbixin (E 160b) is a substance authorised as a colour in a variety of foods in accordance with Annex II to Regulation (EC) No 1333/2008.
- (6) Annatto, Bixin, Norbixin (E 160b) is extracted from the seeds of the annatto tree (*Bixa orellana* L.) and confers a yellow to red colour to food. The main pigments in annatto extracts are bixin and norbixin. In spite of their similarity in structure, bixin and norbixin have significantly different physico-chemical properties and, therefore, different applications depending on the characteristics of the food matrix.
- (7) Article 32(1) of Regulation (EC) No 1333/2008 provides that all food additives that were already permitted in the Union before 20 January 2009 are subject to a new risk assessment by the European Food Safety Authority ('the Authority'). Commission Regulation (EU) No 257/2010 ⁽⁴⁾ provides that the re-evaluation of food colours had to be completed by 31 December 2015.
- (8) On 4 April 2008, an application was submitted for the authorisation of the use of five new annatto extracts categorised as bixin- or norbixin-based, with a view to replacing the currently authorised annatto extracts (E 160b). The application included new proposed uses and use levels for bixin and norbixin separately, while current uses and use levels are listed for a single food additive (Annatto, Bixin, Norbixin (E 160b)). The proposed uses and use levels for bixin and norbixin concern the food categories in which Annatto, Bixin, Norbixin (E 160b) is currently authorised, as well as a few additional food categories in which Annatto, Bixin, Norbixin (E 160b) is currently not authorised, but other food colours are already authorised.

⁽¹⁾ OJ L 354, 31.12.2008, p. 16.

⁽²⁾ Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).

⁽³⁾ Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354, 31.12.2008, p. 1).

⁽⁴⁾ Commission Regulation (EU) No 257/2010 of 25 March 2010 setting up a program for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives (OJ L 80, 26.3.2010, p. 19).

- (9) Pursuant to Article 3(2) of Regulation (EC) No 1331/2008, the Commission is to seek the opinion of the Authority in order to update the Union list of food additives set out in Annex II to Regulation (EC) No 1333/2008 and the specifications set out in the Annex to Regulation (EU) No 231/2012, except where the update in question is not liable to have an effect on human health.
- (10) On 19 May 2008, the Commission requested the Authority to evaluate the safety of the five new annatto extracts, at the proposed uses and use levels. Upon analysis of the application, the Authority identified major data gaps and indicated that new toxicological studies would be needed. Consequently, the Commission decided on 14 January 2011 that the safety evaluation of the five new extracts would be carried out as a part of the re-evaluation of Annatto, Bixin, Norbixin (E 160b), as provided for by Regulation (EU) No 257/2010.
- (11) On 24 August 2016, the Authority issued a scientific opinion on the safety of annatto extracts (E 160b) as a food additive ⁽⁵⁾. As regards the annatto extracts currently authorised the Authority concluded that the safety of their use within the specifications defined in Regulation (EU) No 231/2012 (solvent-extracted bixin and norbixin, alkali-extracted annatto and oil-extracted annatto) could not be assessed due to lack of data, both in terms of identification and toxicological studies. As regards the new annatto extracts and, in particular, aqueous-processed bixin (Annatto E), the Authority could not conclude on its safety due to equivocal genotoxicity results. For the four remaining new extracts ('solvent-extracted bixin', 'solvent-extracted norbixin', 'alkali-processed norbixin, acid-precipitated' and 'alkali-processed norbixin, not acid-precipitated'), the Authority indicated that they should comply with the specifications recommended in the scientific opinion. Finally, the Authority derived an acceptable daily intake (ADI) of 6 mg bixin/kg body weight (bw) per day and an ADI of 0,3 mg norbixin/kg bw per day. Exposure estimates linked to the proposed uses and use levels for bixin were below the ADI for all population groups and for the two refined exposure scenarios (brand-loyal and non-brand-loyal exposure scenarios). However, for norbixin, those estimates exceeded the ADI at the high level (95th percentile) for infants, toddlers and children in the refined brand-loyal exposure scenario.
- (12) Following the publication of this scientific opinion, the Commission requested from the applicant some clarifications about the requested uses and maximum use levels of bixin and norbixin. Based on this, on 16 February 2017, the applicant submitted to the Commission modifications to the original application, such as a removal of some of the requested new uses and a modification of some of the requested use levels. On 2 March 2017, the Commission requested the Authority for technical assistance as regards the estimation of the exposure to bixin and norbixin on the basis of the revised uses and use levels proposed by the applicant.
- (13) As requested, on 10 August 2017, the Authority published a statement on the exposure assessment of bixin and norbixin ⁽⁶⁾ as regards those revised uses and use levels. It concluded that the dietary exposure for bixin did not exceed the ADI in any exposure scenario. However, it concluded that the dietary exposure for norbixin exceeded the ADI at the high level (95th percentile) for toddlers and children in the two refined exposure scenarios (brand-loyal and non-brand-loyal exposure scenarios).
- (14) On 30 August 2017, the applicant submitted data from a new genotoxicity study for Annatto E.
- (15) Taking into account the outcome of the exposure assessment published by the Authority on 10 August 2017, the applicant revised again the proposed uses and uses levels for bixin and norbixin, and submitted to the Commission on 20 July 2018 three alternative scenarios of uses and use levels.
- (16) On 1 August 2018, the Commission requested the Authority to carry out an evaluation on the new genotoxicity data for Annatto E generated by the applicant and to indicate whether it is possible to conclude on the safety of this annatto extract. The Authority was also requested to carry out a new exposure assessment for bixin and norbixin, on the basis of the revised uses and use levels of bixin and norbixin submitted by the applicant in the form of three alternative scenarios.
- (17) On 13 March 2019, the Authority published a scientific opinion on the safety of Annatto E and the exposure to bixin and norbixin ⁽⁷⁾. As regards the safety of Annatto E, the Authority concluded that it does not raise concern for genotoxicity and it stated that the ADIs established in 2016 for bixin and norbixin can be applied also to Annatto E. As regards the exposure at the revised uses and use levels submitted by the applicant on 20 July 2018, for bixin, the

⁽⁵⁾ EFSA Journal 2016;14(8):4544.

⁽⁶⁾ EFSA Journal 2017;15(8):4966.

⁽⁷⁾ EFSA Journal 2019;17(3):5626.

Authority stated that none of the exposure estimates exceeded the ADI of 6 mg/kg bw per day. For norbixin, the Authority found that the ADI was reached at the high level (95th percentile) for toddlers in the two refined exposure assessment scenarios but only in one country. However, considering the uncertainties and the very likely overestimation of the exposure, the Authority concluded that the level of exposure does not raise a health concern for any of the three scenarios of uses and use levels for bixin and norbixin.

- (18) It results from the above considerations that it is appropriate to amend the Annexes to Regulation (EC) No 1333/2008. First, since Annatto bixin (E 160b(i)) and Annatto norbixin (E 160b(ii)) have different toxicological properties and, therefore, different ADIs, the food additive 'Annatto, Bixin, Norbixin (E 160b)' should be deleted from the Union list of authorised food additives in Part B of Annex II to that Regulation and two separate food additives, namely Annatto bixin (E 160b(i)) and Annatto norbixin (E 160b(ii)) should be listed. As a consequence, the authorised uses and conditions of use for the food additive 'Annatto, Bixin, Norbixin (E 160b)' should be deleted from the list of authorised conditions of use in food in Part E of Annex II to Regulation (EC) No 1333/2008, and any references to it contained in the Annexes to the Regulation should be replaced by references to the two new food additives. As regards these two new additives, their authorised uses and use levels should be laid down. On the basis of the Authority's assessments referred to above, the uses as requested by the applicant on its last revision of the application should be authorised but only at the levels used in the third, and most conservative, use and use levels scenario thereof.
- (19) Regulation (EU) No 231/2012 should also be amended. On the one side, the three annatto extracts referred to therein ('solvent-extracted bixin and norbixin', 'alkali-extracted annatto and oil-extracted annatto') should no longer be authorised, since their safety could not be assessed, and, therefore, their specifications should be deleted. On the other side, the two new Annatto bixin extracts ('solvent-extracted bixin' and 'aqueous-processed bixin') and the three new Annatto norbixin extracts ('solvent-extracted norbixin', 'alkali-processed norbixin, acid-precipitated' and 'alkali-processed norbixin, not acid-precipitated') do not pose a safety concern and specifications for them as regards each of the two new additives should be added to the Annex to that Regulation. Those specifications should be those recommended by the Authority in the scientific opinion on the safety of annatto extracts (E 160b) as a food additive, issued on 24 August 2016.
- (20) Annexes II and III to Regulation (EC) No 1333/2008 as well as the Annex to Regulation (EU) No 231/2012 should therefore be amended accordingly.
- (21) Even if the annatto extracts authorised until the date of application of this Regulation should no longer be authorised, since their safety could not be assessed, it is very unlikely that they would have different toxicological properties and therefore pose a health concern which would require that, with immediate effect as of the date of application of this Regulation, they are not at all placed on the market or remain on it. Therefore, in order to allow for a smooth transition between those three extracts and the new ones, it is appropriate to allow that during a transitional period both the old and the new extracts can legally be placed, and remain, on the market.
- (22) For the same reasons, it is also appropriate that foods containing the annatto extracts authorised until the date of application of this Regulation that have been lawfully placed on the market before or during that transitional period may continue to be marketed until the existing stocks are exhausted.
- (23) 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

Annexes II and III to Regulation (EC) No 1333/2008 are amended in accordance with Annex I to this Regulation.

Article 2

The Annex to Regulation (EU) No 231/2012 is amended in accordance with Annex II to this Regulation.

Article 3

1. Until 2 January 2021, the food additive Annatto, Bixin, Norbixin (E 160b) may continue to be placed on the market as such in accordance with the rules applicable before 2 July 2020.
2. Until 2 January 2021, foods containing Annatto, Bixin, Norbixin (E 160b) which are produced and labelled in accordance with the rules applicable before 2 July 2020, may continue to be placed on the market. After that date, they may remain on the market until the exhaustion of stocks.

Article 4

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 June 2020.

For the Commission
The President
Ursula VON DER LEYEN

(1) Annex II to Regulation (EC) No 1333/2008 is amended as follows:

(a) in point 2 of Part A, point 5 is replaced by the following:

‘5. The colours E 123, E 127, E 160b(i), E 160b(ii), E 161g, E 173 and E 180 and mixtures thereof may not be sold directly to the consumer.’

(b) in Part B, point 1: ‘Colours’, the entry for E 160b (Annatto, Bixin, Norbixin) is replaced by the following two entries:

E 160b(i)	Annatto bixin
E 160b(ii)	Annatto norbixin’

(c) Part E is amended as follows:

1) Category 01.4 (Flavoured fermented milk products including heat-treated products) is amended as follows:

(i) the entry for E 160b (Annatto, Bixin, Norbixin) is replaced by the following:

	E 160b(i)	Annatto bixin	15	(94)	
	E 160b(ii)	Annatto norbixin	4	(94)	

(ii) the following footnote (94) is added after footnote (74):

‘(94): When E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are added in combination, the higher individual maximum level applies to the sum, but the individual maximum levels shall not be exceeded.’

2) Category 01.7.2 (Ripened cheese) is amended as follows:

(i) the entries for E 160b (Annatto, Bixin, Norbixin) are replaced by the following:

	E 160b(i)	Annatto bixin	15	(94)	only ripened orange, yellow and broken-white cheese and red and green pesto cheese
	E 160b(ii)	Annatto norbixin	15	(94)	only ripened orange, yellow and broken-white cheese and red and green pesto cheese
	E 160b(ii)	Annatto norbixin	50		only <i>red Leicester</i> cheese
	E 160b(ii)	Annatto norbixin	35		only Mimolette cheese’

(ii) the following footnote (94) is added after footnote (83):

‘(94): When E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are added in combination, the higher individual maximum level applies to the sum, but the individual maximum levels shall not be exceeded.’

3) Category 01.7.3 (Edible cheese rind) is amended as follows:

(i) the entry for E 160b (Annatto, Bixin, Norbixin) is replaced by the following:

	'E 160b(i)	Annatto bixin	20	(94)	
	E 160b(ii)	Annatto norbixin	20	(94)	

(ii) the following footnote (94) is added after footnote (67):

'(94): When E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are added in combination, the higher individual maximum level applies to the sum, but the individual maximum levels shall not be exceeded.'

4) Category 01.7.5 (Processed cheese) is amended as follows:

(i) the entry for E 160b (Annatto, Bixin, Norbixin) is replaced by the following:

	'E 160b(i)	Annatto bixin	15	(94)	
	E 160b(ii)	Annatto norbixin	8	(94)	

(ii) the following footnote (94) is added after footnote (66):

'(94): When E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are added in combination, the higher individual maximum level applies to the sum, but the individual maximum levels shall not be exceeded.'

5) in Category 01.7.6 (Cheese products (excluding products falling in category 16)), the entry for E 160b (Annatto, Bixin, Norbixin) is replaced by the following:

	'E 160b(ii)	Annatto norbixin	8		only ripened orange, yellow and broken-white products'
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6) in category 02.1 (Fats and oils essentially free from water (excluding anhydrous milkfat)), the entry for E 160b (Annatto, Bixin, Norbixin) is replaced by the following:

	'E 160b(i)	Annatto bixin	10		only fats'
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7) in category 02.2.2 (Other fat and oil emulsions including spreads as defined by Council Regulation (EC) No 1234/2007 and liquid emulsions), the entry for E 160b (Annatto, Bixin, Norbixin) is replaced by the following:

	'E 160b(i)	Annatto bixin	10		excluding reduced fat butter'
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8) in category 03 (Edible ices), the entry for E 160b (Annatto, Bixin, Norbixin) is replaced by the following:

	'E 160b(ii)	Annatto norbixin	20'		
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9) Category 04.2.5.2 (Jam, jellies and marmalades and sweetened chestnut purée as defined by Directive 2001/113/EC) is amended as follows:

(i) the following new entries for E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are inserted after the entry for E 160a (Carotenes):

	E 160b(i)	Annatto bixin	20	(94)	except chestnut purée
	E 160b(ii)	Annatto norbixin	20	(94)	except chestnut purée'

(ii) the following footnote (94) is added after footnote (66):

'(94): When E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are added in combination, the higher individual maximum level applies to the sum, but the individual maximum levels shall not be exceeded.'

10) Category 04.2.5.3 (Other similar fruit or vegetable spreads) is amended as follows:

(i) the following new entries for E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are inserted after the entry for E 142 (Green S):

	E 160b(i)	Annatto bixin	20	(94)	except <i>crème de pruneaux</i>
	E 160b(ii)	Annatto norbixin	20	(94)	except <i>crème de pruneaux</i> '

(ii) the following footnote (94) is added after footnote (60):

'(94): When E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are added in combination, the higher individual maximum level applies to the sum, but the individual maximum levels shall not be exceeded.'

11) Category 04.2.6 (Processed potato products) is amended as follows:

(i) the following new entries for E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are inserted after the entry for E 160a (Carotenes):

	E 160b(i)	Annatto bixin	10	(94)	only dried potato granules and flakes
	E 160b(ii)	Annatto norbixin	10	(94)	only dried potato granules and flakes'

(ii) the following footnote (94) is added after footnote (46):

'(94): When E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are added in combination, the higher individual maximum level applies to the sum, but the individual maximum levels shall not be exceeded.'

12) Category 05.2 (Other confectionery including breath freshening microsweets) is amended as follows:

(i) the following new entries for E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are inserted after the entries for E 124 (Ponceau 4R, Cochineal Red A):

	E 160b(i)	Annatto bixin	30	(94)	
	E 160b(ii)	Annatto norbixin	25	(94)	

(ii) the following footnote (94) is added after footnote (72):

'(94): When E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are added in combination, the higher individual maximum level applies to the sum, but the individual maximum levels shall not be exceeded.'

13) Category 05.4 (Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4) is amended as follows:

(i) the entry for E 160b (Annatto, Bixin, Norbixin) is replaced by the following:

	E 160b(i)	Annatto bixin	80	(94)	only decorations and coatings
	E 160b(ii)	Annatto norbixin	20	(94)	only decorations and coatings'

(ii) the following footnote (94) is added after footnote (73):

'(94): When E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are added in combination, the higher individual maximum level applies to the sum, but the individual maximum levels shall not be exceeded.'

14) in category 06.3 (Breakfast cereals), the entry for E 160b (Annatto, Bixin, Norbixin) is replaced by the following:

	E 160b(ii)	Annatto norbixin	20		only extruded puffed and or fruit-flavoured breakfast cereals'
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15) Category 06.5 (Noodles) is amended as follows:

(i) the following new entries for E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are inserted after the entry for group II (Colours at *quantum satis*):

	E 160b(i)	Annatto bixin	20	(94)	
	E 160b(ii)	Annatto norbixin	20	(94)	

(ii) the following footnote (94) is added after footnote (81):

'(94): When E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are added in combination, the higher individual maximum level applies to the sum, but the individual maximum levels shall not be exceeded.'

16) Category 06.6 (Batters) is amended as follows:

(i) the entry for E 160b (Annatto, Bixin, Norbixin) is replaced by the following:

	E 160b(i)	Annatto bixin	50	(94)	only batters for coating
	E 160b(ii)	Annatto norbixin	50	(94)	only batters for coating'

(ii) the following footnote (94) is added after footnote (81):

'(94): When E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are added in combination, the higher individual maximum level applies to the sum, but the individual maximum levels shall not be exceeded.'

17) in category 07.2 (Fine bakery wares), the entry for E 160b (Annatto, Bixin, Norbixin) is replaced by the following:

	E 160b(ii)	Annatto norbixin	10'		
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18) Category 08.2 (Meat preparations as defined by Regulation (EC) No 853/2004) is amended as follows:

(i) the following new entries for E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are inserted after the entry for E 150a-d (Caramels):

	E 160b(i)	Annatto bixin	20	(94)	only <i>breakfast sausages</i> with a minimum cereal content of 6 % and burger meat with a minimum vegetable and/or cereal content of 4 % mixed within the meat; In these products, the meat is minced in such a way so that the muscle and fat tissue are completely dispersed, so that fibre makes an emulsion with the fat, giving those products their typical appearance
	E 160b(ii)	Annatto norbixin	20	(94)	only <i>breakfast sausages</i> with a minimum cereal content of 6 % and burger meat with a minimum vegetable and/or cereal content of 4 % mixed within the meat; In these products, the meat is minced in such a way so that the muscle and fat tissue are completely dispersed, so that fibre makes an emulsion with the fat, giving those products their typical appearance'

(ii) the following footnote (94) is added after footnote (66):

'(94): When E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are added in combination, the higher individual maximum level applies to the sum, but the individual maximum levels shall not be exceeded.'

19) Category 08.3.1 (Non-heat-treated meat products) is amended as follows:

(i) the following new entries for E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are inserted after the entry for E 160a (Carotenes):

	E 160b(i)	Annatto bixin	20	(94)	only <i>chorizo sausage, salchichon, pasturmas</i> and <i>sobrasada</i>
	E 160b(ii)	Annatto norbixin	20	(94)	only <i>chorizo sausage, salchichon, pasturmas</i> and <i>sobrasada</i> '

(ii) the following footnote (94) is added after footnote (66):

'(94): When E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are added in combination, the higher individual maximum level applies to the sum, but the individual maximum levels shall not be exceeded.'

20) Category 08.3.2 (Heat-treated meat products) is amended as follows:

- (i) the following new entries for E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are inserted after the entry for E 160a (Carotenes):

	E 160b(i)	Annatto bixin	20	(94)	only sausages, pâtés, terrines and <i>luncheon meat</i>
	E 160b(ii)	Annatto norbixin	20	(94)	only sausages, pâtés, terrines and <i>luncheon meat</i>

- (ii) the following footnote (94) is added after footnote (66):

‘(94): When E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are added in combination, the higher individual maximum level applies to the sum, but the individual maximum levels shall not be exceeded.’

21) Category 08.3.3 (Casings and coatings and decorations for meat) is amended as follows:

- (i) the entry for E 160b (Annatto, Bixin, Norbixin) is replaced by the following:

	E 160b(i)	Annatto bixin	50	(94)	
	E 160b(ii)	Annatto norbixin	50	(94)	

- (ii) the following footnote (94) is added after footnote (89):

‘(94): When E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are added in combination, the higher individual maximum level applies to the sum, but the individual maximum levels shall not be exceeded.’

22) Category 09.2 (Processed fish and fishery products including molluscs and crustaceans) is amended as follows:

- (i) the entry for E 160b (Annatto, Bixin, Norbixin) concerning ‘only smoked fish’ is replaced by the following new entries for Annatto bixin and Annatto norbixin, respectively for ‘only smoked fish’ and for ‘only surimi and similar products and salmon substitutes’:

	E 160b(i)	Annatto bixin	10	(94)	only smoked fish
	E 160b(i)	Annatto bixin	30	(94)	only surimi and similar products and salmon substitutes
	E 160b(ii)	Annatto norbixin	10	(94)	only smoked fish
	E 160b(ii)	Annatto norbixin	30	(94)	only surimi and similar products and salmon substitutes’

- (ii) the following footnote (94) is added after footnote (85):

‘(94): When E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are added in combination, the higher individual maximum level applies to the sum, but the individual maximum levels shall not be exceeded.’

23) Category 12.5 (Soups and broths) is amended as follows:

- (i) the following new entries for E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are inserted after the entry for Group III (Colours with combined maximum limit):

	'E 160b(i)	Annatto bixin	15	(94)	
	E 160b(ii)	Annatto norbixin	10	(94)	

- (ii) the following footnote (94) is added after footnote (60):

'(94): When E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are added in combination, the higher individual maximum level applies to the sum, but the individual maximum levels shall not be exceeded.'

24) Category 12.6 (Sauces) is amended as follows:

- (i) the following new entries for E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are inserted after the entry for E 110 (Sunset Yellow FCF/Orange Yellow S):

	'E 160b(i)	Annatto bixin	30	(94)	including pickles, relishes, chutney and piccalilli; excluding tomato-based sauces
	E 160b(ii)	Annatto norbixin	30	(94)	including pickles, relishes, chutney and piccalilli; excluding tomato-based sauces'

- (ii) the following footnote (94) is added after footnote (65):

'(94): When E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are added in combination, the higher individual maximum level applies to the sum, but the individual maximum levels shall not be exceeded.'

25) in category 14.1.4 (Flavoured drinks), the following new entry for E 160b(i) (Annatto bixin) is inserted after the entry for E 124 (Ponceau 4R, Cochineal Red A):

	'E 160b(i)	Annatto bixin	20'		
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26) in category 14.2.6 (Spirit drinks as defined in Regulation (EC) No 110/2008), the entry for E 160b (Annatto, Bixin, Norbixin) is replaced by the following:

	'E 160b(i)	Annatto bixin	10		only liqueurs'
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27) in category 14.2.8 (Other alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks and spirits with less than 15 % of alcohol), the entry for E 160b (Annatto, Bixin, Norbixin) is replaced by the following:

	'E 160b(ii)	Annatto norbixin	10		only alcoholic drinks with less than 15 % of alcohol'
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28) Category 15.1 (Potato-, cereal-, flour- or starch-based snacks) is amended as follows:

(i) the two entries for E 160b (Annatto, Bixin, Norbixin) are replaced by the following:

	'E 160b(i)	Annatto bixin	20	(94)	
	E 160b(ii)	Annatto norbixin	20	(94)	

(ii) the following footnote (94) is added after footnote (71):

'(94): When E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are added in combination, the higher individual maximum level applies to the sum, but the individual maximum levels shall not be exceeded.'

29) Category 15.2 (Processed nuts) is amended as follows:

(i) the entry for E 160b (Annatto, Bixin, Norbixin) is replaced by the following:

	'E 160b(i)	Annatto bixin	10	(94)	
	E 160b(ii)	Annatto norbixin	10	(94)	

(ii) the following footnote (94) is added after footnote (60):

'(94): When E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are added in combination, the higher individual maximum level applies to the sum, but the individual maximum levels shall not be exceeded.'

30) Category 16 (Desserts excluding products covered in category 1, 3 and 4) is amended as follows:

(i) the entry for E 160b (Annatto, Bixin, Norbixin) is replaced by the following:

	'E 160b(i)	Annatto bixin	15	(94)	
	E 160b(ii)	Annatto norbixin	7,5	(94)	

(ii) the following footnote (94) is added after footnote (74):

'(94): When E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are added in combination, the higher individual maximum level applies to the sum, but the individual maximum levels shall not be exceeded.'

(2) In Part 2 of Annex III to Regulation (EC) No 1333/2008, the entry for E 900 (Dimethyl polysiloxane) is replaced by the following:

'E 900	Dimethyl polysiloxane	200 mg/kg in the preparation, 0,2 mg/l in final food	Colour preparations of E 160a carotenes, E 160b(i) annatto bixin, E 160b(ii) annatto norbixin, E 160c paprika extract, capsanthin, capsorubin, E 160d lycopene and E 160e beta-apo-8'-carotenal'
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ANNEX II

In the Annex to Regulation (EU) No 231/2012, the respective entries for E 160b Annatto, Bixin, Norbixin: (i) Solvent-extracted bixin and norbixin, (ii) alkali extracted annatto and (iii) oil extracted annatto are replaced by the following:

E 160 b (i) ANNATTO BIXIN

(I) SOLVENT-EXTRACTED BIXIN

Synonyms	Annatto B, Orlean, Terre orellana, L. Orange, CI Natural Orange 4
Definition	<p>Solvent-extracted bixin is obtained by the extraction of the outer coating of the seeds of the annatto tree (<i>Bixa orellana</i> L.) with one or more of the following food grade solvents: acetone, methanol, hexane, ethanol, isopropyl alcohol, ethyl acetate, alkaline alcohol or supercritical carbon dioxide. The resulting preparation may be acidified, followed by the removal of the solvent, drying and milling.</p> <p>Solvent-extracted bixin contains several coloured components; the major colouring principle is cis-bixin, a minor colouring principle is trans-bixin; thermal degradation products of bixin may also be present as a result of processing.</p>
Colour Index No	75120
Einecs	230-248-7
Chemical name	cis-Bixin: Methyl (9-cis)-hydrogen-6,6'-diapo- Ψ,Ψ -carotenedioate
Chemical formula	cis-Bixin: C ₂₅ H ₃₀ O ₄
Molecular weight	394,5
Assay	<p>Not less than 85 % colouring matter (expressed as bixin)</p> <p>E¹_{1cm} 3090 at ca. 487 nm in tetrahydrofuran and acetone</p>
Description	Dark red-brown to red-purple powder
Identification	
Solubility	Insoluble in water, slightly soluble in ethanol
Spectrometry	The sample in acetone shows absorbance maxima at about 425, 457 and 487 nm
Purity	
Norbixin	Not more than 5 % of total colouring matters

Residual Solvents	Acetone: Not more than 30 mg/kg	
	Methanol: Not more than 50 mg/kg	
	Hexane: Not more than 25 mg/kg	
	Ethanol:	not more than 50 mg/kg, singly or in combination
	Isopropyl alcohol:	
	Ethyl acetate:	
Arsenic	Not more than 2 mg/kg	
Lead	Not more than 1 mg/kg	
Mercury	Not more than 1 mg/kg	
Cadmium	Not more than 0,5 mg/kg	

(II) AQUEOUS-PROCESSED BIXIN

Synonyms	Annatto E, Orlean, Terre orellana, L. Orange, CI Natural Orange 4
Definition	<p>Aqueous-processed bixin is prepared by the extraction of the outer coating of the seeds of the annatto tree (<i>Bixa orellana</i> L.) by abrading the seeds in the presence of cold, mildly-alkaline water. The resultant preparation is acidified to precipitate bixin which is then filtered, dried and milled.</p> <p>Aqueous-processed bixin contains several coloured components; the major colouring principle is cis-bixin, a minor colouring principle is trans-bixin; thermal degradation products of bixin may also be present as a result of processing.</p>
Colour Index No	75120
Einecs	230-248-7
Chemical name	cis-Bixin: Methyl (9-cis)-hydrogen-6,6'-diapo- Ψ,Ψ -carotenedioate
Chemical formula	cis-Bixin: $C_{25}H_{30}O_4$
Molecular weight	394,5
Assay	<p>Not less than 25 % colouring matter (expressed as bixin)</p> <p>$E_{1\text{cm}}^{1\%}$ 3090 at ca. 487 nm in tetrahydrofuran and acetone</p>
Description	Dark red-brown to red-purple powder
Identification	
Solubility	Insoluble in water, slightly soluble in ethanol

Spectrometry	The sample in acetone shows absorbance maxima at about 425, 457 and 487 nm
Purity	
Norbixin	Not more than 7 % of total colouring matters
Arsenic	Not more than 2 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 0,5 mg/kg

E 160 b (ii) ANNATTO NORBIXIN

(I) SOLVENT-EXTRACTED NORBIXIN

Synonyms	Annatto C, Orlean, Terre orellana, L. Orange, CI Natural Orange 4
Definition	<p>Solvent-extracted norbixin is obtained from the outer coating of the seeds of the annatto tree (<i>Bixa orellana</i> L.) by washing with one or more of the following food grade solvents: acetone, methanol, hexane, ethanol, isopropyl alcohol, ethyl acetate, alkaline alcohol or supercritical carbon dioxide followed by solvent removal, crystallization and drying. Aqueous alkali is added to the resultant powder, which is then heated to hydrolyse the colouring matter and cooled. The aqueous solution is filtered, and acidified to precipitate the norbixin. The precipitate is filtered, washed, dried and milled, to give a granular powder.</p> <p>Solvent-extracted norbixin contains several coloured components; the major colouring principle is <i>cis</i>-norbixin, a minor colouring principle is <i>trans</i>-norbixin; thermal degradation products of norbixin may also be present as a result of processing.</p>
Colour Index No	75120
Einecs	208-810-8
Chemical name	<p><i>cis</i>-Norbixin: 6,6'-Diapo-Ψ,Ψ-carotenedioic acid</p> <p><i>cis</i>-Norbixin dipotassium salt: Dipotassium 6,6'-diapo-Ψ,Ψ-carotenedioate</p> <p><i>cis</i>-Norbixin disodium salt: Disodium 6,6'-diapo-Ψ,Ψ-carotenedioate</p>
Chemical formula	<p><i>cis</i>-Norbixin: C₂₄H₂₈O₄</p> <p><i>cis</i>-Norbixin dipotassium salt: C₂₄H₂₆K₂O₄</p> <p><i>cis</i>-Norbixin disodium salt: C₂₄H₂₆Na₂O₄</p>

Molecular weight	380,5 (acid), 456,7 (dipotassium salt), 424,5 (disodium salt)	
Assay	Not less than 85 % colouring matter (expressed as norbixin) $E_{1\text{cm}}^{1\%}$ 2870 at ca. 482 nm in 0,5 % potassium hydroxide solution	
Description	Dark red-brown to red-purple powder	
Identification		
Solubility	Soluble in alkaline water, slightly soluble in ethanol	
Spectrometry	The sample in 0,5 % potassium hydroxide solution shows absorbance maxima at about 453 nm and 482 nm	
Purity		
Residual Solvents	Acetone: Not more than 30 mg/kg	
	Methanol: Not more than 50 mg/kg	
	Hexane: Not more than 25 mg/kg	
	Ethanol: Isopropyl alcohol: Ethyl acetate:	not more than 50 mg/kg, singly or in combination
Arsenic	Not more than 2 mg/kg	
Lead	Not more than 1 mg/kg	
Mercury	Not more than 1 mg/kg	
Cadmium	Not more than 0,5 mg/kg	

(II) ALKALI-PROCESSED NORBIXIN, ACID-PRECIPIATED

Synonyms	Annatto F, Orlean, Terre orellana, L. Orange, CI Natural Orange 4
Definition	<p>Alkali-processed norbixin (acid-precipitated) is prepared by the extraction of the outer coating of the seeds of the annatto tree (<i>Bixa orellana</i> L.) with aqueous alkali. The bixin is hydrolysed to norbixin in hot alkaline solution and is acidified to precipitate the norbixin. The precipitate is filtered, dried and milled to give a granular powder.</p> <p>Alkali-processed norbixin contains several coloured components; the major colouring principle is <i>cis</i>-norbixin, a minor colouring principle is <i>trans</i>-norbixin; thermal degradation products of norbixin may also be present as a result of processing.</p>

Colour Index No	75120
Einecs	208-810-8
Chemical name	cis-Norbixin: 6,6'-Diapo- Ψ , Ψ -carotenedioic acid cis-Norbixin dipotassium salt: Dipotassium 6,6'-diapo- Ψ , Ψ -carotenedioate cis-Norbixin disodium salt: Disodium 6,6'-diapo- Ψ , Ψ -carotenedioate
Chemical formula	cis-Norbixin: C ₂₄ H ₂₈ O ₄ cis-Norbixin dipotassium salt: C ₂₄ H ₂₆ K ₂ O ₄ cis-Norbixin disodium salt: C ₂₄ H ₂₆ Na ₂ O ₄
Molecular weight	380,5 (acid), 456,7 (dipotassium salt), 424,5 (disodium salt)
Assay	Not less than 35 % colouring matter (expressed as norbixin) E ^{1%} _{1cm} 2870 at ca. 482 nm in 0,5 % potassium hydroxide solution
Description	Dark red-brown to red-purple powder
Identification	
Solubility	Soluble in alkaline water, slightly soluble in ethanol
Spectrometry	The sample in 0,5 % potassium hydroxide solution shows absorbance maxima at about 453 nm and 482 nm
Purity	
Arsenic	Not more than 2 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 0,5 mg/kg

(III) ALKALI-PROCESSED NORBIXIN, NOT ACID-PRECIPIATED

Synonyms	Annatto G, Orlean, Terre orellana, L. Orange, CI Natural Orange 4
Definition	Alkali-processed norbixin (not acid-precipitated) is prepared by the extraction of the outer coating of the seeds of the annatto tree (<i>Bixa orellana</i> L.) with aqueous alkali. The bixin is hydrolysed to norbixin in hot alkaline solution. The precipitate is filtered, dried and milled to give a granular powder. Extracts contain mainly the potassium or sodium salt of norbixin as the major colouring matter.

	Alkali-processed norbixin (not acid-precipitated) contains several coloured components; the major colouring principle is <i>cis</i> -norbixin, a minor colouring principle is <i>trans</i> -norbixin; thermal degradation products of norbixin may also be present as a result of processing.
Colour Index No	75120
Einecs	208-810-8
Chemical name	<i>cis</i> -Norbixin: 6,6'-Diapo- Ψ , Ψ -carotenedioic acid <i>cis</i> -Norbixin dipotassium salt: Dipotassium 6,6'-diapo- Ψ , Ψ -carotenedioate <i>cis</i> -Norbixin disodium salt: Disodium 6,6'-diapo- Ψ , Ψ -carotenedioate
Chemical formula	<i>cis</i> -Norbixin: C ₂₄ H ₂₈ O ₄ <i>cis</i> -Norbixin dipotassium salt: C ₂₄ H ₂₆ K ₂ O ₄ <i>cis</i> -Norbixin disodium salt: C ₂₄ H ₂₆ Na ₂ O ₄
Molecular weight	380,5 (acid), 456,7 (dipotassium salt), 424,5 (disodium salt)
Assay	Not less than 15 % colouring matter (expressed as norbixin) E ¹ _{1cm} 2870 at ca. 482 nm in 0,5 % potassium hydroxide solution
Description	Dark red-brown to red-purple powder
Identification	
Solubility	Soluble in alkaline water, slightly soluble in ethanol
Spectrometry	The sample in 0,5 % potassium hydroxide solution shows absorbance maxima at about 453 nm and 482 nm
Purity	
Arsenic	Not more than 2 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 0,5 mg/kg'

COMMISSION REGULATION (EU) 2020/772**of 11 June 2020****amending Annexes I, VII and VIII to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards eradication measures for transmissible spongiform encephalopathies in goats and endangered breeds****(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 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies ⁽¹⁾, and in particular the first paragraph of Article 23 and Article 23a(m) thereof,

Whereas:

- (1) Regulation (EC) No 999/2001 lays down rules for the prevention, control and eradication of transmissible spongiform encephalopathies (TSEs) in animals.
- (2) Chapter B of Annex VII to that Regulation lays down the measures to be undertaken following the confirmation of the presence of a case of TSE in bovine, ovine and caprine animals. When a classical scrapie case is confirmed in an ovine or caprine animal, the holding is to be subject to the conditions set out in one of the three options provided in point 2.2.2 of Chapter B of Annex VII.
- (3) Option 2 requires the killing and complete destruction of all ovine and caprine animals of the holding except those ovine animals having a prion protein genotype that is resistant to classical scrapie.
- (4) On 5 July 2017, the European Food Safety Authority (EFSA) adopted a scientific opinion ⁽²⁾ on the genetic resistance to TSE in goats. According to the EFSA opinion, field and experimental data are robust enough to conclude that the K222, D146 and S146 alleles confer genetic resistance against classical scrapie strains known to occur naturally in the EU goat population. The EFSA opinion concludes that outbreak management for classical scrapie in goat herds could be based on the selection of genetically resistant animals, in a similar way as currently laid down in Regulation (EC) No 999/2001 for ovine animals.
- (5) It is therefore appropriate to amend Chapter B of Annex VII to Regulation (EC) No 999/2001 in order to introduce the possibility to restrict the killing and destruction of caprine animals to only those which are susceptible to classical scrapie. The Member States should determine in each case which animals should be exempted from killing and destruction in accordance with their genetic resistance to the disease.
- (6) The EFSA opinion highlights that while breeding for resistance can be an effective tool for controlling classical scrapie in goats, given the low frequencies of presence of these alleles in most breeds, high selection pressure would likely have an adverse effect on genetic diversity. The opinion therefore recommends that measures to build up genetic resistance in a caprine population be adopted at Member State level depending on the breed concerned ⁽³⁾. The Member States should therefore be able to design their breeding strategy based on the frequency of presence of alleles conferring genetic resistance against classical scrapie in their goat population.
- (7) Following EFSA recommendation, in the event of a scrapie outbreak in a holding keeping goats, the Member States should decide, based on the breeding strategy, the particular measures which should be implemented in order to build up the genetic resistance in the caprine population of that holding.

⁽¹⁾ OJ L 147, 31.5.2001, p. 1.⁽²⁾ EFSA Journal 2017;15(8):4962.⁽³⁾ EFSA Journal 2017;15(8):4962, p. 4.

- (8) Council Directive 89/361/EEC ⁽⁴⁾ has been repealed by Regulation (EU) 2016/1012 of the European Parliament and of the Council ⁽⁵⁾ as from 1 November 2018. That Regulation, in its Article 2(24), lays down a definition for ‘endangered breed’, which means a local breed, recognised by a Member State to be endangered, genetically adapted to one or more traditional production systems or environments in that Member State and where the endangered status is scientifically established by a body possessing the necessary skills and knowledge in the area of endangered breeds.
- (9) It is therefore appropriate to amend point 1 of Annex I to Regulation (EC) No 999/2001 accordingly and to replace, in Chapter B of Annex VII and Chapter A of Annex VIII to that Regulation, the references to Directive 89/361/EEC with references to Regulation (EU) 2016/1012 and the expression ‘local breed in danger of being lost to farming’ as laid down in Article 7(2) and (3) of Commission Delegated Regulation (EU) No 807/2014 ⁽⁶⁾ with the expression ‘endangered breed’ as defined in Article 2(24) of Regulation (EU) 2016/1012.
- (10) Annexes I, VII and VIII to Regulation (EC) No 999/2001 should therefore be amended accordingly.
- (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

Annexes I, VII and VIII to Regulation (EC) No 999/2001 are 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, 11 June 2020.

For the Commission

The President

Ursula VON DER LEYEN

⁽⁴⁾ Council Directive 89/361/EEC of 30 May 1989 concerning pure-bred breeding sheep and goats (OJ L 153, 6.6.1989, p. 30).

⁽⁵⁾ Regulation (EU) 2016/1012 of the European Parliament and of the Council of 8 June 2016 on zootechnical and genealogical conditions for the breeding, trade in and entry into the Union of purebred breeding animals, hybrid breeding pigs and the germinal products thereof and amending Regulation (EU) No 652/2014, Council Directives 89/608/EEC and 90/425/EEC and repealing certain acts in the area of animal breeding (‘Animal Breeding Regulation’) (OJ L 171, 29.6.2016, p. 66).

⁽⁶⁾ Commission Delegated Regulation (EU) No 807/2014 of 11 March 2014 supplementing Regulation (EU) No 1305/2013 of the European Parliament and of the Council on support for rural development by the European Agricultural Fund for Rural Development (EAFRD) and introducing transitional provisions (OJ L 227, 31.7.2014, p. 1).

ANNEX

Annexes I, VII and VIII to Regulation (EC) No 999/2001 are amended as follows:

(1) in Annex I, point 1 is amended as follows:

(a) the introductory sentence is replaced by the following:

‘1. For the purpose of this Regulation, the following definitions set out in Regulation (EC) No 1069/2009 of the European Parliament and of the Council (*), Commission Regulation (EU) No 142/2011 (**), Regulation (EC) No 178/2002 of the European Parliament and of the Council (***), Regulation (EC) No 767/2009 of the European Parliament and of the Council (****), Council Directive 2006/88/EC (*****) and Regulation (EU) 2016/1012 of the European Parliament and of the Council (*****') shall apply:

- (*) Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) (OJ L 300, 14.11.2009, p. 1).
- (**) Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive (OJ L 54, 26.2.2011, p. 1).
- (***) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).
- (****) Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC (OJ L 229, 1.9.2009, p. 1).
- (*****) Council Directive 2006/88/EC of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals (OJ L 328, 24.11.2006, p. 14).
- (*****') Regulation (EU) 2016/1012 of the European Parliament and of the Council of 8 June 2016 on zootechnical and genealogical conditions for the breeding, trade in and entry into the Union of purebred breeding animals, hybrid breeding pigs and the germinal products thereof and amending Regulation (EU) No 652/2014, Council Directives 89/608/EEC and 90/425/EEC and repealing certain acts in the area of animal breeding ('Animal Breeding Regulation') (OJ L 171, 29.6.2016, p. 66).';

(b) the following point (f) is added:

‘(f) the definition of “endangered breed” in Article 2(24) of Regulation (EU) 2016/1012.’;

(2) in Annex VII, Chapter B is amended as follows:

(a) in point 2.2.2, the introductory paragraph is replaced by the following:

‘If BSE and atypical scrapie are excluded in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, Part 3, point 3.2, the holding shall be subject to the conditions set out in point (a). In addition, pursuant to the decision of the Member State responsible for the holding, the holding shall be subject to the conditions of either option 1 set out in point (b), or option 2 set out in point (c), or option 3 set out in point (d). In case of a holding with a mixed ovine and caprine flock, the Member State responsible for the holding may decide to apply the conditions of one of the options to the ovine animals of the holding and a different option to the caprine animals of the holding.’;

(b) in point 2.2.2, the penultimate paragraph of point (b) is replaced by the following:

‘Movement of animals mentioned in points (i) and (ii) from the holding to the slaughterhouse shall be allowed.’;

(c) in point 2.2.2, point (c) is replaced by the following:

‘(c) Option 2 – killing and complete destruction of the susceptible animals only

The prion protein genotyping of all ovine and caprine animals present in the holding, except lambs and kids less than three months old provided that they are slaughtered for human consumption not later than when they are three months of age.

Killing and complete destruction, without delay, of all ovine and/or caprine animals, embryos and ova identified by the inquiry referred to in the second and third indents of point 1(b), with the exception of:

- breeding rams of the ARR/ARR genotype,
- breeding ewes carrying at least one ARR allele and no VRQ allele and, where such breeding ewes are pregnant at the time of the inquiry, the lambs subsequently born, if their genotype meets the requirements of this subparagraph,
- ovine animals carrying at least one ARR allele which are intended solely for human consumption,
- caprine animals carrying at least one of the following alleles: K222, D146 and S146,
- if the Member State responsible for the holding so decides, lambs and kids less than three months old provided that they are slaughtered for human consumption not later than when they are three months of age.

The animals over 18 months of age killed for destruction, shall be tested for the presence of TSE in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, Part 3, point 3.2, as laid down in Annex III, Chapter A, Part II, point 5.

By way of derogation from the conditions set out in the first and second paragraph of option 2, Member States may decide instead to carry out the measures listed in (i), (ii) or (iii):

- (i) to replace the killing and complete destruction of the animals referred to in the second paragraph of option 2 by their slaughtering for human consumption, provided that:
 - the animals are slaughtered for human consumption within the territory of the Member State responsible for the holding,
 - all animals over 18 months of age slaughtered for human consumption shall be tested for the presence of TSE in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, Part 3, point 3.2;
- (ii) to delay the genotyping and subsequent killing and complete destruction or slaughtering for human consumption of the animals referred to in the second paragraph of option 2, for a period not exceeding three months. This derogation can be applied in situations where the index case is confirmed close to the commencement of the lambing and/or kidding season, provided that the ewes and/or goats and their new-born are kept isolated from ovine and/or caprine animals of other holdings during the whole period;
- (iii) to delay the killing and complete destruction or slaughtering for human consumption of the animals referred to in the second paragraph of option 2 for a maximum period of three years from the date of confirmation of the index case, in ovine or caprine flocks and holdings where ovine and caprine animals are kept together. The application of the derogation set out in the present paragraph shall be limited to cases where the Member State responsible for the holding considers that the epidemiological situation cannot be handled without killing the relevant animals, but that this cannot be carried out immediately due to the low level of resistance in the ovine and caprine population of the holding, coupled with other considerations, including economic factors. Breeding rams other than those of the ARR/ARR genotype shall be killed or castrated without delay. All possible measures to quickly build up genetic resistance in the ovine and/or caprine population of the holding shall be implemented, including reasoned breeding and culling of ewes to increase the frequency of the ARR allele and eliminate the VRQ allele, and the breeding of bucks carrying the K222, D146 or S146 alleles. The Member State responsible for the holding shall ensure that the number of animals to be killed at the end of the period of delay is not greater than immediately after the index case was confirmed. In the case of the application of the derogation set out in the present paragraph, the measures set out in point 4 shall apply to the holding until the complete destruction or slaughtering for human consumption of the animals referred to in the second paragraph of option 2, after which the restrictions laid down in point 3 shall be applicable.

Following the killing and complete destruction or slaughtering for human consumption of the animals referred to in the second paragraph of option 2, the conditions set out in point 3 shall apply to the holding.;

(d) in point 2.2.2, point (d) is replaced by the following:

‘(d) Option 3 – no mandatory killing and complete destruction of animals

A Member State may decide not to kill and completely destroy the animals identified by the inquiry referred to in the second and third indents of point 1(b) where the criteria laid down in at least one of the following four indents are met:

- it is difficult to obtain replacement male ovine animals of the ARR/ARR genotype and female ovine animals carrying at least one ARR allele and no VRQ allele, or caprine animals carrying at least one of the following alleles: K222, D146 and S146,
- the frequency of the ARR allele within the ovine breed or holding or the K222, D146 or S146 alleles within the caprine breed or holding is low,
- it is deemed necessary in order to avoid inbreeding,
- it is deemed necessary by the Member State based on a reasoned consideration of all the epidemiological factors.

The prion protein genotype of all ovine and caprine animals, up to a maximum of 50 of each species, shall be determined within a period of three months from the date of confirmation of the index case of classical scrapie.

When additional classical scrapie cases are detected in a holding where option 3 is being applied, the relevance of the reasons and criteria founding the decision to apply option 3 to this holding shall be reassessed by the Member State. If it is concluded that applying option 3 does not ensure a proper control of the outbreak, the Member State shall switch the management of this holding from option 3 to either option 1 or option 2 as laid down in points (b) and (c).

The conditions set out in point 4 shall immediately apply to a holding where it has been decided to apply option 3.

The Member States allowing recourse to option 3 in the management of classical scrapie outbreaks shall keep records of the reasons and criteria founding each individual application decision.’;

(e) point 3 is replaced by the following:

‘3. Following the killing and complete destruction or slaughtering for human consumption of all animals identified in a holding in accordance with point 2.2.1, point 2.2.2(b) or point 2.2.2(c), the following restrictions shall apply:

3.1. The holding shall be subject to an intensified TSE monitoring protocol. This shall include the testing for the presence of TSE in animals over the age of 18 months, which have died or have been killed in the holding but not in the framework of a disease eradication campaign. Ovine animals of the ARR/ARR genotype and caprine animals carrying at least one of the K222, D146 or S146 alleles are exempt. Testing shall be carried out in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, Part 3, point 3.2.

3.2. Only the following animals may be introduced to the holding:

- male ovine animals of the ARR/ARR genotype,
- female ovine animals carrying at least one ARR allele and no VRQ allele,
- caprine animals provided that a cleaning and disinfection of all animal housing on the premises has been carried out following destocking.

3.3. Only the following breeding rams, breeding bucks and ovine and caprine germinal products may be used in the holding:

- male ovine animals of the ARR/ARR genotype,
- semen from rams of the ARR/ARR genotype,
- embryos carrying at least one ARR allele and no VRQ allele,
- breeding bucks and caprine germinal products as defined in the measures decided by the Member State to build up genetic resistance in the caprine population of the holding.

- 3.4. Movements of animals from the holding shall either be allowed for the purposes of destruction or shall be subject to the following conditions:
- (a) the following animals may be moved from the holding for all purposes, including breeding:
 - ARR/ARR ovine animals,
 - ewes carrying one ARR allele and no VRQ allele, provided that they are moved to other holdings which are restricted following the application of measures in accordance with points 2.2.2(b) (option 1), 2.2.2(c) (option 2), or 2.2.2(d) (option 3),
 - caprine animals carrying at least one of the following alleles: K222, D146 and S146,
 - caprine animals provided that they are moved to other holdings which are restricted following the application of measures in accordance with points 2.2.2(b) (option 1), 2.2.2(c) (option 2) or 2.2.2(d) (option 3);
 - (b) the following animals may be moved from the holding to go directly for slaughter for human consumption:
 - ovine animals carrying at least one ARR allele,
 - caprine animals,
 - if the Member State so decides, lambs and kids less than three months old on the date of slaughter,
 - all animals when the Member State has decided to apply the derogations laid down in points 2.2.2(b)(i) and 2.2.2(c)(i);
 - (c) if the Member State so decides, lambs and kids may be moved to one other holding located within its territory solely for the purposes of fattening prior to slaughter subject to compliance with the following conditions:
 - the holding of destination does not contain any ovine or caprine animals other than those being fattened prior to slaughter,
 - at the end of the fattening period, the lambs and kids originating from the holdings subject to the eradication measures shall be transported directly to a slaughterhouse located within the territory of the same Member State to be slaughtered not later than when they are 12 months of age.
- 3.5. The restrictions set out in points 3.1 to 3.4 shall continue to apply to the holding:
- (a) until the date of attainment of ARR/ARR status by all ovine animals in the holding, provided that no caprine animals are kept on the holding; or
 - (b) until the date all caprine animals on the holding carry at least one of the K222, D146 or S146 alleles, provided that no ovine animals are kept on the holding; or
 - (c) until the date of attainment of ARR/ARR status by all ovine animals on the holding and all caprine animals on the holding carry at least one of the K222, D146 or S146 alleles; or
 - (d) for a period of two years from the date when all the measures referred to in point 2.2.1, point 2.2.2(b), or point 2.2.2(c) have been completed, provided that no TSE case other than atypical scrapie is detected during this two-year period. If a case of atypical scrapie is confirmed during this two-year period the holding shall also be subject to the measures referred to in point 2.2.3.;
- (f) point 4 is replaced by the following:
- ‘4. Following the decision to implement option 3 laid down in point 2.2.2(d) or the derogation provided for in point 2.2.2(c)(iii) the following measures shall immediately apply to the holding:
- 4.1. The holding shall be subject to an intensified TSE monitoring protocol. This shall include the testing for the presence of TSE in animals over the age of 18 months which:
- have been slaughtered for human consumption,
 - have died or been killed on the holding but not in the framework of a disease eradication campaign.

Ovine animals of the ARR/ARR genotype and caprine animals carrying at least one of the K222, D146 or S146 alleles are exempt. Testing shall be carried out in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, Part 3, point 3.2.

4.2. The conditions set out in points 3.2 and 3.3 shall apply.

However, by way of derogation from points 3.2 and 3.3, a Member State may allow the introduction and use in the holding of

- male ovine animals and their semen carrying at least one ARR allele and no VRQ allele including for breeding,
- female ovine animals carrying no VRQ allele,
- embryos carrying no VRQ allele,

subject to compliance with the following conditions:

- the breed of the animal kept on the holding is an endangered breed,
- the breed of the animal kept on the holding is subject to a breeding programme aiming at the preservation of the breed carried out by a breed society as defined in Article 2(5) of Regulation (EU) 2016/1012 or a competent authority in accordance with Article 38 of that Regulation, and
- the frequency of the ARR allele within that breed is low.

4.3. Movement of animals from the holding shall be allowed for the purposes of destruction or to go directly for slaughter for human consumption or shall be subject to the following conditions:

- (a) rams and ewes of the ARR/ARR genotype and caprine animals carrying at least one of the K222, D146 or S146 alleles, may be moved from the holding for all purposes, including breeding, provided that they are moved to other holdings which are subject to the application of measures in accordance with points 2.2.2(c) (option 2) or 2.2.2(d) (option 3);
- (b) if the Member State so decides, lambs and kids may be moved to one other holding located within its territory solely for the purposes of fattening prior to slaughter subject to compliance with the following conditions:
 - the holding of destination does not contain any ovine or caprine animals other than those being fattened prior to slaughter,
 - at the end of the fattening period, the lambs and kids shall be transported directly to a slaughterhouse located within the territory of the same Member State to be slaughtered not later than when they are 12 months of age.

4.4. The Member State shall ensure that no semen, embryo and ova are dispatched from the holding.

4.5. Common grazing of all ovine and caprine animals in the holding with ovine and caprine animals of other holdings shall be prohibited during the lambing and/or kidding period.

Outside of the lambing and/or kidding period, common grazing shall be subject to restrictions to be determined by the Member State, based on a reasoned consideration of all the epidemiological factors.

4.6. The restrictions set out in points 4.1 to 4.5 shall apply for a period of two years following the detection of the last TSE case, other than atypical scrapie, on the holdings where option 3 laid down in point 2.2.2(d) has been implemented. If a case of atypical scrapie is confirmed during this two-year period the holding shall also be subject to the measures referred to in point 2.2.3.;

(3) in Annex VIII, point 4.1 of Section A of Chapter A is amended as follows:

(a) in point (a), point (iii) is replaced by the following:

‘(iii) in the case of ovine animals, be of the ARR/ARR prion protein genotype and in the case of caprine animals, carry at least one of the K222, D146 or S146 alleles, provided they do not come from a holding subject to the restrictions set out in Annex VII, Chapter B, points 3 and 4.’;

(b) in point (b), point (iii) is replaced by the following:

‘(iii) in the case of ovine animals, be of the ARR/ARR prion protein genotype and in the case of caprine animals, carry at least one of the K222, D146 or S146 alleles, provided they do not come from a holding subject to the restrictions set out in Annex VII, Chapter B, points 3 and 4.’;

(c) in point (d), points (i), (ii) and (iii) are replaced by the following:

‘(i) the breed of the animals is an endangered breed;

(ii) the animals are entered in a breeding book for that breed in the Member State of dispatch. This breeding book is established and maintained by a breed society, recognised in accordance with Article 4(3) of Regulation (EU) 2016/1012, or by a competent authority of that Member State, in accordance with Article 38 of that Regulation. The animals are also to be entered in a breeding book for that breed in the Member State of destination. This breeding book is also established and maintained by a breed society, recognised in accordance with Article 4(3) of Regulation (EU) 2016/1012, or by a competent authority of that Member State in accordance with Article 38 of that Regulation;

(iii) in the Member State of dispatch and in the Member State of destination, the breed societies or competent authorities referred to in point (ii) carry out a breeding programme aimed at the preservation of that breed.’;

(d) in point (d), the first and second paragraphs of point (v) are replaced by the following:

‘following the entry of the animals not fulfilling the requirements set out in points (a) or (b) into the recipient holding in the Member State of destination, the movement of all ovine and caprine animals in that holding shall be restricted in accordance with point 3.4 of Chapter B of Annex VII, for a period of three years. When the Member State of destination has negligible risk of classical scrapie or has an approved national scrapie control programme this restriction shall be maintained for a period of seven years.

By way of derogation from the first paragraph of this point, such restriction on intra-Union trade or to movements of animals within the Member State shall not apply to animals belonging to an endangered breed, which are destined for a holding where this endangered breed is bred. The breed shall be subject to a breeding programme aiming at the preservation of the breed and carried out by a breed society as defined in Article 2(5) of Regulation (EU) 2016/1012 or a competent authority in accordance with Article 38 of that Regulation.’.

DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2020/773

of 11 June 2020

amending the Annex to Implementing Decision 2014/709/EU concerning animal health control measures relating to African swine fever in certain Member States

(notified under document C(2020) 4023)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market ⁽¹⁾, and in particular Article 9(4) thereof,

Having regard to Council Directive 90/425/EEC of 26 June 1990 concerning veterinary checks applicable in intra-Union trade in certain live animals and products with a view to the completion of the internal market ⁽²⁾, and in particular Article 10(4) thereof,

Having regard to Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption ⁽³⁾, and in particular Article 4(3) thereof,

Whereas:

- (1) Commission Implementing Decision 2014/709/EU ⁽⁴⁾ lays down animal health control measures in relation to African swine fever in certain Member States, where there have been confirmed cases of that disease in domestic or feral pigs (the Member States concerned). The Annex to that Implementing Decision demarcates and lists certain areas of the Member States concerned in Parts I to IV thereof, differentiated by the level of risk based on the epidemiological situation as regards that disease. The Annex to Implementing Decision 2014/709/EU has been amended several times to take account of changes in the epidemiological situation in the Union as regards African swine fever that need to be reflected in that Annex. The Annex to Implementing Decision 2014/709/EU was last amended by Commission Implementing Decision (EU) 2020/662 ⁽⁵⁾, following changes in the epidemiological situation as regards that disease in Belgium, Lithuania, Hungary and Poland.
- (2) Council Directive 2002/60/EC ⁽⁶⁾ lays down the minimum Union measures to be taken for the control of African swine fever. In particular, Article 9 of Directive 2002/60/EC provides for the establishment of a protection zone and a surveillance zone when African swine fever has been officially confirmed in pigs on a holding, and Articles 10 and 11 of that Directive lay down the measures to be taken in the protection and surveillance zones in order to prevent the spread of that disease. Recent experience has shown that the measures laid down in Directive 2002/60/EC are effective in controlling the spread of that disease, and in particular, the measures providing for the cleaning and disinfecting of infected holdings and the other measures related to the eradication of that disease from domestic pig population.

⁽¹⁾ OJ L 395, 30.12.1989, p. 13.

⁽²⁾ OJ L 224, 18.8.1990, p. 29.

⁽³⁾ OJ L 18, 23.1.2003, p. 11.

⁽⁴⁾ Commission Implementing Decision 2014/709/EU of 9 October 2014 concerning animal health control measures relating to African swine fever in certain Member States and repealing Implementing Decision 2014/178/EU (OJ L 295, 11.10.2014, p. 63).

⁽⁵⁾ Commission Implementing Decision (EU) 2020/662 of 15 May 2020 amending the Annex to Implementing Decision 2014/709/EU concerning animal health control measures relating to African swine fever in certain Member States (OJ L 155, 18.5.2020, p. 27).

⁽⁶⁾ Council Directive 2002/60/EC of 27 June 2002 laying down specific provisions for the control of African swine fever and amending Directive 92/119/EEC as regards Teschen disease and African swine fever (OJ L 192, 20.7.2002, p. 27).

- (3) Since the date of adoption of Implementing Decision (EU) 2020/662, there have been new occurrences of African swine fever in domestic and feral pigs in Poland. In addition, the epidemiological situation in certain areas of Poland has improved as regards domestic pigs, due to the measures being applied by this Member State in accordance with Directive 2002/60/EC.
- (4) In June 2020, one outbreak of African swine fever in domestic pigs was observed in the district of włodawski in Poland in an area currently listed in Part II of the Annex to Implementing Decision 2014/709/EU. This outbreak of African swine fever in domestic pigs constitutes an increased level of risk, which should be reflected in that Annex. Accordingly, this area of Poland, affected by this recent outbreak of African swine fever, should now be listed in Part III of the Annex to Implementing Decision 2014/709/EU instead of in Part II thereof.
- (5) In May and June 2020, several cases of African swine fever in feral pigs were also observed in the districts of zielonogórski, elbląski and radomski in Poland in areas listed in Part II of the Annex to Implementing Decision 2014/709/EU, located in close proximity to areas listed in Part I thereof. These cases of African swine fever in feral pigs constitute an increased level of risk which should be reflected in that Annex. Accordingly, these areas of Poland currently listed in Part I of the Annex to Implementing Decision 2014/709/EU, that are in close proximity to the areas listed in Part II affected by these recent cases of African swine fever, should now be listed in Part II of that Annex instead of in Part I thereof.
- (6) Following those recent occurrences of African swine fever in domestic and feral pigs in Poland, and taking into account the current epidemiological situation in the Union, regionalisation in this Member State has been reassessed and updated. In addition, the risk management measures in place have also been reassessed and updated. These changes need to be reflected in the Annex to Implementing Decision 2014/709/EU.
- (7) In addition, taking into account the effectiveness of the measures being applied in Poland in accordance with Directive 2002/60/EC, and in particular those laid down in Article 10(4)(b) and Article 10(5) thereof, and in line with the risk mitigation measures for African swine fever set out in the Terrestrial Animal Health Code of the World Organisation for Animal Health ⁽⁷⁾ (the OIE Code), certain areas in the districts of miński, bielski, hajnowski and siemiatycki in Poland, currently listed in Part III of the Annex to Implementing Decision 2014/709/EU should now be listed instead in Part II of that Annex, in view of the expiry of the period of three months from the date of the final cleaning and disinfection of the infected holdings and due to the absence of African swine fever outbreaks in those areas for the past three months in accordance with the provisions of the OIE Code.
- (8) In order to take account of recent developments in the epidemiological evolution of African swine fever in the Union, and in order to combat the risks associated with the spread of that disease in a proactive manner, new high-risk areas of a sufficient size should be demarcated for Poland and duly listed in Parts I, II and III of the Annex to Implementing Decision 2014/709/EU. Given that Part III of the Annex to Implementing Decision 2014/709/EU lists the areas where the epidemiological situation is still evolving and very dynamic, when any amendments are made to areas listed in that Part, particular consideration must always be given to the effect on the surrounding areas, as has been done in this instance. Parts I, II and III of that Annex should therefore be amended accordingly.
- (9) Given the urgency of the epidemiological situation in the Union as regards the spread of African swine fever, it is important that the amendments made to the Annex to Implementing Decision 2014/709/EU by this Decision take effect as soon as possible.
- (10) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS DECISION:

Article 1

The Annex to Implementing Decision 2014/709/EU is replaced by the text set out in the Annex to this Decision.

⁽⁷⁾ <https://www.oie.int/en/standard-setting/terrestrial-code/access-online/>

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 11 June 2020.

For the Commission
Stella KYRIAKIDES
Member of the Commission

ANNEX

The Annex to Implementing Decision 2014/709/EU is replaced by the following:

ANNEX

PART I

1. Belgium

The following areas in Belgium:

in Luxembourg province:

- la zone est délimitée, dans le sens des aiguilles d'une montre, par:
 - Frontière avec la France,
 - Rue Mersinhat à Florenville,
 - La N818 jusque son intersection avec la N83,
 - La N83 jusque son intersection avec la N884,
 - La N884 jusque son intersection avec la N824,
 - La N824 jusque son intersection avec Le Routeux,
 - Le Routeux,
 - Rue d'Orgéo,
 - Rue de la Vierre,
 - Rue du Bout-d'en-Bas,
 - Rue Sous l'Eglise,
 - Rue Notre-Dame,
 - Rue du Centre,
 - La N845 jusque son intersection avec la N85,
 - La N85 jusque son intersection avec la N40,
 - La N40 jusque son intersection avec la N802,
 - La N802 jusque son intersection avec la N825,
 - La N825 jusque son intersection avec la E25-E411,
 - La E25-E411 jusque son intersection avec la N40,
 - N40: Burnaimont, Rue de Luxembourg, Rue Ranci, Rue de la Chapelle,
 - Rue du Tombois,
 - Rue Du Pierroy,
 - Rue Saint-Orban,
 - Rue Saint-Aubain,
 - Rue des Cottages,
 - Rue de Relune,
 - Rue de Rulune,
 - Route de l'Ermitage,
 - N87: Route de Habay,

- Chemin des Ecoliers,
- Le Routy,
- Rue Burgknapp,
- Rue de la Halte,
- Rue du Centre,
- Rue de l'Eglise,
- Rue du Marquisat,
- Rue de la Carrière,
- Rue de la Lorraine,
- Rue du Beynert,
- Millewée,
- Rue du Tram,
- Millewée,
- N4: Route de Bastogne, Avenue de Longwy, Route de Luxembourg,
- Frontière avec le Grand-Duché de Luxembourg,
- Frontière avec la France, jusque son intersection avec la Rue Mersinhat à Florenville.

2. Estonia

The following areas in Estonia:

- Hiiu maakond.

3. Hungary

The following areas in Hungary:

- Békés megye 950950, 950960, 950970, 951950, 952050, 952750, 952850, 952950, 953050, 953150, 953650, 953660, 953750, 953850, 953960, 954250, 954260, 954350, 954450, 954550, 954650, 954750, 954850, 954860, 954950, 955050, 955150, 955250, 955260, 955270, 955350, 955450, 955510, 955650, 955750, 955760, 955850, 955950, 956050, 956060, 956150 és 956160 kódszámú vadgazdálkodási egységeinek teljes területe,
- Bács-Kiskun megye 600150, 600850, 601550, 601650, 601660, 601750, 601850, 601950, 602050, 603250, 603750 és 603850 kódszámú vadgazdálkodási egységeinek teljes területe,
- Budapest 1 kódszámú, vadgazdálkodási tevékenységre nem alkalmas területe,
- Csongrád megye 800150, 800160, 800250, 802220, 802260, 802310 és 802450 kódszámú vadgazdálkodási egységeinek teljes területe,
- Fejér megye 400150, 400250, 400351, 400352, 400450, 400550, 401150, 401250, 401350, 402050, 402350, 402360, 402850, 402950, 403050, 403250, 403350, 403450, 403550, 403650, 403750, 403950, 403960, 403970, 404570, 404650, 404750, 404850, 404950, 404960, 405050, 405750, 405850, 405950, 406050, 406150, 406550, 406650 és 406750 kódszámú vadgazdálkodási egységeinek teljes területe,
- Jász-Nagykun-Szolnok megye 750150, 750160, 750260, 750350, 750450, 750460, 754450, 754550, 754560, 754570, 754650, 754750, 754950, 755050, 755150, 755250, 755350 és 755450 kódszámú vadgazdálkodási egységeinek teljes területe,
- Komárom-Esztergom megye 250850, 250950, 251050, 251150, 251360, 251450, 251550, 251650, 251750, 251850, 251950, 252050, 252150, 252250, 252550, 252650 és 253550 kódszámú vadgazdálkodási egységeinek teljes területe,
- Nógrád megye 553250, 553260, 553350, 553750, 553850 és 553910 kódszámú vadgazdálkodási egységeinek teljes területe,

- Pest megye 570150, 570250, 570350, 570450, 570550, 570650, 570750, 570850, 571050, 571150, 571250, 571350, 571550, 571610, 571750, 571760, 572150, 572250, 572350, 572550, 572650, 572750, 572850, 572950, 573150, 573250, 573260, 573350, 573360, 573450, 573850, 573950, 573960, 574050, 574150, 574350, 574360, 574550, 574650, 574750, 574850, 574860, 574950, 575050, 575150, 575250, 575350, 575550, 575650, 575750, 575850, 575950, 576050, 576150, 576250, 576350, 576450, 576650, 576750, 576850, 576950, 577050, 577150, 577350, 577450, 577650, 577850, 577950, 578050, 578150, 578250, 578350, 578360, 578450, 578550, 578560, 578650, 578850, 578950, 579050, 579150, 579250, 579350, 579450, 579460, 579550, 579650, 579750, 580050, 580250 és 580450 kódszámú vadgazdálkodási egységeinek teljes területe.

4. Latvia

The following areas in Latvia:

- Pāvilostas novads,
- Stopiņu novada daļa, kas atrodas uz rietumiem no autoceļa V36, P4 un P5, Acones ielas, Dauguļupes ielas un Dauguļupītes,
- Ventspils novada Jūrkalnes pagasts,
- Grobiņas novads,
- Rucavas novada Dunikas pagasts.

5. Lithuania

The following areas in Lithuania:

- Klaipėdos rajono savivaldybės: Agluonėnų, Priekulės, Veiviržėnų, Judrėnų, Endriejavo ir Vėžaičių seniūnijos,
- Kretingos rajono savivaldybės: Imbarės, Kartenos ir Kūlupėnų seniūnijos,
- Plungės rajono savivaldybės: Kulių, Nausodžio, Plungės miesto ir Šateikių seniūnijos,
- Skuodo rajono savivaldybės: Lenkimų, Mosėdžio, Skuodo, Skuodo miestoseniūnijos.

6. Poland

The following areas in Poland:

w województwie warmińsko-mazurskim:

- gminy Wielbark i Rozogi w powiecie szczycieńskim,
- gminy Janowiec Kościelny, Janowo i Kozłowo w powiecie nidzickim,
- powiat działdowski,
- gminy Dąbrówno, Grunwald i Ostróda z miastem Ostróda w powiecie ostródzkim,
- gminy Kisielice, Susz, Iława z miastem Iława, Lubawa z miastem Lubawa, w powiecie iławskim,

w województwie podlaskim:

- gminy Kulesze Kościelne, Wysokie Mazowieckie z miastem Wysokie Mazowieckie, Czyżew w powiecie wysokomazowieckim,
- gminy Miastkowo, Nowogród, Śniadowo i Zbójna w powiecie łomżyńskim,
- powiat zambrowski,

w województwie mazowieckim:

- powiat ostrołęcki,
- powiat miejski Ostrołęka,
- gminy Bielsk, Brudzeń Duży, Drobin, Gąbin, Łąck, Nowy Duninów, Radzanowo, Słupno i Stara Biała w powiecie płockim,

- powiat miejski Płock,
 - powiat sierpecki,
 - powiat żuromiński,
 - gminy Andrzejewo, Brok, Małkinia Górna, Stary Lubotyń, Szulborze Wielkie, Wąsewo, Zaręby Kościelne i Ostrów Mazowiecka z miastem Ostrów Mazowiecka w powiecie ostrowskim,
 - gminy Dzierzgowo, Lipowiec Kościelny, miasto Mława, Radzanów, Szreńsk, Szydłowo i Wieczfnia Kościelna, w powiecie mławskim,
 - powiat przasnyski,
 - powiat makowski,
 - gminy Gzy, Obryte, Zatory, Pułtusk i część gminy Winnica położona na wschód od linii wyznaczonej przez drogę łączącą miejscowości Bielany, Winnica i Pokrzywnica w powiecie pułtuskim,
 - gminy Brańszczyk, Długosiodło, Rząśnik, Wyszków, Zabrodzie i część gminy Somianka położona na północ od linii wyznaczonej przez drogę nr 62 w powiecie wyszkowskim,
 - gminy Kowala, Wierzbica, część gminy Wolanów położona na południe od linii wyznaczonej przez drogę nr 12 w powiecie radomskim,
 - powiat miejski Radom,
 - powiat szydłowiecki,
 - powiat gostyniński,
- w województwie podkarpackim:
- gmina Wielkie Oczy w powiecie lubaczowskim,
 - gminy Laszki, Radymno z miastem Radymno, część gminy Wiązownica położona na południe od linii wyznaczonej przez drogę nr 867 i gmina wiejska Jarosław w powiecie jarosławskim,
 - gminy Przeworsk z miastem Przeworsk, Gać Jawornik Polski, Kańczuga, Tryńcza i Zarzecze w powiecie przeworskim,
 - powiat łańcucki,
 - gminy Trzebownisko, Głogów Małopolski i część gminy Sokołów Małopolski położona na południe od linii wyznaczonej przez drogę nr 875 w powiecie rzeszowskim,
 - gminy Dzikowiec, Kolbuszowa, Niwiska i Raniżów w powiecie kolbuszowskim,
 - gminy Borowa, Czermin, Gawłuszowice, Mielec z miastem Mielec, Padew Narodowa, Przeclaw, Tuszów Narodowy w powiecie mieleckim,
- w województwie świętokrzyskim:
- powiat opatowski,
 - powiat sandomierski,
 - gminy Bogoria, Łubnice, Oleśnica, Osiek, Połaniec, Rytwiany i Staszów w powiecie staszowskim,
 - gmina Skarżysko Kościelne w powiecie skarżyskim,
 - gmina Wąchock, część gminy Brody położona na zachód od linii wyznaczonej przez drogę nr 9 oraz na południowy – zachód od linii wyznaczonej przez drogi: nr 0618T biegnącą od północnej granicy gminy do skrzyżowania w miejscowości Lipie, drogę biegnącą od miejscowości Lipie do wschodniej granicy gminy oraz na północ od drogi nr 42 i część gminy Mirzec położona na zachód od linii wyznaczonej przez drogę nr 744 biegnącą od południowej granicy gminy do miejscowości Tychów Stary a następnie przez drogę nr 0566T biegnącą od miejscowości Tychów Stary w kierunku północno – wschodnim do granicy gminy w powiecie starachowickim,
 - powiat ostrowiecki,
 - gminy Gowarczów, Końskie i Stąporków w powiecie koneckim,

w województwie łódzkim:

- gminy Łyszkowice, Kocierzew Południowy, Kiernozia, Chąsno, Nieborów, część gminy wiejskiej Łowicz położona na północ od linii wyznaczonej przez drogę nr 92 biegnącej od granicy miasta Łowicz do zachodniej granicy gminy oraz część gminy wiejskiej Łowicz położona na wschód od granicy miasta Łowicz i na północ od granicy gminy Nieborów w powiecie łowickim,
- gminy Biała Rawska, Cielądz, Rawa Mazowiecka z miastem Rawa Mazowiecka i Regnów w powiecie rawskim,
- powiat skierniewicki,
- powiat miejski Skierniewice,
- gminy Białaczów, Mniszków, Paradyż, Sławno i Żarnów w powiecie opoczyńskim,
- gminy Czerniewice, Inowódz, Lubochnia, Rzeczyca, Tomaszów Mazowiecki z miastem Tomaszów Mazowiecki i Zelechlinek w powiecie tomaszowskim,

w województwie pomorskim:

- gminy Ostaszewo, miasto Krynica Morska oraz część gminy Nowy Dwór Gdański położona na południowy – zachód od linii wyznaczonej przez drogę nr 55 biegnącą od południowej granicy gminy do skrzyżowania z drogą nr 7, następnie przez drogę nr 7 i S7 biegnącą do zachodniej granicy gminy w powiecie nowodworskim,
- gminy Lichnowy, Miłoradz, Nowy Staw, Malbork z miastem Malbork w powiecie malborskim,
- gminy Mikołajki Pomorskie, Stary Targ i Sztum w powiecie sztumskim,
- powiat gdański,
- Miasto Gdańsk,
- powiat tczewski,
- powiat kwidzyński,

w województwie lubuskim:

- gminy Maszewo i Gubin z miastem Gubin w powiecie krośnieńskim,
- gminy Międzyrzecz, Pszczew, Trzciel w powiecie międzyrzeckim,
- gmina Lubrza, Łągów, część gminy Zbąszynek położona na północ od linii wyznaczonej przez linię kolejową biegnącą od Zbąszynia do Świebodzina oraz część położona na północ od linii wyznaczonej przez linię kolejową biegnącą od miasta Zbąszynek w kierunku zachodniej granicy gminy do skrzyżowania z drogą nr 1210F, a następnie przez drogę 1210F biegnącą od skrzyżowania z linią kolejową do zachodniej granicy gminy, część gminy Szczaniec położona na północ od linii wyznaczonej przez linię kolejową, część gminy Świebodzin położona na północ od linii wyznaczonej przez linię kolejową w powiecie świebodzińskim,
- gmina Cybinka w powiecie słubickim,
- część gminy Torzym położona na południe od linii wyznaczonej przez autostradę A2 w powiecie sulęcińskim,

w województwie dolnośląskim:

- gminy Bolesławiec z miastem Bolesławiec, Gromadka i Osiecznica w powiecie bolesławieckim,
- gmina Węgliniec w powiecie zgorzeleckim,
- gminy Chocianów, Przemków, część gminy Radwanice położona na południe od linii wyznaczonej przez drogę nr S3 i część gminy Polkowice położona na północ od linii wyznaczonej przez drogę nr 331 w powiecie polkowickim,
- gmina Jemielno, Niechlów i Góra w powiecie górowskim,
- gmina Rudna i Lubin z miastem Lubin w powiecie lubińskim,

w województwie wielkopolskim:

- gminy Krzemieniewo, Lipno, Osieczna, Rydzyna, część gminy Świąciechowa położona na południe od linii wyznaczonej przez drogę nr 12w powiecie leszczyńskim,

- powiat miejski Leszno,
- powiat nowotomyski,
- gminy Granowo, Grodzisk Wielkopolski i część gminy Kamieniec położona na wschód od linii wyznaczonej przez drogę nr 308 w powiecie grodziskim,
- gminy Czempień, Kościan z miastem Kościan, Krzywiń i część gminy Śmigiel położona na wschód od linii wyznaczonej przez drogę nr S5 w powiecie kościańskim,
- powiat miejski Poznań,
- gminy Rokietnica, Suchy Las, Mosina, miasto Luboń, miasto Puszczykowo, część gminy Komorniki położona na wschód od linii wyznaczonej przez drogę nr 5, część gminy Stęszew położona na południowy – wschód od linii wyznaczonej przez drogi nr 5 i 32 i część gminy Kórnik położona na zachód od linii wyznaczonych przez drogi: nr S11 biegnącą od północnej granicy gminy do skrzyżowania z drogą nr 434 i drogę nr 434 biegnącą od tego skrzyżowania do południowej granicy gminy w powiecie poznańskim,
- gminy Pniewy, Szamotuły, część gminy Duszniki położona na zachód od linii wyznaczonej przez drogę nr 306 biegnącą od południowej granicy gminy do skrzyżowania z drogą nr 92 oraz na północ od linii wyznaczonej przez drogę nr 92 biegnącą od wschodniej granicy gminy do skrzyżowania z drogą nr 306, część gminy Kaźmierz położona na północ i na zachód od linii wyznaczonych przez drogi: nr 92 biegnącą od zachodniej granicy gminy do skrzyżowania z drogą łączącą miejscowości Witkowice – Gorszewice – Kaźmierz (wzdłuż ulic Czereśniowa, Dworcowa, Marii Konopnickiej) – Chlewiska, biegnącą do wschodniej granicy gminy w powiecie szamotulskim.

7. Slovakia

The following areas in Slovakia:

- the whole district of Vranov nad Topľou,
- the whole district of Humenné,
- the whole district of Snina,
- the whole district of Sobrance,
- the whole district of Košice-mesto,
- in the district of Michalovce, the whole municipalities of Tušice, Moravany, Pozdišovce, Michalovce, Zalužice, Lúčky, Závadka, Hnojné, Poruba pod Vihorlatom, Jovsa, Kusín, Klokočov, Kaluža, Vinné, Trnava pri Laborci, Oreské, Staré, Zbudza, Petrovce nad Laborcom, Lesné, Suché, Rakovec nad Ondavou, Nacina Ves, Voľa, Pusté Čemerné and Strážske,
- in the district of Košice – okolie, the whole municipalities not included in Part II.

8. Greece

The following areas in Greece:

- in the regional unit of Drama:
 - the community departments of Sidironero and Skaloti and the municipal departments of Livadero and Ksiropotamo (in Drama municipality),
 - the municipal department of Paranesti (in Paranesti municipality),
 - the municipal departments of Kokkinogeia, Mikropoli, Panorama, Pyrgoi (in Prosotsani municipality),
 - the municipal departments of Kato Nevrokopi, Chrysokefalo, Achladea, Vathytopos, Volakas, Granitis, Dasotos, Eksohi, Katafyto, Lefkogeia, Mikrokleisoura, Mikromilea, Ochyro, Pagoneri, Perithorio, Kato Vrontou and Potamoi (in Kato Nevrokopi municipality),
- in the regional unit of Xanthi:
 - the municipal departments of Kimmerion, Stavroupoli, Gerakas, Dafnonas, Komnina, Kariofyto and Neochori (in Xanthi municipality),

- the community departments of Satres, Thermes, Kotyli, and the municipal departments of Myki, Echinós and Oraio and (in Myki municipality),
- the community department of Selero and the municipal department of Sounio (in Avdira municipality),
- in the regional unit of Rodopi:
 - the municipal departments of Komotini, Anthochorio, Gratini, Thrylorio, Kalhas, Karydia, Kikidio, Kosmio, Pandrosos, Aigeiros, Kallisti, Meleti, Neo Sidirochori and Mega Doukato (in Komotini municipality),
 - the municipal departments of Ipio, Arriana, Darmeni, Archontika, Fillyra, Ano Drosini, Aratos and the Community Departments Kehros and Organi (in Arriana municipality),
 - the municipal departments of Iasmos, Sostis, Asomatoi, Polyanthos and Amvrosia and the community department of Amaxades (in Iasmos municipality),
 - the municipal department of Amaranta (in Maroneia Sapon municipality),
- in the regional unit of Evros:
 - the municipal departments of Kyriaki, Mandra, Mavroklisi, Mikro Dereio, Protokklisi, Roussa, Goniko, Geriko, Sidirochori, Megalo Derio, Sidiro, Giannouli, Agriani and Petrolofos (in Soufli municipality),
 - the municipal departments of Dikaia, Arzos, Elaia, Therapio, Komara, Marasia, Ormenio, Pentalofos, Petrota, Plati, Ptelea, Kyprinos, Zoni, Fulakio, Spilaio, Nea Vyssa, Kavili, Kastanies, Rizia, Sterna, Ampelakia, Valtos, Megali Doxipara, Neochori and Chandras (in Orestiada municipality),
 - the municipal departments of Asvestades, Ellinochori, Karoti, Koufovouno, Kiani, Mani, Sitochori, Alepochori, Asproneri, Metaxades, Vrysika, Doksa, Elafoxori, Ladi, Paliouri and Poimeniko (in Didymoteixo municipality),
- in the regional unit of Serres:
 - the municipal departments of Kerkini, Livadia, Makrynitsa, Neochori, Platanakia, Petritsi, Akritochori, Vyroneia, Gonimo, Mandraki, Megalochori, Rodopoli, Ano Poroia, Katw Poroia, Sidirokastro, Vamvakophyto, Promahonas, Kamaroto, Strymonochori, Charopo, Kastanousi and Chortero and the community departments of Achladochori, Agkistro and Kapnophyto (in Sintiki municipality),
 - the municipal departments of Serres, Elaionas and Oinoussa and the community departments of Orini and Ano Vrontou (in Serres municipality),
 - the municipal departments of Dasochoriou, Irakleia, Valtero, Karperi, Koimisi, Lithotopos, Limnochori, Podismeno and Chrysochorafa (in Irakleia municipality).

PART II

1. Belgium

The following areas in Belgium:

in Luxembourg province:

- la zone est délimitée, dans le sens des aiguilles d'une montre, par:
 - La Rue de la Station (N85) à Florenville jusque son intersection avec la N894,
 - La N894 jusque son intersection avec la rue Grande,
 - La rue Grande jusque son intersection avec la rue de Neufchâteau,
 - La rue de Neufchâteau jusque son intersection avec Hosseuse,
 - Hosseuse,
 - La Roquignole,
 - Les Chanvières,
 - La Fosse du Loup,
 - Le Sart,
 - La N801 jusque son intersection avec la rue de l'Accord,

- La rue de l'Accord,
- La rue du Fet,
- La N40 jusque son intersection avec la E25-E411,
- La E25-E411 jusque son intersection avec la N81 au niveau de Weyler,
- La N81 jusque son intersection avec la N883 au niveau d'Aubange,
- La N883 jusque son intersection avec la N88 au niveau d'Aubange,
- La N88 jusque son intersection avec la N811,
- La N811 jusque son intersection avec la rue Baillet Latour,
- La rue Baillet Latour jusque son intersection avec la N88,
- La N88 (rue Baillet Latour, rue Fontaine des Dames, rue Yvan Gils, rue de Virton, rue de Géroville, Route de Meix) jusque son intersection avec la N981,
- La N981 (rue de Virton) jusque son intersection avec la N83,
- La N83 (rue du Faing, rue de Bouillon, rue Albert 1er, rue d'Arlon) jusque son intersection avec la N85 (Rue de la Station) à Florenville.

2. Bulgaria

The following areas in Bulgaria:

- the whole region of Haskovo,
- the whole region of Yambol,
- the whole region of Stara Zagora,
- the whole region of Pernik,
- the whole region of Kyustendil,
- the whole region of Plovdiv,
- the whole region of Pazardzhik,
- the whole region of Smolyan,
- the whole region of Burgas excluding the areas in Part III.

3. Estonia

The following areas in Estonia:

- Eesti Vabariik (välja arvatud Hiiumaa maakond).

4. Hungary

The following areas in Hungary:

- Békés megye 950150, 950250, 950350, 950450, 950550, 950650, 950660, 950750, 950850, 950860, 951050, 951150, 951250, 951260, 951350, 951450, 951460, 951550, 951650, 951750, 952150, 952250, 952350, 952450, 952550, 952650, 953250, 953260, 953270, 953350, 953450, 953550, 953560, 953950, 954050, 954060, 954150, 956250, 956350, 956450, 956550, 956650 és 956750 kódszámú vadgazdálkodási egységeinek teljes területe,
- Borsod-Abaúj-Zemplén megye 650100, 650200, 650300, 650400, 650500, 650600, 650700, 650800, 650900, 651000, 651100, 651200, 651300, 651400, 651500, 651610, 651700, 651801, 651802, 651803, 651900, 652000, 652100, 652200, 652300, 652601, 652602, 652603, 652700, 652900, 653000, 653100, 653200, 653300, 653401, 653403, 653500, 653600, 653700, 653800, 653900, 654000, 654201, 654202, 654301, 654302, 654400, 654501, 654502, 654600, 654700, 654800, 654900, 655000, 655100, 655200, 655300, 655400, 655500, 655600, 655700, 655800, 655901, 655902, 656000, 656100, 656200, 656300, 656400, 656600, 656701, 656702, 656800, 656900, 657010, 657100, 657300, 657400, 657500, 657600, 657700, 657800, 657900, 658000, 658100, 658201, 658202, 658310, 658401, 658402, 658403, 658404, 658500, 658600, 658700, 658801, 658802, 658901, 658902, 659000, 659100, 659210, 659220, 659300, 659400, 659500, 659601, 659602, 659701, 659800, 659901, 660000, 660100, 660200, 660400, 660501, 660502, 660600 és 660800, valamint 652400, 652500 és 652800 kódszámú vadgazdálkodási egységeinek teljes területe,

- Fejér megye 403150, 403160, 403260, 404250, 404550, 404560, 405450, 405550, 405650, 406450 és 407050 kódszámú vadgazdálkodási egységeinek teljes területe,
- Hajdú-Bihar megye valamennyi vadgazdálkodási egységének teljes területe,
- Heves megye 700150, 700250, 700260, 700350, 700450, 700460, 700550, 700650, 700750, 700850, 700860, 700950, 701050, 701111, 701150, 701250, 701350, 701550, 701560, 701650, 701750, 701850, 701950, 702050, 702150, 702250, 702260, 702350, 702450, 702550, 702750, 702850, 702950, 703050, 703150, 703250, 703350, 703360, 703370, 703450, 703550, 703610, 703750, 703850, 703950, 704050, 704150, 704250, 704350, 704450, 704550, 704650, 704750, 704850, 704950, 705050, 705150, 705250, 705350, 705450, 705510 és 705610 kódszámú vadgazdálkodási egységeinek teljes területe,
- Jász-Nagykun-Szolnok megye 750250, 750550, 750650, 750750, 750850, 750970, 750980, 751050, 751150, 751160, 751250, 751260, 751350, 751360, 751450, 751460, 751470, 751550, 751650, 751750, 751850, 751950, 752150, 752250, 752350, 752450, 752460, 752550, 752560, 752650, 752750, 752850, 752950, 753060, 753070, 753150, 753250, 753310, 753450, 753550, 753650, 753660, 753750, 753850, 753950, 753960, 754050, 754150, 754250, 754360, 754370, 754850, 755550, 755650 és 755750 kódszámú vadgazdálkodási egységeinek teljes területe,
- Komárom-Esztergom megye: 252350, 252450, 252460, 252750, 252850, 252860, 252950, 252960, 253050, 253150, 253250, 253350 és 253450 kódszámú vadgazdálkodási egységeinek teljes területe,
- Nógrád megye 550110, 550120, 550130, 550210, 550310, 550320, 550450, 550460, 550510, 550610, 550710, 550810, 550950, 551010, 551150, 551160, 551250, 551350, 551360, 551450, 551460, 551550, 551650, 551710, 551810, 551821, 552010, 552150, 552250, 552350, 552360, 552450, 552460, 552520, 552550, 552610, 552620, 552710, 552850, 552860, 552950, 552960, 552970, 553050, 553110, 553650 és 554050 kódszámú vadgazdálkodási egységeinek teljes területe,
- Pest megye 570950, 571850, 571950, 572050, 573550, 573650, 574250, 577250 és 580150 kódszámú vadgazdálkodási egységeinek teljes területe,
- Szabolcs-Szatmár-Bereg megye valamennyi vadgazdálkodási egységének teljes területe.

5. Latvia

The following areas in Latvia:

- Ādažu novads,
- Aizputes novads,
- Aglonas novads,
- Aizkraukles novads,
- Aknīstes novads,
- Alojās novads,
- Alsungas novads,
- Alūksnes novads,
- Amatas novads,
- Apes novads,
- Auces novads,
- Babītes novads,
- Baldones novads,
- Baltinavas novads,
- Balvu novads,
- Bauskas novads,
- Beverīnas novads,

- Brocēnu novads,
- Burtnieku novads,
- Carnikavas novads,
- Cēsu novads,
- Cesvaines novads,
- Ciblas novads,
- Dagdas novads,
- Daugavpils novads,
- Dobeles novads,
- Dundagas novads,
- Durbes novads,
- Engures novads,
- Ērgļu novads,
- Garkalnes novads,
- Gulbenes novads,
- Iecavas novads,
- Ikšķiles novads,
- Ilūkstes novads,
- Inčukalna novads,
- Jaunjelgavas novads,
- Jaunpiebalgas novads,
- Jaunpils novads,
- Jēkabpils novads,
- Jelgavas novads,
- Kandavas novads,
- Kārsavas novads,
- Ķeguma novads,
- Ķekavas novads,
- Kocēnu novads,
- Kokneses novads,
- Krāslavas novads,
- Krimuldas novads,
- Krustpils novads,
- Kuldīgas novads,
- Lielvārdes novads,
- Līgatnes novads,
- Limbažu novads,
- Līvānu novads,

- Lubānas novads,
- Ludzas novads,
- Madonas novads,
- Mālpils novads,
- Mārupes novads,
- Mazsalacas novads,
- Mērsraga novads,
- Naukšēnu novads,
- Neretas novads,
- Ogres novads,
- Olaines novads,
- Ozolnieku novads,
- Pārgaujas novads,
- Pļaviņu novads,
- Preiļu novads,
- Priekules novads,
- Priekuļu novads,
- Raunas novads,
- republikas pilsēta Daugavpils,
- republikas pilsēta Jelgava,
- republikas pilsēta Jēkabpils,
- republikas pilsēta Jūrmala,
- republikas pilsēta Rēzekne,
- republikas pilsēta Valmiera,
- Rēzeknes novads,
- Riebiņu novads,
- Rojas novads,
- Ropažu novads,
- Rugāju novads,
- Rundāles novads,
- Rūjienas novads,
- Salacgrīvas novads,
- Salas novads,
- Salaspils novads,
- Saldus novads,
- Saulkrastu novads,
- Sējas novads,
- Siguldas novads,

- Skrīveru novads,
- Skrundas novads,
- Smiltenes novads,
- Stopiņu novada daļa, kas atrodas uz austrumiem no autoceļa V36, P4 un P5, Acones ielas, Dauguļupes ielas un Dauguļupītes,
- Strenču novads,
- Talsu novads,
- Tērvetes novads,
- Tukuma novads,
- Vaiņodes novads,
- Valkas novads,
- Varakļānu novads,
- Vārkavas novads,
- Vecpiebalgas novads,
- Vecumnieku novads,
- Ventspils novada Ances, Tārgales, Popes, Vārves, Užavas, Piltenes, Puzes, Ziru, Ugāles, Usmas un Zlēku pagasts, Piltenes pilsēta,
- Viesītes novads,
- Viļakas novads,
- Viļānu novads,
- Zilupes novads.

6. Lithuania

The following areas in Lithuania:

- Alytaus miesto savivaldybė,
- Alytaus rajono savivaldybė: Alytaus, Alovės, Butrimonių, Daugų, Nemunaičio, Pivašiūnų, Punios, Raitininkų seniūnijos,
- Anykščių rajono savivaldybė,
- Akmenės rajono savivaldybė,
- Biržų miesto savivaldybė,
- Biržų rajono savivaldybė,
- Druskininkų savivaldybė,
- Elektrėnų savivaldybė,
- Ignalinos rajono savivaldybė,
- Jonavos rajono savivaldybė,
- Joniškio rajono savivaldybė,
- Jurbarko rajono savivaldybė,
- Kaišiadorių rajono savivaldybė,
- Kalvarijos savivaldybė,
- Kauno miesto savivaldybė,

- Kauno rajono savivaldybė: Domeikavos, Garliavos, Garliavos apylinkių, Karmėlavos, Lapių, Linksmakalnio, Neveronių, Rokų, Samylų, Taurakiemio, Vandžiogalos ir Vilkijos seniūnijos, Babtų seniūnijos dalis į rytus nuo kelio A1, Užliedžių seniūnijos dalis į rytus nuo kelio A1 ir Vilkijos apylinkių seniūnijos dalis į vakarus nuo kelio Nr. 1907,
- Kazlų rūdos savivaldybė: Kazlų rūdos seniūnija į šiaurę nuo kelio Nr. 230, į rytus nuo kelio Kokė-Užbalių-Čečetai iki kelio Nr. 2610 ir į pietus nuo kelio Nr. 2610,
- Kelmės rajono savivaldybė,
- Kėdainių rajono savivaldybė,
- Kupiškio rajono savivaldybė,
- Lazdijų rajono savivaldybė,
- Marijampolės savivaldybė: Degučių, Marijampolės, Mokolų, Liudvinavo ir Narto seniūnijos,
- Mažeikių rajono savivaldybė,
- Molėtų rajono savivaldybė: Alantos seniūnijos dalis į vakarus nuo kelio 119 ir į šiaurę nuo kelio Nr. 2828, Balninkų, Dubingių, Giedraičių, Jonišio ir Videniškių seniūnijos,
- Pagėgių savivaldybė,
- Pakruojo rajono savivaldybė,
- Panevėžio rajono savivaldybė,
- Panevėžio miesto savivaldybė,
- Pasvalio rajono savivaldybė,
- Radviliškio rajono savivaldybė,
- Rietavo savivaldybė,
- Prienų rajono savivaldybė: Stakliškių ir Veiverių seniūnijos,
- Plungės rajono savivaldybė: Babrungo, Alsėdžių, Žlibinų, Stalgėnų, Paukštakių, Platelių ir Žemaičių Kalvarijos seniūnijos,
- Raseinių rajono savivaldybė,
- Rokiškio rajono savivaldybė,
- Skuodo rajono savivaldybės: Aleksandrijos, Barstyčių, Ylakių, Notėnų ir Šačių seniūnijos,
- Šakių rajono savivaldybė,
- Šalčininkų rajono savivaldybė,
- Šiaulių miesto savivaldybė,
- Šiaulių rajono savivaldybė,
- Šilutės rajono savivaldybė,
- Širvintų rajono savivaldybė,
- Šilalės rajono savivaldybė,
- Švenčionių rajono savivaldybė,
- Tauragės rajono savivaldybė,
- Telšių rajono savivaldybė,
- Trakų rajono savivaldybė,
- Ukmergės rajono savivaldybė,
- Utenos rajono savivaldybė,
- Varėnos rajono savivaldybė,

- Vilniaus miesto savivaldybė,
- Vilniaus rajono savivaldybė,
- Vilkaviškio rajono savivaldybė: Bartninkų, Gražiškių, Keturvalakių, Kybartų, Klausučių, Pajevonio, Šeimenos, Vilkaviškio miesto, Virbalio, Vištyčio seniūnijos,
- Visagino savivaldybė,
- Zarasų rajono savivaldybė.

7. Poland

The following areas in Poland:

w województwie warmińsko-mazurskim:

- gminy Kalinowo, Prostki, Stare Juchy i gmina wiejska Ełk w powiecie ełckim,
- gminy Elbląg, Gronowo Elbląskie, Milejewo, Młynary, Markusy, Rychliki i Tolkmicko w powiecie elbląskim,
- powiat miejski Elbląg,
- powiat gołdapski,
- gmina Wieliczki w powiecie oleckim,
- powiat piski,
- gmina Górowo Iławeckie z miastem Górowo Iławeckie w powiecie bartoszyckim,
- gminy Biskupiec, Gietrwałd, Kolno, Jonkowo, Purda, Stawiguda, Świątki, Olsztynek i miasto Olsztyn oraz część gminy Barczewo położona na południe od linii wyznaczonej przez linię kolejową w powiecie olsztyńskim,
- gminy Łukta, Małdyty, Miłomłyn, Miłakowo, i część gminy Morąg położona na południe od linii wyznaczonej przez linię kolejową biegnącą od Olsztyna do Elbląga w powiecie ostródzkim,
- część gminy Ryn położona na południe od linii wyznaczonej przez linię kolejową łączącą miejscowości Giżycko i Kętrzyn w powiecie giżyckim,
- gminy Braniewo i miasto Braniewo, Frombork, Lelkowo, Pieniężno, Płoskinia oraz część gminy Wilczęta położona na północ od linii wyznaczonej przez drogę nr 509 w powiecie braniewskim,
- gmina Reszel, część gminy Kętrzyn położona na południe od linii kolejowej łączącej miejscowości Giżycko i Kętrzyn biegnącej do granicy miasta Kętrzyn, na zachód od linii wyznaczonej przez drogę nr 591 biegnącą od miasta Kętrzyn do północnej granicy gminy oraz na zachód i na południe od zachodniej i południowej granicy miasta Kętrzyn, miasto Kętrzyn i część gminy Korsze położona na południe od linii wyznaczonej przez drogę biegnącą od wschodniej granicy łączącą miejscowości Krelikiejmy i Sątoczno i na wschód od linii wyznaczonej przez drogę łączącą miejscowości Sątoczno, Sajna Wielka biegnącą do skrzyżowania z drogą nr 590 w miejscowości Glitajny, a następnie na wschód od drogi nr 590 do skrzyżowania z drogą nr 592 i na południe od linii wyznaczonej przez drogę nr 592 biegnącą od zachodniej granicy gminy do skrzyżowania z drogą nr 590 w powiecie kętrzyńskim,
- gminy Lubomino i Orneta w powiecie lidzbarskim,
- gmina Nidzica w powiecie nidzickim,
- gminy Dźwierzuty, Jedwabno, Pasym, Szczytno i miasto Szczytno i Świątajno w powiecie szczywieńskim,
- powiat mrągowski,
- gmina Zalewo w powiecie iławskim,

w województwie podlaskim:

- gminy Orla, Rudka, Brańsk z miastem Brańsk, Boćki w powiecie bielskim,
- powiat grajewski,
- powiat moniecki,

- powiat sejneński,
 - gminy Łomża, Piątnica, Jedwabne, Przytuły i Wiznaw powiecie łomżyńskim,
 - powiat miejski Łomża,
 - gminy Dziadkowice, Grodzisk, Mielnik, Milejczyce, Nurzec-Stacja i Siemiatycze z miastem Siemiatycze w powiecie siemiatyckim,
 - powiat hajnowski,
 - gminy Klukowo, Szepietowo, Kobylin-Borzymy, Nowe Piekuty i Sokoły w powiecie wysokomazowieckim,
 - powiat kolneński z miastem Kolno,
 - gminy Czarna Białostocka, Dobrzyniewo Duże, Gródek, Michałowo, Supraśl, Tykocin, Wasilków, Zabłudów, Zawady, Choroszcz i część gminy Poświętne położona na zachód od linii wyznaczonej przez drogę nr 681 w powiecie białostockim,
 - powiat suwalski,
 - powiat miejski Suwałki,
 - powiat augustowski,
 - powiat sokólski,
 - powiat miejski Białystok,
- w województwie mazowieckim:
- powiat siedlecki,
 - powiat miejski Siedlce,
 - gminy Bielany, Ceranów, Kosów Lacki, Repki i gmina wiejska Sokołów Podlaski w powiecie sokołowskim,
 - powiat węgrowski,
 - powiat łosicki,
 - powiat ciechanowski,
 - powiat sochaczewski,
 - powiat zwoleński,
 - gminy Garbatka – Letnisko, Gniewoszów i Sieciechów w powiecie kozienickim,
 - powiat lipski,
 - gminy Gózd, Iłża, Jastrzębia, Jedlnia Letnisko, Pionki z miastem Pionki, Skaryszew, Jedlińsk, Przytyk, Zakrzew, część gminy Wolanów położona na północ od drogi nr 12 i w powiecie radomskim,
 - gminy Bodzanów, Bulkowo, Staroźreby, Słubice, Wyszogród i Mała Wieś w powiecie płockim,
 - powiat nowodworski,
 - powiat płoński,
 - gminy Pokrzywnica, Świercze i część gminy Winnica położona na zachód od linii wyznaczonej przez drogę łączącą miejscowości Bielany, Winnica i Pokrzywnica w powiecie pułtuskim,
 - powiat wołomiński,
 - część gminy Somianka położona na południe od linii wyznaczonej przez drogę nr 62 w powiecie wyszkowskim,
 - gminy Borowie, Garwolin z miastem Garwolin, Górzno, Miastków Kościelny, Parysów, Pilawa, Trojanów, Żelechów, część gminy Wilga położona na północ od linii wyznaczonej przez rzekę Wilga biegnącą od wschodniej granicy gminy do ujścia do rzeki Wisły w powiecie garwolińskim,

- gmina Boguty – Pianki w powiecie ostrowskim,
 - gminy Stupsk, Wiśniewo i Strzegowo w powiecie mławskim,
 - gminy Dębe Wielkie, Dobrze, Halinów, Latowicz, Stanisławów i miasto Sulejówek w powiecie mińskim,
 - powiat otwocki,
 - powiat warszawski zachodni,
 - powiat legionowski,
 - powiat piaseczyński,
 - powiat pruszkowski,
 - powiat grójecki,
 - powiat grodziski,
 - powiat zyrardowski,
 - gminy Białobrzegi, Promna, Radzanów, Stara Błotnica, Wyśmierzyce w powiecie białobrzesckim,
 - powiat przysuski,
 - powiat miejski Warszawa,
- w województwie lubelskim:
- powiat bialski,
 - powiat miejski Biała Podlaska,
 - gminy Aleksandrów, Biłgoraj z miastem Biłgoraj, Biszczka, Józefów, Księżpol, Łukowa, Obsza, Potok Górny, Tarnogród i Teresopol, część gminy Frampol położona na południe od linii wyznaczonej przez drogę nr 74, część gminy Goraj położona na zachód od linii wyznaczonej przez drogę nr 835, część gminy Turobin położona na zachód od linii wyznaczonej przez drogę nr 835 w powiecie biłgorajskim,
 - powiat janowski,
 - powiat puławski,
 - powiat rycki,
 - gminy Adamów, Krzywda, Stoczek Łukowski z miastem Stoczek Łukowski, Wola Mysłowska, Trzebieszów, Stanin, gmina wiejska Łuków i miasto Łuków w powiecie łukowskim,
 - gminy Bychawa, Głusk, Jabłonna, Krzczonów, Garbów Strzyżewice, Wysokie, Bełżyce, Borzechów, Niedrzwica Duża, Konopnica, Wojciechów i Zakrzew w powiecie lubelskim,
 - gminy Abramów, Kamionka, Michów, Uścimów w powiecie lubartowskim,
 - gminy Mełgiew, Rybczewice, Piaski i miasto Świdnik w powiecie świdnickim,
 - gmina Fajslawice, część gminy Żółkiewka położona na północ od linii wyznaczonej przez drogę nr 842 i część gminy Łopiennik Górny położona na zachód od linii wyznaczonej przez drogę nr 17 w powiecie krasnostawskim,
 - powiat hrubieszowski,
 - gminy Krynice, Rachanie, Tarnawatka, Łaszczów, Telatyn, Tyszowce i Ułhówek w powiecie tomaszowskim,
 - gminy Białopole, Chełm, Dorohusk, Dubienka, Kamień, Leśniowice, Ruda – Huta, Sawin, Wojsławice, Żmudź w powiecie chełmskim,
 - powiat miejski Chełm,
 - gmina Adamów, Miączyn, Sitno, Komarów-Osada, Krasnobród, Łabunie, Zamość, Grabowiec, Zwierzyniec i część gminy Skierbieszów położona na wschód od linii wyznaczonej przez drogę nr 843 w powiecie zamojskim,
 - powiat miejski Zamość,

- powiat kraśnicki,
- powiat opolski,
- gminy Dębowa Kłoda, Jabłoń, Podedwórze, Sosnowica w powiecie parczewskim,
- gminy Stary Brus, Wola Uhruska, część gminy wiejskiej Włodawa położona na południe od południowej granicy miasta Włodawa i część gminy Hańsk położona na wschód od linii wyznaczonej od drogi nr 819 w powiecie włodawskim,
- gmina Kąkolewnica, Komarówka Podlaska i Ulan Majorat w powiecie radzyńskim,

w województwie podkarpackim:

- powiat stalowowolski,
- gminy Horyniec-Zdrój, Cieszanów, Oleszyce, Stary Dzików i Lubaczów z miastem Lubaczów w powiecie lubaczowskim,
- gminy Adamówka i Sieniawa w powiecie przeworskim,
- część gminy Wiązownica położona na północ od linii wyznaczonej przez drogę nr 867 w powiecie jarosławskim,
- gmina Kamień, część gminy Sokołów Małopolski położona na północ od linii wyznaczonej przez drogę nr 875 w powiecie rzeszowskim,
- gminy Cmolas i Majdan Królewski w powiecie kolbuszowskim,

- powiat leżajski,
- powiat niżański,
- powiat tarnobrzeski,

w województwie pomorskim:

- gminy Dzierzgoń i Stary Dzierzgoń w powiecie sztumskim,
- gmina Stare Pole w powiecie malborskim,
- gminy Stegny, Sztutowo i część gminy Nowy Dwór Gdański położona na północny – wschód od linii wyznaczonej przez drogę nr 55 biegnącą od południowej granicy gminy do skrzyżowania z drogą nr 7, następnie przez drogę nr 7 i S7 biegnącą do zachodniej granicy gmin w powiecie nowodworskim,

w województwie świętokrzyskim:

- gmina Tarłów i część gminy Ożarów położona na północ od linii wyznaczonej przez drogę nr 74 w powiecie opatowskim,
- część gminy Brody położona na wschód od linii wyznaczonej przez drogę nr 9 oraz na północny – wschód od linii wyznaczonej przez drogę nr 0618T biegnącą od północnej granicy gminy do skrzyżowania w miejscowości Lipie oraz przez drogę biegnącą od miejscowości Lipie do wschodniej granicy gminy i część gminy Mirzec położona na wschód od linii wyznaczonej przez drogę nr 744 biegnącą od południowej granicy gminy do miejscowości Tychów Stary a następnie przez drogę nr 0566T biegnącą od miejscowości Tychów Stary w kierunku północno – wschodnim do granicy gminy w powiecie starachowickim,

w województwie lubuskim:

- powiat wschowski,
- gminy Bobrowice, Bytnica, Dąbie i Krosno Odrzańskie w powiecie krośnieńskim,
- gminy Bytom Odrzański, Kolsko, Nowe Miasteczko, Siedlisko oraz część gminy Kozuchów położona na południe od linii wyznaczonej przez drogę nr 283 biegnącą od wschodniej granicy gminy do skrzyżowania z drogą nr 290 i na południe od linii wyznaczonej przez drogę nr 290 biegnącej od miasta Miocin Dolny do zachodniej granicy gminy w powiecie nowosolskim,

- gminy Babimost, Czerwieńsk, Kargowa, Nowogród Bobrzański, Sulechów, Świdnica, Trzebiechów oraz część gminy Bojadła położona na północ od linii wyznaczonej przez drogę nr 278 biegnącą od wschodniej granicy gminy do skrzyżowania z drogą nr 282 i na północ od linii wyznaczonej przez drogę nr 282 biegnącą od miasta Bojadła do zachodniej granicy gminy w powiecie zielonogórskim,
- powiat żarski,
- powiat zagański,
- gmina Skąpe, część gminy Zbąszynek położona na południe od linii wyznaczonej przez linię kolejową biegnącą od Zbąszynia do Świebodzina oraz część położona na południe od linii wyznaczonej przez linię kolejową biegnącą od miasta Zbąszynek w kierunku zachodniej granicy gminy do skrzyżowania z drogą nr 1210F, a następnie przez drogę 1210F biegnącą od skrzyżowania z linią kolejową do zachodniej granicy gminy, część gminy Szczaniec położona na południe od linii wyznaczonej przez linię kolejową, część gminy Świebodzin położona na południe od linii wyznaczonej przez linię kolejową w powiecie świebodzińskim,

w województwie dolnośląskim:

- powiat głogowski,
- gmina Gaworzyce, Grębocice i część gminy Radwanice położona na północ od linii wyznaczonej przez drogę nr S3 w powiecie polkowickim,

w województwie wielkopolskim:

- powiat wolsztyński,
- gminy Rakoniewice, Wielichowo i część gminy Kamieniec położona na zachód od linii wyznaczonej przez drogę nr 308 w powiecie grodziskim,
- gminy Wijewo, Włoszakowice i część gminy Święciechowa położona na północ od linii wyznaczonej przez drogę nr 12 w powiecie leszczyńskim,
- część gminy Śmigiel położona na zachód od linii wyznaczonej przez drogę nr S5 w powiecie kościańskim,

w województwie łódzkim:

- gminy Drzewica, Opoczno i Poświętne w powiecie opoczyńskim,
- gmina Sadkowiec w powiecie rawskim.

8. Slovakia

The following areas in Slovakia:

- in the district of Košice – okolie, the whole municipalities of Belza, Bidovce, Blažice, Bohdanovce, Byster, Čaňa, Ďurďošik, Ďurkov, Geča, Gyňov, Haniska, Kalša, Kechnec, Kokšov- Bakša, Košická Polianka, Košický Klečenov, Milhošť, Nižná Hutka, Nižná Myšľa, Nižný Čaj, Nižný Olčvár, Nový Salaš, Olšovany, Rákoš, Ruskov, Seňa, Skároš, Sokoľany, Slančík, Slanec, Slanská Huta, Slanské Nové Mesto, Svinica, Trstené pri Hornáde, Valaliky, Vyšná Hutka, Vyšná Myšľa, Vyšný Čaj, Vyšný Olčvár, Zdoňa and Ždaňa,
- the whole district of Trebišov,
- in the district of Michalovce, the whole municipalities of the district not already included in Part I.

9. Romania

The following areas in Romania:

- Județul Bistrița-Năsăud,
- Județul Suceava.

PART III

1. Bulgaria

The following areas in Bulgaria:

- the whole region of Blagoevgrad,
- the whole region of Dobrich,
- the whole region of Gabrovo,
- the whole region of Kardzhali,
- the whole region of Lovech,
- the whole region of Montana,
- the whole region of Pleven,
- the whole region of Razgrad,
- the whole region of Ruse,
- the whole region of Shumen,
- the whole region of Silistra,
- the whole region of Sliven,
- the whole region of Sofia city,
- the whole region of Sofia Province,
- the whole region of Targovishte,
- the whole region of Vidin,
- the whole region of Varna,
- the whole region of Veliko Tarnovo,
- the whole region of Vratza,
- in Burgas region:
 - the whole municipality of Burgas,
 - the whole municipality of Kameno,
 - the whole municipality of Malko Tarnovo,
 - the whole municipality of Primorsko,
 - the whole municipality of Sozopol,
 - the whole municipality of Sredets,
 - the whole municipality of Tsarevo,
 - the whole municipality of Sungurlare,
 - the whole municipality of Ruen,
 - the whole municipality of Aytos.

2. Lithuania

The following areas in Lithuania:

- Alytaus rajono savivaldybė: Simno, Krokialaukio ir Miroslavo seniūnijos,
- Birštono savivaldybė,

- Kauno rajono savivaldybė: Akademijos, Alšėnų, Batniavos, Čekiškės, Ežerėlio, Kačerginės, Kulautuvos, Raudondvario, Ringaudų ir Zapyškio seniūnijos, Babtų seniūnijos dalis į vakarus nuo kelio A1, Užliedžių seniūnijos dalis į vakarus nuo kelio A1 ir Vilkijos apylinkių seniūnijos dalis į rytus nuo kelio Nr. 1907,
- Kazlų Rūdos savivaldybė: Antanavo, Jankų, Kazlų rūdos seniūnijos dalis Kazlų Rūdos seniūnija į pietus nuo kelio Nr. 230, į vakarus nuo kelio Kokė-Užbaliai-Čečetai iki kelio Nr. 2610 ir į šiaurę nuo kelio Nr. 2610, Plutiškių seniūnijos,
- Marijampolės savivaldybė: Gudelių, Igliaukos, Sasnavos ir Šunskų seniūnijos,
- Molėtų rajono savivaldybė: Alantos seniūnijos dalis į rytus nuo kelio Nr. 119 ir į pietus nuo kelio Nr. 2828, Čiulėnų, Inturkės, Luokesos, Mindaunų ir Suginčių seniūnijos,
- Prienų rajono savivaldybė: Ašmintos, Balbieriškio, Išlaužo, Jiezno, Naujosios Ūtos, Pakuonio, Prienų ir Šilavotos seniūnijos,
- Vilkaviškio rajono savivaldybės: Gižų ir Pilviškių seniūnijos.

3. Poland

The following areas in Poland:

w województwie warmińsko-mazurskim:

- gminy Bisztynek, Sępoleń i Bartoszyce z miastem Bartoszyce w powiecie bartoszyckim,
- gminy Kiwity i Lidzbark Warmiński z miastem Lidzbark Warmiński w powiecie lidzbarskim,
- gminy Srokowo, Barciany, część gminy Kętrzyn położona na północ od linii kolejowej łączącej miejscowości Giżycko i Kętrzyn biegnącej do granicy miasta Kętrzyn oraz na wschód od linii wyznaczonej przez drogę nr 591 biegnącą od miasta Kętrzyn do północnej granicy gminy i część gminy Korsze położona na północ od linii wyznaczonej przez drogę biegnącą od wschodniej granicy łączącą miejscowości Krelikiejmy i Sątoczno i na zachód od linii wyznaczonej przez drogę łączącą miejscowości Sątoczno, Sajna Wielka biegnącą do skrzyżowania z drogą nr 590 w miejscowości Glitajny, a następnie na zachód od drogi nr 590 do skrzyżowania z drogą nr 592 i na północ od linii wyznaczonej przez drogę nr 592 biegnącą od zachodniej granicy gminy do skrzyżowania z drogą nr 590 w powiecie kętrzyńskim,
- część gminy Wilczęta położona na południe od linii wyznaczonej przez drogę nr 509 w powiecie braniewskim,
- część gminy Morąg położona na północ od linii wyznaczonej przez linię kolejową biegnącą od Olsztyna do Elbląga w powiecie ostródzkim,
- gminy Godkowo i Pasłęk w powiecie elbląskim,
- gminy Kowale Oleckie, Olecko i Świętajno w powiecie oleckim,
- powiat węgorzewski,
- gminy Kruklanki, Wydmyny, Miłki, Giżycko z miastem Giżycko i część gminy Ryn położona na północ od linii kolejowej łączącej miejscowości Giżycko i Kętrzyn w powiecie giżyckim,
- gminy Jeziorany, Dywity, Dobre Miasto i część gminy Barczewo położona na północ od linii wyznaczonej przez linię kolejową w powiecie olsztyńskim,

w województwie podlaskim:

- gminy Wyszki, Bielsk Podlaski z miastem Bielsk Podlaski w powiecie bielskim,
- gminy Łapy, Juchnowiec Kościelny, Suraż, Turośń Kościelna, część gminy Poświętne położona na wschód od linii wyznaczonej przez drogę nr 681 w powiecie białostockim,
- gminy Perlejewo i Drohiczyn w powiecie siemiatyckim,
- gmina Ciechanowiec w powiecie wysokomazowieckim,

w województwie mazowieckim:

- gminy Łaskarzew z miastem Łaskarzew, Maciejowice, Sobolew i część gminy Wilga położona na południe od linii wyznaczonej przez rzekę Wilga biegnącą od wschodniej granicy gminy do ujścia dorzeczki Wisły w powiecie garwolińskim,
- gminy Cegłów, Jakubów, Kałuszyn, Mińsk Mazowiecki z miastem Mińsk Mazowiecki, Mrozy i Siennica w powiecie mińskim,
- gminy Jabłonna Lacka, Sabnie i Sterdyń w powiecie sokołowskim,
- gmina Nur w powiecie ostrowskim,
- gminy Grabów nad Pilicą, Magnuszew, Głowaczów, Kozienice w powiecie kozienickim,
- gmina Stromiec w powiecie białobrzeskim,

w województwie lubelskim:

- gminy Bełzec, Jarczów, Lubycza Królewska, Susiec, Tomaszów Lubelski i miasto Tomaszów Lubelski w powiecie tomaszowskim,
- gminy Wierzbica, Rejowiec, Rejowiec Fabryczny z miastem Rejowiec Fabryczny, Siedliszcze w powiecie chełmskim,
- gminy Izbica, Gorzków, Rudnik, Kraśniczyn, Krasnystaw z miastem Krasnystaw, Siennica Różana i część gminy Łopiennik Górny położona na wschód od linii wyznaczonej przez drogę nr 17, część gminy Żółkiewka położona na południe od linii wyznaczonej przez drogę nr 842 w powiecie krasnostawskim,
- gmina Stary Zamość, Radecznica, Szczepieszyn, Sułów, Nielisz i część gminy Skierbieszów położona na zachód od linii wyznaczonej przez drogę nr 843 powiecie zamojskim,
- część gminy Frampol położona na północ od linii wyznaczonej przez drogę nr 74, część gminy Goraj położona na wschód od linii wyznaczonej przez drogę nr 835, część gminy Turobin położona na wschód od linii wyznaczonej przez drogę nr 835 w powiecie biłgorajskim,
- gminy Hanna, Wiryki, Urszulin, część gminy Hańsk położona na zachód od linii wyznaczonej przez drogę nr 819 i część gminy wiejskiej Włodawa położona na północ od linii wyznaczonej przez północną granicę miasta Włodawa i miasto Włodawa w powiecie włodawskim,
- powiat łączyński,
- gmina Trawniki w powiecie świdnickim,
- gminy Serokomla i Wojcieszków w powiecie łukowskim,
- gminy Milanów, Parczew, Siemień w powiecie parczewskim,
- gminy Borki, Czemierniki, Radzyń Podlaski z miastem Radzyń Podlaski, Wołyń w powiecie radzyńskim,
- gminy Lubartów z miastem Lubartów, Firlej, Jeziorzany, Kock, Niedźwiada, Ostrów Lubelski, Ostrówek, Serniki w powiecie lubartowskim,
- gminy Jastków, Niemce i Wólka w powiecie lubelskim,
- powiat miejski Lublin,

w województwie podkarpackim:

- gmina Narol w powiecie lubaczowskim,

w województwie lubuskim:

- gminy Nowa Sól i miasto Nowa Sól, Otyń oraz część gminy Kozuchów położona na północ od linii wyznaczonej przez drogę nr 283 biegnącą od wschodniej granicy gminy do skrzyżowania z drogą nr 290 i na północ od linii wyznaczonej przez drogę nr 290 biegnącej od miasta Mirocin Dolny do zachodniej granicy gminy w powiecie nowosolskim,
- gminy Zabór oraz część gminy Bojadła położona na południe od linii wyznaczonej przez drogę nr 278 biegnącą od wschodniej granicy gminy do skrzyżowania z drogą nr 282 i na południe od linii wyznaczonej przez drogę nr 282 biegnącej od miasta Bojadła do zachodniej granicy gminy w powiecie zielonogórskim,
- powiat miejski Zielona Góra.

w województwie wielkopolskim:

- gminy Buk, Dopiewo, Tarnowo Podgórne, część gminy Komorniki położona na zachód od linii wyznaczonej przez drogę nr 5, część gminy Sęszew położona na północny – zachód od linii wyznaczonej przez drogi nr 5 i 32 w powiecie poznańskim,
- część gminy Duszniki położona na wschód od linii wyznaczonej przez drogę nr 306 biegnącą od południowej granicy gminy do skrzyżowania z drogą nr 92 oraz na południe od linii wyznaczonej przez drogę nr 92 biegnącą od wschodniej granicy gminy do skrzyżowania z drogą nr 306, część gminy Kaźmierz położona na południe i na wschód od linii wyznaczonych przez drogi: nr 92 biegnącą od zachodniej granicy gminy do skrzyżowania z drogą łączącą miejscowości Witkowice – Gorszewice – Kaźmierz (wzdłuż ulic Czereśniowa, Dworcowa, Marii Konopnickiej) – Chlewiska, biegnącą do wschodniej granicy gminy w powiecie szamotulskim.

4. Romania

The following areas in Romania:

- Zona oraşului Bucureşti,
- Judeţul Constanţa,
- Judeţul Satu Mare,
- Judeţul Tulcea,
- Judeţul Bacău,
- Judeţul Bihor,
- Judeţul Brăila,
- Judeţul Buzău,
- Judeţul Călăraşi,
- Judeţul Dâmboviţa,
- Judeţul Galaţi,
- Judeţul Giurgiu,
- Judeţul Ialomiţa,
- Judeţul Ilfov,
- Judeţul Prahova,
- Judeţul Sălaj,
- Judeţul Vaslui,
- Judeţul Vrancea,
- Judeţul Teleorman,
- Judeţul Mehedinţi,
- Judeţul Gorj,
- Judeţul Argeş,
- Judeţul Olt,
- Judeţul Dolj,
- Judeţul Arad,
- Judeţul Timiş,
- Judeţul Covasna,
- Judeţul Braşov,
- Judeţul Botoşani,

- Județul Vâlcea,
- Județul Iași,
- Județul Hunedoara,
- Județul Alba,
- Județul Sibiu,
- Județul Caraș-Severin,
- Județul Neamț,
- Județul Harghita,
- Județul Mureș,
- Județul Cluj,
- Județului Maramureș.

PART IV

Italy

The following areas in Italy:

- tutto il territorio della Sardegna.'
-

COUNCIL IMPLEMENTING DECISION (EU) 2020/774**of 8 June 2020****authorising the Republic of Finland to apply a special measure derogating from Article 287 of Directive 2006/112/EC on the common system of value added tax**

THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to Council Directive 2006/112/EC of 28 November 2006 on the common system of value added tax ⁽¹⁾, and in particular the first subparagraph of Article 395(1) thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) Pursuant to point (5) of Article 287 of Directive 2006/112/EC, Finland may exempt from value added tax ('VAT') taxable persons whose annual turnover is no higher than the equivalent in national currency of ECU 10 000 at the conversion rate on the day of its accession.
- (2) By letter registered with the Commission on 6 January 2020, Finland requested authorisation to introduce a special measure derogating from point (5) of Article 287 of Directive 2006/112/EC ('the special measure') from 1 January 2021 until 31 December 2024 in order to increase the exemption threshold to EUR 15 000. Through the special measure, taxable persons whose annual turnover is no higher than EUR 15 000 would be exempt from certain or all of the VAT obligations set out in Chapters 2 to 6 of Title XI of Directive 2006/112/EC.
- (3) A higher threshold for the special scheme for small enterprises set out in Articles 281 to 294 of Directive 2006/112/EC is a simplification measure, as it may significantly reduce the VAT obligations of small enterprises.
- (4) By letter dated 10 March 2020, the Commission informed the other Member States, pursuant to the second subparagraph of Article 395(2) of Directive 2006/112/EC, of the request made by Finland. By letter dated 11 March 2020, the Commission notified Finland that it had all the information it considered necessary for appraisal of the request.
- (5) The special measure is in line with Council Directive (EU) 2020/285 ⁽²⁾. That Directive amended Chapter 1 of Title XII of Directive 2006/112/EC, which governs the special scheme for small enterprises. Directive (EU) 2020/285 seeks to reduce VAT compliance costs for small enterprises, mitigate distortions of competition at both national and Union level, and reduce the negative impact of transition from exemption to taxation (what is known as the threshold effect). It also seeks to facilitate business compliance by small enterprises and monitoring by tax administrations. The requested threshold of EUR 15 000 is consistent with Article 284 of Directive 2006/112/EC, as amended by Directive (EU) 2020/285.
- (6) The special measure is optional for taxable persons. Taxable persons will still be able to opt for the regular VAT arrangements in accordance with Article 290 of Directive 2006/112/EC.
- (7) According to the information provided by Finland, the special measure will only have a negligible effect on the overall amount of the tax revenue of Finland collected at the stage of final consumption.

⁽¹⁾ OJ L 347, 11.12.2006, p. 1.

⁽²⁾ Council Directive (EU) 2020/285 of 18 February 2020 amending Directive 2006/112/EC on the common system of value added tax as regards the special scheme for small enterprises and Regulation (EU) No 904/2010 as regards the administrative cooperation and exchange of information for the purpose of monitoring the correct application of the special scheme for small enterprises (OJ L 62, 2.3.2020, p. 13).

- (8) The special measure will not adversely affect the Union's own resources accruing from VAT because Finland will carry out a compensation calculation in accordance with Article 6 of Council Regulation (EEC, Euratom) No 1553/89 ⁽³⁾.
- (9) Given that Finland expects the increased threshold to result in reduced VAT obligations and thus a reduction in the administrative burden and compliance costs for small enterprises and for the tax authorities, and given that there will be no major impact on the total VAT revenue generated, Finland should be authorised to apply the special measure.
- (10) The authorisation to apply the special measure should be limited in time. The time limit should be sufficient to allow the effectiveness and appropriateness of the threshold to be evaluated. Moreover, Directive (EU) 2020/285 requires Member States to adopt and publish, by 31 December 2024, the laws, regulations and administrative provisions necessary to comply with Article 1 of that Directive, and apply those provisions from 1 January 2025. It is therefore appropriate to authorise Finland to apply the special measure until 31 December 2024,

HAS ADOPTED THIS DECISION:

Article 1

By way of derogation from point (5) of Article 287 of Directive 2006/112/EC, Finland is authorised to exempt from VAT taxable persons whose annual turnover is no higher than EUR 15 000.

Article 2

This Decision shall take effect on the date of its notification.

This Decision shall apply from 1 January 2021 until 31 December 2024.

Article 3

This Decision is addressed to the Republic of Finland.

Done at Brussels, 8 June 2020.

For the Council
The President
A. METELKO-ZGOMBIĆ

⁽³⁾ Council Regulation (EEC, Euratom) No 1553/89 of 29 May 1989 on the definitive uniform arrangements for the collection of own resources accruing from value added tax (OJ L 155, 7.6.1989, p. 9).

RECOMMENDATIONS

COMMISSION RECOMMENDATION (EU) 2020/775

of 5 June 2020

on the key elements of the fair compensation and other key elements to be included in the technical, legal and financial arrangements between Member States for the application of the assistance mechanism under Article 15 of Regulation (EU) 2019/941 of the European Parliament and of the Council on risk-preparedness in the electricity sector and repealing Directive 2005/89/EC of the European Parliament and of the Council

(notified under document C(2020) 3572)

THE EUROPEAN COMMISSION,

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

Having regard to Article 15(7) of Regulation (EU) 2019/941 of the European Parliament and of the Council of 5 June 2019 on risk-preparedness in the electricity sector and repealing Directive 2005/89/EC ⁽¹⁾,

Whereas:

- (1) Article 194(1) of the Treaty on the Functioning of the European Union (TFEU) states that EU energy policy should aim for security of energy supply in the Union, in a spirit of solidarity between Member States.
- (2) The Regulation on risk-preparedness in the electricity sector is intended to contribute to the implementation of the objectives of the Energy Union, of which energy security, solidarity, trust and an ambitious climate policy are an integral part.
- (3) The Regulation introduces an assistance mechanism between Member States as an instrument to prevent or manage electricity crises within the Union.
- (4) When adopting the measures needed to implement the assistance mechanism, Member States have to agree on a number of technical, legal and financial issues in the regional or bilateral arrangements and describe them in their risk-preparedness plans.
- (5) To assist Member States in implementation, and having consulted the Electricity Coordination Group (ECG) and the Agency for the Cooperation of Energy Regulators (ACER), the Commission has prepared this non-binding guidance on the key elements that should be included in such arrangements,

HAS ADOPTED THIS RECOMMENDATION:

1. Member States should follow the non-binding guidance in the Annex to this Recommendation. This guidance should help Member States put in place technical, legal and financial arrangements to apply the assistance obligations in Article 15 of Regulation (EU) 2019/941 and describe them in the risk-preparedness plans they are required to draw up under the Regulation.
2. This Recommendation shall be published in the *Official Journal of the European Union*.

Done at Brussels, 5 June 2020.

For the Commission
Kadri SIMSON
Member of the Commission

⁽¹⁾ OJ L 158, 14.6.2019, p. 1.

ANNEX

1. INTRODUCTION

Regulation (EU) 2019/941 ('the Regulation') translates the concept of solidarity into practice and establishes an assistance mechanism between the Member States that comes into play when the conditions set out in the relevant provisions are fulfilled. Assistance is a mechanism of last resort to prevent or manage electricity crises.

1.1. The assistance mechanism

If a Member State requests assistance, the assistance mechanism includes an obligation for the other Member States within the regional agreement or with a bilateral agreement ⁽¹⁾ to cooperate in a spirit of solidarity to prevent and manage electricity crises. The limits on the help a Member State can provide are generally:

- the maximum possible, under the specific crisis conditions, available cross-zonal capacity,
- the amount of electricity necessary for the purpose of protecting its own public safety and personal security ⁽²⁾,
- the operational security of its own electricity network.

The different elements of a regional or bilateral arrangement covering the legal, technical and financial aspects of assistance are already partly covered by Article 15 of the Regulation. In addition, the Member States have to agree in their regional or bilateral arrangements on all necessary elements and details, in order to provide certainty and security to all involved in making the assistance mechanism work. These arrangements have to be described in the respective risk-preparedness plans; in particular, the economic compensation mechanism must be included. The Regulation and this guidance do not harmonise all aspects of the fair compensation between Member States.

Compensation as described in Article 15 of the Regulation is wide-ranging. It encompasses payments for the electricity delivered into the territory of the Member State requesting assistance, and additional costs such as associated transmission costs and other reasonable costs incurred by the Member State providing assistance.

There are several conditions for the assistance to work properly.

Firstly, market-based measures should be pursued for as long as possible. Member States need to make every effort to complete the development of coordinated mechanisms or platforms that allow for voluntary demand-side response sharing and the sharing of other flexible capacity. It is in the interest of the potential providing and requesting Member States to avoid situations in which non-market measures – including forced curtailment of customers – need to start at an earlier stage. It is also in line with the general principle in the Regulation that the market should be given maximum leeway to solve electricity supply issues.

Secondly, variation of wholesale prices in accordance with the market rules should be allowed, even in an electricity crisis, as long as the operation of the electricity markets does not cause further deterioration of the electricity crisis. In fact, bidding restrictions and implicit or explicit price caps, which do not comply with well-designed market rules ⁽³⁾, prevent price signals from reflecting the need for additional electricity, thus preventing electricity from flowing where it is needed. This means market prices should be allowed to form based on supply and demand for as long as possible in the lead up to a crisis, and imbalance settlement prices after a crisis should reflect the cost to consumers of any disconnections to supply. This prevents implicit price caps in the balancing rules acting as a disincentive for investments in the flexible and reliable capacity that can help avoid electricity crises.

⁽¹⁾ In accordance with Article 12.1 of the Regulation, 'regional measures' should be agreed within the region concerned between Member States that have the technical ability to provide each other assistance in accordance with Article 15. For that purpose, Member States may also form subgroups within a region and agree on regional measures bilaterally or multilaterally. In addition, 'bilateral measures' should be agreed between Member States which are directly connected but are not within the same region.

⁽²⁾ The ultimate goal of the assistance mechanism is to protect public safety and personal security, as established in Article 15.2 of the Regulation.

⁽³⁾ Rules related to price caps and technical bidding limits are set out in Article 10 of Regulation (EU) 2019/943 of the European Parliament and of the Council of 5 June 2019 on the internal market for electricity (OJ L 158, 14.6.2019, p. 54).

Thirdly, cross-border access to infrastructure should be maintained for as long as is technically and safely possible in accordance with Regulation (EU) 2019/943 of the European Parliament and of the Council ⁽⁴⁾, at all times, even in an electricity crisis. Depending on the technical constraints in each Member State, arrangements should ensure that cross-zonal capacity and demand-side offers, where appropriate, are fully accessible to market players across the border. This will delay the need to curtail customers in the Member State facing supply difficulties.

Fourthly, Member States are encouraged to cooperate throughout all stages of an electricity crisis. Effective cooperation in the early stages could prevent the occurrence or escalation of an electricity crisis, and mitigate its effects.

Assistance can only be triggered by a requesting Member State as a last resort if all options provided by the market have been exhausted or where it is evident that market-based measures alone are not sufficient to prevent a further deterioration of the electricity supply situation, especially when it fails to offer the electricity necessary to protect public safety and personal security. Moreover, the national measures in the requesting Member State's risk-preparedness plan must have been exhausted.

1.2. **Legal basis**

Article 15(7) of the Regulation states that the Commission, after consulting the ECG and ACER, must provide non-binding guidance on the key elements of the fair compensation referred to in paragraphs 3 to 6 and other key elements of the technical, legal and financial arrangements referred to in paragraph 3, as well as on general principles of mutual assistance referred to in paragraph 2.

1.3. **Scope of the guidelines**

Articles 12 and 15 of the Regulation identify several elements and aspects of the assistance mechanism that need to be agreed and included in the regional and bilateral arrangements. However, the Regulation gives Member States wide discretion when agreeing on the content of such coordinated measures and, by consequence, on the content of the assistance that they offer. It is for Member States to decide and agree on such coordinated measures, in particular on the necessary technical, legal and financial arrangements for their implementation.

Offering useful guidance on these and any further elements that might be included in such arrangements first requires a better understanding of the situation in which assistance might be triggered, and the efforts and basic principles that could prevent such a situation from emerging at all. The current non-binding guidance does not, and cannot, provide an exhaustive and prescriptive list appropriate for all Member States, as they must have the freedom to choose solutions that best suit their capabilities, existing frameworks, situation and priorities. Instead, it recommends the use of a set of necessary and optional elements and describes possible ways of running certain assistance measures.

The proposed approach is for Member States to build the coordinated measures on existing national frameworks and procedures wherever possible, and to adapt them as necessary for assistance purposes. This may include the use of existing platforms or mechanisms for demand-side measures or existing customer compensation mechanisms.

2. **LEGAL, TECHNICAL AND FINANCIAL ARRANGEMENTS**

2.1. **Legal arrangements**

The objective of the legal arrangements is to provide legal certainty to all involved in providing or receiving electricity in an electricity crisis. Member States involved in applying the assistance mechanism are advised to put in place clear, transparent and effective legal arrangements so that stakeholders know the rules and procedures for cross-border assistance.

⁽⁴⁾ OJ L 158, 14.6.2019, p. 54.

Article 12 of the Regulation requires that risk-preparedness plans include regional and, where applicable, bilateral measures to ensure that crisis situations with a cross-border impact are properly prevented or managed. When establishing legal arrangements, Member States may also consider the possibility of creating sub-groups within a region ⁽⁷⁾, comprising those Member States which are technically able to provide each other with assistance. This is because not all members of a larger region will necessarily be able to provide electricity to another Member State in a crisis. Thus, there is no need to conclude regional agreements on concrete cross-border measures with all Member States in a region, but only with those which have the technical ability to provide assistance. Bilateral measures should be agreed between Member States which are directly connected but not part of the same region.

There can be particular situations where a Member State is not directly connected to any other Member State. With infrastructure projects for interconnections currently under development, this may change. Should the interconnections come online after the adoption of the risk-preparedness plans, the concerned Member States will need to put in place the legal, financial, and technical arrangements set out in Article 15 of the Regulation at the earliest opportunity, and update their risk-preparedness plans to reflect them.

2.1.1. *Member States concerned*

The Member States concerned by the assistance mechanism are:

- the Member State that requested assistance, and
- all Member States which are technically able to provide assistance within the same region (with a regional agreement) and Member States with bilateral agreements (connected with the requesting Member State but not belonging to the same region).

If the requesting Member State has in place a regional agreement and/or a bilateral agreement, then it should communicate its need of assistance to all the Member States that can provide such assistance.

2.1.2. *Request for assistance*

Since electricity crises call for fast responses, the request for assistance should be short, standardised and contain a minimum amount of necessary information. Ideally, Member States concluding a regional or bilateral arrangement may agree on a template for the request and attach it to the arrangement as an annex. The following information would appear to be the minimum needed to efficiently respond to an assistance request:

- name of the requesting Member State, including the entity in charge and contact person(s),
- name of the Transmission System Operator (TSO) and Nominated Electricity Market Operator (NEMO) and responsible contact person(s),
- indication of the expected deficit in terms of energy and power (measured in a commonly agreed unit) and the anticipated duration of this gap,
- indication by the requesting Member State of the preferable interconnector or delivery points, where relevant (for example, for mobile generators),
- for some particular agreed technical tools (request to reactivate mothballed power plants, transfer of mobile generators, activation of strategic reserves, etc.), a request to indicate the timing of the first possible delivery and the anticipated duration of the provision of supplies (indicating the anticipated period during which the assisting Member State will provide assistance),
- a reference to the commitment by the requesting Member State to pay compensation for assistance.

2.1.3. *Electricity users entitled to receive special protection against disconnection for reasons of public safety and personal security*

Article 11 of the Regulation describes which measures should be included in the risk-preparedness plans as regards the national measures to prevent, prepare for and mitigate an electricity crisis. Point (h) of paragraph 1 allows Member States to specify, with regard to public safety and personal security, which categories of electricity users are, in accordance with national law, entitled to receive special protection against disconnection, and to

⁽⁷⁾ The Regulation defines a 'region' as a group of Member States whose transmission system operators share the same regional coordination centre as referred to in Article 36 of the Electricity Regulation.

justify the need for such protection. 'Public safety and personal security' concern the welfare and protection of the general public, and concern prevention and protection from dangers associated with users entitled to receive special protection against disconnection.

To protect public safety and personal security, Member States should establish special measures to ensure continuity of power supply in light of:

- national, regional or local critical need,
- public health and safety issues,
- the potential for catastrophic damage or a high risk of significant safety issues (due for example to environmental risks),
- potential exposure to security threats,
- technical capabilities for selective disconnections.

Pursuant to the Regulation, Member States can define by national law which categories of electricity users are entitled to receive special protection against disconnection. In defining these categories, Member States should take into account the duration and extent of the crisis, which may influence the list of electricity users entitled to receive special protection against disconnection. If the crisis lasts beyond a certain time or extends beyond a certain scope, it may endanger the life, security or health of larger parts of the population. In any case, the list of electricity users entitled to receive special protection against disconnection should be clearly defined in the risk-preparedness plans, including the category of users that may only be included in the event of an extensive crisis of long duration. The list has to be consistent with the risk scenarios identified at national and at regional levels included in the risk-preparedness plans and with their estimated impact.

Examples of electricity users that could be entitled to receive special protection against disconnection are:

- Energy sector:
 - Electricity subsector: electricity system own critical requirements, particularly those to maintain generating capacity and nuclear safety, and dispatch centres.
 - Gas subsector: critical gas system facilities to maintain the safety of gas installations, and dispatch centres.
 - Oil refineries and vital oil pumping stations to maintain the safety of the installations.
- Transport sector:
 - Air transport: major airports and associated control facilities.
 - Rail transport: significant railway operations if dependent on the general electricity supply.
 - Road transport: traffic management control systems and traffic signals.
 - Maritime transport: major ports and docks and associated control facilities.
- Health sector: healthcare settings including hospitals and private clinics.
- Water supply: essential water and sewage installations.
- Digital and telecommunication services where there is a national need for continued operation.
- Security and safety:
 - Emergency services of national/regional significance.
 - Civil protection facilities.
 - Armed forces sites, notably those that provide civil protection support.
 - Public or private prison services.
- Administration facilities where there is a national need for continued operation.
- Financial services where there is a national or EU-wide need for continued operation.
- Sites with industrial processes not sustainable through standby generation, where disconnection might cause significant safety issues.

For those countries that define by national law electricity users entitled to receive special protection against disconnection, the list should be kept updated, with the estimated consumption for each of the elements.

It is recommended that it be ensured that electricity users entitled to receive special protection against disconnection also have robust business continuity arrangements in place to maintain adequate supply of services in the event of an electricity crisis, rather than relying only on the arrangements under the risk-preparedness plans.

All electricity users entitled to receive special protection against disconnection should also reduce their load as much as possible in the event of an electricity crisis. If the situation deteriorates and the risk of shortfall of supply to these electricity users is imminent, priority should be given to preventing loss of life and to minimising the risk of disasters that could involve loss of life or major damage.

2.1.4. *Start and end of provision of assistance*

Article 15(3) of the Regulation requires that Member States have to agree on the trigger for any assistance and for its suspension. This has to be done subject to the necessary technical, legal and financial arrangements.

Article 2(9) of the Regulation defines an 'electricity crisis' as a present or imminent situation in which there is a significant electricity shortage, as defined by the Member States and described in their risk-preparedness plans, or in which it is impossible to supply electricity to customers. Following the declaration of an electricity crisis by the competent authority of the Member State concerned, all the agreed measures should be implemented to the fullest possible extent.

The trigger to request assistance should be defined in relation to any existing or imminent situation, when non-market measures are expected to be necessary to avoid or minimise impacts of the electricity crisis.

In particular, where categories of electricity users entitled to receive special protection against disconnection are defined by national law, the trigger to request assistance should be defined in relation to an existing or imminent situation in which a Member State cannot ensure protection against disconnection for the categories of electricity users specified with regard to public safety and personal security, despite all national market and non-market measures. For the Member States that do not define by national law categories of electricity users entitled to receive special protection against disconnection, the trigger to request assistance should be defined in relation to an existing or imminent situation in which a Member State cannot supply the amount of electricity necessary for the purpose of protecting its public safety and personal security.

For each risk scenario identified in the risk-preparedness plan, Member States should specify the triggering event. This may be an operational or non-operational event. Operational events may be loss of controllability, lack of balance between generation and demand, lack of reserves or inability to supply electricity due to physical damage to parts of the systems. Non-operational events may, for example, be external security threats.

The risk of misuse of the assistance mechanism by an unjustified assistance request is very small because of the strict conditions that must be fulfilled before the assistance mechanism is triggered.

Without prejudice to what Member States agree in the respective regional or bilateral agreements, the obligation to provide assistance should cease to apply when:

- the Member State that requested assistance informs the Member State(s) providing assistance that it is again in the position to supply electricity to its electricity users entitled to receive special protection against disconnection or to ensure the supply of electricity necessary for the purpose of protecting public safety and personal security,
- the Member State providing assistance can no longer supply its own electricity users, especially the users entitled to receive special protection against disconnection or can no longer ensure the supply of electricity for the purpose of protecting public safety and personal security, due to a deterioration of its own system.

It is also possible that, despite an ongoing acute electricity crisis, the Member State that initially requested assistance decides to request suspension of the assistance, for example because it cannot afford to pay.

2.1.5. *Roles and responsibilities*

Ultimate responsibility for running the assistance mechanism should rest with the Member States. This includes in particular the decision to request assistance and overall monitoring of how the entities responsible for specific tasks are operating the mechanism. The Regulation does not require the creation of new specific entities. Member States are advised to allocate responsibilities preferably to existing entities or, in special circumstances, to new entities, taking account of their organisational structure and experience in crisis management and emergency response. In order to reduce costs, and particularly to avoid fixed costs, Member States should rely on existing mechanisms where possible. The guiding principle in this respect should be that assistance is provided efficiently and effectively.

The competent authorities under the Regulation are responsible for implementing the framework, with tasks and responsibilities clearly assigned to the respective actors, such as the national crisis coordinator, the coordinator or a team composed of the relevant national electricity crisis managers, TSOs, the national regulatory authority and electricity undertakings. The competent authorities are also best placed to prepare the regional and bilateral arrangements together with the competent authorities of other Member States. These arrangements will form the legal basis of the assistance, including payment of compensation and financial settlement after the assistance has been provided. Member States and their competent authorities are also best placed to be responsible for sending or receiving requests for assistance, coordinating measures and notifying when the assistance application has been suspended. Financial responsibility for compensation should also ultimately lie with the Member States, in order to provide sufficient assurances of prompt payment of fair compensation.

Subject to the technical and legal constraints in each Member State, national regulatory authorities are best placed to lead, or at least be involved in, the process of calculating compensation costs. The TSOs should preferably be in charge of dispatching the necessary electricity quantities in a cost-efficient manner.

The TSOs, with the support of the regional coordination centres and the regional security coordinators (pending establishment of regional coordination centres) are best placed to take responsibility for coordinating all technical aspects and implementing all necessary operational measures when assistance is applied. The entity in the Member State that is in charge of providing assistance could also be in charge of collecting claims for electricity and additional costs, verifying them and channelling them to the entity in the Member State that benefited from assistance. In this context, a one-stop-shop approach would be useful. The Member States are advised to identify and agree on which entity is in charge of collecting and channelling claims for compensation for curtailment.

Making provision for a mediator in the regional and bilateral arrangements concluded between Member States might reassure all parties concerning payment and the calculation of compensation costs. The mediator would help resolve any disagreements about the amount of the compensation to be paid.

2.1.6. *Legal form of the regional and bilateral arrangement*

There is no explicit requirement with regard to the legal form of the regional and bilateral arrangements. Member States are free to find a legal form that creates rights and obligations between them if the assistance mechanism is applied. The right to request assistance and the obligation to provide assistance are laid down in Articles 14 and 15 of the Regulation. The regional and bilateral arrangements will define how these rights and obligations, established in Union law, are to be exercised. The arrangements should be operational, not political in nature. Depending on the requirements of the national law of each Member State, it may be enough for implementation purposes for the relevant authorities to conclude a binding administrative arrangement. This might include existing regional or bilateral treaty provisions, contractual arrangements between TSOs, or specific licensing conditions for electricity entities, provided they are overseen by the relevant competent authorities. On the other hand, a non-binding legal instrument such as a memorandum of understanding would not be sufficient on its own, as it does not create legal obligations between the participants. Relying solely on arrangements in the form of a memorandum would therefore fall short of the requirements of Article 15 to create a legally binding system for assistance, and could be interpreted as insufficient implementation of Article 15 ⁽⁶⁾.

⁽⁶⁾ Arrangements in the form of a memorandum of understanding should be complemented by national binding measures that ensure the application of the provisions of the memorandum of understanding.

2.1.7. *Assistance before regional and bilateral agreements have been concluded*

In accordance with Article 15 of the Regulation, in the event of an electricity crisis where Member States have not yet agreed on coordinated measures and technical, legal and financial arrangements, Member States should agree on ad hoc measures and arrangements, including as regards fair compensation. Where a Member State requests assistance before such agreements have been concluded, it should undertake to pay fair compensation prior to receiving assistance.

2.1.8. *Treatment of confidential information*

Any procedures involving Member States or their authorities referred to in the Regulation are to be implemented by them in line with the applicable rules, including national rules related to the handling of confidential information and processes. If this leads to a situation where information cannot be disclosed, including as part of risk-preparedness plans, the Member State or authority in question may provide a non-confidential summary thereof, or must do so upon request.

The Commission, ACER, the ECG, ENTSO-E, Member States, competent authorities, national regulatory authorities and other relevant bodies, entities or persons that receive confidential information pursuant to the Regulation should ensure that the confidentiality of sensitive information is maintained.

2.2. **Technical arrangements**

The purpose of the technical arrangements is to describe all necessary technical provisions and conditions that would enable the assistance mechanism to work in practice. This would require compulsory prior sharing of information about the technical capability and constraints of the relevant electricity infrastructure, and the maximum theoretical amount of electricity relevant for assistance, together with an assessment of the technical constraints that would make assistance difficult. If technical or other constraints exist, Member States are encouraged to identify and agree on mutually acceptable solutions to be applied in order to secure the necessary cross-zonal capacity if the assistance mechanism is triggered.

Depending on the technical constraints within each Member State, it may be that the TSOs, with the support of the regional coordination centre, are best placed to take responsibility for coordinating all technical aspects and implementing all necessary operational measures based on their knowledge of the electricity systems and their existing cross-border cooperation schemes in case of emergency⁽⁷⁾. These existing cooperation structures, agreements and experience should serve as a basis for assistance. In any case, a clear overarching framework should be identified (if already in place) or established, including the technical conditions, so that the necessary cooperation can be undertaken with legal certainty. Technical data can be updated as necessary in the risk-preparedness plans.

2.2.1. *Technical solutions and coordination (Article 15(2))*

Technical solutions and arrangements can be made for the various parts of the infrastructure in a given Member State. This will provide a clear picture of the assistance available, the technical constraints involved and a better estimate of the costs of implementing each measure (if relevant). As potential crisis situations can be very different, it is important that Member States are left with a wide range of options and tools to draw on. An indicative and non-exhaustive list of technical solutions can be described in the technical arrangements, so that the parties are aware of the steps that might be taken for assistance purposes before and during an emergency. Simulations of assistance measures may be beneficial for preparedness for such situations.

The system operation guidelines⁽⁸⁾ and the network code on emergency and restoration⁽⁹⁾ constitute a detailed rulebook governing how transmission system operators and other relevant stakeholders should act and cooperate to ensure system security. They also harmonise TSOs' technical standards and emergency protocols within each synchronous area. These technical rules aim to ensure that most electricity incidents are dealt with effectively at operational level. To address electricity crisis situations that could have a larger scale and impact where market and system operation rules alone no longer suffice, Member States should agree on specific measures going beyond the TSOs' responsibility to prevent, prepare for and manage such situations. Even during these crisis situations, rules governing the internal market, and system operation rules included in the system operation guidelines and the network code on emergency and restoration (which govern transaction curtailment, limitation of provision of cross-zonal capacity for capacity allocation, or limitation of provision of schedules), should be respected.

⁽⁷⁾ For example: Mutual Emergency Assistance Service. (MEAS) TSO-TSO contracts.

⁽⁸⁾ Commission Regulation (EU) 2017/1485 of 2 August 2017 establishing a guideline on electricity transmission system operation (OJ L 220, 25.8.2017, p. 1).

⁽⁹⁾ Commission Regulation (EU) 2017/2196 of 24 November 2017 establishing a network code on electricity emergency and restoration (OJ L 312, 28.11.2017, p. 54).

The network code on emergency and restoration establishes the requirements for the management by TSOs of the emergency, blackout and restoration states and the coordination of system operation across the Union in such states, including the procedure for suspension of market activities, the defence plan and the restoration plan. The system defence plan is the compilation of the technical and organisational measures to be undertaken to prevent the propagation or deterioration of a disturbance in the transmission system, in order to avoid a wide area state disturbance and blackout state.

Technical solutions and arrangements should take full advantage of the opportunities provided by regional cooperation. Therefore, these arrangements should include the agreed technical steps needed to prevent the crisis, as well as the agreed technical steps needed to mitigate its effects and avoid its escalation when the crisis has occurred.

Some of the technical solutions are preventive, i.e. carried out well in advance in order to minimise the risk of future crises (for example, development of winter re-dispatch products for extreme events or modification of the duration of a planned outage). Others are used just before the event, i.e. when there is evidence that the crisis could happen (in the preparation phase). Finally, others are deployed during the disruption to limit or shorten the effects of the crisis.

For each technical solution, it is recommended that risk-preparedness plans include information about its capability (GWh/week), whether or not it has already been verified in practice, start-up time from decision to effect, potential duration, entity responsible for each measurement, dependency on other measures, side effects, and any other remarks. For non-market solutions, in accordance with Article 11.1 (g), it should be indicated how they comply with the requirements laid down in Article 16.

When the crisis is declared existent or imminent, there will have to be coordination across the relevant TSOs, NEMOs, distribution system operators (DSOs), national emergency coordinators, competent authorities, and entities involved in delivering the electricity. They should be involved early enough in the discussions on assistance provisions and possibly tasked to work together to execute the assistance arrangements.

In exceptional cases where cross-zonal capacity has been offered to the market but has remained unused, TSOs should be entitled to utilise those capacities.

2.2.2. *Technical information in the early warning and declaration of crisis (Article 14) and methodology for estimation pursuant to Article 15(3) (which should be re-assessed based on the technical ability to deliver once assistance is required during the crisis)*

For the sake of transparency and as a basis for the discussions on the required assistance, Member States should inform other Member States within their regional agreement and any further bilateral agreements (i.e. potential providers of assistance) about the theoretical maximum electricity quantities they may request, the status and limit of cross-zonal capacity, the possible period when assistance will be required and the trigger for the assistance. Nevertheless, the exact electricity quantities needed, requested and available will only be known once assistance is triggered. For the calculation of these theoretical maximum electricity quantities, the following elements should be taken into consideration as a minimum:

- indication of the expected deficit in terms of energy and power and the anticipated duration of this gap due to unavailability of generation and/or cross-zonal capacity,
- indication of the uncertainty of the expected deficit that is a function of the limited predictability of variable renewable generation, the limited predictability of the actual demand as well as the possibility of unplanned outages of generation assets,
- specific characteristics of the Member State system: the state of interconnectors if relevant (in case of outage), the level of hydro reservoirs and its expected evolution, storage capacity, demand-side response possibilities, possibility of fuel shortages etc.,
- any other critical operational characteristic than can be impacted due to the crisis (for example, a gas shortage might impact the frequency control capabilities of a particular area or reduce the available amounts of frequency containment reserves and automatic frequency restoration reserves).

A good starting point for the analysis of the potential electricity quantities can be the latest seasonal and short-term adequacy assessments. The previous information should be updated when new information is available and when the crisis effectively occurs, to re-assess the requirements and the system state.

2.2.3. *Operational security of networks*

Risk scenarios can consider more extreme events, other exceptional contingencies and out-of-range contingencies not considered in the contingency list ⁽¹⁰⁾, or violations of operational security limits that have to be taken into account. A specific assessment should be carried out to determine the potential non-security situations and the potential lines of action to deal with them.

The arrangements may provide a description of the technical possibilities and constraints of the individual electricity networks that need to be maintained for the electricity system to operate safely and reliably. This is important information for both the assisting and the assisted Member States.

2.2.4. *Observance of market rules*

Pursuant to Article 16 of the Regulation, measures taken to prevent or mitigate electricity crisis situations must comply with the rules governing the internal electricity market and system operation. Notably, markets should remain active and market measures be pursued to the largest possible extent, i.e. prices should follow demand and supply conditions and access to cross-border interconnectors should be kept open under standard conditions. High prices (in hours of scarcity) should be seen as normal in the operation of power markets, as they constitute a key tool to triggering additional electricity to come online and meet demand in both the short and long term.

In the same way, the system operation guideline must be followed for normal and alert states of the system and the emergency and restoration network code must be followed in the event of emergency, blackout and restoration states.

2.2.5. *Activation of non-market-based measures*

Pursuant to Article 16 of the Regulation, non-market-based measures may be activated in an electricity crisis only:

- as a last resort if all options provided by the market have been exhausted, or
- where it is evident that market measures alone are not sufficient to prevent a further deterioration of the electricity supply situation.

In addition, non-market-based measures may not unduly distort competition and the effective functioning of the internal electricity market. They must be necessary, proportionate, non-discriminatory and temporary. Non-market based measures constituting a restriction of electricity flows between Member States cannot go beyond the measures listed in point 2.2.5.1 and can only be initiated as provided by the rules referred under that point.

Non-market-based measures should be activated as late as possible, taking into account the most up-to-date information regarding the situation of the power system (system status and forecasts). In addition, enough time should be allowed to communicate to the Member States, TSOs, relevant stakeholders and NEMOS in the region and to take the necessary actions. The duration of non-market-based measures should be as short as possible and the relevant hours of their application must be established in advance.

2.2.5.1. Non-market based measures constituting a restriction of electricity flows between Member States

Transaction curtailment can be carried out in the following cases:

- (a) curtailment of already allocated cross-zonal capacity (as referred to in Article 51 of Commission Regulation (EU) 2016/1719 of 26 September 2016 establishing a guideline on forward capacity allocation ⁽¹¹⁾ and Article 72 of Commission Regulation (EU) 2015/1222 of 24 July 2015 establishing a guideline on capacity allocation and congestion management ⁽¹²⁾);

⁽¹⁰⁾ Contingency lists are established pursuant to Article 33 of Regulation (EU) 2017/1485 (OJ L 220, 25.8.2017, p. 1).

⁽¹¹⁾ OJ L 259, 27.9.2016, p. 42.

⁽¹²⁾ OJ L 197, 25.7.2015, p. 24.

- (b) limitation of provision of cross-zonal capacity for capacity allocation, (as referred to in Article 16.3 of Regulation (EU) 2019/943 and in Article 35(2)(a) of Commission Regulation (EU) 2017/2196 of 24 November 2017 establishing a network code on emergency and restoration ⁽¹³⁾); or
- (c) limitation of provision of schedules after the outcome of the day-ahead or intra-day markets (as referred in referred to in Article 111(1) and 111(2) of Commission Regulation (EU) 2017/1485 ⁽¹⁴⁾).

The sub-sections below describe the existing rules applicable to each case.

- (a) Curtailment of already allocated cross-zonal capacity (as referred in Regulation (EU) 2016/1719 and in Regulation (EU) 2015/1222)

Article 51 of Regulation (EU) 2016/1719 establishing a guideline on forward capacity allocation establishes that all TSOs must develop harmonised allocation rules (HAR) for long-term transmission rights. Long-term cross-zonal capacity curtailment rules are established in title 9 of the HAR ⁽¹⁵⁾.

Article 72(1) of Regulation (EU) 2015/1222 establishing a guideline on capacity allocation and congestion management establishes that curtailment of allocated cross-zonal capacity is only possible in the event of force majeure or an emergency situation where the TSO must act in an expeditious manner, and re-dispatching and countertrading are not possible. In all cases, curtailment must be undertaken in a coordinated manner following liaison with all directly concerned TSOs. Article 72(3) establishes how the curtailment must be compensated.

- (b) Limitation of provision of cross-zonal capacity for capacity allocation (as referred in Regulation (EU) 2019/943 and Regulation (EU) 2017/2196)

The limitation of provision of cross-zonal capacity for capacity allocation is only possible when it is expected that the transmission system will not be restored to the normal or alert state.

- (c) Limitation of provision of schedules (as referred in Regulation (EU) 2017/1485)

Limitation of schedules due to local problems in the physical network or in ICT systems (tools and communication means) should be communicated as soon as possible. In the case of ICT problems, alternative channels of communication or backup procedures should be in place to limit the impact of the ICT problem. In the case of a problem in the physical network that produces a limitation of schedules, the risk preparedness plans at national level should define the procedure to manage and compensate it.

2.2.5.2. Market suspension

Article 35(1) of Regulation (EU) 2017/2196 establishing a network code on emergency and restoration defines cases in which market activities may be suspended.

Article 35(2) lists the market activities that the TSO may temporarily suspend. TSOs in a region must agree on the decision regarding the suspension of each of the activities and the rationale behind that decision.

No regionally or bilaterally agreed crisis measures or national non-market based measures should result in the suspension of market operations for reasons other than those listed in Article 35(1) of Regulation (EU) 2017/2196 establishing a network code on emergency and restoration.

2.3. Financial arrangements

Financial arrangements should ensure that electricity supplied under the assistance mechanism is paid for at an appropriate price. These arrangements might cover the calculation of costs, compensation for assistance (including compensation for curtailment), and the payment procedures to be identified and established between the relevant entities.

⁽¹³⁾ OJ L 312, 28.11.2017, p. 54.

⁽¹⁴⁾ OJ L 220, 25.8.2017, p. 1.

⁽¹⁵⁾ Decision of the Agency for the Cooperation of Energy Regulators No 03/2017 of 2 October 2017 on the electricity transmission system operators' proposal for harmonised allocation rules for long-term transmission rights.

The financial arrangements should not introduce perverse incentives, which could themselves trigger the need for assistance. Compensation for assistance is supposed to cover no more than the costs actually incurred; it cannot become a source of profit for the providing entity. The Member State receiving assistance should promptly pay the provider Member State a fair price for the electricity received. The latter will then determine how these funds are handled and how they fit with existing rules for imbalance settlement.

Any compensation paid to customers who are curtailed in an emergency – whether this stems from the obligation to provide cross-border assistance, or a national emergency – should be the same as that set out in national law.

In view of the above, Member States may maintain the existing national mechanism (on forced curtailment-related compensation) for purely national emergencies (i.e. where there is no request for assistance). This gives them the freedom to decide whether they wish to pay compensation or not to forcibly curtailed customers. However, when a national emergency develops into a situation where cross-border assistance is triggered, one option may be to distribute the compensation for assistance paid by the requesting Member State to the providing Member State among all forcibly curtailed consumer groups, regardless of whether they were curtailed before or after assistance was triggered. This option would follow a scheme designed in the Member State providing assistance, but would preferably be based on a 'value of lost load'-type approach. Alternatively, Member States may also decide to pay compensation received for assistance into a centrally managed 'assistance fund'. This way, existing national compensation mechanisms for curtailment remain within the Member States' remit and different approaches in Member States will not lead to different treatment of curtailed consumer groups within a country when assistance is provided across borders, where compensation for assistance is obligatory.

The main elements of the compensation for assistance are i. the electricity price and ii. the additional costs to the assisting Member State for making sure the electricity gets across the border, based on costs actually incurred that the national legal framework in the assisting Member State allows to be paid out.

Different approaches to determining the electricity price may be used and agreed in the arrangements. However, it is important that the arrangements are clear about the agreed approach and the circumstances under which it would apply, and that they identify any known parameters that would be used (e.g. the premium, if the last known trade plus premium is chosen).

2.3.1. *Price of electricity*

The financial arrangements should refer to the price of delivered electricity and/or the methodology for setting the price, taking into account the impact on market operations. This latter condition can be understood as aiming at a price or methodology that does not distort the market or create perverse incentives. The electricity price serving as the basis for compensation for assistance is determined (by market or other means) in the Member State providing assistance.

(a) Market price

As a guiding principle, the price of electricity, supplied under the assistance mechanism, should not be lower than the market price, such that would lead to perverse incentives. If the price is kept unfrozen and allowed to dynamically follow electricity demand and supply, it can provide a signal even during a crisis.

Regarding market prices in general terms, a key driver is the level of market integration that is considered as a base case. If full implementation of the internal electricity market is assumed, including balancing markets, then the reference price could be provided directly by any of the future platforms created for the exchange of balancing energy according to Commission Regulation (EU) 2017/2195⁽¹⁶⁾ on electricity balancing. A methodology for calculating a 'reference price' would be needed only when there are no more available bids in the balancing market (which could indicate a simultaneous crisis) or when market specificities (i.e. the existence of purely national balancing products) do not permit their activation by the requesting Member State. Finally, if there are no more available bids in the balancing market (i.e. there are no more available resources in the market) the latest available tool is load shedding. In this case, the price of the energy should reflect the cost of implementing such load shedding (see point (b)).

⁽¹⁶⁾ Commission Regulation (EU) 2017/2195 of 23 November 2017 establishing a guideline on electricity balancing (OJ L 312, 28.11.2017, p. 6).

(b) Administrative pricing/forced curtailment

If there is no market price, other approaches to setting the electricity price may be necessary, such as the last known balancing market price or intra-day market price whichever is higher. Alternatively, the price of the last known electricity trade or measure with or without a premium may also be a pointer. A premium may be considered in order to fill the gap – if such a gap exists – between the last known price and the curtailed customers' value of lost load (VoLL) ⁽¹⁷⁾.

A VoLL calculation can be used to determine the price of the customers being forcibly curtailed in the Member State providing assistance. The value reflects the benefits that the specific consumer group has lost as a result of being curtailed. The VoLL should be derived using the methodology referred to in Article 11 of Regulation (EU) 2019/943.

Usually the adopted values will also be reflected in the curtailment order in the risk-preparedness plans.

Lastly, it may be worth looking at a methodology for price-setting by the national regulatory authority or competent authority, or the use of a proxy, such as the price of call options ⁽¹⁸⁾.

(c) Willingness to pay

It may be reasonable to determine the maximum amount each Member State is willing to pay for electricity in a crisis situation. The maximum value would likely be the VoLL for categories of electricity users who are entitled to receive special protection against disconnection in a given Member State. Should the price of electricity exceed this value, it may not be in the Member State's interest to ask for electricity under the assistance mechanism. This information, however, does not necessarily need to be part of the arrangements or be reflected in the plans.

2.3.2. Other categories of costs

The financial arrangements should cover any other categories of costs, including relevant and reasonable costs for measures established in advance (Article 15(4) of the Regulation) that will have to be covered by fair and prompt compensation. Additional costs should be kept at a minimum and attention paid to avoiding double counting, as some of the additional cost elements may already be reflected in the price of electricity.

(a) Associated transmission costs

The compensation should cover transmission-associated costs related to the capacity needed for the assistance quantities.

(b) Damages for forcibly curtailed customers (compensation for curtailment)

Other costs may also be those incurred under an obligation to pay compensation in the assisting Member State, including damages to forcibly curtailed customers. Such costs can be included in the compensation cost if the national legal framework provides for the obligation to pay damages to forcibly curtailed customers, including compensation for economic damage, on top of the electricity price. The relevant methodology for the calculation needs to be included in the arrangements. There may be an agreement to pass on the amount of compensation actually incurred to the entities that use the assistance electricity in the Member State receiving assistance.

However, the cost of damages to forcibly curtailed customers may only be covered by compensation if it is not reflected in the electricity price that the requesting Member State has to pay. The requesting Member State should not have to pay compensation for the same costs twice.

⁽¹⁷⁾ There are cases where the premium covers the 'insurance value' of the freed-up electricity.

⁽¹⁸⁾ Call options give the buyer of the call option the right, but not the obligation, to purchase a specific quantity of electricity at a fixed price in the future. The buyer of the option pays a premium for the right to exercise the option. Options are composed of a strike price, a pricing period, settlement methodology, and a premium. Options are traded at exchanges or they can be private bilateral deals OTC.

(c) Cost of judicial proceedings in the assisting Member State

Other costs may also relate to reimbursement for any costs resulting from judicial proceedings, arbitration proceedings and settlements, along with any related costs from such proceedings involving the assisting Member State vis-à-vis the entities involved in providing such assistance (Article 15(4)(b) of the Regulation). However, such compensation should only be paid against proof of costs incurred.

In the event of litigation involving a Member State and the entity providing assistance over (insufficient) compensation from the Member State receiving assistance, there should be safeguards to protect the latter Member State. There may be circumstances in which the entity concerned and the Member State where it is established take each other to court to obtain a higher electricity price or more compensation for the entity, and act to the detriment of the requesting Member State, which is not a party in the legal proceedings. Such circumstances should be avoided.

The above situation is different from a situation where a company in the assisting Member State launches judicial proceedings against an entity in the receiving Member State over the price of electricity or compensation for curtailment. In such a situation the company or entity that loses the case would be liable to pay the costs involved.

2.3.3. *Indication of the method of calculating fair compensation*

The following methods may be considered in calculating fair compensation:

- simple sum of all the applicable elements described in the section above,
- time value of money: payment should be made promptly. However, Member States may agree on an interest rate to be applied to the compensation once a realistic period has elapsed after the provision of assistance, and once the exact amount of the compensation has been calculated and agreed,
- agreement between Member States using different currencies on the currency in which compensation should be calculated and paid, including the relevant exchange rate.

2.3.4. *Calculating the compensation of all relevant and reasonable costs and undertaking to pay for compensation*

It is likely that the calculation of the exact payment to the Member State that provided assistance and to entities in that Member State can only realistically happen some time after the electricity requested under the assistance mechanism has been delivered. In their regional or bilateral arrangement, Member States can agree on the approach to calculating the price of electricity and additional costs, and on a realistic deadline for the payment.

Information about the electricity quantities actually delivered and any other relevant information for calculating the compensation should be sent to the relevant contact person(s) in the Member States involved in the assistance exercise, so that both can carry out a final calculation of the compensation. The information may be available from the TSO, DSO, strategic reserve operator, a supplier or NEMO, depending on the measure applied. The calculation of the compensation may be delegated to another predefined entity.

2.3.5. *Arrangements for payment*

As a guiding principle, existing procedures for domestic payments and compensation (or balancing-type transactions) in a Member State and existing roles and responsibilities in this regard should be maintained and applied wherever possible to compensation payments for assistance between Member States as well. Arrangements between Member States should focus on how to connect or implement an interface between these existing national frameworks. The nature of assistance may require making the Member State or competent authority the interface bearing ultimate financial responsibility.

2.3.6. *Roles and responsibilities – who pays whom and who arranges payments*

When voluntary demand-side measures are still possible in the assisting Member State, access to the relevant platform and cross-zonal capacity needs to be maintained. It should be possible for a buyer across the border to make payments in the same way as a local buyer would do for the electricity, according to what is defined in the electricity balancing guideline.

When curtailments are introduced, any existing legal framework, payment process or authority responsible for managing the payments in the Member State providing assistance could be used or adapted as necessary for compensation payments from a neighbouring country.

The ultimate beneficiary of assistance is the supplied consumer. In the event of curtailment, the electricity supplier of the curtailed non-protected customer should be sure of continued payments, taking into account the assistance volumes. These should be settled according to the compensation scheme in the Member State. The potential roles and responsibilities can be distributed as described in point 1.5.

2.3.7. *Description/steps of the payment process*

Depending on the existing frameworks and how the interface between these frameworks is agreed by the Member States, the agreed procedures need to be included in the arrangements.

Assuming Member-State-to-Member-State involvement in financial aspects – and in particular monitoring, checking and channelling claims after assistance electricity has been delivered – the relevant entity in the assisting Member State calculates the amount of the compensation based on the quantity of electricity delivered, the agreed cost elements and the agreed calculation method, and submits its request for payment to the relevant entity in the requesting Member State. The requesting Member State then confirms the service received, checks the calculation and, if it has no objections, pays within the agreed deadline. Financial processes within the Member States – such as distribution of compensation or charging compensation for assistance – follow national rules (e.g. they may be applied directly to the offering/curtailed entity or socialised –distributed among all customers).

The deadlines for the compensation calculation for assistance, scrutiny and payment should be included in the arrangements. The same applies to the applicable law and dispute settlement options in the event of a dispute arising from use of the assistance mechanism.

3. CONCLUSION

Thanks to the Regulation on risk preparedness, the political desire for assistance between Member States has become a reality on the ground. Moreover, the Regulation elevates assistance from the status of a nationally applied concept to that of an EU-wide protection of public safety and personal security. For the purpose of protecting public safety and personal security, it introduces far-reaching rights and obligations that provide electricity users entitled to receive special protection against disconnection with the certainty and security of an uninterrupted electricity supply. The guidance in this document offers a wide range of options for making the assistance mechanism work, while Member States remain free to choose the solutions that best suit them.

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