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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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[1] Text with EEA relevance.

II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) 2021/976

of 4 June 2021

amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for cycloxydim, mepiquat, *Metschnikowia fructicola* strain NRRL Y-27328 and prohexadione 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 5(1) and Article 14(1)(a) thereof,

Whereas:

(1) For prohexadione, maximum residue levels (MRLs) were set in Annex II to Regulation (EC) No 396/2005. For cycloxydim and mepiquat, MRLs were set in Part A of Annex III to that Regulation. For *Metschnikowia fructicola* strain NRRL Y-27328, no specific MRLs were set nor was that substance included in Annex IV to that Regulation, so the default value of 0,01 mg/kg laid down in Article 18(1)(b) thereof applies.

(2) In the context of a procedure for the authorisation of the use of a plant protection product containing the active substance cycloxydim on strawberries, an application was submitted in accordance with Article 6(1) of Regulation (EC) No 396/2005 for modification of the existing MRL.

(3) As regards mepiquat, such an application was submitted for cotton seeds. As regards prohexadione, such an application was submitted for linseeds, poppy seeds, sunflower seeds, rapeseeds, mustard seeds and gold of pleasure seeds.

(4) In accordance with Article 8 of Regulation (EC) No 396/2005, those applications were evaluated by the Member States concerned and the evaluation reports were forwarded to the Commission.

(5) The European Food Safety Authority ('the Authority') assessed the applications and the evaluation reports, examining in particular the risks to the consumer and, where relevant, to animals and gave reasoned opinions on the proposed MRLs ([2]). It forwarded those opinions to the applicants, the Commission and the Member States and made them available to the public.

([1]) OJ L 70, 16.3.2005, p. 1.

([2]) EFSA scientific reports available online: http://www.efsa.europa.eu:
Reasoned opinion on the modification of the existing maximum residue level for cycloxidim in strawberries. EFSA Journal 2018;16(8):5404.
Reasoned opinion on the modification of the existing maximum residue levels for mepiquat in cotton seeds and animal commodities. EFSA Journal 2018;16(10):5428.
Reasoned opinion on the modification of the existing maximum residue levels for prohexadione in various oilseeds. EFSA Journal 2018;16(8):5397.

(6) As regards mepiquat, the Authority recommended increasing the MRLs for certain products of animal origin following the use of the substance on cotton seeds.

(7) As regards all applications, the Authority concluded that all requirements with respect to data were met and that the modifications to the MRLs requested by the applicants were acceptable with regard to consumer safety on the basis of a consumer exposure assessment for 27 specific European consumer groups. It took into account the most recent information on the toxicological properties of the substances. Neither the lifetime exposure to these substances via consumption of all food products that may contain them, nor the short-term exposure due to high consumption of the relevant products showed that there is a risk that the acceptable daily intake or the acute reference dose is exceeded.

(8) In the context of the approval of the active substance *Metschnikowia fructicola* strain NRRL Y-27328, an MRL application was included in the summary dossier in accordance with Article 8(1)(g) of Regulation (EC) No 1107/2009 of the European Parliament and of the Council ([3]). That application was evaluated by the Member State concerned in accordance with Article 11(2) of that Regulation. The Authority assessed the application and delivered a conclusion on the peer review of the pesticide risk assessment ([4]). In that framework, the Authority could not conclude on the dietary risk assessment for consumers as some information was not available and further consideration by risk managers was required. Such further consideration was reflected in the review report ([5]) which concluded that the organism is not pathogenic to humans and no toxins or toxic metabolites are expected to occur in food following the use of the active substance. In view of those conclusions, the Commission considers that the inclusion of *Metschnikowia fructicola* strain NRRL Y-27328 in Annex IV to Regulation (EC) No 396/2005 is appropriate.

(9) For mepiquat in cotton seeds, a temporary MRL valid until 30 June 2021 was set in Regulation (EC) No 396/2005 by Commission Regulation (EU) 2018/832 ([6]). In the interest of legal certainty, it is appropriate for the MRLs provided for by this Regulation to apply from 1 July 2021.

(10) 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.

(11) Regulation (EC) No 396/2005 should therefore be amended accordingly.

(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, III and IV to Regulation (EC) No 396/2005 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*.

([3]) Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).

([4]) Conclusion on the peer review of the pesticide risk assessment of the active substance *Metschnikowia fructicola* strain NRRL Y-27328. EFSA Journal 2017;15(12):5084.

([5]) Review report for the active substance *Metschnikowia fructicola* strain NRRL Y-27328 (SANTE/10472/2018 Rev. 2).

([6]) Commission Regulation (EU) 2018/832 of 5 June 2018 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for cyantraniliprole, cymoxanil, deltamethrin, difenoconazole, fenamidone, flubendiamide, fluopicolide, folpet, fosetyl, mandestrobin, mepiquat, metazachlor, propamocarb, propargite, pyrimethanil, sulfoxaflor and trifloxystrobin in or on certain products (OJ L 140, 6.6.2018, p. 38).

It shall however apply from 1 July 2021 as regards the MRLs for mepiquat.

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

Done at Brussels, 4 June 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

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

(1) in Annex II, the column for prohexadione is replaced by the following:

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

Code number	Groups and examples of individual products to which the MRLs apply [a]	Prohexadione (prohexadione (acid) and its salts expressed as prohexadione-calcium)
0100000	**FRUITS, FRESH or FROZEN; TREE NUTS**	
0110000	**Citrus fruits**	0.01 (*)
0110010	Grapefruits	
0110020	Oranges	
0110030	Lemons	
0110040	Limes	
0110050	Mandarins	
0110990	Others (2)	
0120000	**Tree nuts**	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)	
0130000	**Pome fruits**	0.1
0130010	Apples	
0130020	Pears	
0130030	Quinces	
0130040	Medlars	
0130050	Loquats/Japanese medlars	
0130990	Others (2)	
0140000	**Stone fruits**	
0140010	Apricots	0.01 (*)

0140020	Cherries (sweet)	0.4
0140030	Peaches	0.01 (*)
0140040	Plums	0.05
0140990	Others (2)	0.01 (*)
0150000	**Berries and small fruits**	
0151000	(a) **grapes**	0.01 (*)
0151010	Table grapes	
0151020	Wine grapes	
0152000	(b) **strawberries**	0.15
0153000	(c) **cane fruits**	0.01 (*)
0153010	Blackberries	
0153020	Dewberries	
0153030	Raspberries (red and yellow)	
0153990	Others (2)	
0154000	(d) **other small fruits and berries**	0.01 (*)
0154010	Blueberries	
0154020	Cranberries	
0154030	Currants (black, red and white)	
0154040	Gooseberries (green, red and yellow)	
0154050	Rose hips	
0154060	Mulberries (black and white)	
0154070	Azaroles/Mediterranean medlars	
0154080	Elderberries	
0154990	Others (2)	
0160000	**Miscellaneous fruits with**	0.01 (*)
0161000	(a) **edible peel**	
0161010	Dates	
0161020	Figs	
0161030	Table olives	
0161040	Kumquats	
0161050	Carambolas	
0161060	Kaki/Japanese persimmons	
0161070	Jambuls/jambolans	
0161990	Others (2)	
0162000	(b) **inedible peel, small**	
0162010	Kiwi fruits (green, red, yellow)	
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	
0163020	Bananas	
0163030	Mangoes	
0163040	Papayas	
0163050	Granate apples/pomegranates	
0163060	Cherimoyas	
0163070	Guavas	
0163080	Pineapples	
0163090	Breadfruits	
0163100	Durians	
0163110	Soursops/guanabanas	
0163990	Others (2)	
0200000	**VEGETABLES, FRESH or FROZEN**	
0210000	**Root and tuber vegetables**	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**	0.01 (*)
0220010	Garlic	
0220020	Onions	
0220030	Shallots	
0220040	Spring onions/green onions and Welsh onions	
0220990	Others (2)	
0230000	**Fruiting vegetables**	0.01 (*)
0231000	(a) **Solanaceae and Malvaceae**	
0231010	Tomatoes	
0231020	Sweet peppers/bell peppers	
0231030	Aubergines/eggplants	
0231040	Okra/lady's fingers	
0231990	Others (2)	
0232000	(b) **cucurbits with edible peel**	
0232010	Cucumbers	
0232020	Gherkins	
0232030	Courgettes	
0232990	Others (2)	
0233000	(c) **cucurbits with inedible peel**	
0233010	Melons	
0233020	Pumpkins	
0233030	Watermelons	
0233990	Others (2)	
0234000	(d) **sweet corn**	
0239000	(e) **other fruiting vegetables**	
0240000	**Brassica vegetables (excluding brassica roots and brassica baby leaf crops)**	0.01 (*)
0241000	(a) **flowering brassica**	
0241010	Broccoli	
0241020	Cauliflowers	
0241990	Others (2)	
0242000	(b) **head brassica**	
0242010	Brussels sprouts	
0242020	Head cabbages	
0242990	Others (2)	
0243000	(c) **leafy brassica**	
0243010	Chinese cabbages/pe-tsai	
0243020	Kales	
0243990	Others (2)	

0244000	(d) **kohlrabies**	
0250000	**Leaf vegetables, herbs and edible flowers**	
0251000	(a) **lettuces and salad plants**	0.01 (*)
0251010	Lamb's lettuces/corn salads	
0251020	Lettuces	
0251030	Escaroles/broad-leaved endives	
0251040	Cresses and other sprouts and shoots	
0251050	Land cresses	
0251060	Roman rocket/rucola	
0251070	Red mustards	
0251080	Baby leaf crops (including brassica species)	
0251990	Others (2)	
0252000	(b) **spinaches and similar leaves**	0.01 (*)
0252010	Spinaches	
0252020	Purslanes	
0252030	Chards/beet leaves	
0252990	Others (2)	
0253000	(c) **grape leaves and similar species**	0.01 (*)
0254000	(d) **watercresses**	0.01 (*)
0255000	(e) **witloofs/Belgian endives**	0.01 (*)
0256000	(f) **herbs and edible flowers**	0.02 (*)
0256010	Chervil	
0256020	Chives	
0256030	Celery leaves	
0256040	Parsley	
0256050	Sage	
0256060	Rosemary	
0256070	Thyme	
0256080	Basil and edible flowers	
0256090	Laurel/bay leaves	
0256100	Tarragon	
0256990	Others (2)	
0260000	**Legume vegetables**	0.01 (*)
0260010	Beans (with pods)	
0260020	Beans (without pods)	
0260030	Peas (with pods)	
0260040	Peas (without pods)	
0260050	Lentils	
0260990	Others (2)	

0270000	**Stem vegetables**	0.01 (*)
0270010	Asparagus	
0270020	Cardoons	
0270030	Celeries	
0270040	Florence fennels	
0270050	Globe artichokes	
0270060	Leeks	
0270070	Rhubarbs	
0270080	Bamboo shoots	
0270090	Palm hearts	
0270990	Others (2)	
0280000	**Fungi, mosses and lichens**	0.01 (*)
0280010	Cultivated fungi	
0280020	Wild fungi	
0280990	Mosses and lichens	
0290000	**Algae and prokaryotes organisms**	0.01 (*)
0300000	**PULSES**	0.02 (*)
0300010	Beans	
0300020	Lentils	
0300030	Peas	
0300040	Lupins/lupini beans	
0300990	Others (2)	
0400000	**OILSEEDS AND OIL FRUITS**	
0401000	**Oilseeds**	
0401010	Linseeds	**0.05**
0401020	Peanuts/groundnuts	0.9
0401030	Poppy seeds	**0.05**
0401040	Sesame seeds	0.01 (*)
0401050	Sunflower seeds	**0.06**
0401060	Rapeseeds/canola seeds	**0.015**
0401070	Soyabeans	0.01 (*)
0401080	Mustard seeds	**0.05**
0401090	Cotton seeds	0.01 (*)
0401100	Pumpkin seeds	0.01 (*)
0401110	Safflower seeds	0.01 (*)
0401120	Borage seeds	0.01 (*)
0401130	Gold of pleasure seeds	**0.05**

0401140	Hemp seeds	0.01 (*)
0401150	Castor beans	0.01 (*)
0401990	Others (2)	0.01 (*)
0402000	**Oil fruits**	0.01 (*)
0402010	Olives for oil production	
0402020	Oil palms kernels	
0402030	Oil palms fruits	
0402040	Kapok	
0402990	Others (2)	
0500000	**CEREALS**	
0500010	Barley	0.1
0500020	Buckwheat and other pseudocereals	0.02 (*)
0500030	Maize/corn	0.02 (*)
0500040	Common millet/proso millet	0.02 (*)
0500050	Oat	0.1
0500060	Rice	0.02 (*)
0500070	Rye	0.1
0500080	Sorghum	0.02 (*)
0500090	Wheat	0.1
0500990	Others (2)	0.02 (*)
0600000	**TEAS, COFFEE, HERBAL INFUSIONS, COCOA AND CAROBS**	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**	0.01 (*)
0800000	**SPICES**	
0810000	**Seed spices**	0.05 (*)
0810010	Anise/aniseed	
0810020	Black caraway/black cumin	
0810030	Celery	
0810040	Coriander	
0810050	Cumin	
0810060	Dill	
0810070	Fennel	
0810080	Fenugreek	
0810090	Nutmeg	
0810990	Others (2)	
0820000	**Fruit spices**	0.05 (*)
0820010	Allspice/pimento	
0820020	Sichuan pepper	
0820030	Caraway	
0820040	Cardamom	
0820050	Juniper berry	
0820060	Peppercorn (black, green and white)	
0820070	Vanilla	
0820080	Tamarind	
0820990	Others (2)	
0830000	**Bark spices**	0.05 (*)
0830010	Cinnamon	
0830990	Others (2)	
0840000	**Root and rhizome spices**	
0840010	Liquorice	0.05 (*)
0840020	Ginger (10)	0.05 (*)
0840030	Turmeric/curcuma	0.05 (*)
0840040	Horseradish (11)	

0840990	Others (2)	0.05 (*)
0850000	**Bud spices**	0.05 (*)
0850010	Cloves	
0850020	Capers	
0850990	Others (2)	
0860000	**Flower pistil spices**	0.05 (*)
0860010	Saffron	
0860990	Others (2)	
0870000	**Aril spices**	0.05 (*)
0870010	Mace	
0870990	Others (2)	
0900000	**SUGAR PLANTS**	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 (*)
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	
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	
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 (*)
1020010	Cattle	
1020020	Sheep	
1020030	Goat	
1020040	Horse	
1020990	Others (2)	
1030000	**Birds eggs**	0.01 (*)
1030010	Chicken	
1030020	Duck	

1030030	Geese	
1030040	Quail	
1030990	Others (2)	
1040000	**Honey and other apiculture products (7)**	0.05 (*)
1050000	**Amphibians and Reptiles**	0.01 (*)
1060000	**Terrestrial invertebrate animals**	0.01 (*)
1070000	**Wild terrestrial vertebrate animals**	0.01 (*)
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. '

(2) in Part A of Annex III, the columns for cycloxydim and mepiquat are replaced by the following:

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

Code number	**Groups and examples of individual products to which the MRLs apply** ([a])	**Cycloxydim including degradation and reaction products which can be determined as 3-(3-thianyl) glutaric acid S-dioxide (BH 517-TGSO2) and/or 3-hydroxy-3-(3-thianyl) glutaric acid S-dioxide (BH 517-5-OH-TGSO2) or methyl esters thereof, calculated in total as cycloxydim**	**Mepiquat (sum of mepiquat and its salts, expressed as mepiquat chloride)**
0100000	**FRUITS, FRESH or FROZEN; TREE NUTS**		
0110000	**Citrus fruits**	0.05 (*)	0.02 (*)
0110010	Grapefruits		
0110020	Oranges		
0110030	Lemons		
0110040	Limes		
0110050	Mandarins		
0110990	Others (2)		
0120000	**Tree nuts**	0.05 (*)	0.05 (*)
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)		
0130000	**Pome fruits**		0.02 (*)
0130010	Apples	0.1	
0130020	Pears	0.1	
0130030	Quinces	0.09	
0130040	Medlars	0.09	
0130050	Loquats/Japanese medlars	0.09	
0130990	Others (2)	0.09	
0140000	**Stone fruits**		0.02 (*)
0140010	Apricots	0.2	
0140020	Cherries (sweet)	0.09	
0140030	Peaches	0.2	
0140040	Plums	0.09	
0140990	Others (2)	0.09	
0150000	**Berries and small fruits**		0.02 (*)
0151000	(a) **grapes**	0.5	
0151010	Table grapes		
0151020	Wine grapes		
0152000	(b) **strawberries**	**4**	
0153000	(c) **cane fruits**	0.05 (*)	
0153010	Blackberries		
0153020	Dewberries		
0153030	Raspberries (red and yellow)		
0153990	Others (2)		
0154000	(d) **other small fruits and berries**	0.05 (*)	
0154010	Blueberries		
0154020	Cranberries		

0154030	Currants (black, red and white)		
0154040	Gooseberries (green, red and yellow)		
0154050	Rose hips		
0154060	Mulberries (black and white)		
0154070	Azaroles/Mediterranean medlars		
0154080	Elderberries		
0154990	Others (2)		
0160000	**Miscellaneous fruits with**		0.02 (*)
0161000	(a) **edible peel**	0.05 (*)	
0161010	Dates		
0161020	Figs		
0161030	Table olives		
0161040	Kumquats		
0161050	Carambolas		
0161060	Kaki/Japanese persimmons		
0161070	Jambuls/jambolans		
0161990	Others (2)		
0162000	(b) **inedible peel, small**	0.05 (*)	
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	0.05 (*)	
0163020	Bananas	0.05 (*)	
0163030	Mangoes	0.2	
0163040	Papayas	0.05 (*)	
0163050	Granate apples/pomegranates	0.05 (*)	
0163060	Cherimoyas	0.05 (*)	
0163070	Guavas	0.05 (*)	
0163080	Pineapples	0.05 (*)	
0163090	Breadfruits	0.05 (*)	
0163100	Durians	0.05 (*)	
0163110	Soursops/guanabanas	0.05 (*)	
0163990	Others (2)	0.05 (*)	

0200000	**VEGETABLES, FRESH or FROZEN**		
0210000	**Root and tuber vegetables**		0.02 (*)
0211000	(a) **potatoes**	3	
0212000	(b) **tropical root and tuber vegetables**	0.2	
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	0.9	
0213020	Carrots	5	
0213030	Celeriacs/turnip rooted celeries	5	
0213040	Horseradishes	0.9	
0213050	Jerusalem artichokes	0.9	
0213060	Parsnips	0.9	
0213070	Parsley roots/Hamburg roots parsley	0.2	
0213080	Radishes	0.2	
0213090	Salsifies	1.5	
0213100	Swedes/rutabagas	0.2	
0213110	Turnips	1	
0213990	Others (2)	0.2	
0220000	**Bulb vegetables**		0.02 (*)
0220010	Garlic	1	
0220020	Onions	3	
0220030	Shallots	1	
0220040	Spring onions/green onions and Welsh onions	1	
0220990	Others (2)	1	
0230000	**Fruiting vegetables**		0.02 (*)
0231000	(a) **Solanaceae and Malvaceae**		
0231010	Tomatoes	1.5	
0231020	Sweet peppers/bell peppers	9	
0231030	Aubergines/eggplants	1.5	
0231040	Okra/lady's fingers	0.05 (*)	
0231990	Others (2)	0.05 (*)	
0232000	(b) **cucurbits with edible peel**	0.05 (*)	
0232010	Cucumbers		
0232020	Gherkins		

0232030	Courgettes		
0232990	Others (2)		
0233000	(c) **cucurbits with inedible peel**	0.05 (*)	
0233010	Melons		
0233020	Pumpkins		
0233030	Watermelons		
0233990	Others (2)		
0234000	(d) **sweet corn**	0.05 (*)	
0239000	(e) **other fruiting vegetables**	0.05 (*)	
0240000	**Brassica vegetables (excluding brassica roots and brassica baby leaf crops)**		0.02 (*)
0241000	(a) **flowering brassica**		
0241010	Broccoli	2	
0241020	Cauliflowers	5	
0241990	Others (2)	2	
0242000	(b) **head brassica**		
0242010	Brussels sprouts	6	
0242020	Head cabbages	5	
0242990	Others (2)	2	
0243000	(c) **leafy brassica**		
0243010	Chinese cabbages/pe-tsai	3	
0243020	Kales	3	
0243990	Others (2)	2	
0244000	(d) **kohlrabies**	2	
0250000	**Leaf vegetables, herbs and edible flowers**		
0251000	(a) **lettuces and salad plants**		0.02 (*)
0251010	Lamb's lettuces/corn salads	0.5	
0251020	Lettuces	1.5	
0251030	Escaroles/broad-leaved endives	1	
0251040	Cresses and other sprouts and shoots	0.5	
0251050	Land cresses	0.5	
0251060	Roman rocket/rucola	0.5	
0251070	Red mustards	0.2	
0251080	Baby leaf crops (including brassica species)	0.2	
0251990	Others (2)	0.5	

0252000	(b) **spinaches and similar leaves**		0.02 (*)
0252010	Spinaches	2	
0252020	Purslanes	0.6	
0252030	Chards/beet leaves	0.6	
0252990	Others (2)	0.2	
0253000	(c) **grape leaves and similar species**	0.2	0.02 (*)
0254000	(d) **watercresses**	0.2	0.02 (*)
0255000	(e) **witloofs/Belgian endives**	0.2	0.02 (*)
0256000	(f) **herbs and edible flowers**		0.05 (*)
0256010	Chervil	0.2	
0256020	Chives	0.2	
0256030	Celery leaves	1	
0256040	Parsley	0.2	
0256050	Sage	0.2	
0256060	Rosemary	0.2	
0256070	Thyme	0.2	
0256080	Basil and edible flowers	0.2	
0256090	Laurel/bay leaves	0.2	
0256100	Tarragon	0.2	
0256990	Others (2)	0.2	
0260000	**Legume vegetables**		0.02 (*)
0260010	Beans (with pods)	15	
0260020	Beans (without pods)	2	
0260030	Peas (with pods)	5	
0260040	Peas (without pods)	15	
0260050	Lentils	1	
0260990	Others (2)	1	
0270000	**Stem vegetables**		0.02 (*)
0270010	Asparagus	0.2	
0270020	Cardoons	0.2	
0270030	Celeries	1	
0270040	Florence fennels	0.2	
0270050	Globe artichokes	2	
0270060	Leeks	4	
0270070	Rhubarbs	0.2	
0270080	Bamboo shoots	0.2	
0270090	Palm hearts	0.2	
0270990	Others (2)	0.2	
0280000	**Fungi, mosses and lichens**	0.05 (*)	

0280010	Cultivated fungi		0.09 (+)
0280020	Wild fungi		0.02 (*)
0280990	Mosses and lichens		0.02 (*)
0290000	**Algae and prokaryotes organisms**	0.05 (*)	0.02 (*)
0300000	**PULSES**		0.02 (*)
0300010	Beans	30	
0300020	Lentils	5	
0300030	Peas	30	
0300040	Lupins/lupini beans	5	
0300990	Others (2)	5	
0400000	**OILSEEDS AND OIL FRUITS**		
0401000	**Oilseeds**		
0401010	Linseeds	7	40
0401020	Peanuts/groundnuts	0.2	0.05 (*)
0401030	Poppy seeds	0.2	40
0401040	Sesame seeds	0.2	0.05 (*)
0401050	Sunflower seeds	6	40
0401060	Rapeseeds/canola seeds	9	15
0401070	Soyabeans	80	0.05 (*)
0401080	Mustard seeds	5	40
0401090	Cotton seeds	0.5	**6**
0401100	Pumpkin seeds	0.2	0.05 (*)
0401110	Safflower seeds	0.2	0.05 (*)
0401120	Borage seeds	0.2	0.05 (*)
0401130	Gold of pleasure seeds	0.2	40
0401140	Hemp seeds	0.2	0.05 (*)
0401150	Castor beans	0.2	0.05 (*)
0401990	Others (2)	0.2	0.05 (*)
0402000	**Oil fruits**	0.05 (*)	0.05 (*)
0402010	Olives for oil production		
0402020	Oil palms kernels		
0402030	Oil palms fruits		
0402040	Kapok		
0402990	Others (2)		
0500000	**CEREALS**		
0500010	Barley	0.05 (*)	4
0500020	Buckwheat and other pseudocereals	0.05 (*)	0.02 (*)
0500030	Maize/corn	0.2	0.02 (*)
0500040	Common millet/proso millet	0.05 (*)	0.02 (*)

0500050	Oat	0.05 (*)	3
0500060	Rice	0.09	0.02 (*)
0500070	Rye	0.05 (*)	3
0500080	Sorghum	0.05 (*)	0.02 (*)
0500090	Wheat	0.05 (*)	3
0500990	Others (2)	0.05 (*)	0.02 (*)
0600000	**TEAS, COFFEE, HERBAL INFUSIONS, COCOA AND CAROBS**		0.1 (*)
0610000	**Teas**	0.05 (*)	
0620000	**Coffee beans**	0.05 (*)	
0630000	**Herbal infusions from**		
0631000	(a) **flowers**	0.05 (*)	
0631010	Chamomile		
0631020	Hibiscus/roselle		
0631030	Rose		
0631040	Jasmine		
0631050	Lime/linden		
0631990	Others (2)		
0632000	(b) **leaves and herbs**	0.05 (*)	
0632010	Strawberry		
0632020	Rooibos		
0632030	Mate/maté		
0632990	Others (2)		
0633000	(c) **roots**	7	
0633010	Valerian		
0633020	Ginseng		
0633990	Others (2)		
0639000	(d) **any other parts of the plant**	0.05 (*)	
0640000	**Cocoa beans**	0.05 (*)	
0650000	**Carobs/Saint John's breads**	0.05 (*)	
0700000	**HOPS**	0.05 (*)	0.1 (*)
0800000	**SPICES**		
0810000	**Seed spices**	0.05 (*)	0.1 (*)
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 (*)	0.1 (*)
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 (*)	0.1 (*)
0830010	Cinnamon		
0830990	Others (2)		
0840000	**Root and rhizome spices**		
0840010	Liquorice	0.05 (*)	0.1 (*)
0840020	Ginger (10)	0.05 (*)	0.1 (*)
0840030	Turmeric/curcuma	0.05 (*)	0.1 (*)
0840040	Horseradish (11)		
0840990	Others (2)	0.05 (*)	0.1 (*)
0850000	**Bud spices**	0.05 (*)	0.1 (*)
0850010	Cloves		
0850020	Capers		
0850990	Others (2)		
0860000	**Flower pistil spices**	0.05 (*)	0.1 (*)
0860010	Saffron		
0860990	Others (2)		
0870000	**Aril spices**	0.05 (*)	0.1 (*)
0870010	Mace		
0870990	Others (2)		
0900000	**SUGAR PLANTS**		0.02 (*)
0900010	Sugar beet roots	0.5	
0900020	Sugar canes	0.05 (*)	

0900030	Chicory roots	0.05 (*)	
0900990	Others (2)	0.05 (*)	
1000000	**PRODUCTS OF ANIMAL ORIGIN -TERRESTRIAL ANIMALS**		
1010000	**Commodities from**		
1011000	(a) **swine**		
1011010	Muscle	0.06	**0.05**
1011020	Fat	0.1	**0.05**
1011030	Liver	0.5	0.07
1011040	Kidney	0.5	0.07
1011050	Edible offals (other than liver and kidney)	0.5	0.05 (*)
1011990	Others (2)	0.05 (*)	0.05 (*)
1012000	(b) **bovine**		
1012010	Muscle	0.06	0.09
1012020	Fat	0.1	0.06
1012030	Liver	0.5	0.5
1012040	Kidney	0.5	0.8
1012050	Edible offals (other than liver and kidney)	0.5	0.8
1012990	Others (2)	0.05 (*)	0.05 (*)
1013000	(c) **sheep**		
1013010	Muscle	0.06	0.09
1013020	Fat	0.1	0.06
1013030	Liver	0.5	0.6
1013040	Kidney	0.5	0.8
1013050	Edible offals (other than liver and kidney)	0.5	0.8
1013990	Others (2)	0.05 (*)	0.05 (*)
1014000	d) **goat**		
1014010	Muscle	0.06	0.09
1014020	Fat	0.1	0.06
1014030	Liver	0.5	0.6
1014040	Kidney	0.5	0.8
1014050	Edible offals (other than liver and kidney)	0.5	0.8
1014990	Others (2)	0.05 (*)	0.05 (*)
1015000	(e) **equine**		
1015010	Muscle	0.06	0.09

1015020	Fat	0.1	0.06
1015030	Liver	0.5	0.5
1015040	Kidney	0.5	0.8
1015050	Edible offals (other than liver and kidney)	0.5	0.8
1015990	Others (2)	0.05 (*)	0.05 (*)
1016000	(f) **poultry**	0.05 (*)	
1016010	Muscle		**0.05**
1016020	Fat		**0.05**
1016030	Liver		**0.05**
1016040	Kidney		0.05 (*)
1016050	Edible offals (other than liver and kidney)		0.05 (*)
1016990	Others (2)		0.05 (*)
1017000	(g) **other farmed terrestrial animals**		
1017010	Muscle	0.06	0.09
1017020	Fat	0.1	0.06
1017030	Liver	0.5	0.5
1017040	Kidney	0.5	0.8
1017050	Edible offals (other than liver and kidney)	0.5	0.8
1017990	Others (2)	0.05 (*)	0.05 (*)
1020000	**Milk**	0.05 (*)	
1020010	Cattle		0.07
1020020	Sheep		0.15
1020030	Goat		0.15
1020040	Horse		0.07
1020990	Others (2)		0.07
1030000	**Birds eggs**	0.05 (*)	0.07
1030010	Chicken		
1030020	Duck		
1030030	Geese		
1030040	Quail		
1030990	Others (2)		
1040000	**Honey and other apiculture products (7)**	0.05 (*)	0.05 (*)
1050000	**Amphibians and Reptiles**	0.05 (*)	0.05 (*)

1060000	**Terrestrial invertebrate animals**	0.05 (*)	0.05 (*)
1070000	**Wild terrestrial vertebrate animals**	0.05 (*)	0.05 (*)
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.
Mepiquat (sum of mepiquat and its salts, expressed as mepiquat chloride)

(+) The following MRL applies to oyster mushrooms: 0.7 mg/kg. Monitoring data show that cross-contamination of untreated cultivated fungi may occur with straw lawfully treated with mepiquat. When reviewing the MRL, the Commission will take into account the information, if it is submitted by 31 December 2022, or, if that information is not submitted by that date, the lack of it.

0280010 Cultivated fungi'

(3) in Annex IV, the following entry is inserted in alphabetical order: '*Metschnikowia fructicola* strain NRRL Y-27328'.

COMMISSION IMPLEMENTING REGULATION (EU) 2021/977

of 7 June 2021

amending Implementing Regulation (EU) 2019/1844 to make administrative changes to the Union authorisation of the biocidal product family 'BPF_Iodine_VET'

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ([1]), and in particular the first subparagraph of Article 44(5) and Article 50(2) thereof,

Whereas:

(1) On 22 October 2019, Commission Implementing Regulation (EU) 2019/1844 ([2]) granted a Union authorisation with authorisation number EU-0020540-0000 to Applied Biocide GmbH for the making available on the market and use of the biocidal product family 'BPF_Iodine_VET'.

(2) On 10 April 2020, Applied Biocide GmbH submitted a notification to the European Chemicals Agency ('the Agency'), in accordance with Article 11(1) of Commission Implementing Regulation (EU) No 354/2013 ([3]), regarding administrative changes to the Union authorisation for the biocidal product family 'BPF_Iodine_VET' as referred to in Sections 1 and 2 of Title 1 of the Annex to that Regulation.

(3) Applied Biocide GmbH proposed the changes in the names of the manufacturers of the biocidal products in the first information level, administrative information, the changes in the names of one product in the third information level in meta-SPC 2 and one product in meta-SPC 6 and the addition of trade names for the individual products in meta SPCs 2 and 5, in the summary of the product characteristics for the biocidal product family 'BPF_Iodine_VET' as set out in the Annex to Implementing Regulation (EU) 2019/1844. The notification was recorded under the case number BC-VD058524-35 in the Register for Biocidal Products.

(4) On 9 June 2020, the Agency submitted an opinion ([4]) on the proposed changes to the Commission, in accordance with Article 11(3) of Implementing Regulation (EU) No 354/2013. The opinion concludes that the amendments to the existing authorisation sought by the authorisation holder fall under Article 50(3)(a) of Regulation (EU) No 528/2012, and that after the implementation of the changes the conditions of Article 19 of that Regulation are still met. On the same date, the Agency transmitted to the Commission the revised summary of the biocidal product characteristics in all the official languages of the Union in accordance with Article 11(6) of Implementing Regulation (EU) No 354/2013.

(5) The Commission concurs with the opinion of the Agency and therefore considers it appropriate to amend the Union authorisation of the biocidal product family 'BPF_Iodine_VET'.

(6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

([1]) OJ L 167, 27.6.2012, p. 1.

([2]) Commission Implementing Regulation (EU) 2019/1844 of 22 October 2019 granting a Union authorisation for the biocidal product family BPF_Iodine_VET (OJ L 283, 5.11.2019, p. 1).

([3]) Commission Implementing Regulation (EU) No 354/2013 of 18 April 2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 109, 19.4.2013, p. 4).

([4]) ECHA opinion of 9 June 2020 on the administrative change of the Union authorisation of the biocidal product family 'BPF_Iodine_VET', https://echa.europa.eu/documents/10162/22836226/opinion_for_ua-admin_changes_bc-vd058524-35_en.pdf/b95474e7-89d4-a601-8d02-b42d95cecde5

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Implementing Regulation (EU) 2019/1844 is replaced by 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, 7 June 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Summary of product characteristics for a biocidal product family

BPF_Iodine_VET

Product type 3 – Veterinary hygiene (Disinfectants)

Authorisation number: EU-0020540-0000

R4BP asset number: EU-0020540-0000

PART I

FIRST INFORMATION LEVEL

1. ADMINISTRATIVE INFORMATION

1.1. Family name

Name	BPF_Iodine_VET

1.2. Product type(s)

Product type(s)	PT03 – Veterinary hygiene (Disinfectants)

1.3. Authorisation holder

Name and address of the authorisation holder	Name	Applied Biocide GmbH
	Address	Siemensstraße 42, 59199 Bönen, Germany
Authorisation number	EU-0020540-0000	
R4BP asset number	EU-0020540-0000	
Date of the authorisation	25 November 2019	
Expiry date of the authorisation	31 October 2029	

1.4. Manufacturer(s) of the biocidal products

Name of manufacturer	THESEO Deutschland GmbH
Address of manufacturer	Kolpingstrasse 4, 49835 Wietmarschen Germany
Location of manufacturing sites	Kolpingstrasse 4, 49835 Wietmarschen Germany

Name of manufacturer	FINK TEC GmbH
Address of manufacturer	Oberster Kamp 23, 59069 Hamm Germany
Location of manufacturing sites	Oberster Kamp 23, 59069 Hamm Germany

Name of manufacturer	I.R.C.A. SERVICE S.p.A.
Address of manufacturer	S.S. Cremasca 591 no. 10, 24040 Fornovo S. Giovanni (BG) Italy
Location of manufacturing sites	S.S. Cremasca 591 no. 10, 24040 Fornovo S. Giovanni (BG) Italy

Name of manufacturer	Laboratorios Maymó S.A.
Address of manufacturer	Via Augusta, 302, 08017 Barcelona Spain
Location of manufacturing sites	Via Augusta, 302, 08017 Barcelona Spain

1.5. **Manufacturer(s) of the active substance(s)**

Active substance	Iodine
Name of manufacturer	Cosayach S.A. Compania de Salitre y Yodo
Address of manufacturer	Amunátegui 178, 7th Floor, 8320000 Santiago Chile
Location of manufacturing sites	S.C.M. Cosayach Cala Cala, 1180000 Pozo Almonte Chile Chile

Active substance	Iodine
Name of manufacturer	ACF Minera S.A.
Address of manufacturer	San Martin 499, 1100000 Iquique Chile
Location of manufacturing sites	Lagunas mine, 1180000 Pozo Almonte Chile

Active substance	Iodine
Name of manufacturer	Sociedad Quimica y Minera SA
Address of manufacturer	Los Militares 4290, 7550000 Las Condes Chile
Location of manufacturing sites	Nueva Victoria, 1180000 Pozo Almonte Chile Pedro de Valdivia, 1240000 Antofagasta Chile

2. **PRODUCT FAMILY COMPOSITION AND FORMULATION**

2.1. **Qualitative and quantitative information on the composition of the family**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine		Active Substance	7553-56-2	231-442-4	0,1	3,0
Phosphoric Acid	Trihydroxi-dooxidopho-sphorus phosphoric acid	Non-active substance	7664-38-2	231-633-2	0,0	10,0

Poly (oxy-1,2-ethanediyl). alpha.-tridecyl-. omega.-hydroxy-, branched	Poly (oxy-1,2-ethanediyl).alpha.-tridecyl-. omega.-hydroxy-, branched	Non-active substance	69011-36-5	500-241-6	0,0	31,8
Isotridecanol, ethoxylated 90 %, C 9-11 Alcohol Ethoxylate	Isotridecanol, ethoxylated 90 %, C 9-11 Alcohol Ethoxylate	Non-active substance	68439-46-3	614-482-0	0,0	31,8

2.2. **Type(s) of formulation**

Formulation(s)	meta SPC 1-5: AL – any other liquid meta SPC 6-8: SL – soluble concentrate

PART II

SECOND INFORMATION LEVEL – META SPC(S)

META SPC 1

1. **META SPC 1 ADMINISTRATIVE INFORMATION**

1.1. **Meta SPC 1 identifier**

Identifier	Meta SPC 1

1.2. **Suffix to the authorisation number**

Number	1-1

1.3. **Product type(s)**

Product type(s)	PT03 – Veterinary hygiene (Disinfectants)

2. **META SPC 1 COMPOSITION**

2.1. **Qualitative and quantitative information on the composition of the meta SPC 1**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine		Active Substance	7553-56-2	231-442-4	0,15	0,15

Phosphoric Acid	Trihydroxi-dooxidopho-sphorus phosphoric acid	Non-active substance	7664-38-2	231-633-2	0,0	0,0
Poly (oxy-1,2-ethanediyl). alpha.-tridecyl-. omega.-hydroxy-, branched	Poly (oxy-1,2-etha-nediyl).alpha.-tridecyl-. omega.-hydroxy-, branched	Non-active substance	69011-36-5	500-241-6	0,0	0,0
Isotridecanol, ethoxylated 90 %, C 9-11 Alcohol Ethoxylate	Isotridecanol, ethoxylated 90 %, C 9-11 Alcohol Ethoxylate	Non-active substance	68439-46-3	614-482-0	0,0	0,0

2.2. **Type(s) of formulation of the meta SPC 1**

Formulation(s)	AL – any other liquid

3. **HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 1**

Hazard statements	May be corrosive to metals.
Precautionary statements	Keep only in original packaging. Absorb spillage to prevent material damage. Store in corrosive resistant container with a resistant inner liner.

4. **AUTHORISED USE(S) OF THE META SPC 1**

4.1. **Use description**

Table 1. Use # 1 – Veterinary hygiene – animal husbandry – teat disinfectant – professional – indoors – spraying (post milking)

Product type	PT03 – Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor
Application method(s)	Open system: spray treatment
	Spraying: Manual and automated non-medical disinfection of teats with a ready-to-use spray (on cows, post-milking)

Application rate(s) and frequency	Application rate: 10-15 mL per cow
	Application frequency: During lactation period: • manual: 2 applications per day (post-milking) • automated: 3 applications per day (post-milking) During dry period: 1 application per day
Category(ies) of users	Professional
Pack sizes and packaging material	Bottle high-density polyethylene (HDPE): 1 liter, cap is made of PP Jerry can HDPE: 5 – 60 liters Drum HDPE: 200 liters IBC HDPE: 600 – 1000 liters

4.1.1. *Use-specific instructions for use*

…

4.1.2. Use-specific risk mitigation measures

…

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

…

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

…

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

…

5. GENERAL DIRECTIONS FOR USE [1]OF THE META SPC 1

5.1. Instructions for use

Always read the label or leaflet before use and follow all the instructions provided.

The product must be brought to a temperature above 20 °C before use.

The use of a dosing pump for filling the product into the application equipment is recommended.

Immediately after each cow has been milked, spray the entire surface of each teat with the solution. Leave the product until next milking. Do not clean the teats directly after disinfection.

Keep the cows standing until the product has dried (at least 5 minutes).

Product can be applied manually or by means of automatic teat sprayer.

Before the next milking the teats have to be cleaned, preferably with one new wet cloth per cow.

Application frequency must not exceed two applications per cow and day considering manual spraying and must not exceed three applications per cow and day considering automatic teat sprayer (post-milking).

[1] Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 1.

5.2. **Risk mitigation measures**

Keep out of reach of children.

Wear protective chemical resistant gloves, coated coverall and boots during product handling and application phase (material to be specified by the authorisation holder in the product information).

In case a combination of pre- and post-milking disinfection is necessary, using another product not containing Iodine has to be considered for pre-milking disinfection.

5.3. **Particulars of likely direct or indirect effects, first aid instructions and emergencymeasures to protect the environment**

After inhalation: Supply fresh air; consult doctor in case of complaints.

After skin contact: Wash skin thoroughly.

After eye contact: Rinse opened eye, remove contact lenses, keep rinsing for several minutes under running water. Then consult a doctor.

After swallowing: Rinse out mouth and then drink some water. Do not induce vomiting; call for medical help immediately.

When asking for medical advice keep packaging or label at hand and call your local poison control center [insert local number here].

Environmental emergency measures:

Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). To prevent malfunctioning of an individual wastewater treatment plant, possible residues containing the product must be discharged to the manure storage (for spreading on agricultural soils or fermentation into biogas installation) or to the municipal sewer if legally allowed.

5.4. **Instructions for safe disposal of the product and its packaging**

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.

European Waste Catalogue: 200130-detergents other than those mentioned in 20 01 29.

5.5. **Conditions of storage and shelf-life of the product under normal conditions of storage**

Store the product at room temperature, away from direct sunlight and in opaque containers. Protect from frost. Keep container tightly closed.

Shelf-life: 12 months in HDPE

6. **OTHER INFORMATION**

7. **THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 1**

7.1. **Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)	FINK – Io Spray 15 FINK – Euter-DIP PVP-S FINK Pattedyp PVP IOSpray 15 PVP				
Authorisation number	EU-0020540-0001 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,15

META SPC 2

1. **META SPC 2 ADMINISTRATIVE INFORMATION**

1.1. **Meta SPC 2 identifier**

Identifier	Meta SPC 2

1.2. **Suffix to the authorisation number**

Number	1-2

1.3. **Product type(s)**

Product type(s)	PT03 – Veterinary hygiene (Disinfectants)

2. **META SPC 2 COMPOSITION**

2.1. **Qualitative and quantitative information on the composition of the meta SPC 2**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine		Active Substance	7553-56-2	231-442-4	0,3	0,5
Phosphoric Acid	Trihydroxi-dooxidopho-sphorus phosphoric acid	Non-active substance	7664-38-2	231-633-2	0,0	0,0
Poly (oxy-1,2-ethanediyl). alpha.-tridecyl-. omega.-hydroxy-, branched	Poly (oxy-1,2-etha-nediyl).alpha.-tridecyl-. omega.-hydroxy-, branched	Non-active substance	69011-36-5	500-241-6	0,0	0,0
Isotridecanol, ethoxylated 90 %, C 9-11 Alcohol Ethoxylate	Isotridecanol, ethoxylated 90 %, C 9-11 Alcohol Ethoxylate	Non-active substance	68439-46-3	614-482-0	0,0	0,0

2.2. **Type(s) of formulation of the meta SPC 2**

Formulation(s)	AL – any other liquid

3. **HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 2**

Hazard statements	May be corrosive to metals. Harmful to aquatic life with long lasting effects.
Precautionary statements	Keep only in original packaging. Avoid release to the environment. Absorb spillage to prevent material damage. Store in corrosive resistant container with a resistant inner liner. Dispose of contents to/container in accordance with the local/national regulations.

4. **AUTHORISED USE(S) OF THE META SPC 2**

4.1. **Use description**

Table 2. Use # 1 – Veterinary hygiene – animal husbandry – teat disinfectant – professional – indoors – spraying (post milking)

Product-type	PT03 – Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor
Application method(s)	Open system: spray treatment Spraying: Manual and automated non-medical disinfection of teats with a ready-to-use spray (on cows, post-milking)
Application rate(s) and frequency	Application rate: 10-15 mL per cow Application frequency: During lactation period: • manual: 2 applications per day (post-milking) • automated: 3 applications per day (post-milking) During dry period: 1 application per day
Category(ies) of users	Professional
Pack sizes and packaging material	Bottle HDPE: 1 liter, cap is made of PP Jerry can HDPE: 5 – 60 liters Drum HDPE: 200 liters IBC HDPE: 600 – 1000 liters

4.1.1. *Use-specific instructions for use*

…

4.1.2. *Use-specific risk mitigation measures*

…

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

…

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

…

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

…

5. GENERAL DIRECTIONS FOR USE [2]OF THE META SPC 2

5.1. Instructions for use

Always read the label or leaflet before use and follow all the instructions provided.

The product must be brought to a temperature above 20 °C before use.

The use of a dosing pump for filling the product into the application equipment is recommended.

Immediately after each cow has been milked, spray the entire surface of each teat with the solution. Leave the product until next milking. Do not clean the teats directly after disinfection.

Keep the cows standing until the product has dried (at least 5 minutes).

Product can be applied manually or by means of automatic teat sprayer.

Before the next milking the teats have to be cleaned, preferably with one new wet cloth per cow.

Application frequency must not exceed two applications per cow and day considering manual spraying and must not exceed three applications per cow and day considering automatic teat sprayer (post-milking).

5.2. Risk mitigation measures

Keep out of reach of children.

Wear protective chemical resistant gloves, coated coverall and boots during product handling and application phase (material to be specified by the authorisation holder in the product information).

In case a combination of pre- and post-milking disinfection is necessary, using another product not containing Iodine has to be considered for pre-milking disinfection.

5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

After inhalation: Supply fresh air; consult doctor in case of complaints.

After skin contact: Wash skin thoroughly.

After eye contact: Rinse opened eye, remove contact lenses, keep rinsing for several minutes under running water. Then consult a doctor.

After swallowing: Rinse out mouth and then drink some water. Do not induce vomiting; call for medical help immediately.

When asking for medical advice keep packaging or label at hand and call your local poison control center [insert local number here].

Environmental emergency measures:

Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). To prevent malfunctioning of an individual wastewater treatment plant, possible residues containing the product must be discharged to the manure storage (for spreading on agricultural soils or fermentation into biogas installation) or to the municipal sewer if legally allowed.

[2] Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 2.

5.4. **Instructions for safe disposal of the product and its packaging**

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.

European Waste Catalogue: 200130-detergents other than those mentioned in 20 01 29.

5.5. **Conditions of storage and shelf-life of the product under normal conditions of storage**

Store the product at room temperature, away from direct sunlight and in opaque containers. Protect from frost. Keep container tightly closed.

Shelf-life: 12 months in HDPE

6. **OTHER INFORMATION**

7. **THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 2**

7.1. **Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)	FINK – Io Spray 30 ST-Io Spray DESINTEC MH Iodine S DESINTEC MH Raidip plus Iodine Spray 3000 Iodine Spray Io Spray 30 Iodine Spray 30				
Authorisation number	EU-0020540-0002 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,3

7.2. **Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)	Fink – Io Spray 50 DESINTEC MH Raidip 5000 Iodine Spray 5000				
Authorisation number	EU-0020540-0003 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,5

META SPC 3

1. **META SPC 3 ADMINISTRATIVE INFORMATION**

1.1. **Meta SPC 3 identifier**

Identifier	Meta SPC 3

1.2. **Suffix to the authorisation number**

Number	1-3

1.3. **Product type(s)**

Product type(s)	PT03 – Veterinary hygiene (Disinfectants)

2. **META SPC 3 COMPOSITION**

2.1. **Qualitative and quantitative information on the composition of the meta SPC 3**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine		Active Substance	7553-56-2	231-442-4	0,5	0,5
Phosphoric Acid	Trihydroxi-dooxidopho-sphorus phosphoric acid	Non-active substance	7664-38-2	231-633-2	0,0	0,0
Poly (oxy-1,2-ethanediyl). alpha.-tridecyl-. omega.-hydroxy-, branched	Poly (oxy-1,2-etha-nediyl).alpha.-tridecyl-. omega.-hydroxy-, branched	Non-active substance	69011-36-5	500-241-6	0,0	0,0
Isotridecanol, ethoxylated 90 %, C 9-11 Alcohol Ethoxylate	Isotridecanol, ethoxylated 90 %, C 9-11 Alcohol Ethoxylate	Non-active substance	68439-46-3	614-482-0	0,0	0,0

2.2. **Type(s) of formulation of the meta SPC 3**

Formulation(s)	AL – any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 3

Hazard statements	May be corrosive to metals. Harmful to aquatic life with long lasting effects.
Precautionary statements	Keep only in original packaging. Avoid release to the environment. Absorb spillage to prevent material damage. Store in corrosive resistant container with a resistant inner liner. Dispose of contents to/container in accordance with the local/national regulations.

4. AUTHORISED USE(S) OF THE META SPC 3

4.1. Use description

Table 3. Use # 1 – Veterinary hygiene – animal husbandry – teat disinfectant – professional – indoors – spraying (post milking)

Product type	PT03 – Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor
Application method(s)	Open system: spray treatment Spraying: Manual and automated non-medical disinfection of teats with a ready-to-use spray (on cows, post-milking)
Application rate(s) and frequency	Application rate: 10-15 mL per cow Application frequency: During lactation period: • manual: 2 applications per day (post-milking) • automated: 3 applications per day (post-milking) During dry period: 1 application per day
Category(ies) of users	Professional
Pack sizes and packaging material	Bottle HDPE: 1 liter, cap is made of PP Jerry can HDPE: 5 – 60 liters Drum HDPE: 200 liters IBC HDPE: 600 – 1000 liters

4.1.1. *Use-specific instructions for use*

…

4.1.2. *Use-specific risk mitigation measures*

…

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

…

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

…

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

…

5. GENERAL DIRECTIONS FOR USE ([3])OF THE META SPC 3

5.1. Instructions for use

Always read the label or leaflet before use and follow all the instructions provided.

The product must be brought to a temperature above 20 °C before use.

The use of a dosing pump for filling the product into the application equipment is recommended.

Immediately after each cow has been milked, spray the entire surface of each teat with the solution. Leave the product until next milking. Do not clean the teats directly after disinfection.

Keep the cows standing until the product has dried (at least 5 minutes).

Product can be applied manually or by means of automatic teat sprayer.

Before the next milking the teats have to be cleaned, preferably with one new wet cloth per cow.

Application frequency must not exceed two applications per cow and day considering manual spraying and must not exceed three applications per cow and day considering automatic teat sprayer (post-milking).

5.2. Risk mitigation measures

Keep out of reach of children.

Wear protective chemical resistant gloves, coated coverall and boots during product handling and application phase (material to be specified by the authorisation holder in the product information).

In case a combination of pre- and post-milking disinfection is necessary, using another product not containing Iodine has to be considered for pre-milking disinfection.

.

5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

After inhalation: Supply fresh air; consult doctor in case of complaints.

After skin contact: Wash skin thoroughly.

After eye contact: Rinse opened eye, remove contact lenses, keep rinsing for several minutes under running water. Then consult a doctor.

After swallowing: Rinse out mouth and then drink some water. Do not induce vomiting; call for medical help immediately.

When asking for medical advice keep packaging or label at hand and call your local poison control center [insert local number here].

([3]) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 3.

Environmental emergency measures:

Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). To prevent malfunctioning of an individual wastewater treatment plant, possible residues containing the product must be discharged to the manure storage (for spreading on agricultural soils or fermentation into biogas installation) or to the municipal sewer if legally allowed.

5.4. **Instructions for safe disposal of the product and its packaging**

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.

European Waste Catalogue: 200130-detergents other than those mentioned in 20 01 29.

5.5. **Conditions of storage and shelf-life of the product under normal conditions of storage**

Store the product at room temperature, away from direct sunlight and in opaque containers. Protect from frost. Keep container tightly closed.

Shelf-life: 12 months in HDPE

6. **OTHER INFORMATION**

7. **THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 3**

7.1. **Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)	Fink – Io Spray 50 (Jodophor) Fink – Io Spray 50 (Iodophor)				
Authorisation number	EU-0020540-0004 1-3				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,5

META SPC 4

1. **META SPC 4 ADMINISTRATIVE INFORMATION**

1.1. **Meta SPC 4 identifier**

Identifier	Meta SPC 4

1.2. **Suffix to the authorisation number**

Number	1-4

1.3. **Product type(s)**

Product type(s)	PT03 – Veterinary hygiene (Disinfectants)

2. **META SPC 4 COMPOSITION**

2.1. **Qualitative and quantitative information on the composition of the meta SPC 4**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine		Active Substance	7553-56-2	231-442-4	0,1	0,15
Phosphoric Acid	Trihydroxi-dooxidopho-sphorus phosphoric acid	Non-active substance	7664-38-2	231-633-2	0,0	0,0
Poly (oxy-1,2-ethanediyl). alpha.-tridecyl-. omega.-hydroxy-, branched	Poly (oxy-1,2-etha-nediyl).alpha.-tridecyl-. omega.-hydroxy-, branched	Non-active substance	69011-36-5	500-241-6	0,0	0,0
Isotridecanol, ethoxylated 90 %, C 9-11 Alcohol Ethoxylate	Isotridecanol, ethoxylated 90 %, C 9-11 Alcohol Ethoxylate	Non-active substance	68439-46-3	614-482-0	0,0	0,0

2.2. **Type(s) of formulation of the meta SPC 4**

Formulation(s)	AL – any other liquid

3. **HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 4**

Hazard statements	May be corrosive to metals.
Precautionary statements	Keep only in original packaging. Absorb spillage to prevent material damage. Store in corrosive resistant container with a resistant inner liner.

4. AUTHORISED USE(S) OF THE META SPC 4

4.1. Use description

Table 4. Use # 1 – Veterinary hygiene – animal husbandry – teat disinfectant – professional – indoors – dipping (post milking)

Product type	PT03 – Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor
Application method(s)	Open system: dip treatment Teat-dipping: Manual non-medical disinfection of teats with a ready-to-use liquid (on cows, post-milking)
Application rate(s) and frequency	Application rate: 5-10 mL per cow Application frequency: During lactation period: • 2 applications per day (post-milking) During dry period: 1 application per day
Category(ies) of users	Professional
Pack sizes and packaging material	Bottle HDPE: 1 liter, cap is made of PP Jerry can HDPE: 5 – 60 liters Drum HDPE: 200 liters IBC HDPE: 600 – 1000 liters

4.1.1. *Use-specific instructions for use*

…

4.1.2. *Use-specific risk mitigation measures*

…

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

…

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

…

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

…

5. GENERAL DIRECTIONS FOR USE ([4])OF THE META SPC 4

5.1. Instructions for use

Always read the label or leaflet before use and follow all the instructions provided.

The product must be brought to a temperature above 20 °C before use.

([4]) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 4.

The use of a dosing pump for filling the product into the application equipment is recommended.

Fill up a teat dipping cup with 2/3 of product. Immediately after each cow has been milked, dip each teat manually in the solution. Ensure that at least two thirds of the teats, preferably the entire teats, come in contact with the solution.

Do not clean the teats directly after disinfection. Leave the product until next milking. Keep the cows standing until the product has dried (at least 5 minutes).

Refill the cup as necessary.

Teat dipping cups should be emptied after milking and washed before re-use. Before the next milking the teats have to be cleaned, preferably with one new wet cloth per cow.

Application frequency must not exceed two applications per cow and day (post-milking).

5.2. **Risk mitigation measures**

Keep out of reach of children.

In case a combination of pre- and post-milking disinfection is necessary, using another product not containing Iodine has to be considered for pre-milking disinfection.

5.3. **Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment**

After inhalation: Supply fresh air; consult doctor in case of complaints.

After skin contact: Wash skin thoroughly.

After eye contact: Rinse opened eye, remove contact lenses, keep rinsing for several minutes under running water. Then consult a doctor.

After swallowing: Rinse out mouth and then drink some water. Do not induce vomiting; call for medical help immediately.

When asking for medical advice keep packaging or label at hand and call your local poison control center [insert local number here].

Environmental emergency measures:

Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). To prevent malfunctioning of an individual wastewater treatment plant, possible residues containing the product must be discharged to the manure storage (for spreading on agricultural soils or fermentation into biogas installation) or to the municipal sewer if legally allowed.

5.4. **Instructions for safe disposal of the product and its packaging**

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.

European Waste Catalogue: 200130-detergents other than those mentioned in 20 01 29.

5.5. **Conditions of storage and shelf-life of the product under normal conditions of storage**

Store the product at room temperature, away from direct sunlight and in opaque containers. Protect from frost. Keep container tightly closed.

Shelf-life: 12 months in HDPE

6. **OTHER INFORMATION**

7. **THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 4**

7.1. **Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)	FINK – Io Dip 10 IODip 10 PVP				
Authorisation number	EU-0020540-0005 1-4				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,1

7.2. **Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)	FINK – Io Dip Protect DESINTEC MH Iodine Barrier TvP – Barrier Dip				
Authorisation number	EU-0020540-0006 1-4				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,15

META SPC 5

1. **META SPC 5 ADMINISTRATIVE INFORMATION**

1.1. **Meta SPC 5 identifier**

Identifier	Meta SPC 5

1.2. **Suffix to the authorisation number**

Number	1-5

1.3. **Product type(s)**

Product type(s)	PT03 – Veterinary hygiene (Disinfectants)

2. META SPC 5 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 5

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine		Active Substance	7553-56-2	231-442-4	0,3	0,45
Phosphoric Acid	Trihydroxi-dooxidopho-sphorus phosphoric acid	Non-active substance	7664-38-2	231-633-2	0,35	0,4
Poly (oxy-1,2-ethanediyl). alpha.-tridecyl-. omega.-hydroxy-, branched	Poly (oxy-1,2-etha-nediyl).alpha.-tridecyl-. omega.-hydroxy-, branched	Non-active substance	69011-36-5	500-241-6	0,0	0,0
Isotridecanol, ethoxylated 90 %, C 9-11 Alcohol Ethoxylate	Isotridecanol, ethoxylated 90 %, C 9-11 Alcohol Ethoxylate	Non-active substance	68439-46-3	614-482-0	0,0	0,0

2.2. Type(s) of formulation of the meta SPC 5

Formulation(s)	AL – any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 5

Hazard statements	May be corrosive to metals. Harmful to aquatic life with long lasting effects.
Precautionary statements	Keep only in original packaging. Avoid release to the environment. Absorb spillage to prevent material damage. Store in corrosive resistant container with a resistant inner liner. Dispose of contents to/container in accordance with the local/national regulations.

4. AUTHORISED USE(S) OF THE META SPC 5

4.1. Use description

Table 5. Use # 1 – Veterinary hygiene – animal husbandry – teat disinfectant – professional – indoors – dipping (post milking)

Product type	PT03 – Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	-

Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor
Application method(s)	Open system: dip treatment Teat-dipping: Manual non-medical disinfection of teats with a ready-to-use liquid (on cows, post-milking)
Application rate(s) and frequency	Application rate: 5-10 mL per cow Application frequency: During lactation period: • 2 applications per day (post-milking) During dry period: 1 application per day
Category(ies) of users	Professional
Pack sizes and packaging material	Bottle HDPE: 1 liter, cap is made of PP Jerry can HDPE: 5 – 60 liters Drum HDPE: 200 liters IBC HDPE: 600 – 1000 liters

4.1.1. *Use-specific instructions for use*

…

4.1.2. *Use-specific risk mitigation measures*

…

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

…

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

…

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

…

5. GENERAL DIRECTIONS FOR USE [5] OF THE META SPC 5

5.1. Instructions for use

Always read the label or leaflet before use and follow all the instructions provided.

The product must be brought to a temperature above 20 °C before use.

The use of a dosing pump for filling the product into the application equipment is recommended.

Fill up a teat dipping cup with 2/3 of product. Immediately after each cow has been milked, dip each teat manually in the solution. Ensure that at least two thirds of the teats, preferably the entire teats, come in contact with the solution.

Do not clean the teats directly after disinfection. Leave the product until next milking.

Keep the cows standing until the product has dried (at least 5 minutes).

[5] Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 5.

Refill the cup as necessary.

Teat dipping cups should be emptied after milking and washed before re-use. Before the next milking the teats have to be cleaned, preferably with one new wet cloth per cow.

Application frequency must not exceed two applications per cow and day (post-milking).

5.2. **Risk mitigation measures**

Keep out of reach of children.

In case a combination of pre- and post-milking disinfection is necessary, using another product not containing Iodine has to be considered for pre-milking disinfection.

5.3. **Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment**

After inhalation: Supply fresh air; consult doctor in case of complaints.

After skin contact: Wash skin thoroughly.

After eye contact: Rinse opened eye, remove contact lenses, keep rinsing for several minutes under running water. Then consult a doctor.

After swallowing: Rinse out mouth and then drink some water. Do not induce vomiting; call for medical help immediately.

When asking for medical advice keep packaging or label at hand and call your local poison control center [insert local number here].

Environmental emergency measures:

Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). To prevent malfunctioning of an individual wastewater treatment plant, possible residues containing the product must be discharged to the manure storage (for spreading on agricultural soils or fermentation into biogas installation) or to the municipal sewer if legally allowed.

5.4. **Instructions for safe disposal of the product and its packaging**

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.

European Waste Catalogue: 200130-detergents other than those mentioned in 20 01 29.

5.5. **Conditions of storage and shelf-life of the product under normal conditions of storage**

Store the product at room temperature, away from direct sunlight and in opaque containers. Protect from frost. Keep container tightly closed.

Shelf-life: 12 months in HDPE

6. **OTHER INFORMATION**

7. **THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 5**

7.1. **Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)	Jodofilm 75/5 4500 ppm IOFILMO SUPER SUPERIO 4.5 PROTEGO 4500 TIGER 50 ASSOLUTO 5 REDFOX S SUPER MANGUST AUGUSTO P5 IO-DIN 45				
Authorisation number	EU-0020540-0007 1-5				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,45
Phosphoric Acid	Trihydroxi-dooxidopho-sphorus phosphoric acid	Non-active substance	7664-38-2	231-633-2	0,4

7.2. **Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)	Jodofilm 75/5 3000 ppm JODOFILM 75/3 IOFILMO SUPERIO 3.0 PROTEGO 3000 TIGER 30 ASSOLUTO 3 REDFOX E MANGUST AUGUSTO P3 IO-DIN 30				
Authorisation number	EU-0020540-0008 1-5				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,3
Phosphoric Acid	Trihydroxi-dooxidopho-sphorus phosphoric acid	Non-active substance	7664-38-2	231-633-2	0,35

META SPC 6

1. META SPC 6 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 6 identifier

Identifier	Meta SPC 6

1.2. Suffix to the authorisation number

Number	1-6

1.3. Product type(s)

Product type(s)	PT03 – Veterinary hygiene (Disinfectants)

2. META SPC 6 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 6

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine		Active Substance	7553-56-2	231-442-4	1,75	2,4
Phosphoric Acid	Trihydroxi-dooxidopho-sphorus phosphoric acid	Non-active substance	7664-38-2	231-633-2	3,0	10,0
Poly (oxy-1,2-ethanediyl). alpha.-tridecyl-. omega.-hydroxy-, branched	Poly (oxy-1,2-etha-nediyl).alpha.-tridecyl-. omega.-hydroxy-, branched	Non-active substance	69011-36-5	500-241-6	0,0	25,6
Isotridecanol, ethoxylated 90 %, C 9-11 Alcohol Ethoxylate	Isotridecanol, ethoxylated 90 %, C 9-11 Alcohol Ethoxylate	Non-active substance	68439-46-3	614-482-0	0,0	31,8

2.2. Type(s) of formulation of the meta SPC 6

Formulation(s)	SL – soluble concentrate

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 6

Hazard statements	May be corrosive to metals. Harmful if swallowed. Causes severe skin burns and eye damage. Causes serious eye damage. May cause damage to thyroid gland through prolonged or repeated exposure. Harmful to aquatic life with long lasting effects.
Precautionary statements	Keep only in original packaging. Do not breathe mist. Do not breathe spray. Avoid release to the environment. Wear protective gloves. Wear protective clothing. Wear face protection. IF ON SKIN (or hair):Take off immediately all contaminated clothing. Rinse skin with water. IF IN EYES:Rinse cautiously with water for several minutes.Remove contact lenses, if present and easy to do. Continue rinsing. Absorb spillage to prevent material damage. Store locked up. Keep out of reach of children.

4. AUTHORISED USE(S) OF THE META SPC 6

4.1. Use description

Table 6. Use # 1 – Veterinary hygiene – animal husbandry – hard surface disinfectant – professional – indoors – spraying

Product type	PT03 – Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Bacteria Yeasts Viruses
Field(s) of use	Indoor
Application method(s)	Open system: spray treatment Disinfectant for hard surfaces in stables (excluding hatcheries). Spraying of diluted concentrate by means of a hand-held knapsack sprayer (4-7 bar)
Application rate(s) and frequency	100 mL/m2 – Concentration of Iodine in application solution: 750 ppm (0,075 %w/w). Application frequency per year: Dairy cows: 1 Beef cattle: 1 Veal calves: 4 Sows, in individual pens: 5 Sows in groups: 5 Fattening pigs: 3 Laying hens in battery cages without treatment: 1 Laying hens in battery cages with aeration (belt drying): 1

	Laying hens in battery cages with forced drying (deep pit, high rise): 1 Laying hens in compact battery cages: 1 Laying hens in free range with litter floor (partly litter floor, partly slatted): 1 Broilers in free range with litter floor: 7 Laying hens in free range with grating floor (aviery system): 1 Parent broilers in free range with grating floor: 1 Parent broilers in rearing with grating floor: 3 Turkeys in free range with litter floor: 2 Ducks in free range with litter floor: 13 Geese in free range with litter floor: 6
Category(ies) of users	Professional
Pack sizes and packaging material	Bottle HDPE: 1 liter, cap is made of PP Jerry can HDPE: 5 – 60 liters Drum HDPE: 200 liters IBC HDPE: 600 – 1000 liters

4.1.1. *Use-specific instructions for use*

Iodosan 30: Mix 29 mL product with 971 mL water to obtain 1 L application solution.

Iodosan 18: Mix 40 mL product with 960 mL water to obtain 1 L application solution.

4.1.2. *Use-specific risk mitigation measures*

…

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

…

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

…

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

…

5. GENERAL DIRECTIONS FOR USE [6] OF THE META SPC 6

5.1. Instructions for use

Always read the label or leaflet before use and follow all the instructions provided.

To prepare the disinfectant solution, mix the liquid product with water. Always pour in water first and then carefully stir in the product.

Use max. 100 mL application solution per m^2 treated area. Do not prepare more fluid than strictly necessary.

The product shall only be applied in empty (unpopulated) animal houses after surfaces have been thoroughly cleaned with a suitable cleaner.

[6] Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 6.

Pre-cleaning is mandatory. Rinse or wipe the surfaces which will be treated afterwards. Leave them to dry for about 24 up to 36h before disinfection to obtain earth-moist surfaces. Soak installations and equipment thoroughly with a thin layer of the prepared solution by spraying, using suitable devices (4 to 7 bar). During the process and for the duration of contact time (min. 30 minutes), all openings have to be closed and the ventilation has to be switched off.

5.2. **Risk mitigation measures**

Keep out of reach of children.

The form of the bottle of the product should minimise risk for splashes in order to prevent eye and skin exposure during diluting the product.

During the mixing and loading phase: The use of a face shield and protection gloves (glove material to be specified by the authorisation holder in the product information) is mandatory.

During the application phase of the in use dilution by spraying: Gloves and a protective coverall (at least type X, EN XXXXX) which is impermeable for the biocidal product shall be worn (glove and coverall material to be specified by the authorisation holder in the product information). Use new gloves for each work shift.

Professionals must not carry out animal house disinfection more than 3 times per month. These professionals should not use Iodine products for additional purposes.

Only use one kind of Iodine-containing product per day.

Stable disinfection should not be carried out more than once per year or once per lifetime for calf and pigs. Feeding troughs must be covered during application.

5.3. **Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment**

After inhalation: Supply fresh air; consult doctor in case of complaints.

After skin contact: Immediately take off contaminated clothing and wash skin thoroughly.

After eye contact: Immediately rinse opened eye, remove contact lenses, keep rinsing for several minutes under running water. Then consult a doctor.

After swallowing: Rinse out mouth and then drink some water. Do not induce vomiting; call for medical help immediately.

In case of unconsciousness place patient stably in left side position for transportation. Never give anything by mouth to an unconscious individual

When asking for medical advice keep packaging or label at hand and call your local poison control center [insert local number here].

Environmental emergency measures:

Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). To prevent malfunctioning of an individual wastewater treatment plant, possible residues containing the product must be discharged to the manure storage (for spreading on agricultural soils or fermentation into biogas installation) or to the municipal sewer if legally allowed.

Methods and material for containment and cleaning up:

Stop leak if safe to do so. Absorb spillage with liquid-binding material (sand, earth, diatomite, acid binders, universal binders, sawdust) and place in container for disposal according to local/national regulations.

5.4. **Instructions for safe disposal of the product and its packaging**

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.

European Waste Catalogue: 200130-detergents other than those mentioned in 20 01 29.

5.5. **Conditions of storage and shelf-life of the product under normal conditions of storage**

Store the product away from direct sunlight and in opaque containers. Protect from frost. Keep container tightly closed.

Shelf-life: 24 months in HDPE

6. **OTHER INFORMATION**

7. **THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 6**

7.1. **Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)	IODOSAN 30 IODOSAN JODAT DESINTEC FL-JODES ROTIE-SOL J Disinfect Jod FINK – Jodophos 15 Jod-Reiniger sauer Tankrein extra				
Authorisation number	EU-0020540-0009 1-6				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	2,4
Phosphoric Acid	Trihydroxi-dooxidopho-sphorus phosphoric acid	Non-active substance	7664-38-2	231-633-2	10,0
Poly(oxy-1,2-ethanediyl). alpha.-tridecyl-.omega.-hydroxy-,branched	Poly (oxy-1,2-etha-nediyl).alpha.-tridecyl-. omega.-hydroxy-, branched	Non-active substance	69011-36-5	500-241-6	25,6

7.2. **Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)	IODOSAN 18				
Authorisation number	EU-0020540-0010 1-6				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	1,75

Phosphoric Acid	Trihydroxi-dooxidopho-sphorus phosphoric acid	Non-active substance	7664-38-2	231-633-2	3,0
Isotridecanol, ethoxylated 90 %, C 9-11 Alcohol Ethoxylate	Isotridecanol, ethoxylated 90 %, C 9-11 Alcohol Ethoxylate	Non-active substance	68439-46-3	614-482-0	31,8

META SPC 7

1. **META SPC 7 ADMINISTRATIVE INFORMATION**

1.1. **Meta SPC 7 identifier**

Identifier	Meta SPC 7

1.2. **Suffix to the authorisation number**

Number	1-7

1.3. **Product type(s)**

Product type(s)	PT03 – Veterinary hygiene (Disinfectants)

2. **META SPC 7 COMPOSITION**

2.1. **Qualitative and quantitative information on the composition of the meta SPC 7**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine		Active Substance	7553-56-2	231-442-4	3,0	3,0
Phosphoric Acid	Trihydroxi-dooxidopho-sphorus phosphoric acid	Non-active substance	7664-38-2	231-633-2	10,0	10,0
Poly (oxy-1,2-ethanediyl). alpha.-tridecyl-. omega.-hydroxy-, branched	Poly (oxy-1,2-etha-nediyl).alpha.-tridecyl-. omega.-hydroxy-, branched	Non-active substance	69011-36-5	500-241-6	31,8	31,8

Isotridecanol, ethoxylated 90 %, C 9-11 Alcohol Ethoxylate	Isotridecanol, ethoxylated 90 %, C 9-11 Alcohol Ethoxylate	Non-active substance	68439-46-3	614-482-0	0,0	0,0

2.2. **Type(s) of formulation of the meta SPC 7**

Formulation(s)	SL – soluble concentrate

3. **HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 7**

Hazard statements	May be corrosive to metals. Harmful if swallowed. Causes severe skin burns and eye damage. Causes serious eye damage. May cause damage to thyroid gland through prolonged or repeated exposure. Toxic to aquatic life with long lasting effects.
Precautionary statements	Keep only in original packaging. Do not breathe mist. Do not breathe spray. Avoid release to the environment. Wear protective gloves. Wear protective clothing. Wear face protection. IF ON SKIN (or hair):Take off immediately all contaminated clothing. Rinse skin with water. IF IN EYES:Rinse cautiously with water for several minutes.Remove contact lenses, if present and easy to do. Continue rinsing. Absorb spillage to prevent material damage. Store locked up. Keep out of reach of children.

4. **AUTHORISED USE(S) OF THE META SPC 7**

4.1. **Use description**

Table 7. Use # 1 – Veterinary hygiene – animal husbandry – hard surface disinfectant – professional – indoors – spraying

Product type	PT03 – Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Bacteria Yeasts Viruses
Field(s) of use	Indoor
Application method(s)	Open system: spray treatment Disinfectant for hard surfaces in stables (excluding hatcheries). Spraying of diluted concentrate by means of a hand-held knapsack sprayer (4-7 bar)

Application rate(s) and frequency	100 mL/m2 – Concentration of Iodine in application solution: 750 ppm (0,075 %w/w). Application frequency per year: Dairy cows: 1 Beef cattle: 1 Veal calves: 4 Sows, in individual pens: 5 Sows in groups: 5 Fattening pigs: 3 Laying hens in battery cages without treatment: 1 Laying hens in battery cages with aeration (belt drying): 1 Laying hens in battery cages with forced drying (deep pit, high rise): 1 Laying hens in compact battery cages: 1 Laying hens in free range with litter floor (partly litter floor, partly slatted): 1 Broilers in free range with litter floor: 7 Laying hens in free range with grating floor (aviery system): 1 Parent broilers in free range with grating floor: 1 Parent broilers in rearing with grating floor: 3 Turkeys in free range with litter floor: 2 Ducks in free range with litter floor: 13 Geese in free range with litter floor: 6
Category(ies) of users	Professional
Pack sizes and packaging material	Bottle HDPE: 1 liter, cap is made of PP Jerry can HDPE: 5 – 60 liters Drum HDPE: 200 liters IBC HDPE: 600 – 1000 liters

4.1.1. *Use-specific instructions for use*

Iodosan 30 plus: Mix 23 mL product with 977 mL water to obtain 1 L application solution.

4.1.2. *Use-specific risk mitigation measures*

…

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

…

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

…

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

…

5. GENERAL DIRECTIONS FOR USE [7]OF THE META SPC 7

5.1. Instructions for use

Always read the label or leaflet before use and follow all the instructions provided.

To prepare the disinfectant solution, mix the liquid product with water. Always pour in water first and then carefully stir in the product.

Use max. 100 mL application solution per m^2 treated area. Do not prepare more fluid than strictly necessary.

The product shall only be applied in empty (unpopulated) animal houses after surfaces have been thoroughly cleaned with a suitable cleaner.

Pre-cleaning is mandatory. Rinse or wipe the surfaces which will be treated afterwards. Leave them to dry for about 24 up to 36h before disinfection to obtain earth-moist surfaces. Soak installations and equipment thoroughly with a thin layer of the prepared solution by spraying, using suitable devices (4 to 7 bar). During the process and for the duration of contact time (min. 30 minutes), all openings have to be closed and the ventilation has to be switched off.

5.2. Risk mitigation measures

Keep out of reach of children.

The form of the bottle of the product should minimise risk for splashes in order to prevent eye and skin exposure during diluting the product.

During the mixing and loading phase: The use of a face shield and protection gloves (glove material to be specified by the authorisation holder in the product information) is mandatory.

During the application phase of the in use dilution by spraying: Gloves and a protective coverall (at least type X, EN XXXXX) which is impermeable for the biocidal product shall be worn (glove and coverall material to be specified by the authorisation holder in the product information). Use new gloves for each work shift.

Professionals must not carry out animal house disinfection more than 3 times per month. These professionals should not use Iodine products for additional purposes.

Only use one kind of Iodine-containing product per day.

Stable disinfection should not be carried out more than once per year or once per lifetime for calf and pigs. Feeding troughs must be covered during application.

5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

After inhalation: Supply fresh air; consult doctor in case of complaints.

After skin contact: Immediately take off contaminated clothing and wash skin thoroughly.

After eye contact: Immediately rinse opened eye, remove contact lenses, keep rinsing for several minutes under running water. Then consult a doctor.

After swallowing: Rinse out mouth and then drink some water. Do not induce vomiting; call for medical help immediately.

In case of unconsciousness place patient stably in left side position for transportation. Never give anything by mouth to an unconscious individual.

When asking for medical advice keep packaging or label at hand and call your local poison control center [insert local number here].

Environmental emergency measures: Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). To prevent malfunctioning of an individual wastewater treatment plant, possible residues containing the product must be discharged to the manure storage (for spreading on agricultural soils or fermentation into biogas installation) or to the municipal sewer if legally allowed.

([7]) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 7.

Methods and material for containment and cleaning up:

Stop leak if safe to do so. Absorb spillage with liquid-binding material (sand, earth, diatomite, acid binders, universal binders, sawdust) and place in container for disposal according to local/national regulations.

5.4. **Instructions for safe disposal of the product and its packaging**

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.

European Waste Catalogue: 200130-detergents other than those mentioned in 20 01 29.

5.5. **Conditions of storage and shelf-life of the product under normal conditions of storage**

Store the product away from direct sunlight and in opaque containers. Protect from frost. Keep container tightly closed.

Shelf-life: 24 months in HDPE

6. **OTHER INFORMATION**

7. **THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 7**

7.1. **Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)	IODOSAN 30 Plus YODO CONTROL YODIVEN				
Authorisation number	EU-0020540-0011 1-7				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	3,0
Phosphoric Acid	Trihydroxi-dooxidopho-sphorus phosphoric acid	Non-active substance	7664-38-2	231-633-2	10,0
Poly(oxy-1,2-ethanediyl). alpha.-tridecyl-.omega.-hydroxy-,branched	Poly (oxy-1,2-etha-nediyl).alpha.-tridecyl-. omega.-hydroxy-, branched	Non-active substance	69011-36-5	500-241-6	31,8

META SPC 8

1. **META SPC 8 ADMINISTRATIVE INFORMATION**

1.1. **Meta SPC 8 identifier**

Identifier	Meta SPC 8

1.2. **Suffix to the authorisation number**

Number	1-8

1.3. **Product type(s)**

Product type(s)	PT03 – Veterinary hygiene (Disinfectants)

2. **META SPC 8 COMPOSITION**

2.1. **Qualitative and quantitative information on the composition of the meta SPC 8**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine		Active Substance	7553-56-2	231-442-4	1,5	1,5
Phosphoric Acid	Trihydroxi-dooxidopho-sphorus phosphoric acid	Non-active substance	7664-38-2	231-633-2	3,0	3,0
Poly (oxy-1,2-ethanediyl). alpha.-tridecyl-. omega.-hydroxy-, branched	Poly (oxy-1,2-etha-nediyl).alpha.-tridecyl-. omega.-hydroxy-, branched	Non-active substance	69011-36-5	500-241-6	18,0	18,0
Isotridecanol, ethoxylated 90 %, C 9-11 Alcohol Ethoxylate	Isotridecanol, ethoxylated 90 %, C 9-11 Alcohol Ethoxylate	Non-active substance	68439-46-3	614-482-0	0,0	0,0

2.2. **Type(s) of formulation of the meta SPC 8**

Formulation(s)	SL – soluble concentrate

3. **HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 8**

Hazard statements	May be corrosive to metals. Causes severe skin burns and eye damage. Causes serious eye damage. May cause damage to thyroid gland through prolonged or repeated exposure. Harmful to aquatic life with long lasting effects.

Precautionary statements	Keep only in original packaging. Do not breathe mist. Do not breathe spray. Avoid release to the environment. Wear protective gloves. Wear protective clothing. Wear face protection. IF ON SKIN (or hair):Take off immediately all contaminated clothing.Rinse skin with water. IF IN EYES:Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Absorb spillage to prevent material damage. Store locked up. Keep out of reach of children.

4. AUTHORISED USE(S) OF THE META SPC 8

4.1. Use description

Table 8. Use # 1 – Veterinary hygiene – animal husbandry – hard surface disinfectant – professional – indoors – spraying

Product type	PT03 – Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Bacteria Yeasts Viruses
Field(s) of use	Indoor
Application method(s)	Open system: spray treatment Disinfectant for hard surfaces in stables (excluding hatcheries). Spraying of diluted concentrate by means of a hand-held knapsack sprayer (4-7 bar)
Application rate(s) and frequency	100 mL/m2 – Concentration of Iodine in application solution: 750 ppm (0,075 %w/w). Application frequency per year: Dairy cows: 1 Beef cattle: 1 Veal calves: 4 Sows, in individual pens: 5 Sows in groups: 5 Fattening pigs: 3 Laying hens in battery cages without treatment: 1 Laying hens in battery cages with aeration (belt drying): 1 Laying hens in battery cages with forced drying (deep pit, high rise): 1 Laying hens in compact battery cages: 1 Laying hens in free range with litter floor (partly litter floor, partly slatted): 1

	Broilers in free range with litter floor: 7 Laying hens in free range with grating floor (aviery system): 1 Parent broilers in free range with grating floor: 1 Parent broilers in rearing with grating floor: 3 Turkeys in free range with litter floor: 2 Ducks in free range with litter floor: 13 Geese in free range with litter floor: 6
Category(ies) of users	Professional
Pack sizes and packaging material	Bottle HDPE: 1 liter, cap is made of PP Jerry can HDPE: 5 – 60 liters Drum HDPE: 200 liters IBC HDPE: 600 – 1000 liters

4.1.1. *Use-specific instructions for use*

Iodosan 15: Mix 46 mL product with 954 mL water to obtain 1 L application solution.

4.1.2. *Use-specific risk mitigation measures*

…

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

…

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

…

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

…

5. GENERAL DIRECTIONS FOR USE [8] OF THE META SPC 8

5.1. Instructions for use

Always read the label or leaflet before use and follow all the instructions provided.

To prepare the disinfectant solution, mix the liquid product with water. Always pour in water first and then carefully stir in the product.

Use max. 100 mL application solution per m^2 treated area. Do not prepare more fluid than strictly necessary.

The product shall only be applied in empty (unpopulated) animal houses after surfaces have been thoroughly cleaned with a suitable cleaner.

Pre-cleaning is mandatory. Rinse or wipe the surfaces which will be treated afterwards. Leave them to dry for about 24 up to 36h before disinfection to obtain earth-moist surfaces. Soak installations and equipment thoroughly with a thin layer of the prepared solution by spraying, using suitable devices (4 to 7 bar). During the process and for the duration of contact time (min. 30 minutes), all openings have to be closed and the ventilation has to be switched off.

[8] Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 8.

5.2. **Risk mitigation measures**

Keep out of reach of children.

The form of the bottle of the product should minimise risk for splashes in order to prevent eye and skin exposure during diluting the product.

During the mixing and loading phase: The use of a face shield and protection gloves (glove material to be specified by the authorisation holder in the product information) is mandatory.

During the application phase of the in use dilution by spraying: Gloves and a protective coverall (at least type X, EN XXXXX) which is impermeable for the biocidal product shall be worn (glove and coverall material to be specified by the authorisation holder in the product information). Use new gloves for each work shift.

Professionals must not carry out animal house disinfection more than 3 times per month. These professionals should not use Iodine products for additional purposes.

Only use one kind of Iodine-containing product per day.

Stable disinfection should not be carried out more than once per year or once per lifetime for calf and pigs. Feeding troughs must be covered during application.

5.3. **Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment**

After inhalation: Supply fresh air; consult doctor in case of complaints.

After skin contact: Immediately take off contaminated clothing and wash skin thoroughly.

After eye contact: Immediately rinse opened eye, remove contact lenses, keep rinsing for several minutes under running water. Then consult a doctor.

After swallowing: Rinse out mouth and then drink some water. Do not induce vomiting; call for medical help immediately.

In case of unconsciousness place patient stably in left side position for transportation. Never give anything by mouth to an unconscious individual.

When asking for medical advice keep packaging or label at hand and call your local poison control center [insert local number here].

Environmental emergency measures: Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). To prevent malfunctioning of an individual wastewater treatment plant, possible residues containing the product must be discharged to the manure storage (for spreading on agricultural soils or fermentation into biogas installation) or to the municipal sewer if legally allowed.

Methods and material for containment and cleaning up:

Stop leak if safe to do so. Absorb spillage with liquid-binding material (sand, earth, diatomite, acid binders, universal binders, sawdust) and place in container for disposal according to local/national regulations.

5.4. **Instructions for safe disposal of the product and its packaging**

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.

European Waste Catalogue: 200130-detergents other than those mentioned in 20 01 29.

5.5. **Conditions of storage and shelf-life of the product under normal conditions of storage**

Store the product away from direct sunlight and in opaque containers. Protect from frost. Keep container tightly closed.

Shelf-life: 24 months in HDPE

6. **OTHER INFORMATION**

7. **THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 8**

7.1. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	IODOSAN 15				
Authorisation number	EU-0020540-0012 1-8				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	1,5
Phosphoric Acid	Trihydroxi-dooxidopho-sphorus phosphoric acid	Non-active substance	7664-38-2	231-633-2	3,0
Poly(oxy-1,2-ethanediyl). alpha.-tridecyl-.omega.-hydroxy-,branched	Poly (oxy-1,2-etha-nediyl).alpha.-tridecyl-. omega.-hydroxy-, branched	Non-active substance	69011-36-5	500-241-6	18,0

COMMISSION IMPLEMENTING REGULATION (EU) 2021/978

of 10 June 2021

granting a Union authorisation for the biocidal product family "Lyso IPA Surface Disinfection"

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ([1]), and in particular the first subparagraph of Article 44(5) thereof,

Whereas:

(1) On 22 June 2016, Schuelke & Mayr GmbH submitted to the European Chemicals Agency ('the Agency') an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 and Article 4 of Commission Implementing Regulation (EU) No 414/2013 ([2]) for authorisation of the same biocidal product family, as referred to in Article 1 of Implementing Regulation (EU) No 414/2013, named "Lyso IPA Surface Disinfection", of product-types 2 and 4, as described in Annex V to Regulation (EU) No 528/2012. The application was recorded under case number BC-GX025200-35 in the Register for Biocidal Products ('the Register'). The application also indicated the application number of the related reference product family "perform-IPA", recorded in the Register under case number BC-AB023095-72.

(2) The same biocidal product family "Lyso IPA Surface Disinfection" contains propan-2-ol, as the active substance, which is included in the Union list of approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012.

(3) On 12 May 2020, the Agency submitted to the Commission an opinion ([3]) and the draft summary of the biocidal product characteristics ('SPC') of "Lyso IPA Surface Disinfection" in accordance with Article 6(1) and (2) of Implementing Regulation (EU) No 414/2013.

(4) The opinion concludes that "Lyso IPA Surface Disinfection" is a biocidal product family within the meaning of Article 3(1)(s) of Regulation (EU) No 528/2012, that the proposed differences between the same biocidal product family and the related reference biocidal product family are limited to information which can be the subject of an administrative change in accordance with Commission Implementing Regulation (EU) No 354/2013 ([4]), that "Lyso IPA Surface Disinfection" is eligible for Union authorisation in accordance with Article 42(1) of Regulation (EU) No 528/2012, and that based on the assessment of the related reference "perform-IPA" product family and subject to compliance with the draft SPC, the same biocidal product family meets the conditions laid down in Article 19(1) and (6) of Regulation (EU) No 528/2012.

(5) On 6 November 2020, the Agency transmitted to the Commission the draft SPC in all the official languages of the Union in accordance with Article 44(4) of Regulation (EU) No 528/2012.

(6) The Commission concurs with the opinion of the Agency and considers it therefore appropriate to grant a Union authorisation for the same biocidal product family "Lyso IPA Surface Disinfection".

([1]) OJ L 167, 27.6.2012, p. 1.

([2]) Commission Implementing Regulation (EU) No 414/2013 of 6 May 2013 specifying a procedure for the authorisation of same biocidal products in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 125, 7.5.2013, p. 4).

([3]) ECHA opinion of 11 May 2020 on the Union authorisation of the same biocidal product family "Lyso IPA Surface Disinfection", https://echa.europa.eu/en/opinions-on-union-authorisation

([4]) Commission Implementing Regulation (EU) No 354/2013 of 18 April 2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 109, 19.4.2013, p. 4).

(7) The same biocidal product family "Lyso IPA Surface Disinfection" contains the non-active substance diethyl phthalate, for which it was not possible to conclude whether it meets the scientific criteria for the determination of endocrine-disrupting properties set out in Commission Delegated Regulation (EU) 2017/2100 ([5]) within the period for the evaluation of the application for the related reference biocidal product family. Further examination of diethyl phthalate should therefore take place. If it is concluded that diethyl phthalate is considered as having endocrine-disrupting properties, the Commission will consider whether to cancel or amend the Union authorisation for "Lyso IPA Surface Disinfection" in accordance with Article 48 of Regulation (EU) No 528/2012.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

Article 1

A Union authorisation with authorisation number EU-0023860-0000 is granted to Schuelke & Mayr GmbH for the making available on the market and use of the same biocidal product family "Lyso IPA Surface Disinfection" in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 8 July 2021 until 30 November 2030.

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, 10 June 2021.

For the Commission
The President
Ursula VON DER LEYEN

([5]) Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council (OJ L 301, 17.11.2017, p. 1).

ANNEX

Summary of product characteristics for a biocidal product family

Lyso IPA Surface Disinfection

Product type 2 – Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)

Product type 4 – Food and feed area (Disinfectants)

Authorisation number: EU-0023860-0000

R4BP asset number: EU-0023860-0000

PART I

FIRST INFORMATION LEVEL

1. ADMINISTRATIVE INFORMATION

1.1. Family name

Name	Lyso IPA Surface Disinfection

1.2. Product type(s)

Product type(s)	PT02 – Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants) PT04 – Food and feed area (Disinfectants)

1.3. Authorisation holder

Name and address of the authorisation holder	Name	Schülke & Mayr GmbH
	Address	Robert-Koch-Str. 2, 22851, Norderstedt, Germany
Authorisation number	EU-0023860-0000	
R4BP asset number	EU-0023860-0000	
Date of the authorisation	8 July 2021	
Expiry date of the authorisation	30 November 2030	

1.4. Manufacturer(s) of the biocidal products

Name of manufacturer	Schülke & Mayr GmbH
Address of manufacturer	Robert-Koch-Str. 2, 22851 Norderstedt Germany
Location of manufacturing sites	Robert-Koch-Str. 2, 22851 Norderstedt Germany

Name of manufacturer	BOCHEMIE a.s.
Address of manufacturer	Lidická 326, 735 95 Bohumín Czech Republic
Location of manufacturing sites	Lidická 326, 735 95 Bohumín Czech Republic

Name of manufacturer	Imeco
Address of manufacturer	Boschstr. 5, 63768 Hösbach Germany
Location of manufacturing sites	Boschstr. 5, 63768 Hösbach Germany Neue Straße 2-4, 09471 Köningswalde Germany

Name of manufacturer	Tristel Solutions Limited
Address of manufacturer	Lynx Business Park, Fordham Road, Snailwell, CB8 7NY Cambridgeshire United Kingdom
Location of manufacturing sites	Lynx Business Park, Fordham Road, Snailwell, CB8 7NY Cambridgeshire United Kingdom

Name of manufacturer	Techtex
Address of manufacturer	Units 7&8 Rhodes Bus. Park Silburn Way, M24 4NE Middleton United Kingdom
Location of manufacturing sites	Units 7&8 Rhodes Bus. Park Silburn Way, M24 4NE Middleton United Kingdom

Name of manufacturer	A.F.P. GmbH
Address of manufacturer	Otto Brenner Straße 16, 21337 Lüneburg Germany
Location of manufacturing sites	Otto Brenner Straße 16, 21337 Lüneburg Germany

Name of manufacturer	Innovate GmbH
Address of manufacturer	Am Hohen Stein 11, 06618 Naumbourg (Saale) Germany
Location of manufacturing sites	Am Hohen Stein 11, 06618 Naumbourg (Saale) Germany

Name of manufacturer	Lysoform Dr. Hans Rosemann GmbH
Address of manufacturer	Kaiser-Wilhelm-Straße 133, 12247 Berlin Germany
Location of manufacturing sites	Kaiser-Wilhelm-Straße 133, 12247 Berlin Germany

Name of manufacturer	Sterisol AB
Address of manufacturer	Kronoängsgatan 3, 592 23 Vadstena Sweden
Location of manufacturing sites	Kronoängsgatan 3, 592 23 Vadstena Sweden

Name of manufacturer	Rudolf Dankwardt GmbH
Address of manufacturer	Gutenbergring 50-52, 22848 Norderstedt Germany
Location of manufacturing sites	Gutenbergring 50-52, 22848 Norderstedt Germany Lagerstr. 15, 19249 Jessenitz - Werk/Lübtheen Germany

1.5. **Manufacturer(s) of the active substance(s)**

Active substance	Propan-2-ol
Name of manufacturer	Ineos Solvents Germany GmbH (formerly Sasol)
Address of manufacturer	Römerstraße 733, 47443 Moers Germany
Location of manufacturing sites	Römerstraße 733, 47443 Moers Germany Shamrockstr. 88, 44643 Herne Germany

Active substance	Propan-2-ol
Name of manufacturer	Shell Chemicals Europe B.V.
Address of manufacturer	Postbus 2334, 3000 CH Rotterdam Netherlands
Location of manufacturing sites	Shell Nederland Raffinaderij B.V., Vondelingenweg 601, 3196 KK Rotterdam-Pernis Netherlands

2. **PRODUCT FAMILY COMPOSITION AND FORMULATION**

2.1. **Qualitative and quantitative information on the composition of the family**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,1	63,1

2.2. **Type(s) of formulation**

Formulation(s)	Any other liquid (AL), ready-to-use Any other liquid (AL), ready-to-use, wipes impregnated with disinfectant formulation

PART II

SECOND INFORMATION LEVEL – META SPC(S)

META SPC 1

1. META SPC 1 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 1 identifier

Identifier	meta-SPC1

1.2. Suffix to the authorisation number

Number	1-1

1.3. Product type(s)

Product type(s)	PT02 – Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants) PT04 – Food and feed area (Disinfectants)

2. META SPC 1 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,1	63,1

2.2. Type(s) of formulation of the meta SPC 1

Formulation(s)	Any other liquid (AL), ready-to-use

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 1

Hazard statements	Highly flammable liquid and vapour. Causes serious eye irritation. May cause drowsiness or dizziness. Repeated exposure may cause skin dryness or cracking.
Precautionary statements	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Keep container tightly closed.

	Ground and bond container and receiving equipment. Use explosion-proof electrical/ventilating/lighting equipment. Use non-sparking tools. Take action to prevent static discharges. Avoid breathing vapours. Avoid breathing spray. Use only outdoors or in a well-ventilated area. Wear eye protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Call a POISON CENTER or doctor if you feel unwell. If eye irritation persists: Get medical advice. If eye irritation persists: Get medical attention. In case of fire: Use alcohol-resistant foam, carbon dioxide or water mist to extinguish. Store in a well-ventilated place. Keep cool. Store locked up. Dispose of contents/container to an approved waste disposal plant.

4. **AUTHORISED USE(S) OF THE META SPC 1**

4.1. **Use description**

Table 1. Use # 1 – Disinfection of surfaces – spraying

Product type	PT02 – Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: - Development stage: - Scientific name: Yeast Common name: - Development stage: -
Field(s) of use	Indoor Disinfection of clean non-porous surfaces such as small work surfaces in medical and non-medical areas as well as surfaces in cleanrooms (class A/B)
Application method(s)	Spraying Product will be sprayed directly on the surface
Application rate(s) and frequency	Ready-to-use. Do not apply more than 25 ml/m^2. Disinfection after each production and cleaning process or when required according to standard operating procedure (SOP)
Category(ies) of users	Industrial Professional

Pack sizes and packaging material	Bottle: 250-1000 ml packaging material: high-density polyethylene (HDPE), surlyn/ polypropylene (PP) closure material is either: PP, polyoxymethylene (POM), low-density polyethylene (LDPE), HDPE, polyethylene (PE), ethylene-vinyl acetate (EVA), stainless steel, polybutylene terephthalate (PBT), (LD)PE, exp. polytetrafluoroethylene (PTFE), linear low density polyethylene (LLDPE), expanded PE (EXPPE), Co Polymer PP canister: 5-10 L packaging material: HDPE. closure material is either: HDPE/LDPE Revolver BAG: 1 L packaging material: EVA closure material: PP/Silicone/EVA

4.1.1. *Use-specific instructions for use*

Spray ready-to-use product on the surface and allow to take effect at room temperature (20 ± 2 °C) for at least 1 minute.

4.1.2. *Use-specific risk mitigation measures*

The following personal risk mitigation measure can be applied for refilling procedure unless it can be replaced by technical and/or organisational measures: Wear eye protection during handling of the product.

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use.

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use.

4.2. **Use description**

Table 2. Use # 2 – Disinfection of surfaces – wiping

Product type	PT02 – Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: - Development stage: - Scientific name: Yeast Common name: - Development stage: -

Field(s) of use	Indoor Disinfection of clean non-porous surfaces such as small work surfaces in medical and non-medical areas as well as surfaces in cleanrooms (class A/B)
Application method(s)	Wiping Product will be sprayed or poured on the surface and wiped afterwards or the wipe will be wetted by spraying or pouring with the product and thereafter the product should be wiped on the surface.
Application rate(s) and frequency	Ready-to-use. Do not apply more than 25 ml/m^2. Disinfection after each production and cleaning process or when required according to SOP.
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	Bottle: 250-1000 ml packaging material: HDPE, surlyn/PP closure material is either: PP, POM, LDPE, HDPE, PE, EVA, stainless steel, PBT, (LD)PE, exp. PTFE, LLDPE, EXPPE, Co Polymer PP. canister: 5-10 L packaging material: HDPE. closure material is either: HDPE/LDPE Revolver BAG: 1 L packaging material: EVA closure material: PP/Silicone/EVA.

4.2.1. *Use-specific instructions for use*

Spray or pour ready-to-use product on the surface and wipe afterwards or wet a wipe with the ready-to-use product by spraying or pouring and thereafter wipe the surface. Allow to take effect for at least 5 minutes at room temperature (20 ± 2 °C).

4.2.2. *Use-specific risk mitigation measures*

The following personal risk mitigation measure can be applied for refilling procedure unless it can be replaced by technical and/or organisational measures: Wear eye protection during handling of the product.

4.2.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use.

4.2.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

4.2.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use.

4.3. **Use description**

Table 3. Use # 3 – Disinfection of surfaces with food and feed contact – spraying

Product type	PT04 – Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: - Development stage: - Scientific name: Yeast Common name: - Development stage: - Scientific name: Viruses Common name: - Development stage: -
Field(s) of use	Indoor Disinfection of clean non-porous surfaces in kitchens and food industry including cleanrooms (class A/B)
Application method(s)	Spraying Product will be sprayed directly on the surface.
Application rate(s) and frequency	Ready-to-use. Do not apply more than 25 ml/m^2. Disinfection after each production and cleaning process or when required according to SOP.
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	Bottle: 250-1000 ml packaging material: HDPE, surlyn/PP closure material is either: PP, POM, LDPE, HDPE, PE, EVA, stainless steel, PBT, (LD)PE, exp. PTFE, LLDPE, EXPPE, Co Polymer PP. canister: 5-10 L packaging material: HDPE. closure material is either: HDPE/LDPE Revolver BAG: 1 L packaging material: EVA closure material: PP/Silicone/EVA.

4.3.1. *Use-specific instructions for use*

Spray ready-to-use product on the surface and allow to take effect at room temperature (20 ± 2 °C) for at least 1 minute (bactericidal and yeasticidal activity) or 2 minutes (virucidal activity).

4.3.2. *Use-specific risk mitigation measures*

The following personal risk mitigation measure can be applied for disinfection of food processing machinery and for refilling procedure unless it can be replaced by technical and/or organisational measures: Wear eye protection during handling of the product.

4.3.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use.

4.3.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

-

4.3.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use.

4.4. **Use description**

Table 4. Use # 4 – Disinfection of surfaces with food and feed contact – wiping

Product type	PT04 – Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: - Development stage: - Scientific name: Yeast Common name: - Development stage: - Scientific name: Viruses Common name: - Development stage: -
Field(s) of use	Indoor Disinfection of clean non-porous surfaces in kitchens and food industry including cleanrooms (class A/B)
Application method(s)	Wiping Product will be sprayed or poured on the surface and wiped afterwards or the wipe will be wetted by spraying or pouring with the product and thereafter the product should be wiped on the surface.
Application rate(s) and frequency	Ready-to-use. Do not apply more than 25 ml/m^2. Disinfection after each production and cleaning process or when required according to SOP.
Category(ies) of users	Industrial Professional

Pack sizes and packaging material	Bottle: 250-1000 ml packaging material: HDPE, surlyn/PP closure material is either: PP, POM, LDPE, HDPE, PE, EVA, stainless steel, PBT, (LD)PE, exp. PTFE, LLDPE, EXPPE, Co Polymer PP. canister: 5-10 L packaging material: HDPE. closure material is either: HDPE/LDPE Revolver BAG: 1 L packaging material: EVA closure material: PP/Silicone/EVA.

4.4.1. *Use-specific instructions for use*

Spray ready-to-use product on the surface and wipe afterwards or wet a wipe with the ready-to-use product by spraying or pouring and thereafter wipe the surface. Allow to take effect for at least 5 minutes at room temperature (20 ± 2 °C).

4.4.2. *Use-specific risk mitigation measures*

The following personal risk mitigation measure can be applied for disinfection of food processing machinery and for refilling procedure unless it can be replaced by technical and/or organisational measures:

Wear eye protection during handling of the product.

4.4.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use.

4.4.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

-

4.4.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use.

5. GENERAL DIRECTIONS FOR USE ([1]) OF THE META SPC 1

5.1. Instructions for use

Clean the surface carefully before use.

Remove excess water from the surface before disinfection, if appropriate.

Do not apply more than 25 ml/m^2.

Make sure to wet surfaces completely.

Used wipes must be disposed in a closed container.

5.2. Risk mitigation measures

The product must only be applied for disinfection of small surfaces.

Ensure adequate ventilation to prevent the formation of explosive atmospheres.

([1]) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 1.

Avoid contact with eyes.

Apply a funnel for refilling.

Keep out of reach of children and pets.

Keep children and pets away from rooms where disinfection is taking place. Provide adequate ventilation before children and pets enter treated rooms. This does not apply to hospital patient rooms.

5.3. **Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment**

First aid:

In case of accident: Call a poison centre or a doctor.

IF INHALED: Remove person to fresh air and keep comfortable for breathing.

If on skin: Wash with water. If skin irritation occurs: Get medical advice.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

5.4. **Instructions for safe disposal of the product and its packaging**

-

5.5. **Conditions of storage and shelf-life of the product under normal conditions of storage**

Shelf-life: 36 months

Keep container tightly closed.

Store in a well-ventilated place.

Protect from sunlight.

Store at room temperature in the original container.

6. **OTHER INFORMATION**

The product contains propan-2-ol (CAS No.: 67-63-0), for which a European reference value of 129,28 mg/m^3 for the professional user was agreed and used for the risk assessment of the product.

7. **THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 1**

7.1. **Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)	Schülke® 6			Market area: EU	
Authorisation number	EU-0023860-0001 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,1

META SPC 2

1. META SPC 2 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 2 identifier

Identifier	meta-SPC 2

1.2. Suffix to the authorisation number

Number	1-2

1.3. Product type(s)

Product type(s)	PT02 – Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants) PT04 – Food and feed area (Disinfectants)

2. META SPC 2 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,1	63,1

2.2. Type(s) of formulation of the meta SPC 2

Formulation(s)	Any other liquid (AL), ready-to-use, wipes impregnated with disinfectant formulation

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 2

Hazard statements	Highly flammable liquid and vapour. Causes serious eye irritation. May cause drowsiness or dizziness. Repeated exposure may cause skin dryness or cracking.
Precautionary statements	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Keep container tightly closed. Ground and bond container and receiving equipment. Use explosion-proof electrical/ventilating/lighting equipment. Use non-sparking tools.

	Take action to prevent static discharges. Avoid breathing vapours. Avoid breathing spray. Use only outdoors or in a well-ventilated area. Wear eye protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Call a POISON CENTER or doctor if you feel unwell. If eye irritation persists: Get medical advice. If eye irritation persists: Get medical attention. In case of fire: Use alcohol-resistant foam, carbon dioxide or water mist to extinguish. Store in a well-ventilated place. Keep cool. Store locked up. Dispose of contents/container to an approved waste disposal plant.

4. AUTHORISED USE(S) OF THE META SPC 2

4.1. Use description

Table 5. Use # 1 – Disinfection of surfaces – wiping

Product type	PT02 – Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: - Development stage: - Scientific name: Yeast Common name: - Development stage: -
Field(s) of use	Indoor Disinfection of clean non-porous surfaces such as small work surfaces in medical and non-medical areas as well as surfaces in cleanrooms (class A/B)
Application method(s)	Wiping Product will be wiped directly on the surface.
Application rate(s) and frequency	Ready-to-use wipes Disinfection after each production and cleaning process or when required according to SOP.
Category(ies) of users	Industrial Professional

Pack sizes and packaging material	Soft pack: 1-200 wipes Packaging material: LDPE/Alu/PET; LDPE/PET; biaxially oriented polypropylene (BOPP) + cast polypropylene (CPP) Pouch: 10-200 wipes Packaging material: LDPE/PET Tub: 50-200 wipes Packaging material: HDPE Closure material is either PP, PE3385

4.1.1. *Use-specific instructions for use*

Thoroughly wipe the surface with the wipe and allow to take effect for at least 5 minutes at room temperature (20 ± 2 °C).

4.1.2. *Use-specific risk mitigation measures*

See general directions for use.

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use.

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

-

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use.

4.2. **Use description**

Table 6. Use # 2 – Disinfection of surfaces with food and feed contact – wiping

Product type	PT04 – Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: - Development stage: - Scientific name: Yeast Common name: - Development stage: - Scientific name: Viruses Common name: - Development stage: -
Field(s) of use	Indoor Disinfection of clean non-porous surfaces in kitchens and food industry including cleanrooms (class A/B)

Application method(s)	Wiping Product will be wiped directly on the surface.
Application rate(s) and frequency	Ready-to-use wipes Disinfection after each production and cleaning process or when required according to SOP.
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	Soft pack: 1-200 wipes Packaging material: LDPE/Alu/PET; LDPE/PET; BOPP+CPP Pouch: 10-200 wipes Packaging material: LDPE/PET Tub: 50-200 wipes Packaging material: HDPE closure material is either PP, PE3385

4.2.1. *Use-specific instructions for use*

Thoroughly wipe the surface with the wipe and allow to take effect for at least 5 minutes at room temperature (20 ± 2 °C).

4.2.2. *Use-specific risk mitigation measures*

See general directions for use.

4.2.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use.

4.2.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

-

4.2.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use.

5. **GENERAL DIRECTIONS FOR USE** [2] **OF THE META SPC 2**

5.1. **Instructions for use**

Clean the surface carefully before use.

Remove excess water from the surface before disinfection, if appropriate.

Make sure to wet surfaces completely.

Used wipes must be disposed in a closed container.

[2] Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 2.

5.2. **Risk mitigation measures**

The product must only be applied for disinfection of small surfaces.

Ensure adequate ventilation to prevent the formation of explosive atmospheres.

Avoid contact with eyes.

Keep out of reach of children and pets.

Keep children and pets away from rooms where disinfection is taking place. Provide adequate ventilation before children and pets enter treated rooms. This does not apply to hospital patient rooms.

5.3. **Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment**

First aid:

In case of accident: Call a poison centre or a doctor.

IF INHALED: Remove person to fresh air and keep comfortable for breathing.

If on skin: Wash with water. If skin irritation occurs: Get medical advice.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

5.4. **Instructions for safe disposal of the product and its packaging**

-

5.5. **Conditions of storage and shelf-life of the product under normal conditions of storage**

Shelf-life: 24 months

Keep container tightly closed.

Store in a well-ventilated place.

Protect from sunlight.

Store at room temperature in the original container.

6. **OTHER INFORMATION**

The product contains propan-2-ol (CAS No.: 67-63-0), for which a European reference value of 129,28 mg/m^3 for the professional user was agreed and used for the risk assessment of the product.

7. **THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 2**

7.1. **Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)	Schülke® 7			Market area: EU	
Authorisation number	EU-0023860-0002 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,1

META SPC 3

1. **META SPC 3 ADMINISTRATIVE INFORMATION**

1.1. **Meta SPC 3 identifier**

Identifier	meta-SPC 3

1.2. **Suffix to the authorisation number**

Number	1-3

1.3. **Product type(s)**

Product type(s)	PT02 – Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants) PT04 – Food and feed area (Disinfectants)

2. **META SPC 3 COMPOSITION**

2.1. **Qualitative and quantitative information on the composition of the meta SPC 3**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,1	63,1

2.2. **Type(s) of formulation of the meta SPC 3**

Formulation(s)	Any other liquid (AL), ready-to-use

3. **HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 3**

Hazard statements	Highly flammable liquid and vapour. Causes serious eye irritation. May cause drowsiness or dizziness. Repeated exposure may cause skin dryness or cracking.
Precautionary statements	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Keep container tightly closed. Ground and bond container and receiving equipment. Use explosion-proof electrical/ventilating/lighting equipment. Use non-sparking tools.

	Take action to prevent static discharges. Avoid breathing vapours. Avoid breathing spray. Use only outdoors or in a well-ventilated area. Wear eye protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Call a POISON CENTER or doctor if you feel unwell. If eye irritation persists: Get medical advice. If eye irritation persists: Get medical attention. In case of fire: Use alcohol-resistant foam, carbon dioxide or water mist to extinguish. Store in a well-ventilated place. Keep cool. Store locked up. Dispose of contents/container to an approved waste disposal plant.

4. AUTHORISED USE(S) OF THE META SPC 3

4.1. Use description

Table 7. Use # 1 – disinfection of surfaces – spraying

Product type	PT02 – Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria including Mycobacterium tuberculosis Common name: - Development stage: - Scientific name: Yeast Common name: - Development stage: -
Field(s) of use	Indoor Disinfection of clean non-porous surfaces such as small work surfaces in medical and non-medical areas as well as surfaces in cleanrooms (class A/B)
Application method(s)	Spraying Product will be sprayed directly on the surface
Application rate(s) and frequency	Ready-to-use. Do not apply more than 25 ml/m^2. Disinfection when required according to SOP.
Category(ies) of users	Industrial Professional

Pack sizes and packaging material	Bottle: 250-1000 ml packaging material: HDPE, surlyn/PP closure material is either: PP, POM, LDPE, HDPE, PE, EVA, stainless steel, PBT, (LD)PE, exp. PTFE, LLDPE, EXPPE, Co Polymer PP canister: 5-10 L packaging material: HDPE. closure material is either: HDPE/LDPE Revolver BAG: 1 L packaging material: EVA Closure: PP/Silicone/EVA

4.1.1. *Use-specific instructions for use*

Spray ready-to-use product on the surface and allow to take effect at room temperature (20 ± 2 °C) for at least 1 minute.

4.1.2. *Use-specific risk mitigation measures*

The following personal risk mitigation measure can be applied for refilling procedure unless it can be replaced by technical and/or organisational measures:

Wear eye protection during handling of the product.

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use.

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

-

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use

4.2. **Use description**

Table 8. Use # 2 – Disinfection of surfaces – wiping

Product type	PT02 – Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria including Mycobacterium tuberculosis Common name: - Development stage: - Scientific name: Yeast Common name: - Development stage: -

Field(s) of use	Indoor Disinfection of clean non-porous surfaces such as small work surfaces in medical and non-medical areas as well as surfaces in cleanrooms (class A/B)
Application method(s)	Wiping Product will be sprayed or poured on the surface and wiped afterwards or the wipe will be wetted by spraying or pouring with the product and thereafter the product should be wiped on the surface.
Application rate(s) and frequency	Ready-to-use. Do not apply more than 25 ml/m^2. Disinfection when required according to SOP.
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	Bottle: 250-1000 ml packaging material: HDPE, surlyn/PP closure material is either: PP, POM, LDPE, HDPE, PE, EVA, stainless steel, PBT, (LD)PE, exp. PTFE, LLDPE, EXPPE, Co Polymer PP canister: 5-10 L packaging material: HDPE. closure material is either: HDPE/LDPE Revolver BAG: 1 L packaging material: EVA Closure: PP/Silicone/EVA

4.2.1. *Use-specific instructions for use*

Spray or pour ready-to-use product on the surface and wipe afterwards or wet a wipe with the ready-to-use product by spraying or pouring and thereafter wipe the surface. Allow to take effect for at least 5 minutes at room temperature (20 ± 2 °C).

4.2.2. *Use-specific risk mitigation measures*

The following personal risk mitigation measure can be applied for refilling procedure unless it can be replaced by technical and/or organisational measures:

Wear eye protection during handling of the product.

4.2.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use.

4.2.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

-

4.2.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use

4.3. **Use description**

Table 9. Use # 3 – Disinfection of surfaces with food and feed contact – spraying

Product type	PT04 – Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria including Mycobacterium tuberculosis Common name: - Development stage: - Scientific name: Yeast Common name: - Development stage: - Scientific name: Viruses Common name: - Development stage: -
Field(s) of use	Indoor Disinfection of clean non-porous surfaces in kitchens and food industry including cleanrooms (class A/B)
Application method(s)	Spraying Product will be sprayed directly on the surface.
Application rate(s) and frequency	Ready-to-use. Do not apply more than 25 ml/m^2. Disinfection when required according to SOP.
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	Bottle: 250-1000 ml packaging material: HDPE, surlyn/PP closure material is either: PP, POM, LDPE, HDPE, PE, EVA, stainless steel, PBT, (LD)PE, exp. PTFE, LLDPE, EXPPE, Co Polymer PP canister: 5-10 L packaging material: HDPE. closure material is either: HDPE/LDPE Revolver BAG: 1 L packaging material: EVA Closure: PP/Silicone/EVA

4.3.1. *Use-specific instructions for use*

Spray ready-to-use product on the surface and allow to take effect at room temperature (20 ± 2 °C) for at least 1 minute (bactericidal and yeasticidal activity) or 2 minutes (virucidal activity).

4.3.2. *Use-specific risk mitigation measures*

The following personal risk mitigation measure can be applied for disinfection of food processing machinery and for refilling procedure unless it can be replaced by technical and/or organisational measures:

Wear eye protection during handling of the product.

4.3.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use.

4.3.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

-

4.3.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use

4.4. **Use description**

Table 10. Use # 4 – Disinfection of surfaces with food and feed contact – wiping

Product type	PT04 – Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria including Mycobacterium tuberculosis Common name: - Development stage: - Scientific name: Yeast Common name: - Development stage: - Scientific name: Viruses Common name: - Development stage: -
Field(s) of use	Indoor Disinfection of clean non-porous surfaces in kitchens and food industry including cleanrooms (class A/B)
Application method(s)	Wiping Product will be sprayed or poured on the surface and wiped afterwards or the wipe will be wetted by spraying or pouring with the product and thereafter the product should be wiped on surface.
Application rate(s) and frequency	Ready-to-use. Do not apply more than 25 ml/m^2. Disinfection when required according to SOP.
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	Bottle: 250-1000 ml packaging material: HDPE, surlyn/PP closure material is either: PP, POM, LDPE, HDPE, PE, EVA, stainless steel, PBT, (LD)PE, exp. PTFE, LLDPE, EXPPE, Co Polymer PP canister: 5-10 L packaging material: HDPE. closure material is either: HDPE/LDPE Revolver BAG: 1 L packaging material: EVA Closure: PP/Silicone/EVA

4.4.1. *Use-specific instructions for use*

Spray or pour ready-to-use product on the surface and wipe afterwards or wet a wipe with the ready-to-use product by spraying or pouring and thereafter wipe the surface. Allow to take effect for at least 5 minutes at room temperature (20 ± 2 °C).

4.4.2. *Use-specific risk mitigation measures*

The following personal risk mitigation measure can be applied for disinfection of food processing machinery and for refilling procedure unless it can be replaced by technical and/or organisational measures:

Wear eye protection during handling of the product.

4.4.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use.

4.4.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

-

4.4.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use

5. GENERAL DIRECTIONS FOR USE ([3]) OF THE META SPC 3

5.1. Instructions for use

Clean the surface carefully before use.

Remove excess water from the surface before disinfection, if appropriate.

Do not apply more than 25 ml/m^2.

Make sure to wet surfaces completely.

Used wipes must be disposed in a closed container.

5.2. Risk mitigation measures

The product must only be applied for disinfection of small surfaces.

Ensure adequate ventilation to prevent the formation of explosive atmospheres.

Avoid contact with eyes.

Apply a funnel for refilling.

Keep out of reach of children and pets.

Keep children and pets away from rooms where disinfection is taking place. Provide adequate ventilation before children and pets enter treated rooms. This does not apply to hospital patient rooms.

5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

First aid:

In case of accident: Call a poison centre or a doctor.

IF INHALED: Remove person to fresh air and keep comfortable for breathing.

If on skin: Wash with water. If skin irritation occurs: Get medical advice.

([3]) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 3.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

5.4. **Instructions for safe disposal of the product and its packaging**

-

5.5. **Conditions of storage and shelf-life of the product under normal conditions of storage**

Shelf-life: 36 months

Keep container tightly closed.

Store in a well-ventilated place.

Protect from sunlight.

Store at room temperature in the original container.

6. **OTHER INFORMATION**

The product contains propan-2-ol (CAS No.: 67-63-0), for which a European reference value of 129,28 mg/m³ for the professional user was agreed and used for the risk assessment of the product.

7. **THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 3**

7.1. **Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)	Schülke® 8			Market area: EU	
Authorisation number	EU-0023860-0003 1-3				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,1

META SPC 4

1. **META SPC 4 ADMINISTRATIVE INFORMATION**

1.1. **Meta SPC 4 identifier**

Identifier	meta-SPC 4

1.2. **Suffix to the authorisation number**

Number	1-4

1.3. **Product type(s)**

Product type(s)	PT02 – Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants) PT04 – Food and feed area (Disinfectants)

2. **META SPC 4 COMPOSITION**

2.1. **Qualitative and quantitative information on the composition of the meta SPC 4**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,1	63,1

2.2. **Type(s) of formulation of the meta SPC 4**

Formulation(s)	Any other liquid (AL), ready-to-use, wipes impregnated with disinfectant formulation

3. **HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 4**

Hazard statements	Highly flammable liquid and vapour. Causes serious eye irritation. May cause drowsiness or dizziness. Repeated exposure may cause skin dryness or cracking.
Precautionary statements	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Keep container tightly closed. Ground and bond container and receiving equipment. Use explosion-proof electrical/ventilating/lighting equipment. Use non-sparking tools. Take action to prevent static discharges. Avoid breathing vapours. Avoid breathing spray. Use only outdoors or in a well-ventilated area. Wear eye protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Call a POISON CENTER or doctor if you feel unwell. If eye irritation persists: Get medical advice. If eye irritation persists: Get medical attention. In case of fire: Use alcohol-resistant foam, carbon dioxide or water mist to extinguish.

	Store in a well-ventilated place. Keep cool. Store locked up. Dispose of contents/container to an approved waste disposal plant.

4. AUTHORISED USE(S) OF THE META SPC 4

4.1. Use description

Table 11. Use # 1 – disinfection of surfaces – wiping

Product type	PT02 – Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria including Mycobacterium tuberculosis Common name: - Development stage: - Scientific name: Yeast Common name: - Development stage: -
Field(s) of use	Indoor Disinfection of clean non-porous surfaces such as small work surfaces in medical and non-medical areas as well as surfaces in cleanrooms (class A/B)
Application method(s)	Wiping Product will be wiped directly on the surface.
Application rate(s) and frequency	Ready-to-use wipes – - Disinfection when required according to SOP.
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	Soft pack: 1-200 wipes Packaging material: LDPE/Alu/PET; LDPE/PET; BOPP+CPP Pouch: 10-200 wipes Packaging material: LDPE/PET Tub: 50-200 wipes Packaging material: HDPE closure material is either PP, PE3385

4.1.1. *Use-specific instructions for use*

Thoroughly wipe the surface with the wipe and allow to take effect for at least 5 minutes at room temperature (20 ± 2 °C).

4.1.2. *Use-specific risk mitigation measures*

See general directions for use.

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use.

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

-

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use.

4.2. **Use description**

Table 12. Use # 2 – Disinfection of surfaces with food and feed contact – wiping

Product type	PT04 – Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria incl. Mycobacterium tuberculosis Common name: - Development stage: - Scientific name: Yeast Common name: - Development stage: - Scientific name: Viruses Common name: - Development stage: -
Field(s) of use	Indoor Disinfection of clean non-porous surfaces in kitchens and food industry including cleanrooms (class A/B)
Application method(s)	Wiping Product will be wiped directly on the surface.
Application rate(s) and frequency	Ready-to-use wipes Disinfection when required according to SOP.
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	Soft pack: 1-200 wipes Packaging material: LDPE/Alu/PET; LDPE/PET; BOPP+CPP Pouch: 10-200 wipes Packaging material: LDPE/PET

	Tub: 50-200 wipes Packaging material: HDPE closure material is either PP, PE3385

4.2.1. *Use-specific instructions for use*

Thoroughly wipe the surface with the wipe and allow to take effect for at least 5 minutes at room temperature (20 ± 2 °C).

4.2.2. *Use-specific risk mitigation measures*

See general directions for use.

4.2.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use.

4.2.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

-

4.2.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use.

5. GENERAL DIRECTIONS FOR USE ([4]) OF THE META SPC 4

5.1. Instructions for use

Clean the surface carefully before use.

Remove excess water from the surface before disinfection, if appropriate.

Make sure to wet surfaces completely.

Used wipes must be disposed in a closed container.

5.2. Risk mitigation measures

The product must only be applied for disinfection of small surfaces.

Ensure adequate ventilation to prevent the formation of explosive atmospheres.

Avoid contact with eyes.

Keep out of reach of children and pets.

Keep children and pets away from rooms where disinfection is taking place. Provide adequate ventilation before children and pets enter treated rooms. This does not apply to hospital patient rooms.

5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

First aid:

In case of accident: Call a poison centre or a doctor.

IF INHALED: Remove person to fresh air and keep comfortable for breathing.

If on skin: Wash with water. If skin irritation occurs: Get medical advice.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

([4]) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 4.

IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

5.4. **Instructions for safe disposal of the product and its packaging**

-

5.5. **Conditions of storage and shelf-life of the product under normal conditions of storage**

Shelf-life: 24 months

Keep container tightly closed.

Store in a well-ventilated place.

Protect from sunlight.

Store at room temperature in the original container.

6. **OTHER INFORMATION**

The product contains propan-2-ol (CAS No.: 67-63-0), for which a European reference value of 129,28 mg/m³ for the professional user was agreed and used for the risk assessment of the product.

7. **THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 4**

7.1. **Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)	Schülke® 9			Market area: EU	
Authorisation number	EU-0023860-0004 1-4				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,1

META SPC 5

1. **META SPC 5 ADMINISTRATIVE INFORMATION**

1.1. **Meta SPC 5 identifier**

Identifier	meta-SPC 5

1.2. **Suffix to the authorisation number**

Number	1-5

1.3. **Product type(s)**

Product type(s)	PT02 – Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants) PT04 – Food and feed area (Disinfectants)

2. **META SPC 5 COMPOSITION**

2.1. **Qualitative and quantitative information on the composition of the meta SPC 5**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,1	63,1

2.2. **Type(s) of formulation of the meta SPC 5**

Formulation(s)	Any other liquid (AL), ready-to-use, wipes impregnated with disinfectant formulation

3. **HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 5**

Hazard statements	Highly flammable liquid and vapour. Causes serious eye irritation. May cause drowsiness or dizziness. Repeated exposure may cause skin dryness or cracking.
Precautionary statements	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Keep container tightly closed. Ground and bond container and receiving equipment. Use explosion-proof electrical/ventilating/lighting equipment. Use non-sparking tools. Take action to prevent static discharges. Avoid breathing vapours. Avoid breathing spray. Use only outdoors or in a well-ventilated area. Wear eye protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Call a POISON CENTER or doctor if you feel unwell. If eye irritation persists: Get medical advice. If eye irritation persists: Get medical attention.

	In case of fire: Use alcohol-resistant foam, carbon dioxide or water mist to extinguish. Store in a well-ventilated place. Keep cool. Store locked up. Dispose of contents/container to an approved waste disposal plant.

4. AUTHORISED USE(S) OF THE META SPC 5

4.1. Use description

Table 13. Use # 1 – Disinfection of surfaces – wiping

Product type	PT02 – Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria including Mycobacterium tuberculosis Common name: - Development stage: - Scientific name: Yeast Common name: - Development stage: -
Field(s) of use	Indoor Disinfection of clean non-porous surfaces such as small work surfaces in medical and non-medical areas as well as surfaces in cleanrooms (class A/B)
Application method(s)	Wiping Product will be wiped directly on the surface.
Application rate(s) and frequency	Ready-to-use wipes
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	Soft pack: 1-200 wipes Packaging material: LDPE/Alu/PET; LDPE/PET; BOPP+CPP Pouch: 10-200 wipes Packaging material: LDPE/PET Tub: 50-200 wipes Packaging material: HDPE closure material is either PP, PE3385

4.1.1. *Use-specific instructions for use*

Thoroughly wipe the surface with the wipe and allow to take effect for at least 5 minutes at room temperature (20 ± 2 °C).

4.1.2. *Use-specific risk mitigation measures*

See general directions for use.

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use.

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

-

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use.

4.2. **Use description**

Table 14. Use # 2 – Disinfection of surfaces with food and feed contact – wiping

Product type	PT04 – Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria including Mycobacterium tuberculosis Common name: - Development stage: - Scientific name: Yeast Common name: - Development stage: - Scientific name: Viruses Common name: - Development stage: -
Field(s) of use	Indoor Disinfection of clean non-porous surfaces in kitchens and food industry including cleanrooms (class A/B)
Application method(s)	Wiping Product will be wiped directly on the surface.
Application rate(s) and frequency	Ready-to-use wipes
Category(ies) of users	Industrial Professional

Pack sizes and packaging material	Soft pack: 1-200 wipes Packaging material: LDPE/Alu/PET; LDPE/PET; BOPP+CPP Pouch: 10-200 wipes Packaging material: LDPE/PET Tub: 50-200 wipes Packaging material: HDPE closure material is either PP, PE3385

4.2.1. *Use-specific instructions for use*

Thoroughly wipe the surface with the wipe and allow to take effect for at least 5 minutes at room temperature (20 ± 2 °C).

4.2.2. *Use-specific risk mitigation measures*

See general directions for use.

4.2.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use.

4.2.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

-

4.2.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use.

5. GENERAL DIRECTIONS FOR USE ([5]) OF THE META SPC 5

5.1. Instructions for use

Clean the surface carefully before use.

Remove excess water from the surface before disinfection, if appropriate.

Make sure to wet surfaces completely.

Used wipes must be disposed in a closed container.

5.2. Risk mitigation measures

The product must only be applied for disinfection of small surfaces.

Ensure adequate ventilation to prevent the formation of explosive atmospheres.

Avoid contact with eyes.

Keep out of reach of children and pets.

Keep children and pets away from rooms where disinfection is taking place. Provide adequate ventilation before children and pets enter treated rooms. This does not apply to hospital patient rooms.

5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

First aid:

In case of accident: Call a poison centre or a doctor.

IF INHALED: Remove person to fresh air and keep comfortable for breathing.

([5]) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 5.

If on skin: Wash with water. If skin irritation occurs: Get medical advice.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

5.4. **Instructions for safe disposal of the product and its packaging**

-

5.5. **Conditions of storage and shelf-life of the product under normal conditions of storage**

Shelf-life: 24 months

Keep container tightly closed.

Store in a well-ventilated place.

Protect from sunlight.

Store at room temperature in the original container.

6. **OTHER INFORMATION**

The product contains propan-2-ol (CAS No.: 67-63-0), for which a European reference value of 129,28 mg/m³ for the professional user was agreed and used for the risk assessment of the product.

7. **THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 5**

7.1. **Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)	Schülke® 10			Market area: EU	
Authorisation number	EU-0023860-0005 1-5				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,1

META SPC 6

1. **META SPC 6 ADMINISTRATIVE INFORMATION**

1.1. **Meta SPC 6 identifier**

Identifier	meta-SPC6 kodan wipes IPA

1.2. **Suffix to the authorisation number**

Number	1-6

1.3. **Product type(s)**

Product type(s)	PT02 – Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants) PT04 – Food and feed area (Disinfectants)

2. **META SPC 6 COMPOSITION**

2.1. **Qualitative and quantitative information on the composition of the meta SPC 6**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,1	63,1

2.2. **Type(s) of formulation of the meta SPC 6**

Formulation(s)	Any other liquid (AL), ready-to-use, wipes impregnated with disinfectant formulation

3. **HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 6**

Hazard statements	Highly flammable liquid and vapour. Causes serious eye irritation. May cause drowsiness or dizziness. Repeated exposure may cause skin dryness or cracking.
Precautionary statements	If medical advice is needed, have product container or label at hand. Keep out of reach of children. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Keep container tightly closed. Ground and bond container and receiving equipment. Use explosion-proof electrical/ventilating/lighting equipment. Use non-sparking tools. Take action to prevent static discharges. Avoid breathing vapours. Avoid breathing spray. Use only outdoors or in a well-ventilated area. IF INHALED: Remove person to fresh air and keep comfortable for breathing. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Call a POISON CENTER or doctor if you feel unwell.

	If eye irritation persists: Get medical advice. If eye irritation persists: Get medical attention. In case of fire: Use alcohol-resistant foam, carbon dioxide or water mist to extinguish. Store in a well-ventilated place. Keep cool. Store locked up. Dispose of contents/container to an approved waste disposal plant.

4. AUTHORISED USE(S) OF THE META SPC 6

4.1. Use description

Table 15. Use # 1 – Disinfection of surfaces – wiping

Product type	PT02 – Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria including Mycobacterium tuberculosis Common name: - Development stage: - Scientific name: Yeast Common name: - Development stage: -
Field(s) of use	Indoor Disinfection of clean non-porous surfaces such as small work surfaces in medical and non-medical areas as well as surfaces in cleanrooms (class A/B)
Application method(s)	Wiping Product will be wiped directly on the surface.
Application rate(s) and frequency	Ready-to-use wipes
Category(ies) of users	Industrial Professional General public (non-professional)
Pack sizes and packaging material	Soft pack: 1-200 wipes Packaging material: LDPE/Alu/PET; LDPE/PET; BOPP+CPP Pouch: 10-200 wipes Packaging material: LDPE/PET Tub: 50-200 wipes Packaging material: HDPE closure material is either PP, PE3385

4.1.1. *Use-specific instructions for use*

Thoroughly wipe the surface with the wipe and allow to take effect for at least 5 minutes at room temperature (20 ± 2 °C).

4.1.2. *Use-specific risk mitigation measures*

See general directions for use.

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use.

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

-

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use.

4.2. **Use description**

Table 16. Use # 2 – Disinfection of surfaces with food and feed contact – wiping

Product type	PT04 – Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria including Mycobacterium tuberculosis Common name: - Development stage: - Scientific name: Yeast Common name: - Development stage: - Scientific name: Viruses Common name: - Development stage: -
Field(s) of use	Indoor Disinfection of clean non-porous surfaces in kitchens and food industry including cleanrooms (class A/B)
Application method(s)	Wiping Product will be wiped directly on the surface.
Application rate(s) and frequency	Ready-to-use wipes

Category(ies) of users	Industrial Professional General public (non-professional)
Pack sizes and packaging material	Soft pack: 1-200 wipes Packaging material: LDPE/Alu/PET; LDPE/PET; BOPP+CPP Pouch: 10-200 wipes Packaging material: LDPE/PET Tub: 50-200 wipes Packaging material: HDPE closure material is either PP, PE3385

4.2.1. *Use-specific instructions for use*

Thoroughly wipe the surface with the wipe and allow to take effect for at least 5 minutes at room temperature (20 ± 2 °C).

4.2.2. *Use-specific risk mitigation measures*

See general directions for use.

4.2.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use.

4.2.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

-

4.2.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use.

5. GENERAL DIRECTIONS FOR USE ([6]) OF THE META SPC 6

5.1. Instructions for use

Clean the surface carefully before use.

Remove excess water from the surface before disinfection, if appropriate.

Make sure to wet surfaces completely.

Used wipes must be disposed in a closed container.

5.2. Risk mitigation measures

The product must only be applied for disinfection of small surfaces.

Ensure adequate ventilation to prevent the formation of explosive atmospheres.

Avoid contact with eyes.

Keep out of the reach of children and pets.

Keep children and pets away from rooms where disinfection is taking place. Provide adequate ventilation before children and pets enter treated rooms. This does not apply to hospital patient rooms.

([6]) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 6.

5.3. **Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment**

First aid:

In case of accident: Call a poison centre or a doctor.

IF INHALED: Remove person to fresh air and keep comfortable for breathing.

If on skin: Wash with water. If skin irritation occurs: Get medical advice.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

5.4. **Instructions for safe disposal of the product and its packaging**

-

5.5. **Conditions of storage and shelf-life of the product under normal conditions of storage**

Shelf-life: 24 months

Keep container tightly closed.

Store in a well-ventilated place.

Protect from sunlight.

Store at room temperature in the original container.

6. **OTHER INFORMATION**

The product contains propan-2-ol (CAS No.: 67-63-0), for which a European reference value of 129,28 mg/m³ for the professional user was agreed and used for the risk assessment of the product.

7. **THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 6**

7.1. **Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)	Schülke® 11			Market area: EU	
Authorisation number	EU-0023860-0006 1-6				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,1

META SPC 7

1. **META SPC 7 ADMINISTRATIVE INFORMATION**

1.1. **Meta SPC 7 identifier**

Identifier	meta-SPC7

1.2. **Suffix to the authorisation number**

Number	1-7

1.3. **Product type(s)**

Product type(s)	PT02 – Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants) PT04 – Food and feed area (Disinfectants)

2. **META SPC 7 COMPOSITION**

2.1. **Qualitative and quantitative information on the composition of the meta SPC 7**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,1	63,1

2.2. **Type(s) of formulation of the meta SPC 7**

Formulation(s)	Any other liquid (AL), ready-to-use

3. **HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 7**

Hazard statements	Highly flammable liquid and vapour. Causes serious eye irritation. May cause drowsiness or dizziness. Repeated exposure may cause skin dryness or cracking.
Precautionary statements	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Keep container tightly closed. Ground and bond container and receiving equipment. Use explosion-proof electrical/ventilating/lighting equipment. Use non-sparking tools. Take action to prevent static discharges. Avoid breathing vapours. Avoid breathing spray. Use only outdoors or in a well-ventilated area. Wear eye protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

	Call a POISON CENTER or doctor if you feel unwell. If eye irritation persists: Get medical advice. If eye irritation persists: Get medical attention. In case of fire: Use alcohol-resistant foam, carbon dioxide or water mist to extinguish. Store in a well-ventilated place. Keep cool. Store locked up. Dispose of contents/container to an approved waste disposal plant.

4. AUTHORISED USE(S) OF THE META SPC 7

4.1. Use description

Table 17. Use # 1 – Disinfection of surfaces – spraying

Product type	PT02 – Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: - Development stage: - Scientific name: Yeast Common name: - Development stage: -
Field(s) of use	Indoor Disinfection of clean non-porous surfaces such as small work surfaces in medical and non-medical areas as well as surfaces in cleanrooms (class A/B)
Application method(s)	Spraying Product will be sprayed directly on the surface.
Application rate(s) and frequency	Ready-to-use. Do not apply more than 25 ml/m^2.
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	Bottle: 125-1000 ml packaging material: HDPE Clack cap material: PP; Fine mist-sprayer: complex system (PE-LD, PP, PBT, POM, EVA, stainless steel); Spray head: complex system (PP, PE, POM, Synthetic oil, Silicon oil)

4.1.1. *Use-specific instructions for use*

Spray ready-to-use product onto the surfaces and allow to take effect for at least 1 minute at room temperature (20 ± 2 °C).

4.1.2. *Use-specific risk mitigation measures*

The following personal risk mitigation measure can be applied for refilling procedure unless it can be replaced by technical and/or organisational measures:

Wear eye protection during handling of the product.

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use.

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

-

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use.

4.2. **Use description**

Table 18. Use # 2 – disinfection of surfaces – wiping

Product type	PT02 – Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: - Development stage: - Scientific name: Yeast Common name: - Development stage: -
Field(s) of use	Indoor Disinfection of clean non-porous surfaces such as small work surfaces in medical and non-medical areas as well as surfaces in cleanrooms (class A/B)
Application method(s)	Wiping Product is applied on wipes by pouring, spraying or soaking and the surface is thoroughly wiped with the soaked wipe afterwards (wet-wiping).
Application rate(s) and frequency	Ready-to-use. Do not apply more than 25 ml/m^2.
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	Bottle: 125-1000 ml packaging material: HDPE Clack cap material: PP

	Fine mist-sprayer: complex system (PE-LD, PP, PBT, POM, EVA, stainless steel); Spray head: complex system (PP, PE, POM, Synthetic oil, Silicon oil) Canister: 5-30 L packaging material: HDPE closure material: HDPE

4.2.1. *Use-specific instructions for use*

Apply the ready-to-use product on wipes by pouring, spraying or soaking and wipe the surface thoroughly with the wet wipe (wet-wiping). Allow to take effect for at least 5 minutes at room temperature (20 ± 2 °C).

4.2.2. *Use-specific risk mitigation measures*

The following personal risk mitigation measure can be applied for refilling procedure unless it can be replaced by technical and/or organisational measures:

Wear eye protection during handling of the product.

4.2.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use.

4.2.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

-

4.2.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use.

4.3. **Use description**

Table 19. Use # 3 – Disinfection of surfaces with food and feed contact – spraying

Product type	PT04 – Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: - Development stage: - Scientific name: Yeast Common name: - Development stage: - Scientific name: Viruses Common name: - Development stage: -
Field(s) of use	Indoor Disinfection of clean non-porous surfaces in kitchens and food industry including cleanrooms (class A/B)

Application method(s)	Spraying Product will be sprayed directly on the surface.
Application rate(s) and frequency	Ready-to-use. Do not apply more than 25 ml/m^2. -
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	Bottle: 125-1000 ml packaging material: HDPE Clack cap material: PP Fine mist-sprayer: complex system (PE-LD, PP, PBT, POM, EVA, stainless steel) Spray head: complex system (PP, PE, POM, Synthetic oil, Silicon oil)

4.3.1. *Use-specific instructions for use*

Spray ready-to-use product onto the surface and allow to take effect at room temperature (20 ± 2 °C) for at least 1 minute (bactericidal and yeasticidal activity) or 2 minutes (virucidal activity).

4.3.2. *Use-specific risk mitigation measures*

The following personal risk mitigation measure can be applied for disinfection of food processing machinery and for refilling procedure unless it can be replaced by technical and/or organisational measures:

Wear eye protection during handling of the product.

4.3.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use.

4.3.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

-

4.3.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use.

4.4. **Use description**

Table 20. Use # 4 – Disinfection of surfaces with food and feed contact – wiping

Product type	PT04 – Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-

Target organism(s) (including development stage)	Scientific name: Bacteria Common name: - Development stage: - Scientific name: Yeast Common name: - Development stage: - Scientific name: Viruses Common name: - Development stage: -
Field(s) of use	Indoor Disinfection of clean non-porous surfaces in kitchens and food industry including cleanrooms (class A/B)
Application method(s)	Wiping Product is applied on wipes by pouring, spraying or soaking and the surface is thoroughly wiped with the soaked wipe afterwards (wet-wiping).
Application rate(s) and frequency	Ready-to-use. Do not apply more than 25 ml/m^2.
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	Bottle: 125-1000 ml packaging material: HDPE Clack cap material: PP Fine mist-sprayer: complex system (PE-LD, PP, PBT, POM, EVA, stainless steel); Spray head: complex system (PP, PE, POM, Synthetic oil, Silicon oil) Canister: 5-30 L packaging material: HDPE closure material: HDPE

4.4.1. *Use-specific instructions for use*

Apply the ready-to-use product on wipes by pouring, spraying or soaking and wipe the surface thoroughly with the wet wipe (wet-wiping). Allow to take effect for at least 5 minutes at room temperature (20 ± 2 °C).

4.4.2. *Use-specific risk mitigation measures*

The following personal risk mitigation measure can be applied for disinfection of food processing machinery and for refilling procedure unless it can be replaced by technical and/or organisational measures:

Wear eye protection during handling of the product.

4.4.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use.

4.4.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

-

4.4.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use.

5. GENERAL DIRECTIONS FOR USE ([7]) OF THE META SPC 7

5.1. Instructions for use

Clean the surface carefully before use.

Remove excess water from the surface before disinfection, if appropriate.

Do not apply more than 25 ml/m^2.

Make sure to wet surfaces completely.

Used wipes must be disposed in a closed container.

5.2. Risk mitigation measures

The product must only be applied for disinfection of small surfaces.

Ensure adequate ventilation to prevent the formation of explosive atmospheres.

Avoid contact with eyes.

Apply a funnel for refilling.

Keep out of reach of children and pets.

Keep children and pets away from rooms where disinfection is taking place. Provide adequate ventilation before children and pets enter treated rooms. This does not apply to hospital patient rooms.

5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

First aid:

In case of accident: Call a poison centre or a doctor.

IF INHALED: Remove person to fresh air and keep comfortable for breathing.

If on skin: Wash with water. If skin irritation occurs: Get medical advice.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

5.4. Instructions for safe disposal of the product and its packaging

-

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

Shelf-life: 36 months

Keep container tightly closed.

Store in a well-ventilated place.

Protect from sunlight.

Store at room temperature in the original container.

([7]) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 7.

6. **OTHER INFORMATION**

The product contains propan-2-ol (CAS No.: 67-63-0), for which a European reference value of 129,28 mg/m³ for the professional user was agreed and used for the risk assessment of the product.

7. **THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 7**

7.1. **Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)	Superficid® Desocid rapid Neoseptin rapid Novosept rapid Novoseptin rapid Lyorthol rapid Cosmo rapid Fordesin rapid Saltero rapid Prop70 rapid Aldovet rapid Vetfarm rapid MDI rapid Antiseptica rapid Sterisol Surface MENNO® I-QUICK plus		Market area: EU Market area: EU Market area: EU Market area: EU Market area: EU Market area: EU Market area: EU Market area: EU Market area: EU Market area: EU Market area: EU Market area: EU Market area: EU Market area: EU Market area: EU Market area: EU Market area: EU		
Authorisation number	EU-0023860-0007 1-7				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,1

7.2. **Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)	Superficid® pure Desocid rapid pure Neoseptin rapid pure Novosept rapid pure Novoseptin rapid pure Lyorthol rapid pure Cosmo rapid pure Fordesin rapid pure Saltero rapid pure Prop70 rapid pure Aldovet rapid pure Vetfarm rapid pure MDI rapid pure Antiseptica rapid pure Sterisol Surface pure BTS 6000 MENNO® I-QUICK EWA® DES ready Kiehl-Rapinol Des A	Market area: EU Market area: EU Market area: EU Market area: EU Market area: EU Market area: EU Market area: EU Market area: EU Market area: EU Market area: EU Market area: EU Market area: EU Market area: EU Market area: EU Market area: EU Market area: EU Market area: EU Market area: EU Market area: EU Market area: EU

Authorisation number	EU-0023860-0008 1-7				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,1

META SPC 8

1. **META SPC 8 ADMINISTRATIVE INFORMATION**

1.1. **Meta SPC 8 identifier**

Identifier	meta-SPC8

1.2. **Suffix to the authorisation number**

Number	1-8

1.3. **Product type(s)**

Product type(s)	PT02 – Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants) PT04 – Food and feed area (Disinfectants)

2. **META SPC 8 COMPOSITION**

2.1. **Qualitative and quantitative information on the composition of the meta SPC 8**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,1	63,1

2.2. **Type(s) of formulation of the meta SPC 8**

Formulation(s)	Any other liquid (AL), ready-to-use wipes impregnated with disinfectant formulation

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 8

Hazard statements	Highly flammable liquid and vapour. Causes serious eye irritation. May cause drowsiness or dizziness. Repeated exposure may cause skin dryness or cracking.
Precautionary statements	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Keep container tightly closed. Ground and bond container and receiving equipment. Use explosion-proof electrical/ventilating/lighting equipment. Use non-sparking tools. Take action to prevent static discharges. Avoid breathing vapours. Avoid breathing spray. Use only outdoors or in a well-ventilated area. Wear eye protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Call a POISON CENTER or doctor if you feel unwell. If eye irritation persists: Get medical advice. If eye irritation persists: Get medical attention. In case of fire: Use alcohol-resistant foam, carbon dioxide or water mist to extinguish. Store in a well-ventilated place. Keep cool. Store locked up. Dispose of contents/container to an approved waste disposal plant.

4. AUTHORISED USE(S) OF THE META SPC 8

4.1. Use description

Table 21. Use # 1 – Disinfection of surfaces – wiping

Product type	PT02 – Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: - Development stage: - Scientific name: Yeast Common name: - Development stage: -
Field(s) of use	Indoor Disinfection of clean non-porous surfaces such as small work surfaces in medical and non-medical areas as well as surfaces in cleanrooms (class A/B)

Application method(s)	Wiping Product will be wiped directly on the surface.
Application rate(s) and frequency	Ready-to-use wipes
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	Can: 100-150 wipes Packaging: HDPE Closure material: HDPE Pack: 100-150 wipes Packaging: PET/PE

4.1.1. *Use-specific instructions for use*

Thoroughly wipe the surface with the wipe and allow to take effect for at least 5 minutes at room temperature (20 ± 2 °C).

4.1.2. *Use-specific risk mitigation measures*

See general directions for use.

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use.

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

-

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use.

4.2. **Use description**

Table 22. Use # 2 – Disinfection of surfaces with food and feed contact – wiping

Product type	PT04 – Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: - Development stage: - Scientific name: Yeast Common name: - Development stage: -

	Scientific name: Viruses Common name: - Development stage: -
Field(s) of use	Indoor Disinfection of clean non-porous surfaces in kitchens and food industry including cleanrooms (class A/B)
Application method(s)	Wiping Product will be wiped directly on the surface.
Application rate(s) and frequency	Ready-to-use wipes
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	Can: 100-150 wipes Packaging: HDPE Closure material: HDPE Pack: 100-150 wipes Packaging: PET/PE

4.2.1. *Use-specific instructions for use*

Thoroughly wipe the surface with the wipe and allow to take effect for at least 5 minutes at room temperature (20 ± 2 °C).

4.2.2. *Use-specific risk mitigation measures*

See general directions for use.

4.2.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use.

4.2.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

-

4.2.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use.

5. GENERAL DIRECTIONS FOR USE ([8]) OF THE META SPC 8

5.1. Instructions for use

Clean the surface carefully before use.

Remove excess water from the surface before disinfection, if appropriate.

Make sure to wet surfaces completely.

([8]) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 8.

Used wipes must be disposed in a closed container.

5.2. **Risk mitigation measures**

The product must only be applied for disinfection of small surfaces.

Ensure adequate ventilation to prevent the formation of explosive atmospheres.

Avoid contact with eyes.

Keep out of reach of children and pets.

Keep children and pets away from rooms where disinfection is taking place. Provide adequate ventilation before children and pets enter treated rooms. This does not apply to hospital patient rooms.

5.3. **Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment**

First aid:

In case of accident: Call a poison centre or a doctor.

IF INHALED: Remove person to fresh air and keep comfortable for breathing.

If on skin: Wash with water. If skin irritation occurs: Get medical advice.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

5.4. **Instructions for safe disposal of the product and its packaging**

-

5.5. **Conditions of storage and shelf-life of the product under normal conditions of storage**

Shelf-life: 24 months

Keep container tightly closed.

Store in a well-ventilated place.

Protect from sunlight.

Store at room temperature in the original container.

6. **OTHER INFORMATION**

The product contains propan-2-ol (CAS No.: 67-63-0), for which a European reference value of 129,28 mg/m³ for the professional user was agreed and used for the risk assessment of the product.

7. **THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 8**

7.1. **Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)	Descorapid® Tücher	Market area: EU
	Desocid Tücher	Market area: EU
	Neoseptin Tücher	Market area: EU
	Novosept Tücher	Market area: EU
	Novoseptin Tücher	Market area: EU
	Lyorthol Tücher	Market area: EU
	Cosmo Tücher	Market area: EU
	Fordesin Tücher	Market area: EU
	Saltero Tücher	Market area: EU
	Prop70 Tücher	Market area: EU
	Manosafe Tücher	Market area: EU
	Dermoguard Tücher	Market area: EU

	Dermosafe Tücher Aldovet Tücher Vetfarm Tücher MDI Tücher Antiseptica Tücher Antiseptica wipes MENNO®WIP Descorapid® wipes Desocid wipes Neoseptin wipes Novosept wipes Novoseptin wipes Lyorthol wipes Cosmo wipes Fordesin wipes Saltero wipes Prop70 wipes Manosafe wipes Dermoguard wipes Dermosafe wipes Aldovet wipes Vetfarm wipes MDI wipes	Market area: EU Market area: EU
Authorisation number	EU-0023860-0009 1-8	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,1

7.2. **Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)	Superficid® pure wipes Desocid rapid pure wipes Neoseptin rapid pure wipes Novosept rapid pure wipes Novoseptin rapid pure wipes Lyorthol rapid pure wipes Cosmo rapid pure wipes Fordesin rapid pure wipes Saltero rapid pure wipes Prop70 rapid pure wipes Aldovet rapid pure wipes Vetfarm rapid pure wipes MDI rapid pure wipes Antiseptica rapid pure wipes	Market area: EU Market area: EU Market area: EU Market area: EU Market area: EU Market area: EU Market area: EU Market area: EU Market area: EU Market area: EU Market area: EU Market area: EU Market area: EU Market area: EU
Authorisation number	EU-0023860-0010 1-8	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,1

COMMISSION REGULATION (EU) 2021/979

of 17 June 2021

amending Annexes VII to XI to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC ([1]), and in particular Article 131 thereof,

Whereas:

(1) Regulation (EC) No 1907/2006 imposes specific registration duties and obligations on manufacturers, importers and downstream users with a view to generate data on substances they manufacture, import or use, to assess the risks related to those substances and to develop and recommend appropriate risk management measures.

(2) Annexes VII to X to Regulation (EC) No 1907/2006 set out standard information requirements for substances manufactured or imported in quantities of 1 tonne or more, 10 tonnes or more, 100 tonnes or more and 1 000 tonnes or more, respectively. Annex XI to that Regulation sets out the general rules for adaptation of the standard testing regime set out in Annexes VII to X thereto.

(3) In June 2019 the Commission and the European Chemicals Agency ('the Agency') concluded in REACH Evaluation Joint Action Plan ([2]) that certain provisions in the Annexes to Regulation (EC) No 1907/2006 should be amended to provide more clarity on the obligations of registrants and on the role and responsibilities of the Agency under Titles II and VI of that Regulation, respectively.

(4) Experience has shown that the introductory texts of Annexes VII to X to Regulation (EC) No 1907/2006 are insufficient and that additional requirements should be introduced for human health and environmental purposes as regards the chosen study design where a test method offers flexibility. This should, among others, ensure that animal testing is performed at appropriately high dose levels.

(5) In order to ensure the provision of useful information, certain provisions on information on the physicochemical properties of the substance in Annex VII to Regulation (EC) No 1907/2006 should be clarified as regards the information requirements for surface tension and water solubility of metals and sparingly soluble metal compounds.

(6) Certain provisions on toxicological information in Annex VII to Regulation (EC) No 1907/2006 should be modified with a view to clarifying the obligations for registrants and the responsibilities of the Agency as regards the performance of in vitro studies for eye irritation.

(7) Various provisions on toxicological information in Annex VIII to Regulation (EC) No 1907/2006 have been found to be unclear and should be rephrased. Those provisions concern, in particular, the performance of in vivo studies for skin or eye irritation and of the 28-day repeated dose toxicity study.

(8) Certain provisions on information on the physicochemical properties of the substance in Annex IX to Regulation (EC) No 1907/2006 should be clarified in order to add new specific rules for adaptation for dissociation constant and viscosity.

([1]) OJ L 396, 30.12.2006, p. 1.

([2]) European Commission and European Chemicals Agency REACH Evaluation Joint Action Plan of June 2019 (https://echa.europa.eu/documents/10162/21877836/final_echa_com_reach_evaluation_action_plan_en).

(9) The provisions on toxicological information in Annex IX to Regulation (EC) No 1907/2006 require certain clarifications on when the sub-chronic toxicity study does not need to be conducted. In addition, it is necessary to amend the specific rules laid down in Annexes IX and X to Regulation (EC) No 1907/2006 about adaptation for the reproductive toxicity studies in order to better specify the cases where testing does not need to be conducted. It should also be clarified how to demonstrate low toxicological activity of a substance in order to adapt testing. Finally, the provision setting out the conditions under which no further testing is necessary for sexual function and fertility or developmental toxicity should be simplified.

(10) Annex IX to Regulation (EC) No 1907/2006 should also be amended in order to exclude the waiving of conducting relevant studies on fate and behaviour in the environment on the sole basis of a low octanol water partition coefficient where this is not appropriate.

(11) In Annex IX and Annex X to Regulation (EC) No 1907/2006, the waiving options on the basis of classification should be aligned with the terminology of Article 3 of Regulation (EC) No 1272/2008.

(12) The general rules for adaptation of the standard testing regime in Annex XI to Regulation (EC) No 1907/2006 should be modified in order to update them and to avoid ambiguity of certain provisions. Those changes concern, in particular, the provisions on use of existing data, weight of evidence and grouping of substances.

(13) Given uncertainty with regard to what can be considered as existing data, that term as used in Annex XI, subsection 1.1, to Regulation (EC) No 1907/2006 should be clarified by aligning it to Article 13(3) and (4) of that Regulation. The reference to good laboratory practice should be deleted to ensure consistency with the enacting terms of that Regulation.

(14) In Annex XI to Regulation (EC) No 1907/2006, it should be clarified how a 'weight of evidence' adaptation can be applied to specific information requirements and how it should be documented.

(15) It is necessary to clarify the rules laid down in Annex XI to Regulation (EC) No 1907/2006 concerning the establishment of structural similarity. It should be clarified further what documentation is required for read-across, including specifically for substances of unknown or variable composition, complex reaction products and biological materials. In addition, the reference to the Agency issuing guidance on this topic should be removed as the guidance has already been published.

(16) The footnote in the section 'Substance-tailored exposure-driven testing' of Annex XI to Regulation (EC) No 1907/2006 should be moved to the main text to enhance its visibility. Finally, the provisions of that section should be amended to clarify the legal text and align it to the changes on toxicological information.

(17) Regulation (EC) No 1907/2006 should therefore be amended accordingly.

(18) The proposed amendments aim at providing clarifications of certain information requirements and at increasing the legal certainty of the evaluation practices already applied by the Agency. Nevertheless, it cannot be discarded that the amended provisions might trigger an update of registration dossiers. Therefore, the application of this Regulation should be deferred.

(19) The measures provided for in this Regulation are in accordance with the opinion of the Committee established under Article 133 of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS REGULATION:

Article 1

Annexes VII to XI to Regulation (EC) No 1907/2006 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*.

It shall apply from 8 January 2022.

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

Done at Brussels, 17 June 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Regulation (EC) No 1907/2006 is amended as follows:

(1) Annex VII is amended as follows:

(a) in the introductory part, the following paragraph is inserted after the sixth paragraph:

'Where a test method offers flexibility in the study design, for example in relation to the choice of dose levels, the chosen study design shall ensure that the data generated are adequate for hazard identification and risk assessment. To this end, testing shall be performed at appropriately high dose levels. If dose (concentration) selection is limited by the physicochemical properties or biological effects of the test substance, justification shall be provided.';

(b) in subsection 7.6, in column 1, the text is replaced by the following:

'7.6. Surface tension of an aqueous solution';	

(c) in subsection 7.7, in column 2, the following paragraph is added:

	'For metals and sparingly soluble metal compounds, information on transformation/dissolution in aqueous media shall be provided.';

(d) in point 8.2.1, in column 2, the text is replaced by the following:

	'8.2.1. If results from a first in vitro study do not allow a conclusive decision on the classification of a substance or on the absence of eye irritation potential, (an)other in vitro study/studies for this endpoint shall be performed by the registrant or may be required by the Agency.'.

(2) Annex VIII is amended as follows:

(a) in the introductory part, the following paragraph is inserted after the fourth paragraph:

'Where a test method offers flexibility in the study design, for example in relation to the choice of dose levels, the chosen study design shall ensure that the data generated are adequate for hazard identification and risk assessment. To this end, testing shall be performed at appropriately high dose levels. If dose (concentration) selection is limited by the physicochemical properties or biological effects of the test substance, justification shall be provided.';

(b) in subsection 8.1, in column 2, the first paragraph is replaced by the following:

	'8.1. An in vivo study for skin corrosion/irritation shall be conducted only if the in vitro study/studies under points 8.1.1 and/or 8.1.2 of Annex VII is(are) not applicable, or the results of this/these study/studies is/are not adequate for classification and risk assessment.';

(c) in subsection 8.2, in column 2, the first paragraph is replaced by the following:

	'8.2. An in vivo study for serious eye damage/eye irritation shall be conducted only if the in vitro study/studies) under point 8.2.1 of Annex VII is/are not applicable, or the results of this/these study/studies) are not adequate for classification and risk assessment.';

(d) in point 8.6.1, in column 2, in the first paragraph, the first indent is replaced by the following:

	'- da reliable sub-chronic (90 days) or chronic toxicity study is available or proposed by the registrant, provided that an appropriate species, dosage, solvent and route of administration are used, or';

(e) in point 8.6.1, in column 2, the fourth and fifth paragraphs are replaced by the following:

	'For nanoforms without high dissolution rate in biological media, the study shall include toxicokinetic investigations on, among others, the recovery period and, where relevant, lung clearance. Toxicokinetic investigations do not need to be performed if equivalent toxicokinetic information on the nanoform is already available. The sub-chronic toxicity study (90 days) (Annex IX, point 8.6.2) shall be proposed by the registrant, or may be required by the Agency if: the frequency and duration of human exposure indicates that a longer term study is appropriate; and one of the following conditions is met: — other available data indicate that the substance may have a dangerous property that cannot be detected in a short-term toxicity study, or — appropriately designed toxicokinetic studies reveal accumulation of the substance or its metabolites in certain tissues or organs which would possibly remain undetected in a short-term toxicity study but which are liable to result in adverse effects after prolonged exposure.';

(f) in point 9.3.1, in column 2, the following paragraph is inserted after the first paragraph:

		'The study may not be waived on the basis of low octanol-water partition coefficient alone, unless the adsorptive properties of the substance are solely driven by lipophilicity. For instance, the study may not be waived on the basis of low octanol-water partition coefficient alone if the substance is surface active or ionisable at environmental pH (pH 4 – 9).'.

(3) Annex IX is amended as follows:

(a) in the introductory part, the following paragraph is inserted after the fifth paragraph:

'Where a test method offers flexibility in the study design, for example in relation to the choice of dose levels, the chosen study design shall ensure that the data generated are adequate for hazard identification and risk assessment. To this end, testing shall be performed at appropriately high dose levels. If dose (concentration) selection is limited by the physicochemical properties or biological effects of the test substance, justification shall be provided.';

(b) in subsection 7.16, in column 2, the following indent is added:

	'- or based on the structure, the substance does not have any chemical group that can dissociate.';

(c) in subsection 7.17, in column 2, the following text is added:

	'For hydrocarbon substances the kinematic viscosity shall be determined at 40 °C.';

(d) point 8.6.1 is deleted;

(e) in point 8.6.2, in column 2, in the first paragraph, the introductory sentence and the first and second indents are replaced by the following:

	'8.6.2. The sub-chronic toxicity study (90 days) does not need to be conducted if: — a reliable short-term toxicity study (28 days) is available showing severe toxicity effects meeting the criteria for classifying the substance as STOT RE (category 1 or 2), for which the observed NOAEL-28 days, with the application of an appropriate uncertainty factor, allows the extrapolation towards the NOAEL-90 days for the same route of exposure, or

	— a reliable chronic toxicity study is available or proposed by the registrant, provided that an appropriate species and route of administration are used, or';

(f) in point 8.6.2, in column 2, the fourth paragraph is replaced by the following:

	'For nanoforms without high dissolution rate in biological media, the study shall include toxicokinetic investigations on, among others, the recovery period and, where relevant, lung clearance. Toxicokinetic investigations do not need to be performed if equivalent toxicokinetic information on the nanoform is already available.'

(g) in subsection 8.7, in column 2, the text is replaced by the following:

	'8.7. The studies do not need to be conducted if: — the substance is known to be a genotoxic carcinogen, meeting the criteria for classification both in the hazard class germ cell mutagenicity (category 1A or 1B or 2) and carcinogenicity (category 1A or 1B), and appropriate risk management measures are implemented, or — the substance is known to be a germ cell mutagen, meeting the criteria for classification in the hazard class germ cell mutagenicity (category 1A or 1B) and appropriate risk management measures are implemented, or — the substance is of low toxicological activity (a comprehensive and informative dataset showing no toxicity in any of the tests available), it can be proven from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure (e.g. plasma/blood concentrations below detection limit using a sensitive method and absence of the substance and of metabolites of

	the substance in urine, bile or exhaled air) and there is no or no significant human exposure. If a substance is known to have an adverse effect on sexual function and fertility, meeting the criteria for classification in the hazard class reproductive toxicity (category 1A or 1B: May damage fertility (H360F)), and the available data are adequate to support a robust risk assessment, then no further testing for sexual function and fertility shall be necessary. If a substance is known to cause developmental toxicity, meeting the criteria for classification in the hazard class reproductive toxicity (category 1A or 1B: May damage the unborn child (H360D)), and the available data are adequate to support a robust risk assessment, then no further testing for developmental toxicity shall be necessary.'

(h) in point 9.3.2, in column 2, the following paragraph is inserted after the first paragraph:

	'The study may not be waived on the basis of low octanol-water partition coefficient alone, unless the potential for bioaccumulation of the substance is solely driven by lipophilicity. For instance, the study may not be waived on the basis of low octanol-water partition coefficient alone if the substance is surface active or ionisable at environmental pH (pH 4 – 9).';

(i) in point 9.3.3, in column 2, the following paragraph is inserted after the first paragraph:

	'The study may not be waived on the basis of low octanol-water partition coefficient alone, unless the adsorptive properties of the substance are solely driven by lipophilicity. For instance, the study may not be waived on the basis of low octanol-water partition coefficient alone if the substance is surface active or ionisable at environmental pH (pH 4 – 9).'

(4) Annex X is amended as follows:

(a) in the introductory part, the following paragraph is inserted after the fifth paragraph:

'Where a test method offers flexibility in the study design, for example in relation to the choice of dose levels, the chosen study design shall ensure that the data generated are adequate for hazard identification and risk assessment. To this end, testing shall be performed at appropriately high dose levels. If dose (concentration) selection is limited by the physicochemical properties or biological effects of the test substance, justification shall be provided.';

(b) in subsection 8.7, in column 2, the text is replaced by the following:

	'8.7. The studies do not need to be conducted if: — the substance is known to be a genotoxic carcinogen, meeting the criteria for classification both in the hazard class germ cell mutagenicity (category 1A or 1B or 2) and carcinogenicity (category 1A or 1B), and appropriate risk management measures are implemented, or — the substance is known to be a germ cell mutagen, meeting the criteria for classification in the hazard class germ cell mutagenicity (category 1A or 1B) and appropriate risk management measures are implemented, or — the substance is of low toxicological activity (a comprehensive and informative dataset showing no toxicity seen in any of the tests available), it can be proven from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure (e.g. plasma/blood concentrations below detection limit using a sensitive method and absence of the substance and of metabolites of the substance in urine, bile or exhaled air) and there is no or no significant human exposure. If a substance is known to have an adverse effect on sexual function and fertility, meeting the criteria for classification in the hazard class reproductive toxicity (category 1A or 1B: May damage fertility (H360F)), and the available data are adequate to support a robust risk assessment, then no further testing for sexual function and fertility shall be necessary.

	If a substance is known to cause developmental toxicity, meeting the criteria for classification in the hazard class reproductive toxicity (category 1A or 1B: May damage the unborn child (H360D)), and the available data are adequate to support a robust risk assessment, then no further testing for developmental toxicity shall be necessary.'.

(5) Annex XI is amended as follows:

(a) section 1 ('TESTING DOES NOT APPEAR SCIENTIFICALLY NECESSARY') is amended as follows:

(i) under the header of subsection 1.1 ('Use of existing data'), the following text is added:

'Any data generated as from 1 June 2008 shall not be considered as existing data and shall not be subject to the general rules for adaptation laid down in this point (1.1).';

(ii) the header of point 1.1.1 is replaced by the following:

'1.1.1. Data on physical-chemical properties from experiments not carried out according to the test methods referred to in Article 13(3)';

(iii) in subsection 1.2. ('Weight of evidence'), the text is replaced by the following:

'There is sufficient weight of evidence when information from several independent sources together enable, through a reasoned justification, a conclusion on the information requirement, while the information from each single source alone is insufficient to fulfil the information requirement. The justification must have regard to the information that would otherwise be obtained from the study that shall normally be performed for this information requirement.

There may also be sufficient weight of evidence from the use of newly developed test methods, not yet included in the test methods referred to in Article 13(3), leading to a reasoned justification that they provide the information that would enable a conclusion on the information requirement.

Weight of evidence may lead to the conclusion that a substance has or has not a particular property.

If there is sufficient weight of evidence, the information requirement is fulfilled. Consequently, further testing on vertebrate animals shall be omitted and further testing not involving vertebrate animals may be omitted.

In all cases, the information provided shall be adequate for the purpose of classification, labelling and/or risk assessment, and adequate and reliable documentation shall be provided, including:

— robust study summaries of the studies used as sources of information;

— a justification explaining why the sources of information together provide a conclusion on the information requirement.

When nanoforms are covered by the registration, the above approach shall address the nanoforms separately.';

(iv) in subsection 1.5 ('Grouping of substances and read-across approach'), the text is replaced by the following:

'Substances whose physicochemical, toxicological and ecotoxicological properties are likely to be similar or follow a regular pattern as a result of structural similarity, may be considered as a group, or category, of substances. Application of the group concept requires that physicochemical properties, human health effects and environmental effects or environmental fate may be predicted from data for reference substance(s) within the group by interpolation to other substances in the group (read-across approach). This avoids the need to test every substance for every endpoint.

When nanoforms are covered by the registration, the above approach shall address the nanoforms separately. For grouping different nanoforms of the same substance, the molecular structural similarities alone may not serve as a justification.

If nanoforms covered by a registration are grouped or placed in a 'category' with other forms, including other nanoforms, of the substance in the same registration the obligations above shall apply in the same manner.

The similarities may be based on any of the following:

(1) a common functional group;

(2) the common precursors and/or the likelihood of common breakdown products via physical and biological processes, which result in structurally similar chemicals;

(3) a constant pattern in the changing of the potency of the properties across the category.

Structural similarity for UVCB substances shall be established on the basis of similarities in the structures of the constituents, together with the concentration of these constituents and variability in the concentration of these constituents. If it can be demonstrated that the identification of all individual constituents is not technically possible or impractical, the structural similarity may be demonstrated by other means, to enable a quantitative and qualitative comparison of the actual composition between substances.

If the group concept is applied, substances shall be classified and labelled on this basis.

In all cases, results shall fulfil all of the following conditions:

— be adequate for the purpose of classification and labelling and/or risk assessment,

— have adequate and reliable coverage of the key parameters addressed in the corresponding study that shall normally be performed for a particular information requirement,

— cover an exposure duration comparable to or longer than the corresponding study that shall normally be performed for a particular information requirement if exposure duration is a relevant parameter.

In all cases, adequate and reliable documentation of the applied method shall be provided. Such documentation shall include:

— a robust study summary for each source study used in the adaptation;

— an explanation why the properties of the registered substance may be predicted from other substances in the group;

— supporting information to scientifically justify such explanation for prediction of properties.';

(b) section 3 ('SUBSTANCE-TAILORED EXPOSURE-DRIVEN TESTING') is amended as follows:

(i) subsection 3.1 is replaced by the following:

'3.1. Testing in accordance with Section 8.7 of Annex VIII and in accordance with Annex IX and Annex X may be omitted, based on the exposure scenario(s) developed in the Chemical Safety Report. Testing in accordance with Section 8.6.1 of Annex VIII may be omitted only for registrants producing less than 100 tonnes per year per manufacturer or importer, based on the exposure scenario(s) developed in the Chemical Safety Report.'

(ii) point 3.2(a)(ii) is replaced by the following:

'(ii) a DNEL or a PNEC can be derived from results of available test data for the substance concerned taking full account of the increased uncertainty resulting from the omission of the information requirement, and that DNEL or PNEC is relevant and appropriate both to the information requirement to be omitted and for risk assessment purposes. For this purpose and without prejudice to column 2 of Sections 8.6 and 8.7 of

Annexes IX and X, a DNEL derived from a 28-day repeated dose toxicity study shall not be considered appropriate to omit a 90-day repeated dose toxicity study, and a DNEL derived from a screening test for reproductive/developmental toxicity shall not be considered appropriate to omit a prenatal developmental toxicity study or an extended one-generation reproductive toxicity study.'.

COMMISSION IMPLEMENTING REGULATION (EU) 2021/980

of 17 June 2021

amending Implementing Regulation (EU) 2019/661 as regards information requirements for registration in the electronic registry for quotas for placing hydrofluorocarbons on the market

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 517/2014 of the European Parliament and of the Council of 16 April 2014 on fluorinated greenhouse gases and repealing Regulation (EC) No 842/2006 ([1]), and in particular Article 17(2) thereof,

Whereas:

(1) Commission Implementing Regulation (EU) 2019/661 ([2]) lays down the requirements for undertakings whose registration in the registry established in accordance with Article 17(1) of Regulation (EU) No 517/2014 is compulsory.

(2) Pursuant to Implementing Regulation (EU) 2019/661, undertakings established in the Union must provide their Economic Operators Registration and Identification (EORI) number to the Commission for the purposes of becoming registered in the registry, if applicable. Undertakings established outside the Union that have mandated an only representative within the meaning of Article 16(5) of Regulation (EU) No 517/2014, must only provide that information with respect to their only representative. The only representative may be mandated as such by more than one undertaking established outside the Union. The EORI number of such only representative does not, therefore, necessarily correspond to one undertaking established outside the Union.

(3) In accordance with Article 17(4) of Regulation (EU) No 517/2014, the registry is accessible to national competent authorities, including customs authorities, for information purposes.

(4) When enforcing the placing on the market restrictions and prohibitions set out in Regulation (EU) No 517/2014, customs authorities must be able to identify the undertakings placing hydrofluorocarbons on the market in accordance with that Regulation via their EORI numbers. In particular, this can also facilitate controls by customs authorities when using digital tools. The identification of the concerned undertaking can be achieved if that undertaking's EORI number is available in the registry. Therefore, it is necessary to require from the undertakings established outside the Union that have mandated an only representative to provide their own EORI number. The requirement for these undertakings to provide the EORI number of their only representative should be removed since it is superfluous.

(5) Implementing Regulation (EU) 2019/661 should therefore be amended accordingly.

(6) The measures provided for in this Regulation are in accordance with the opinion of the Committee established under Article 24(1) of Regulation (EU) No 517/2014,

HAS ADOPTED THIS REGULATION:

Article 1

Article 3, paragraph 2 of Implementing Regulation (EU) 2019/661 is amended as follows:

(1) point (b) is replaced with the following:

'(b) the information listed in paragraph 1, points (d) and (i), but with respect to the only representative rather than the undertaking;';

([1]) OJ L 150, 20.5.2014, p. 195.

([2]) Commission Implementing Regulation (EU) 2019/661 of 25 April 2019 ensuring the smooth functioning of the electronic registry for quotas for placing hydrofluorocarbons on the market (OJ L 112, 26.4.2019, p. 11).

(2) the following point (g) is added:

'(g) the undertaking's EORI number, if applicable.'.

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, 17 June 2021.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2021/981

of 17 June 2021

concerning the renewal of the authorisation of a preparation of endo-1,4-beta-xylanase produced by *Aspergillus niger* CBS 109.713 and endo-1,4-beta-glucanase produced by *Aspergillus niger* DSM 18404 as a feed additive for poultry species, ornamental birds and weaned piglets (holder of the authorisation: BASF SE), and repealing Regulation (EC) No 271/2009 and Implementing Regulation (EU) No 1068/2011

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ([1]), and in particular Article 9(2) thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting and renewing such authorisation.

(2) An enzyme preparation of endo-1,4-beta-xylanase produced by *Aspergillus niger* CBS 109.713 and endo-1,4-beta-glucanase produced by *Aspergillus niger* DSM 18404 ('the preparation concerned') was authorised for 10 years as a feed additive for weaned piglets, chickens for fattening, laying hens, turkeys for fattening and ducks for fattening by Commission Regulation (EC) No 271/2009 ([2]) and for chickens reared for laying, turkeys for breeding purposes, turkeys reared for breeding, other minor avian species (other than ducks for fattening) and ornamental birds by Commission Implementing Regulation (EU) No 1068/2011 ([3]).

(3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of the preparation concerned as feed additive for poultry species, ornamental birds and weaned piglets in the additive category 'zootechnical additives'. The application was accompanied by the particulars and documents required under Article 14(2) of Regulation (EC) No 1831/2003.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 18 November 2020 ([4]) that the applicant had provided data demonstrating that the preparation concerned complies with the conditions of authorisation under the proposed conditions of use. The Authority confirmed its previous conclusions that the preparation concerned does not have an adverse effect on animal health, consumer health or the environment. It also stated that the additive is to be considered as a potential skin and respiratory sensitiser. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. The Authority also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) The assessment of the preparation concerned shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the authorisation of this additive should be renewed as specified in the Annex to this Regulation.

([1]) OJ L 268, 18.10.2003, p. 29.

([2]) Commission Regulation (EC) No 271/2009 of 2 April 2009 concerning the authorisation of a preparation of endo-1,4-beta-xylanase and endo-1,4-beta-glucanase as a feed additive for weaned piglets, chickens for fattening, laying hens, turkeys for fattening and ducks for fattening (holder of the authorisation BASF SE) (OJ L 91, 3.4.2009, p. 5.).

([3]) Commission Implementing Regulation (EU) No 1068/2011 of 21 October 2011 concerning the authorisation of an enzyme preparation of endo-1,4-beta-xylanase produced by *Aspergillus niger* (CBS 109.713) and endo-1,4-beta-glucanase produced by *Aspergillus niger* (DSM 18404) as a feed additive for chickens reared for laying, turkeys for breeding purposes, turkeys reared for breeding, other minor avian species (other than ducks for fattening) and ornamental birds (holder of authorisation BASF SE) (OJ L 277, 22.10.2011, p. 11).

([4]) *EFSA Journal* 2020;18(12):6331.

(6) As a consequence of the renewal of the authorisation of the preparation concerned as a feed additive, Regulation (EC) No 271/2009 and Implementing Regulation (EU) No 1068/2011 should be repealed.

(7) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation for the preparation concerned, it is appropriate to provide a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the renewal of the authorisation.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

The authorisation of the preparation of endo-1,4-beta-xylanase produced by *Aspergillus niger* CBS 109.713 and endo-1,4-beta-glucanase produced by *Aspergillus niger* DSM 18404 specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'digestibility enhancers', is renewed subject to the conditions laid down in that Annex.

Article 2

1. The preparation of endo-1,4-beta-xylanase produced by *Aspergillus niger* CBS 109.713 and endo-1,4-beta-glucanase produced by *Aspergillus niger* DSM 18404 and premixtures containing it, which are produced and labelled before 8 January 2022 in accordance with the rules applicable before 8 July 2021 may continue to be placed on the market and used until the existing stocks are exhausted.

2. Feed materials and compound feed containing the preparation referred to in paragraph 1, which are produced and labelled before 8 July 2022 in accordance with the rules applicable before 8 July 2021 may continue to be placed on the market and used until the existing stocks are exhausted, where they are intended for food-producing animals.

3. Feed materials and compound feed containing the preparation referred to in paragraph 1, which are produced and labelled before 8 July 2023 in accordance with the rules applicable before 8 July 2021 may continue to be placed on the market and used until the existing stocks are exhausted, where they are intended for non-food-producing animals.

Article 3

Regulation (EC) No 271/2009 and Implementing Regulation (EU) No 1068/2011 are repealed.

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, 17 June 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						Units of activity/kg of complete feed with a moisture content of 12 %			
Category: zootechnical additives. Functional group: digestibility enhancers.									
4a7	BASF SE	Endo-1,4-beta-xylanase (EC 3.2.1.8) and endo-1,4-beta-glucanase (EC 3.2.1.4)	***Additive composition*** Preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Aspergillus niger* CBS 109.713 and endo-1,4-beta-glucanase (EC 3.2.1.4) produced by *Aspergillus niger* DSM 18404 having a minimum activity of 5 600 TXU ([1]) and 2 500 TGU ([2])/g in solid or liquid form ***Characterisation of active substance*** Endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Aspergillus niger* CBS 109.713 and endo-1,4-beta-glucanase (EC 3.2.1.4) produced by *Aspergillus niger* DSM 18404 ***Analytical method*** ([3]) For quantification of endo-1,4-beta-xylanase in the feed additive, premixtures, feed materials and compound feed: Viscosimetric method based on decrease of viscosity produced by action of endo-1,4-beta- xylanase on the xylan containing substrate (wheat arabinoxylan) at pH = 3,5 and 55 °C.	Chickens for fattening and reared for laying Laying hens All minor poultry species for fattening and laying Ornamental birds	-	280 TXU 125 TGU	-	1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including skin and breathing protection.	8 July 2031
				Turkeys Weaned piglets		560 TXU 250 TGU			

			For quantification of endo-1,4-beta-glucanase in the feed additive, premixtures, feed materials and compound feed: Viscosimetric method based on decrease of viscosity produced by action of endo-1,4-beta- glucanase on the glucan containing substrate (barley betaglucan) at pH = 3,5 and 40 °C.						

(1) One TXU is defined as the amount of enzyme that liberates 5 µmol of reducing sugars (xylose equivalents) from wheat arabinoxylan per minute at pH = 3,5 and 55 °C
(2) One TGU is defined as the amount of enzyme that liberates 1 µmol of reducing sugars (glucose equivalents) from barley betaglucan per minute at pH = 3,5 and 40 °C
(3) Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports

COMMISSION IMPLEMENTING REGULATION (EU) 2021/982

of 17 June 2021

concerning the renewal of the authorisation of a preparation of 6-phytase produced by *Trichoderma reesei* CBS 122001 as a feed additive for pigs and poultry (holder of the authorisation: Roal Oy), and repealing Regulations (EU) No 277/2010, (EU) No 891/2010 and Implementing Regulation (EU) No 886/2011

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ([1]), and in particular Article 9(2) thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting and renewing such authorisation.

(2) A preparation of 6-phytase produced by *Trichoderma reesei* CBS 122001 was authorised for 10 years as a feed additive for poultry for fattening and breeding other than turkeys for fattening, for poultry for laying and for pigs other than sows by Commission Regulation (EU) No 277/2010 ([2]), for turkeys by Commission Regulation (EU) No 891/2010 ([3]) and for sows by Commission Implementing Regulation (EU) No 886/2011 ([4]).

(3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of the preparation of 6-phytase produced by *Trichoderma reesei* CBS 122001 as feed additive for poultry for fattening, breeding and laying, and pigs in the additive category 'zootechnical additives' and in the functional group 'digestibility enhancers'. The application was accompanied by the particulars and documents required under Article 14(2) of Regulation (EC) No 1831/2003.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 18 November 2020 ([5]) that the applicant had provided data demonstrating that the additive complies with the conditions of authorisation under the proposed conditions of use. The Authority confirmed its previous conclusions that the preparation of 6-phytase produced by *Trichoderma reesei* CBS 122001 does not have an adverse effect on animal health, consumer health or the environment. It also stated that the additive should be considered a potential respiratory sensitiser. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. The Authority also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) The assessment of the preparation of 6-phytase produced by *Trichoderma reesei* (CBS 122001) shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the authorisation of this additive should be renewed as specified in the Annex to this Regulation.

(6) As a consequence of the renewal of the authorisation of the preparation of 6-phytase produced by *Trichoderma reesei* CBS 122001 as a feed additive under the conditions laid down in the Annex to this Regulation, Regulations (EU) No 277/2010, (EU) No 891/2010 and Implementing Regulation (EU) No 886/2011 should be repealed.

([1]) OJ L 268, 18.10.2003, p. 29.

([2]) Commission Regulation (EU) No 277/2010 of 31 March 2010 concerning the authorisation of 6-phytase as a feed additive for poultry for fattening and breeding other than turkeys for fattening, for poultry for laying and for pigs other than sows (holder of authorisation Roal Oy), (OJ L 86, 1.4.2010, p. 13.).

([3]) Commission Regulation (EU) No 891/2010 of 8 October 2010 concerning the authorisation of a new use of 6-phytase as a feed additive for turkeys (holder of authorisation Roal Oy), (OJ L 266, 9.10.2010, p. 4.).

([4]) Commission Implementing Regulation (EU) No 886/2011 of 5 September 2011 concerning the authorisation of 6-phytase (EC 3.1.3.26) produced by *Trichoderma reesei* (CBS 122001) as a feed additive for sows (holder of authorisation Roal Oy), (OJ L 229, 6.9.2011, p. 5.).

([5]) *EFSA Journal* 2020;18(12):6336.

(7) As regards the composition of this additive, minor changes have been applied to the manufacturing during the last years to improve the fermentation process. Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation for the preparation of 6-phytase produced by *Trichoderma reesei* CBS 122001, it is appropriate to provide a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the renewal of the authorisation.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

The authorisation of the preparation of 6-phytase produced by *Trichoderma reesei* CBS 122001 specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'digestibility enhancers' is renewed subject to the conditions laid down in the Annex.

Article 2

1. The preparation of 6-phytase produced by *Trichoderma reesei* CBS 122001 and premixtures containing it, which are produced and labelled before 8 January 2022 in accordance with the rules applicable before 8 July 2021 may continue to be placed on the market and used until the existing stocks are exhausted.

2. Feed materials and compound feed containing the preparation referred to in point 1, which are produced and labelled before 8 July 2022 in accordance with the rules applicable before 8 July 2021 may continue to be placed on the market and used until the existing stocks are exhausted, where they are intended for food-producing animals.

Article 3

Regulations (EU) No 277/2010, (EU) No 891/2010 and Implementing Regulation (EU) No 886/2011 are repealed.

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, 17 June 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						Units of activity/kg of complete feed with a moisture content of 12 %			
Category: zootechnical additives. Functional group: digestibility enhancers.									
4a12	Roal Oy	6-Phytase (EC 3.1.3.26)	**Additive composition** Preparation of 6-phytase (EC 3.1.3.26) produced by *Trichoderma reesei* CBS 122001 with a minimum content of Solid form: 40 000 PPU (1)/g Liquid form: 10 000 PPU/g **Characterisation of active substance** 6-phytase (EC 3.1.3.26) produced by *Trichoderma reesei* (CBS 122001) **Analytical method** (2) Colorimetric method quantifying the activity of 6-phytase by measuring released inorganic phosphate from sodium phytate by analysing the colour formed by reduction of a phosphomolybdate complex.	Poultry for fattening and breeding Pigs	-	250 PPU	-	1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection.	8 July 2031
				Poultry for laying		125 PPU			

(1) 1 PPU is the amount of enzyme which liberates 1 µmol of inorganic phosphate from sodium phytate per minute at pH = 5,0 and 37 °C.
(2) Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports

COMMISSION IMPLEMENTING REGULATION (EU) 2021/983

of 17 June 2021

imposing a provisional anti-dumping duty on imports of aluminium converter foil originating in the People's Republic of China

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2016/1036 of the European Parliament and of the Council of 8 June 2016 on protection against dumped imports from countries not members of the European Union ('the basic Regulation') ([1]), and in particular Article 7 thereof,

After consulting the Member States,

Whereas:

1. PROCEDURE

1.1. Initiation

(1) On 22 October 2020, the European Commission ('the Commission') initiated an anti-dumping investigation with regard to imports of aluminium converter foil originating in People's Republic of China ('the PRC', 'China' or the 'country concerned') on the basis of Article 5 of Regulation (EU) 2016/1036. It published a Notice of Initiation in the *Official Journal of the European Union* ([2]) ('the Notice of Initiation').

(2) The Commission initiated the investigation following a complaint lodged on 7 September 2020 ([3]) by six Union producers ('the complainants'), representing more than 50 % of the total Union production of aluminium converter foil ('ACF' or the 'product under investigation). The complaint contained evidence of dumping and of resulting material injury that was sufficient to justify the initiation of the investigation.

1.2. Registration

(3) Pursuant to Article 14(5a) of the basic Regulation, the Commission should register imports subject to an anti-dumping investigation during the period of pre-disclosure unless it has sufficient evidence that certain requirements are not met. One of these requirements, as indicated in Article 10(4)(d) of the basic Regulation, is that there is a further substantial rise in imports in addition to the level of imports which caused injury during the investigation period. As can be seen in Table 1, the imports of aluminium converter foil originating in the PRC showed a decrease of 22 % in the five months following initiation as compared to the investigation period (1 July 2019 to 30 June 2020). As there were no indications on the file that imports of aluminium converter foil as defined in recital (45) below are subject to seasonal fluctuations, the Commission did not consider it necessary to also compare the level of imports during the period November 2019 to March 2020 with the level of imports during the same months in the investigation period. The data following initiation was based upon the TARIC codes created for the product concerned at initiation. This was compared to the monthly average imports from the PRC for the IP.

([1]) OJ L 176, 30.6.2016, p. 21.

([2]) Notice of Initiation of an anti-dumping proceeding concerning imports of aluminium converter foil originating in the People's Republic of China (OJ C 352 I, 22.10.2020, p. 1).

([3]) See Corrigendum to Notice of initiation of an anti-dumping proceeding concerning imports of aluminium converter foil originating in the People's Republic of China (OJ C 398, 23.11.2020, p. 32).

Table 1

Imports from China in the IP and after initiation (tonnes)

	Investigation period	Investigation period monthly average	November 2020 - March 2021	November 2020 - March 2021 monthly average
Imports from China in the EU	44 276	3 689	14 465	2 893

Source: Eurostat and Surveillance II database.

(4) Consequently, the Commission did not make imports of the product concerned subject to registration under Article 14(5a) of the basic Regulation, as the condition in Article 10(4)(d) of the basic Regulation, that is a further substantial rise in imports, was not met.

1.3. **Interested parties**

(5) In the Notice of Initiation, the Commission invited interested parties to contact it in order to participate in the investigation. In addition, it specifically informed the complainants, known Union producers, known exporting producers and the authorities in the PRC, known importers and users as well as associations known to be concerned about the initiation of the investigation and invited them to participate.

(6) Interested parties had an opportunity to comment on the initiation of the investigation and to request a hearing with the Commission and/or the Hearing Officer in trade proceedings.

(7) Several parties requested a hearing with the Commission services. Parties who made a request within the stipulated deadlines were granted an opportunity to be heard.

1.4. **Comments on initiation**

(8) One user, Manreal, as well as a consortium of five importers, Cartonal Italia, Cutting Packaging, Now Plastics, QualityFoil and Transparent Paper, claimed the information in the complaint was often inconsistent and based on unsubstantiated and unreliable assumptions. One of the exporting producers, Xiamen, put forward similar arguments.

(9) First, the interested parties argued that the complaint is inconsistent as to the manner in which the data concerning the EU industry and the share of the total ACF production held by the complainants was aggregated. The complainants would indicate their proportion of Union industry with different values: 69,93 %, 61,20 % and 70 % of the total Union production.

(10) The Commission considered the explanations given for these different values in the complaint to be sufficiently clear. As indicated on page 6 of the complaint, 69,93 % represent the percentage of the total Union production of all complainants. This would go down to 61,20 %, should the Commission consider that one of the complaining companies needed to be excluded from the calculation, since this company imports limited quantities of ACF from the PRC. On page 36, the complainants indicate that the injury analysis pertains to a group of companies which include the non-complainant Novelis and who together represent at least 70 % of the Union production. This 70 % refers to the share of EU production of all complainants, namely 69,93 %, plus that of Novelis, and is a rounded value. As the 70 % is used for a description and not a calculation, there is also no influence on the analysis resulting from the rounding. In any case, all these percentages meet the threshold established in Article 5(4) of the basic Regulation.

(11) Second, the interested parties consider it to be inconsistent that the complainants included data of Novelis, who stopped its production of the product concerned in 2019, in its injury analysis. The impact of the interruption of Novelis' production on the total Union production of ACF in 2019 and the investigation period (see recital (38)) as well as the share of the total Union production destined for captive use would be unreliable.

(12) The Commission considered the explanations regarding the impact of the data of Novelis in the complaint to be reliable. The complaint throughout the injury analysis indicated specific data or details related to Novelis, which demonstrated the impact of this data. Furthermore, the exit of Novelis from the production of the product concerned is part of the development of the Union industry during the period considered. As the inclusion of data of Novelis was clearly stated, the Commission was in a position to assess the influence on the captive use, relevant for the injury. The evidence, including the data of Novelis, was considered sufficient and reliable to justify the initiation of an investigation.

(13) Third, the interested parties criticized the complainants' approach to base their calculation of the total Union production on EAFA (European Aluminium Foil Association) data adjusted to the production volume of the complainants, applying a further adjustment of 5 % to take into account that two complaining companies did not produce household foil, to be inherently uncertain and based on assumptions. Xiamen added that the decrease of the production would follow the trend in consumption and would be even slightly better than the decrease in consumption. Furthermore, the exit of various Union producers from the ACF market was allegedly described in a misrepresentative way as a consequence of injury, contrary to press releases praising that move to be based on voluntary business decisions.

(14) The Commission considered the calculation method based on the EAFA data as sufficiently reliable to justify the initiation of an investigation. Xiamen's argument that the decrease of production would just follow the decrease in consumption is not consistent with the fact that Union producers during this period lost market share. Positively sounding press releases of Union producers who have decided to exit the market are, moreover, not definitive evidence of the actual underlying reasons for which the producers concerned may have exited the market.

(15) Fourth, the interested parties claimed the complainants' method to estimate the total volume of sales as "the consumption of the product concerned in the EU minus the total imports of the product concerned" to be distorted as it would not include a distinction of captive sales. They argued that only the production destined for the EU free market should be relevant for the analysis. Xiamen added the argument that at least one Union producer allegedly produced almost exclusively aluminium household foils, thus further distorting the estimated total volume of sales.

(16) The Commission considered the complainants' method to be sufficiently precise for the purpose of the complaint. As is evident from the analysis of the sales during the period considered in recital (271), captive sales are not significant enough to call the overall injury analysis into question.

(17) Fifth, the interested parties claimed the data to be distorted due to the metric used. Whereas the complaint provides data in tonnes, it should have been complemented with data in micron (micrometre) average as the market trend to reduce thickness would lead to a higher output of m^2 per tonne.

(18) The Commission considered that the trend to use thinner gauges of ACF does not render the data provided in tonnes unreliable as it is also complemented with market share data and the trend to move to thinner foil affects all producers equally.

(19) Sixth, the interested parties contested the reliability and accuracy of the indicators in the complaint by referring to multiple isolated elements concerning differences in amounts in the tables contained in the complaint, compared to the tables contained in the open versions of the Annex 1A.2 to the complaint, that allegedly affected the indicators.

(20) The Commission noted that the alleged discrepancies in values originate from the fact that Annex 1A.2 provides a summary of the aggregated figures of the complaining companies, while in the confidential version detailed figures per company are indicated. Furthermore, the tables in the complaint include figures of Novelis, which however the document clearly indicates. The discrepancies in figures between the main document and the Annexes therefore do not result in inconsistencies. In addition, the Commission relied for its assessment on the more detailed company specific Annexes in the confidential version. Therefore, the different ways to display the figures did not affect the Commission's capability to assess the injury indicators.

(21) Seventh, the interested parties claimed that the complaint did not contain positive evidence on the existence of material injury by imports originating in the PRC and referred to flaws in the allegations on macro and micro indicators. on the grounds that several indicators did not show a decrease or only a slight decrease.

(22) The Commission recalled that Article 5(2) of the basic Regulation requires that the complaint shall contain, to the extent that it is reasonably available to the complainant, information on changes in the volume of the allegedly dumped imports, the effect of those imports on prices of the like product on the Union market and the consequent impact of the imports on the Union industry, as demonstrated by relevant (but not necessarily all) factors and indices having a bearing on the state of the Union industry, such as those listed in Article 3(3) and (5) of the basic Regulation. In the present case, the specific injury analysis in the complaint contained evidence pointing to a significant penetration of the EU market by Chinese imports made at prices which substantially undercut and undersell the Union industry's prices. The Commission thus considered that the complaint contained sufficient evidence that this had materially injured the Union industry. Consequently, these claims were rejected.

(23) One user, Alupol Packaging, argued that contrary to the product definition put forward by the complainants, which included "not further worked than rolled", ACF purchased would regularly undergo further treatment by the producer, including splitting, cutting into required width, wounding on given cores and diameters as well as annealing (normalizing).

(24) The Commission considered the additional production steps indicated by Alupol Packaging to be an inherent part of the production process and to qualify as "not further worked than rolled". Furthermore, the width forms part of the product control number ('PCN') structure. Therefore, this claim was rejected.

(25) In their comments on initiation various interested parties included comments related to exclusion requests for ACF with a gauge below 6 microns and for ACF used for electric car batteries. At the stage of the initiation there was no indication that such segments needed to be analysed separately. However, the Commission decided to collect additional data related to these requests. These comments, as well as comments related to the introduction of a lower end for gauges into the product definition in general, are addressed separately in section 2.3 concerning the exclusion requests. Comments related to an expected supply shortage in case of the imposition of duties, including those resulting from captive consumption as well as claims of insufficient investments by the Union industry, are addressed in section 6 on Union interest.

1.5. **Sampling**

(26) In the Notice of Initiation, the Commission stated that it might sample the interested parties in accordance with Article 17 of the basic Regulation.

1.5.1. *Sampling of Union producers*

(27) In the Notice of Initiation, the Commission stated that it had provisionally selected a sample of Union producers. It selected the sample based on the volume of production and sales of the like product in the Union during the investigation period. The sample consisted of three Union producers. The sampled Union producers accounted for more than 50 % of the estimated total production and 40 % of the estimated total Union sales volume of the like product. The Commission invited interested parties to comment on the provisional sample. No comments on the provisional sample were received.

(28) In light of the above, the sample was considered to be representative of the Union industry.

1.5.2. *Sampling of importers*

(29) To decide whether sampling was necessary and, if so, to select a sample, the Commission asked unrelated importers to provide the information specified in the Notice of Initiation.

(30) Two unrelated importers provided the requested information and agreed to be included in the sample. Given the small number of replies, sampling of unrelated importers was not necessary.

1.5.3. *Sampling of exporting producers*

(31) In order to decide whether sampling was necessary and, if so, to select a sample, the Commission asked all known exporting producers in the PRC to provide the information specified in the Notice of Initiation. In addition, the Commission asked the Mission of the People's Republic of China to the European Union to identify and/or contact other exporting producers, if any, that could be interested in participating in the investigation.

(32) Nine exporting producers in the country concerned provided the requested information and agreed to be included in the sample. In accordance with Article 17(1) of the basic Regulation, the Commission selected a sample of three companies on the basis of the largest representative volume of exports to the Union that could reasonably be investigated within the time available. These companies represented over 90 % of the estimated total Union imports of the product concerned. In accordance with Article 17(2) of the basic Regulation, all known exporting producers concerned and the authorities of the country concerned were given the opportunity to comment on the selection of the sample. No comments were received.

1.6. **Individual examination**

(33) Six exporting producers in China, which requested individual examination under Article 17(3) of the basic Regulation, were invited to submit a questionnaire response. However, no exporting producer submitted a completed questionnaire within the deadline. Therefore, no individual examination request could be examined.

1.7. **Questionnaire replies and verification visits**

(34) The Commission sent a questionnaire concerning the existence of significant distortions in China within the meaning of Article 2(6a)(b) of the basic Regulation to the Government of the People's Republic of China ('GOC'). It also sent to the GOC a questionnaire concerning raw material distortions within the meaning of Article 7(2a) and (2b) of the basic Regulation.

(35) The Commission sent questionnaires to the sampled Union producers, selected importers, users and sampled exporting producers. The same questionnaires had also been made available online ([4]) on the day of initiation.

(36) The Commission received questionnaire replies from three sampled Union producers, six non-sampled Union producers (macro questionnaire), one unrelated importer, nine users and three exporting producers.

(37) In view of the outbreak of COVID-19 and the confinement measures put in place by various Member States as well as by various third countries, the Commission could not carry out verification visits pursuant to Article 16 of the basic Regulation at provisional stage. The Commission instead cross-checked remotely all the information deemed necessary for its provisional determinations in line with its Notice on the consequences of the COVID-19 outbreak on anti-dumping and anti-subsidy investigations ([5]). The Commission carried out remote crosschecks ('RCC') of the following companies/parties:

Union producers

— Carcano Antonio Spa, ("Carcano"), Italy

— Eurofoil Luxembourg S.A. ("Eurofoil"), Luxembourg

— Hydro Aluminium Rolled Products GmbH ("Hydro"), Germany

([4]) https://trade.ec.europa.eu/tdi/case_details.cfm?id=2487

([5]) Notice on the consequences of the COVID-19 outbreak on anti-dumping and anti-subsidy investigations (OJ C 86, 16.3.2020, p. 6).

Exporting producers in China

— Jiangsu Zhongji Lamination Materials Co., Ltd ("Zhongji")

— Yantai Donghai Aluminum Foil Co., Ltd ("Donghai")

— Xiamen Xiashun Aluminium Foil Co., Ltd ("Xiamen")

1.8. **Investigation period and period considered**

(38) The investigation of dumping and injury covered the period from 1 July 2019 to 30 June 2020 ('the investigation period' or 'IP'). The examination of trends relevant for the assessment of injury covered the period from 1 January 2017 to the end of the investigation period ('the period considered').

1.9. **Withdrawal of the United Kingdom from the EU**

(39) This case was initiated during the transition period following the withdrawal of the United Kingdom ('UK') from the EU. During this transition period, the UK remained subject to Union law. The transition period ended on 31 December 2020. Consequently, as of 1 January 2021, companies and associations located in the UK no longer qualified as interested parties in this proceeding. In conclusion, as the UK is no longer subject to the Union law, the findings on dumping and injury are based on the EU-27 market data.

2. **PRODUCT CONCERNED AND LIKE PRODUCT**

2.1. **Product concerned**

(40) The product subject to this investigation is aluminium converter foil ('ACF') of a thickness of less than 0,021 mm, not backed, not further worked than rolled, in rolls of a weight exceeding 10 kg originating in the People's Republic of China currently classified under CN code ex 7607 11 19 (TARIC codes 7607 11 19 60 and 7607 11 19 91) ('the product concerned'). The CN and TARIC codes are given for information only.

The following products are excluded:

— Aluminium household foil of a thickness of not less than 0,008 mm and not more than 0,018 mm, not backed, not further worked than rolled, in rolls of a width not exceeding 650 mm and of a weight exceeding 10 kg.

— Aluminium household foil of a thickness of not less than 0,007 mm and less than 0,008 mm, regardless of the width of the rolls, whether or not annealed.

— Aluminium household foil of a thickness of not less than 0,008 mm and not more than 0,018 mm and in rolls of a width exceeding 650 mm, whether or not annealed.

— Aluminium household foil of a thickness of more than 0,018 mm and less than 0,021 mm, regardless of the width of the rolls, whether or not annealed.

(41) ACF is supplied in jumbo reels and then processed on a converter (laminated, coated, lacquered, extruded (printed) formatted). Following conversion, ACF is used in a wide variety of applications including food, pharma, cosmetic and tobacco packaging as well as in building materials.

(42) ACF is manufactured by first rolling heated ingots (hot rolling) down to coils of thickness between 2 and 4 mm. The coils are then successively cold rolled to the required foil thicknesses. A second possible foil rolling method, continuous casting, bypasses the ingot stage and converts molten metal directly into a thick strip, which is immediately rolled into the coil from which the foil is then rolled.

2.2. **Like product**

(43) The investigation showed that the following products have the same basic physical, chemical and technical characteristics as well as the same basic uses:

— the product concerned;

— the product produced and sold on the domestic market of the PRC; and

— the product produced and sold in the Union by the Union industry.

(44) The Commission decided at this stage that those products are therefore like products within the meaning of Article 1(4) of the basic Regulation.

2.3. **Claims regarding product scope**

(45) Several parties submitted product exclusion requests concerning the following products: ACF of gauge below 6 microns ('ACF<6') and ACF for electric car batteries ('car battery ACF').

2.3.1. *ACF of gauge below 6 microns*

(46) Several users, Walki, Gascogne and Alupol, claimed that Union producers do not offer ACF<6. This is allegedly evidenced by the fact that Union producers do not promote such products on their webpages, in their brochures and by their refusal of orders of such products. Neither are the Union producers interested in offering ACF<6, since their production capacity is filled with other product orders, taking into account also the expected demand for automotive battery foil. Union producers are not in a position to provide the requested "commercial" quality, especially regarding porosity/permeability, measured in maximum pinholes per square meters. The use of thinner ACF is furthermore more environmentally friendly and should also for this reason be excluded from the scope.

(47) In addition, users Tetrapak and Huhtamäki argued that the Union industry has supply constraints for thinner ACF.

(48) The Commission has requested all nine users that cooperate with the investigation to specify their current demand for and sources of ACF<6. Only one user confirmed to have purchased during the IP an amount of ACF<6 that surpassed the quality threshold for commercial production, from a single Chinese producer. However, even for this user ACF<6 represents a very small part of its ACF consumption. Other users only indicated requests from their respective customers for products that included ACF<6, which have triggered trial orders both to the Union ACF industry and to Chinese producers post IP.

(49) The replies indicated that the demand for ACF<6 has only very recently started and is in an increasing trend. As mentioned in recital (50) there was some limited demand for it over the past ten years, but no clear pattern. This is in line with explanations from the Union producers that in the past there was also a gradual movement into thinner gauges of ACF, from the 7-8 microns range being the lower range in the past into 6 and 6,35 microns becoming the current standard for many applications.

(50) While a survey amongst the Union producers has shown that, apart from direct negotiations, none of them currently actively markets ACF<6, the Commission has collected ample evidence that the Union producers are capable to produce ACF<6. This includes test roll production post IP, which according to testing documentation met the purchaser's technical demands. Furthermore, the Commission could confirm sales of ACF<6 of various Union producers in commercial production quantities, even if on a limited scale, over a period of ten years prior to the IP. The Commission could also observe investments in quality control. The Commission therefore concluded that the Union industry can provide quality to fit the market demand.

(51) Second, the capacity to produce ACF<6 is limited by the last step i.e. the rolling mills. Therefore, the Commission has analysed the capacity of various Union producers in this last step, also taking into account the demand for other products in the various production steps. All sampled Union producers have sufficient free capacity to enable them to provide ACF<6, even if demand for car battery foil increases in the future. The Commission could therefore not confirm the risk of a supply shortage for a future increase in ACF<6 demand.

(52) Third, regarding the argument that the use of thinner ACF is more environmentally friendly, the Commission recalled that the intended effect of trade defence measures in the form of duties is not to prevent imports of a given product but to ensure that those imports are traded at non-injurious prices. The Commission also recalled the capability of the Union producers to manufacture ACF<6 as described in recital (50) above.

(53) Finally, as to the argument of Tetrapak and Huhtamäki concerning the supply constraint, the investigation revealed that the production capacity of the Union industry of ACF<6 is considerably greater than the demand.

(54) In view of the above considerations, the Commission provisionally rejected the request for exclusion of ACF<6 from the product scope of the product under investigation.

2.3.2. *ACF for car batteries*

(55) One interested party, Xiamen, requested the exclusion of aluminium car battery foil on the following grounds:

— Aluminium car battery foil is a very different product with a different usage, as it uses the 1050 / 1060 / 1100 / 3003 alloys while the major alloys to produce ACF for packaging are 8079 / 8011 alloys;

— the production equipment and processes is different, resulting in two bright surfaces as opposed to the dull/bright surface of other ACF. This also leads to different cost of production and sales prices;

— it is not manufactured by the Union producers; and

— it is currently not exported to the EU.

(56) In response, the Commission first noted that all the alloys named by the interested party share the same characteristic in that they all contain more than 98 % of aluminum and the complaint is not limited to a specific alloy. The use of different alloys for different product variations is not unusual and cannot serve as an exclusion criteria.

(57) Second, the bright/dull surface is a consequence of rolling two layers of ACF together in the last rolling mill, where the sides of ACF facing each other during the rolling turn out dull. This production method was covered by the complaint, which explicitly stated that both surfaces of ACF can be bright if specified by the customer ([6]). The intended use of ACF for car batteries cannot therefore justify any exclusion from the product scope as the physical characteristics of the product are the same. The same applies to the higher cost due to single layer rolling.

(58) Third, the car battery production in the Union is still in its starting phase. The Commission collected evidence demonstrating that the Union producers are preparing to meet the demand of this emerging market segment. Furthermore, the argument runs counter to the claim made by Walki related to the exclusion of ACF<6, that the Union industry might focus so much on car battery foil that they would potentially not be interested in dedicating sufficient production capacity to ACF<6.

(59) Fourth, the fact that currently there are no major exports from the PRC reflects the fact that the electric car battery production in the EU is still in its infancy, and this is thus not a viable argument for an exclusion.

(60) The analysis has shown that ACF for electric car batteries is technically ACF included in the defined scope of the investigation.

(61) In view of the above considerations, the Commission provisionally rejected the request for exclusion of ACF for electric car batteries from the product scope of the product under investigation.

([6]) Consolidated version of the complaint, p. 13.

3. DUMPING

3.1. Procedure for the determination of the normal value under Article 2(6a) of the basic Regulation

(62) The evidence available at the initiation of the investigation pointed to the existence of significant distortions in the PRC within the meaning of Article 2(6a), point (b) of the basic Regulation. The Commission therefore considered it appropriate to initiate the investigation having regard to Article 2(6a) of the basic Regulation.

(63) In order to collect the necessary data for a possible application of Article 2(6a) of the basic Regulation the Commission invited all exporting producers in the country concerned to provide information regarding the inputs used for producing ACF. Seven exporting producers submitted the relevant information.

(64) In addition, the Commission invited all interested parties to make their views known, submit information and provide supporting evidence regarding the application of Article 2(6a) of the basic Regulation within 37 days of the date of publication of the Notice of Initiation in the Official Journal of the European Union.

(65) In point 5.3.2 of the Notice of Initiation the Commission informed interested parties that based on the information available at that stage possible appropriate representative countries pursuant to Article 2(6a)(a) of the basic Regulation could be Turkey and Brazil. The Commission also stated that it would examine other possibly appropriate representative countries in accordance with the criteria set out in 2(6a)(a) first indent of the basic Regulation.

(66) On 25 November 2020, the Commission issued a First note on the sources for the determination of the normal value (the 'First Note') by which it informed interested parties on the relevant sources it intended to use for the determination of the normal value. In that note, the Commission provided a list of all factors of production such as raw materials, labour and energy used in the production of ACF. In addition, the Commission identified Brazil, Russia and Turkey as possible appropriate representative countries. The Commission gave all interested parties opportunity to comment. The Commission received comments from all sampled exporting producers.

(67) On 17 March 2021, and after having analysed the comments received, the Commission issued the Second note on the sources for the determination of the normal value (the 'Second Note') (the First Note and Second Note are collectively referred to as the "Notes"). In the Second Note, the Commission updated the list of factors of production and informed interested parties of its intention to use Turkey as the representative country under Article 2(6a)(a), first indent of the basic Regulation. It also informed interested parties that it would establish selling, general and administrative costs ('SG&A') and profits based on publicly available financial statements of aluminium extrusion producers in Turkey. The Commission invited interested parties to comment. Comments were received from all sampled exporting producers.

(68) After having analysed the comments and information received on the Second Note, the Commission provisionally concluded that Turkey was an appropriate choice as representative country from which undistorted prices and costs would be sourced for the determination of the normal value. The underlying reasons for that choice are further described in detail in Section 3.4 below.

3.2. Application of Article 18 of the basic Regulation

(69) Upon initiation of the investigation on the basis of Article 2(6a)(a) of the basic Regulation, the Commission sent two questionnaires concerning the existence of distortions to the GOC. The GOC however did not submit any replies. The Commission informed the GOC by Note Verbale on 8 December 2020 that it intended to make use of the provision of Article 18 of the basic Regulation with regard to the possible existence of significant distortions on the Chinese domestic market for aluminium converter foil within the meaning of Article 2(6a) of the basic Regulation, and the possible existence of raw material distortions within the meaning of Article 7(2a) of the basic Regulation. The Commission invited the GOC to submit its comment on the application of Article 18. No comments were received.

3.3. **Normal value**

(70) According to Article 2(1) of the basic Regulation, *"the normal value shall normally be based on the prices paid or payable, in the ordinary course of trade, by independent customers in the exporting country"*.

(71) However, according to Article 2(6a)(a) of the basic Regulation, *"in case it is determined […] that it is not appropriate to use domestic prices and costs in the exporting country due to the existence in that country of significant distortions within the meaning of point (b), the normal value shall be constructed exclusively on the basis of costs of production and sale reflecting undistorted prices or benchmarks"*, and *"shall include an undistorted and reasonable amount of administrative, selling and general costs and for profits"* (*"administrative, selling and general costs"* is referred hereinafter as 'SG&A').

(72) As further explained below, the Commission concluded in the present investigation that, based on the evidence available and given the lack of cooperation of the GOC, the application of Article 2(6a) of the basic Regulation was appropriate.

3.3.1. *Existence of significant distortions*

3.3.1.1. Introduction

(73) Article 2(6a)(b) of the basic Regulation stipulates that 'significant distortions are those distortions which occur when reported prices or costs, including the costs of raw materials and energy, are not the result of free market forces as they are affected by substantial government intervention. In assessing the existence of significant distortions regard shall be given, inter alia, to the potential impact of one or more of the following elements:

— the market in question being served to a significant extent by enterprises which operate under the ownership, control or policy supervision or guidance of the authorities of the exporting country;

— state presence in firms allowing the state to interfere with respect to prices or costs;

— public policies or measures discriminating in favour of domestic suppliers or otherwise influencing free market forces;

— the lack, discriminatory application or inadequate enforcement of bankruptcy, corporate or property laws;

— wage costs being distorted;

— access to finance granted by institutions which implement public policy objectives or otherwise not acting independently of the state.

(74) As the list in Article 2(6a)(b) is non-cumulative, not all the elements need to be given regard to for a finding of significant distortions. Moreover, the same factual circumstances may be used to demonstrate the existence of one or more of the elements of the list. However, any conclusion on significant distortions within the meaning of Article 2(6a)(a) must be made on the basis of all the evidence at hand. The overall assessment on the existence of distortions may also take into account the general context and situation in the exporting country, in particular where the fundamental elements of the exporting country's economic and administrative set-up provides the government with substantial powers to intervene in the economy in such a way that prices and costs are not the result of the free development of market forces.

(75) Article 2(6a)(c) of the basic Regulation provides that *'[w]here the Commission has well-founded indications of the possible existence of significant distortions as referred to in point (b) in a certain country or a certain sector in that country, and where appropriate for the effective application of this Regulation, the Commission shall produce, make public and regularly update a report describing the market circumstances referred to in point (b) in that country or sector'*.

(76) Pursuant to this provision, the Commission has issued a country report concerning the PRC (hereinafter 'the Report') ([7]), showing the existence of substantial government intervention at many levels of the economy, including specific distortions in many key factors of production (such as land, energy, capital, raw materials and labour) as well as in specific sectors (such as steel and chemicals). The Report was placed on the investigation file at the initiation stage. The complaint also contained some relevant evidence complementing the Report. Interested parties were invited to rebut, comment or supplement the evidence contained in the investigation file at the time of initiation.

(77) The complaint contained information on additional studies and reports analysing the situation of the aluminium industry in the PRC. First, the complainant listed the OECD paper titled "Measuring distortions in international markets – The aluminium value chain" ("OECD Study") ([8]), which closely analyses the issue of financial subsidies granted to companies in the aluminium industry. As noted by the complainants, based on the OECD Study, the Chinese 2016-20 Non-ferrous Metal Industry Development Plan among others calls for safeguard measures via the extension of financial and tax support, including company bail-outs or help with non-performing loans. Second, the complainants referred to a report prepared for WVMetalle, the German nonferrous metals industry association, dated 24 April 2017 ([9]) ("WV Metalle Report"), which supports the findings made in the Report as well as in the OECD Study. Moreover, the complainants pointed out that in a recent expiry review regarding anti-dumping duties on imports of certain aluminium foil in rolls originating in China ([10]), the Commission confirmed the existence of significant distortions in the price of aluminium and maintained that this finding was not limited to the product concerned in that particular investigation, but also extended to ACF, using the same input material and having identical manufacturing processes. Lastly, the complainants refer to an anti-subsidy investigation by the United States Department of Commerce ("DOC") on Chinese aluminium foil, concluded in 2018 ([11]), which established the existence of Chinese government support for the Chinese aluminium foil industry and subsidisation of primary aluminium.

(78) As indicated in recital (69), the GOC did not comment or provide evidence supporting or rebutting the existing evidence on the case file at the initiation stage, including the Report and the additional evidence provided by the complainant, on the existence of significant distortions and/or on the appropriateness of the application of Article 2(6a) of the basic Regulation in the case at hand. Comments received in this respect from a number of interested parties are addressed in Section 3.3.1.11 below.

(79) The Commission examined whether it was appropriate or not to use domestic prices and costs in the PRC, due to the existence of significant distortions within the meaning of point (b) of Article 2(6a) of the basic Regulation. The Commission did so on the basis of the evidence available on the file, including the evidence contained in the Report, which relies on publicly available sources. That analysis covered the examination of the substantial government interventions in the PRC's economy in general, but also the specific market situation in the relevant sector including the product concerned. The Commission further supplemented these evidentiary elements with its own research on the various criteria relevant to confirm the existence of significant distortions in the PRC.

([7]) Commission Staff Working Document on Significant Distortions in the Economy of the People's Republic of China for the purposes of Trade Defence Investigations, 20 December 2017, SWD(2017) 483 final/2.

([8]) OECD (2019), 'Measuring distortions in international markets: the aluminium value chain', OECD Trade Policy Papers, No. 218, OECD Publishing, Paris, https://doi.org/10.1787/c82911ab-en (last accessed on 03/09/2020).

([9]) Think!Desk China Consulting & Research, Final Report – Analysis of Market Distortions in the Chinese Non- Ferreous Metal Industry, 24 April 2017 (Annex 2A.6 of the Complaint).

([10]) Commission Implementing Regulation (EU) 2019/915 of 4 June 2019 imposing a definitive anti-dumping duty on imports of certain aluminium foil in rolls originating in the People's Republic of China following an expiry review under Article 11(2) of Regulation (EU) 2016/1036 of the European Parliament and of the Council (OJ L 146, 5.6.2019, p. 63).

([11]) Certain Aluminium Foil from the People's Republic of China: Amended Final Affirmative Countervailing Duty Determination and Countervailing Duty Order, 83 Fed. Reg. 17,360 (Dep't Comm, Apr. 19, 2018) (see Annex 2A.2 of the Complaint).

3.3.1.2. Significant distortions affecting the domestic prices and costs in China

(80) The Chinese economic system is based on the concept of a '*socialist market economy*'. That concept is enshrined in the Chinese Constitution and determines the economic governance of the PRC. The core principle is the '*socialist public ownership of the means of production, namely, ownership by the whole people and collective ownership by the working people*'. The State-owned economy is the *'leading force of the national economy'* and the State has the mandate *'to ensure its consolidation and growth'* ([12]). Consequently, the overall setup of the Chinese economy not only allows for substantial government interventions into the economy, but such interventions are expressly mandated. The notion of supremacy of public ownership over the private one permeates the entire legal system and is emphasized as a general principle in all central pieces of legislation. The Chinese property law is a prime example: it refers to the primary stage of socialism and entrusts the State with upholding the basic economic system under which the public ownership plays a dominant role. Other forms of ownership are tolerated, with the law permitting them to develop side by side with the State ownership ([13]).

(81) In addition, under Chinese law, the socialist market economy is developed under the leadership of the Chinese Communist Party ('CCP'). The structures of the Chinese State and of the CCP are intertwined at every level (legal, institutional, personal), forming a superstructure in which the roles of CCP and the State are indistinguishable. Following an amendment of the Chinese Constitution in March 2018, the leading role of the CCP was given an even greater prominence by being reaffirmed in the text of Article 1 of the Constitution. Following the already existing first sentence of the provision: '[t]*he socialist system is the basic system of the People's Republic of China*' a new second sentence was inserted which reads: '[t]*he defining feature of socialism with Chinese characteristics is the leadership of the Communist Party of China*.' ([14]). This illustrates the unquestioned and ever growing control of the CCP over the economic system of the PRC. This leadership and control is inherent to the Chinese system and goes well beyond the situation customary in other countries where the governments exercise general macroeconomic control within the boundaries of which free market forces are at play.

(82) The Chinese State engages in an interventionist economic policy in pursuance of goals, which coincide with the political agenda set by the CCP rather than reflecting the prevailing economic conditions in a free market ([15]). The interventionist economic tools deployed by the Chinese authorities are manifold, including the system of industrial planning, the financial system, as well as the level of the regulatory environment.

(83) First, on the level of overall administrative control, the direction of the Chinese economy is governed by a complex system of industrial planning which affects all economic activities within the country. The totality of these plans cover a comprehensive and complex matrix of sectors and crosscutting policies and is present on all levels of government. Plans at provincial level are detailed while national plans set broader targets. Plans also specify the means in order to support the relevant industries/sectors as well as the timeframes in which the objectives need to be achieved. Some plans still contain explicit output targets while this was a regular feature in previous planning cycles. Under the plans, individual industrial sectors and/or projects are being singled out as (positive or negative) priorities in line with the government priorities and specific development goals are attributed to them (industrial upgrade, international expansion etc.). The economic operators, private and State-owned alike, must effectively adjust their business activities according to the realities imposed by the planning system. This is not only because of the binding nature of the plans but also because the relevant Chinese authorities at all levels of government adhere to the system of plans and use their vested powers accordingly, thereby inducing the economic operators to comply with the priorities set out in the plans (see also section 3.3.1.5 below) ([16]).

([12]) Report – Chapter 2, p. 6-7.
([13]) Report – Chapter 2, p. 10.
([14]) Available at http://www.fdi.gov.cn/1800000121_39_4866_0_7.html (last viewed 8 September 2020).
([15]) Report – Chapter 2, p. 20-21.
([16]) Report – Chapter 3, p. 41, 73-74.

(84) Second, on the level of allocation of financial resources, the financial system of the PRC is dominated by the State-owned commercial banks. Those banks, when setting up and implementing their lending policy need to align themselves with the government's industrial policy objectives rather than primarily assessing the economic merits of a given project (see also section 3.3.1.8 below) ([17]). The same applies to the other components of the Chinese financial system, such as the stock markets, bond markets, private equity markets etc. Also these parts of the financial sector other than the banking sector are institutionally and operationally set up in a manner not geared towards maximizing the efficient functioning of the financial markets but towards ensuring control and allowing intervention by the State and the CCP ([18]).

(85) Third, on the level of regulatory environment, the interventions by the State into the economy take a number of forms. For instance, the public procurement rules are regularly used in pursuit of policy goals other than economic efficiency, thereby undermining market based principles in the area. The applicable legislation specifically provides that public procurement shall be conducted in order to facilitate the achievement of goals designed by State policies. However, the nature of these goals remains undefined, thereby leaving broad margin of appreciation to the decision-making bodies ([19]). Similarly, in the area of investment, the GOC maintains significant control and influence over destination and magnitude of both State and private investment. Investment screening as well as various incentives, restrictions, and prohibitions related to investment are used by authorities as an important tool for supporting industrial policy goals, such as maintaining State control over key sectors or bolstering domestic industry ([20]).

(86) In sum, the Chinese economic model is based on certain basic axioms, which provide for and encourage manifold government interventions. Such substantial government interventions are at odds with free play of market forces, resulting in distorting the effective allocation of resources in line with market principles ([21]).

3.3.1.3. Significant distortions according to Article 2(6a)(b), first indent of the basic Regulation: the market in question being served to a significant extent by enterprises which operate under the ownership, control or policy supervision or guidance of the authorities of the exporting country

(87) In the PRC, enterprises operating under the ownership, control and/or policy supervision or guidance by the State represent an essential part of the economy.

(88) The GOC and the CCP maintain structures that ensure their continued influence over enterprises, and in particular State-owned enterprises (SOEs). The State (and in many aspects also the CCP) not only actively formulates and oversees the implementation of general economic policies by individual SOEs, but it also claims its rights to participate in operational decision making in SOEs. This is typically done through rotation of cadres between government authorities and SOEs, through presence of party members on SOEs executive bodies and of party cells in companies (see also section 3.3.1.4), as well as through shaping the corporate structure of the SOE sector ([22]). In exchange, SOEs enjoy a particular status within the Chinese economy, which entails a number of economic benefits, in particular shielding from competition and preferential access to relevant inputs, including finance ([23]). The elements that point to the existence of government control over enterprises in the aluminium sector are further developed in Section 3.3.1.5 below.

([17]) Report – Chapter 6, p. 120-121.
([18]) Report – Chapter 6. p. 122 -135.
([19]) Report – Chapter 7, p. 167-168.
([20]) Report – Chapter 8, p. 169-170, 200-201.
([21]) Report – Chapter 2, p. 15-16, Report – Chapter 4, p. 50, p. 84, Report – Chapter 5, p. 108-9.
([22]) Report – Chapter 3, p. 22-24 and Chapter 5, p. 97-108.
([23]) Report – Chapter 5, p. 104-9.

(89) The OECD Study, submitted as evidence by the complainant, refers to SOEs in the aluminium sector which specifically emphasize in their regulatory filings how State ownership influences relevant industrial policies and how State ownership translates into government support. More specifically, one SOE mentions in its 2016 bond prospectus that it is one of the 52 backbone State-owned enterprises, that it plays a key role in the formulation and implementation of policies in the power sector and that it receives comprehensive and sustained support from the GOC. Another SOE refers in its 2017 bond prospectus to the fact that the respective provincial government can exert significant influence on the group ([24]).

(90) The PRC is the largest aluminium producer in the world, with several large SOEs amongst the top individual producers worldwide. The WV Metalle Report points out that SOEs account for a dominant share of the domestic market ([25]) which is confirmed by other estimates according to which SOEs account for more than 50 % of the total primary aluminium output in the PRC ([26]). While an increase in capacity in recent years is attributed partly to privately owned companies, such capacity increases would usually also entail various forms of (local) government involvement, such as tolerating illegal capacity expansion ([27]). Moreover, the aluminium production capacity amongst the main SOEs has also increased, though to a lesser extent ([28]).

(91) Apart from controlling the SOEs, the GOC is also influencing the privately owned companies in the PRC. During the investigation, it was established that the ACF producers received subsidies from the government. For example, all sampled companies listed a number of governmental subsidies in the companies' annual reports. The granting of all these subsidies also shows the substantial government intervention in the market.

(92) With a high level of government intervention in the aluminium industry and a high share of SOEs in the sector, even privately owned aluminium producers operating in the ACF segment are prevented from operating under market conditions. Indeed, both public and privately owned enterprises in the aluminium sector are also subject to policy supervision and guidance as set out in section 3.3.1.5 below.

3.3.1.4. Significant distortions according to Article 2(6a)(b), second indent of the basic Regulation: State presence in firms allowing the state to interfere with respect to prices or costs

(93) Apart from exercising control over the economy by means of ownership of SOEs and other tools, the GOC is in position to interfere with prices and costs through State presence in firms. While the right to appoint and to remove key management personnel in SOEs by the relevant State authorities, as provided for in the Chinese legislation, can be considered to reflect the corresponding ownership rights ([29]), CCP cells in enterprises, State-owned and private alike, represent another important channel through which the State can interfere with business decisions. According to the Chinese company law, a CCP organisation is to be established in every company (with at least three CCP members as specified in the CCP Constitution ([30])) and the company shall provide the necessary conditions for the activities of the party organisation. In the past, this requirement appears not to have always been

([24]) OECD Study, p. 29.
([25]) See p.51 of WV Metalle Report.
([26]) Australian Anti-Dumping Commission, *Aluminium Extrusions from China*, REP 248, p. 79 (13 July 2015).
([27]) See for example a report concerning Shandong provincial government's failure to curb aluminium capacity expansion: https://mp.weixin.qq.com/s?__biz=MzI2OTUyMzA0Nw==&mid=2247494318&idx=1&sn=9690ca50845c19f38eafff659516817a&chksm=eaddaba6ddaa22b071a5e2588aa787ed6f6a1a964ccae55c4d85c6f7ccbfcb5cedd3cdceac9d&scene=0&pass_ticket=JFplYZoDqNTFmOPYUGJbMwF0XlC1N3hAJ3EYPpsKx6rkt4fSeZ4TwIvB5BffX4du#rd (accessed on 7 September 2020).
([28]) The Report – Chapter 15, p. 387-388.
([29]) Report – Chapter 5, p. 100-1.
([30]) Report – Chapter 2, p. 26.

followed or strictly enforced. However, since at least 2016 the CCP has reinforced its claims to control business decisions in SOEs as a matter of political principle. The CCP is also reported to exercise pressure on private companies to put 'patriotism' first and to follow party discipline ([31]). In 2017, it was reported that party cells existed in 70 % of some 1,86 million privately owned companies, with growing pressure for the CCP organisations to have a final say over the business decisions within their respective companies ([32]). These rules are of general application throughout the Chinese economy, across all sectors, including to the producers of aluminium products and the suppliers of their inputs.

(94) In addition, on 15 September 2020 a document titled "General Office of CCP Central Committee's Guidelines on stepping up the United Front work in the private sector for the new era" ([33]) was released, which further expanded the role of the party committees in private enterprises. According to the guidelines, Section II.4: "*We must raise the Party's overall capacity to lead private-sector United Front work and effectively step up the work in this area*"; and Section III.6: "*We must further step up Party building in private enterprises and enable the Party cells to play their role effectively as a fortress and enable Party members to play their parts as vanguards and pioneers*." By this document, the party emphasised the role of the private enterprises in the "United Front work" in an effort to increase the role of the CCP in non-party organisations and entities ([34]).

(95) The following examples illustrate the above trend of an increasing level of intervention by the GOC in the aluminium sector.

(96) As found by the Commission in another investigation on certain aluminium foil in rolls originating in China ([35]), in 2017, a Chinese state-owned aluminium producer, China Aluminium International Engineering Corporation Limited ('Chalieco'), amended its Articles of Association giving more prominence to the role of party cells within the company. It included a whole chapter on the Party Committee, and Article 113 thereof states: '*In deciding major corporate issues, the Board shall consult the Party Committee of the Company in advance*.' ([36]). Furthermore, in their 2017 Annual Report ([37]), the Aluminum Corporation of China ('Chalco') stated that a number of directors, supervisors, and senior management – including the Chairman and Executive Director, and the Chairman of the Supervisory Committee – are members of the CCP.

(97) With regard to the enterprises active in manufacturing of ACF products, Xiamen explains the party building exercises in the following way: "*Xiashun actively promotes party building and labour union work, and remains committed to the system of joint meetings between Party, government and workers over the years, providing an important platform for employees to participate in decision-making, protect their rights and interests, and build a harmonious atmosphere*." ([38]).

(98) The State's presence and intervention in the financial markets (see also section 3.3.1.8 below) as well as in the provision of raw materials and inputs further have an additional distorting effect on the market ([39]). Thus, the State presence in firms, including SOEs, in the aluminium and other sectors (such as the financial and input sectors) allow the GOC to interfere with respect to prices and costs.

([31]) The Report – Chapter 2, p. 31-2.
([32]) Available at https://www.reuters.com/article/us-china-congress-companies-idUSKCN1B40JU (last viewed 9 September 2020).
([33]) Available at www.gov.cn/zhengce/2020-09/15/content_5543685.htm (last viewed on 10 March 2021).
([34]) Financial Times (2020) "Chinese Communist Party asserts greater control over private enterprise", available at: https://on.ft.com/3mYxP4j
([35]) Commission Implementing Regulation (EU) 2019/915 of 4 June 2019 (OJ L 146, 5.6.2019, p. 63).
([36]) The Report – Chapter 15, p. 388.
([37]) http://www.chalco.com.cn/chalcoen/rootfiles/2018/04/19/1524095189602052-1524095189604257.pdf, (accessed on 8 March 2019).
([38]) http://act.chinatt315.org.cn/hy/tthy/2014/0906/13763.html
([39]) The Report – Chapters 14.1 to 14.3.

3.3.1.5. Significant distortions according to Article 2(6a)(b), third indent of the basic Regulation: public policies or measures discriminating in favour of domestic suppliers or otherwise influencing free market forces

(99) The direction of the Chinese economy is to a significant degree determined by an elaborate system of planning which sets out priorities and prescribes the goals the central and local governments must focus on. Relevant plans exist on all levels of government and cover virtually all economic sectors. The objectives set by the planning instruments are of binding nature and the authorities at each administrative level monitor the implementation of the plans by the corresponding lower level of government. Overall, the system of planning in the PRC results in resources being driven to sectors designated as strategic or otherwise politically important by the government, rather than being allocated in line with market forces ([40]).

(100) For instance, the government plays a key role in the development of the Chinese aluminium sector. This is confirmed in the numerous plans, directives and other documents pertaining directly or indirectly to the sector, which are issued at national, regional and municipal level. Through these and other instruments, the government directs and controls virtually every aspect of the development and functioning of the aluminium sector. Such policies have an important direct or indirect impact on the production costs of aluminium products.

(101) In line with the Commission's findings in the case on certain aluminium foil in rolls originating in China ([41]), in the case of aluminium extrusions ([42]) and in the case on aluminium flat-rolled products (provisional measures) ([43]), the following facts are equally applicable to the present product concerned, which is, similarly, an aluminium downstream product.

(102) Although the 13th Five Year Plan on Economic and Social Development ([44]), covering the investigation period, does not contain specific provisions on aluminium, for the non-ferrous metal industry in general it envisages a strategy of promoting cooperation on international production capacity and equipment manufacturing. To achieve these goals, the plan confirms that it will enhance supporting systems related to taxation, finance, insurance, investment and financing platforms, as well as risk assessment platforms ([45]).

(103) The corresponding sectoral plan, the Non-Ferrous Metal Industry Development Plan (2016-2020) ('the Plan')sets out specific policies and targets that the government aims to achieve for a number of non-ferrous metals industries ([46]), including aluminium.

(104) The Plan aims at upgrading the range of product types produced by the Chinese aluminium industry, inter alia, through supporting innovation. It calls for swift development of the mixed ownership system and a boost to SOEs' vitality. It further provides for the possibility of stockpiling non-ferrous metals, improving the security of resources, including aluminium and it sets specific quantitative targets for reducing power consumption, increasing the ratio of recycled aluminium in production and increasing capacity utilisation ([47]).

(105) The Plan further provides for structural adjustments with stricter control on new smelting facilities and elimination of outdated capacity. It provides for geographical distribution of processing plants, focuses on projects to increase bauxite and alumina resource exploitation and covers electricity supply and pricing policy ([48]).

([40]) The Report – Chapter 4, p. 41-42, 83.
([41]) Commission Implementing Regulation (EU) 2019/915 of 4 June 2019 (OJ L 146, 5.6.2019, p. 63).
([42]) Commission Implementing Regulation (EU) 2021/546 of 29 March 2021 (OJ L 109, 30.3.2021, p. 1).
([43]) Commission Implementing Regulation (EU) 2021/582 of 9 April 2021 (OJ L 124, 12.4.2021, p. 40).
([44]) The 13th Five-Year Plan for Economic and Social Development of the People's Republic of China (2016-2020), http://en.ndrc.gov.cn/newsrelease/201612/P020161207645765233498.pdf
([45]) The Report – Chapter 15, p. 377.
([46]) The Report – Chapter 12, p. 275-282 and Chapter 15, p. 378-382.
([47]) The Report – Chapter 12, p. 275 – 282.
([48]) The Report – Chapter 15, p. 378–382, 390.

(106) With this wide range of measures and policies, the Plan represents a continuation of the 2009 Non-Ferrous Metals Industry Adjustment and Revitalization Plan which was adopted to alleviate the negative effects on the non-ferrous metal industry of the financial crisis. The key objectives, set out in the plan include inter alia, production volume control, restructuring, raw material sourcing, export tax policy, security of resources, stockpiling, technological innovation, financial policy and planning and implementation ([49]).

(107) Another policy document targeting the aluminium sector are the Standard Conditions applicable to the Aluminium Industry, issued by MIIT on 18 July 2013, in order to speed up structural adjustment and curb disorderly expansion of the aluminium smelting capacities. The Standard Conditions introduce minimum production quantities for new plants, quality standards and security of supply for imported and domestically sourced bauxite and alumina. The Standard Conditions indicate that MIIT is the authority in charge of the standardisation and management of the aluminium industry, as well as of the publication of the list of companies authorised to operate in the aluminium industry ([50]).

(108) In the Guiding Opinion on creating an excellent market environment, fostering the non-ferrous metal industry's structural adjustment and transformation and increasing benefits, issued by the General Office of the State Council in 2016 (2016/42) ([51]), the Chinese authorities state as main objectives: '*optimize the non-ferrous metal industry structure; Basically balance supply and demand of key product categories; Maintain the utilization rate of electrolytic aluminium production capacity above 80 %; Significantly increase the mineral resources supply security capacity for minerals such as copper and aluminium*' ([52]). The document also aims to '*strictly control new production capacity.*' To achieve this, it is necessary to: '*Ensure the implementation of indispensable electrolytic aluminium new (reformed, expanded) construction projects; […] Use social supervision and other tools; Step up supervision and inspection efforts; Strictly investigate and deal with new electrolytic aluminium projects breaching regulations*' ([53]). These provisions demonstrate the substantial degree of the GOC's intervention into the non-ferrous metals sector, including the aluminium sector.

(109) The above State interference in the functioning of the aluminium sector by means of planning documents is reflected also at the provincial level. For example, the Shandong Province (where Donghai, a major ACF producer, is established) Government's Notice on the implementation plan for accelerating the high-quality development of the seven energy-intensive industries (2018/248) of 6 November 2018 aims to '*foster the extension of the electrolytic aluminium industry chain*' through the following actions: '*Further increase the proportion of fine and deep processing of electrolytic aluminium liquid and aluminium processing materials; Speed up and foster the extension of the aluminium industry chain to finished products and high-end products; Expand the use of high-end aluminium materials; Increase the development possibilities of the aluminium processing industry* ([54]).'

(110) The State has been intervening in the functioning of the aluminium sector for many years before the issuance of the above policy documents, which is, for example, illustrated by the Guidelines for Accelerating the Restructuring of the Aluminium Industry ('Restructuring Guidelines') ([55]), issued by the National Development and Reform Commission in April 2006. The latter regarded aluminium as a fundamental product in the development of the national economy. The Restructuring Guidelines stated that, in implementing the Industrial Development Policy approved by the State Council, specific objectives shall be achieved in certain areas. These areas were: enhance the concentration in the industry; access to financial capital (see also section 3.3.1.8 below); organisation of the industry; strict control of exports of electrolytic aluminium; and elimination of outdated capacity.

([49]) The Report – Chapter 15, p. 384–385.
([50]) The Report – Chapter 15, p. 382–383.
([51]) See http://www.gov.cn/zhengce/content/2016-06/16/content_5082726.htm (accessed on 20 July 2020).
([52]) Ibid, Section 3.
([53]) Ibid, Section 4.
([54]) See: http://gxt.shandong.gov.cn/art/2018/11/6/art_15681_3450015.html (accessed on 20 July 2020), Section 13.
([55]) The Report – Chapter 15, p. 386.

(111) Moreover, the price of key inputs such as energy and electricity are also influenced by different types of government intervention ([56]). Notably, the State intervened in favour of Chinese producers through differentiated, more advantageous energy pricing. In the Guiding Opinion on creating an excellent market environment, fostering the non-ferrous metal industry's structural adjustment and transformation and increasing benefits mentioned above, the Chinese authorities acknowledged as a policy goal to '*continue to implement the differentiated electricity price policy; Encourage eligible electricity users to conclude direct deals with power generation companies; Determine prices through negotiation*.' ([57]). The Commission also established that similar policies were implemented at the provincial level. For example, in the Yunnan Province, according to information reported by the China Industry Journal in November 2019: '*In order to implement the plan, Yunnan has successively issued specific policies such as the "Implementing Opinion on Promoting the Integrated Development of Hydropower and Aluminium Materials" and the "Plan implementing preferential prices to promote the use of Hydropower". It appears clearly that any enterprise bringing its capacity quota to Yunnan shall benefit from the "preferential price, full transmission" policy, which means that for the first 5 years, electrolytic aluminium shall benefit from special preferential electricity price of RMB 0,25 per kWh. As to deep processing of materials, a special preferential electricity price of RMB 0,20 per kWh shall be granted. According to reports, the integrated projects of Henan Shenhuo and Sichuan Qiya's bringing quotas to be built in Yunnan have already benefitted from the policy for integration projects and have signed relevant agreements with local governments, power grid companies, and power generation companies*.' ([58]).

(112) As another example of State interference, at the provincial level, in the Shandong Province Government's Notice on the implementation plan for accelerating the high-quality development of the seven energy-intensive industries (see recital (109)), the authorities have issued transformation and upgrading targets for the electrolytic aluminium industry with regard to energy use: '*By 2022, the electricity consumption of electrolytic aluminium per ton of aluminium shall drop to approximately 12 800 kWh, the electrolytic deep processing rate of electrolytic aluminium in the province shall reach approximately 50 %, and the added value of aluminium per ton shall increase by more than 30 % on average*' ([59]).

(113) With respect to the enforcement of the provisions contained in the planning documents above, Chinese industry associations play an important role. These entities are to guarantee that industry implements the policies of the GOC. This responsibility is confirmed by the fact that in their activity, they liaise closely with State authorities, which is reflected in their statutes. In the case of the aluminium sector, the Articles of association of the China Non-Ferrous Metals Industry Association assert notably that '*[t]he Association adheres to the party's basic line and various principles and policies, abides by the Constitution, laws, regulations and national policies, and abides by social and moral values. It shall stick to the purpose of serving the government, the industry, the enterprises and business managers; it shall set up and improve the industry self-discipline mechanism; it shall fully involve government's staff to get assistance; it shall play a bridging role between the government and enterprises*.' (Article 3). Along the same lines, Article 25 states that the Association's chairman, vice-chairman and secretary general must: '*Adhere to the party's line, principles and policies, and have good political qualities*' ([60]).

(114) Similarly, the Articles of association of the China Non-Ferrous Fabrication Industry Association stipulate that '*the Association accepts business guidance as well as supervision and management from the State-owned Assets Supervision and Administration Commission of the State Council, the Ministry of Civil Affairs and the China Nonferrous Metals Industry Association*' (Article 4). One of the established elements of the Association's business scope is also to '*Actively put forward suggestions and opinions on industry development, industry policies, laws and regulations, in accordance with the Party's and the State's general principles and tasks concerning the building of a socialist market economy system and taking into*

([56]) The Report – Chapter 15, pp. 390 – 391. Provision of discounted electricity is reported also by other sources. See for example: Economic Information Daily: Worrying over growth downturns, western region releasing preferential policies to support high energy consumption industries http://jjckb.xinhuanet.com/2012-07/24/content_389459.htm (accessed on 4 September 2020), reporting on how western Chinese provinces like Shaanxi, Ningxia, Qinghai and Gansu have continued to provide cheap electricity to attract more investments.

([57]) See: http://www.gov.cn/zhengce/content/2016-06/16/content_5082726.htm, Section 10.

([58]) See: https://finance.sina.com.cn/money/future/indu/2019-11-26/doc-iihnzahi3508583.shtml (accessed on 20 July 2020).

([59]) See: http://gxt.shandong.gov.cn/art/2018/11/6/art_15681_3450015.html, section 6.

([60]) See http://www.chinania.org.cn/html/introduce/xiehuizhangcheng/ (accessed on 21 July 2020).

account the industry's actual situation.' (Article 6). Finally, Article 22 also prescribes that the Association's chairman, deputy chairman and secretary general must, among other conditions: '*Adhere to the party's line, principles and policies, and have good political qualities*' ([61]).

(115) Thus, the numerous plans, directives and other documents pertaining to aluminium, issued at the national, regional and municipal level, clearly show the high degree of intervention of the Chinese government in the aluminium sector ([62]). Through these and other instruments, the government directs and controls virtually every aspect of the development and functioning of the sector.

(116) Beyond the plans, the government's intervention in the sector has taken the form, inter alia, of export-related measures, including export duties, export quotas, export performance requirements and minimum export price requirements on different raw materials for aluminium.

(117) The GOC further discourages exports of primary aluminium and its inputs, aiming at promoting higher added-value aluminium products. This objective is pursued by granting full or partial VAT rebates on downstream aluminium products in combination with incomplete VAT rebates and export taxes on primary aluminium ([63]).

(118) Other types of government intervention leading to market distortions include the stockpiling policy through the State Reserve Bureau and the role of the Shanghai Futures Exchange (SHFE) ([64]). In addition, several trade defence investigations have established that the Chinese government has consistently granted different types of State support measures to aluminium producers ([65]). The extensive intervention of the GOC in the aluminium sector has led to overcapacity ([66]), which is arguably the clearest illustration of the implications of the GOC's policies and the resulting distortions.

(119) The OECD Study also identified additional government support influencing market forces in the aluminium sector. Such support would typically take the form of inputs, in particular electricity and primary alumina, sold at below-market prices ([67]). The OECD Study further describes how the GOC objectives for the aluminium sector are translated into industrial policies and specific actions on the provincial and local level, including for example capital injections, priority possession rights to mineral resources, governmental grants and subsidies or tax incentives ([68]).

(120) In sum, the GOC has measures in place to induce operators to comply with the public policy objectives of supporting key industries, including the aluminium sector, which encompasses the production of ACF products. Such measures impede market forces from operating freely.

3.3.1.6. Significant distortions according to Article 2(6a)(b), fourth indent of the basic Regulation: the lack, discriminatory application or inadequate enforcement of bankruptcy, corporate or property laws

(121) According to the information on file, the Chinese bankruptcy system delivers inadequately on its own main objectives such as to fairly settle claims and debts and to safeguard the lawful rights and interests of creditors and debtors. This appears to be rooted in the fact that while the Chinese bankruptcy law formally rests on principles that are similar to those applied in corresponding laws in countries other than China, the Chinese system is characterised by systematic under-enforcement. The number of bankruptcies remains notoriously low in relation to

([61]) See: http://www.cnfa.net.cn/about/1546.aspx (accessed on 21 July 2020).
([62]) The Report – Chapter 15, pp. 377- 387.
([63]) The Report – Chapter 15, p. 378 and 389; OECD Study, p. 25-26.
([64]) The Report – Chapter 15, pp. 392 – 393.
([65]) The Report – Chapter 15, pp. 393 – 394.
([66]) The Report – Chapter 15, pp. 395 – 396.
([67]) Ibid, p. 16, p. 30. However, the Chinese authorities interfere with respect to other inputs, too. A typical example is coal, where the government retains the power to subdue coal price rises. See: https://policycn.com/policy_ticker/coal-price-unlikely-to-jump-during-heating-season/?iframe=1&secret=c8uthafuthefra4e (accessed on 4 September 2020).
([68]) Ibid. p. 16-18.

the size of the country's economy, not least because the insolvency proceedings suffer from a number of shortcomings, which effectively function as a disincentive for bankruptcy filings. Moreover, the role of the State in the insolvency proceedings remains strong and active, often having direct influence on the outcome of the proceedings ([69]).

(122) In addition, the shortcomings of the system of property rights are particularly obvious in relation to ownership of land and land-use rights in the PRC ([70]). All land is owned by the Chinese State (collectively owned rural land and State-owned urban land). Its allocation remains solely dependent on the State. There are legal provisions that aim at allocating land use rights in a transparent manner and at market prices, for instance by introducing bidding procedures. However, these provisions are regularly not respected, with certain buyers obtaining their land for free or below market rates ([71]). Moreover, authorities often pursue specific political goals including the implementation of the economic plans when allocating land ([72]).

(123) Much like other sectors in the Chinese economy, producers of ACF products are subject to the ordinary rules on Chinese bankruptcy, corporate, and property laws. That has the effect that these companies, too, are subject to the top-down distortions arising from the discriminatory application or inadequate enforcement of bankruptcy and property laws. The present investigation revealed nothing that would call those findings into question. As such, the Commission concluded that the Chinese bankruptcy and property laws do not work properly, thus generating distortions when maintaining insolvent firms afloat and when allocating land use rights in the PRC. Those considerations, on the basis of the evidence available, appear to be fully applicable also in the ACF products sector.

(124) This finding is supported by the provisional affirmative determination of the DOC in the investigation of certain Aluminium Foil from China, which found, using facts available, that the Government of China's provision of land for Less Than Adequate Remuneration constitutes a financial contribution within the meaning of Section 771 (5)(D) of the Tariff Act of 1930, as amended ([73]).

(125) In light of the above, the Commission concluded that there was discriminatory application or inadequate enforcement of bankruptcy and property laws in the aluminium sector, including with respect to the product concerned.

3.3.1.7. Significant distortions according to Article 2(6a)(b), fifth indent of the basic Regulation: wage costs being distorted

(126) A system of market-based wages cannot fully develop in the PRC as workers and employers are impeded in their rights to collective organisation. China has not ratified a number of fundamental conventions of the International Labour Organisation ('ILO'), in particular those on freedom of association and on collective bargaining ([74]). Under national law, only one trade union organisation is active. However, this organisation lacks independence from the State authorities and its engagement in collective bargaining and protection of workers' rights remains rudimentary ([75]). Moreover, the mobility of the Chinese workforce is restricted by the household registration system, which limits access to the full range of social security and other benefits to local residents of a given administrative area. This typically results in workers who are not in possession of the local residence registration finding themselves in a vulnerable employment position and receiving lower income than the holders of the residence registration ([76]). Those findings lead to the distortion of wage costs in the PRC.

([69]) Report – Chapter 6, p. 138-149.
([70]) Report – Chapter 9, p. 216.
([71]) Report – Chapter 9, p. 213-215.
([72]) Report – Chapter 9, p. 209-211.
([73]) Decision Memorandum for the Preliminary Affirmative Determination: Countervailing Duty Investigation of certain Aluminium Foil from The People's Republic of China, published by the International Trade Administration, Department of Commerce, on 7 August 2017, IX.E. p. 30, available at https://enforcement.trade.gov/frn/summary/prc/2017-17113-1.pdf (last accessed on 11 March 2019).
([74]) Report – Chapter 13, p. 332-337.
([75]) Report – Chapter 13, p. 336.
([76]) Report – Chapter 13, p. 337-341.

(127) No relevant evidence was submitted to the effect that the aluminium sector, including the producers of ACF products, would not be subject to the Chinese labour law system described. The aluminium sector is thus affected by the distortions of wage costs both directly (when making the product concerned or the main raw materials for its production) as well as indirectly (when having access to capital or inputs from companies subject to the same labour system in the PRC).

3.3.1.8. Significant distortions according to Article 2(6a)(b), sixth indent of the basic Regulation: access to finance granted by institutions which implement public policy objectives or otherwise not acting independently of the State

(128) Access to capital for corporate actors in the PRC is subject to various distortions.

(129) Firstly, the Chinese financial system is characterised by the strong position of State-owned banks ([77]), which, when granting access to finance, take into consideration criteria other than the economic viability of a project. Similarly to non-financial SOEs, the banks remain connected to the State not only through ownership but also via personal relations (the top executives of large State-owned financial institutions are ultimately appointed by the CCP) ([78]) and, again just like non-financial SOEs, the banks regularly implement public policies designed by the government. In doing so, the banks comply with an explicit legal obligation to conduct their business in accordance with the needs of the national economic and social development and under the guidance of the industrial policies of the State ([79]). This is compounded by additional existing rules, which direct finances into sectors designated by the government as encouraged or otherwise important ([80]).

(130) While it is acknowledged that various legal provisions refer to the need to respect normal banking behaviour and prudential rules such as the need to examine the creditworthiness of the borrower, the overwhelming evidence, including findings made in trade defence investigations, suggests that these provisions play only a secondary role in the application of the various legal instruments.

(131) For example, the GOC has very recently clarified that even private commercial banking decisions must be overseen by the CCP and remain in line with national policies. One of the State's three overarching goals in relation to banking governance is now to strengthen the Party's leadership in the banking and insurance sector, including in relation to operational and management issues in companies ([81]). Also, the performance evaluation criteria of

([77]) Report – Chapter 6, p. 114-117.
([78]) Report – Chapter 6, p. 119.
([79]) Report – Chapter 6, p. 120.
([80]) Report – Chapter 6, p. 121-122, 126-128, 133-135.
([81]) See official policy document of the China Banking and Insurance Regulatory Commission ("CBIRC") of 28 August 2020: *Three-year action plan for improving corporate governance of the banking and insurance sectors (2020-2022)*. http://www.cbirc.gov.cn/cn/view/pages/ItemDetail.html?docId=925393&itemId=928 (last viewed on 3 April 2021). The Plan instructs to *'further implement the spirit embodied in General Secretary Xi Jinping's keynote speech on advancing the reform of corporate governance of the financial sector'*. Moreover, the Plan's section II aims at promoting the organic integration of the Party's leadership into corporate governance: '*we shall make the integration of the Party's leadership into corporate governance more systematic, standardised and procedure-based […] Major operational and management issues must have been discussed by the Party Committee before being decided upon by the Board of Directors or the senior management.*'

commercial banks have now to, notably, take into account how entities '*serve the national development objectives and the real economy*', and in particular how they '*serve strategic and emerging industries*' ([82]).

(132) Furthermore, bond and credit ratings are often distorted for a variety of reasons including the fact that the risk assessment is influenced by the firm's strategic importance to the GOC and the strength of any implicit guarantee by the government. Estimates strongly suggest that Chinese credit ratings systematically correspond to lower international ratings ([83]).

(133) This is compounded by additional existing rules, which direct finances into sectors designated by the government as encouraged or otherwise important ([84]). This results in a bias in favour of lending to SOEs, large well-connected private firms and firms in key industrial sectors, which implies that the availability and cost of capital is not equal for all players on the market.

(134) In this respect, the OECD Study refers to anecdotal evidence that certain aluminium producers in the PRC have obtained financing on preferential terms, with cost of financing being seemingly decoupled from the corresponding level of corporate leverage. According to that study, one state-owned aluminium producer explicitly stated in its 2016 bond prospectus that it attracts considerable financial support from Chinese policy banks bearing interest rate below benchmark. Similarly, the 2017 bond prospectus of another state-owned producer refers to the strong ties which the company maintains with Chinese banks, including policy banks that have provided that company with low-cost financing sources. The OECD Study concludes in this connection that while there can be many reasons why interest rates are low for these firms, the contrast between poor financial indicators and low interest rates may suggest some potential under-pricing of the risk associated with those borrowers ([85]).

(135) Secondly, borrowing costs have been kept artificially low to stimulate investment growth. This has led to the excessive use of capital investment with ever lower returns on investment. This is illustrated by the growth in corporate leverage in the state sector despite a sharp fall in profitability, which suggests that the mechanisms at work in the banking system do not follow normal commercial responses.

(136) Thirdly, although nominal interest rate liberalisation was achieved in October 2015, price signals are still not the result of free market forces, but are influenced by government induced distortions. Indeed, the share of lending at or below the benchmark rate still represents at least one-third of all lending as of the end of 2018 ([86]). Official media in the PRC have recently reported that the CCP called for '*guiding the loan market interest rate downwards.*' ([87]). Artificially low interest rates result in under-pricing, and consequently, the excessive utilization of capital.

(137) Overall credit growth in the PRC indicates a worsening efficiency of capital allocation without any signs of credit tightening that would be expected in an undistorted market environment. As a result, non-performing loans have increased rapidly in recent years. Faced with a situation of increasing debt-at-risk, the GOC has opted to avoid defaults. Consequently, bad debt issues have been handled by rolling over debt, thus creating so called 'zombie' companies, or by transferring the ownership of the debt (e.g. via mergers or debt-to-equity swaps), without necessarily removing the overall debt problem or addressing its root causes.

([82]) See CBIRC's *Notice on the Commercial banks performance evaluation method,* issued on 15 December 2020. http://jrs.mof.gov.cn/gongzuotongzhi/202101/t20210104_3638904.htm (last viewed on 12 April 2021).

([83]) See IMF Working Paper 'Resolving China's Corporate Debt Problem', by Wojciech Maliszewski, Serkan Arslanalp, John Caparusso, José Garrido, Si Guo, Joong Shik Kang, W. Raphael Lam, T. Daniel Law, Wei Liao, Nadia Rendak, Philippe Wingender, Jiangyan, October 2016, WP/16/203.

([84]) Report – Chapter 6, p. 121-122, 126-128, 133-135.

([85]) OECD Study, p. 21.

([86]) See OECD (2019), OECD Economic Surveys: China 2019, OECD Publishing, Paris. p. 29. https://doi.org/10.1787/eco_surveys-chn-2019-en.

([87]) See: http://www.xinhuanet.com/fortune/2020-04/20/c_1125877816.htm (last viewed on 12 April 2021).

(138) In essence, despite the steps that have been taken to liberalize the market, the corporate credit system in the PRC is affected by significant distortions resulting from the continuing pervasive role of the state in the capital markets.

(139) No evidence was submitted to the effect that the aluminium sector, including the producers of ACF products, would be exempted from the above-described government intervention in the financial system. Therefore, the substantial government intervention in the financial system leads to the market conditions being severely affected at all levels.

3.3.1.9. Systemic nature of the distortions described

(140) The Commission noted that the distortions described in the Report are characteristic for the Chinese economy. The evidence available shows that the facts and features of the Chinese system as described above in Sections 3.3.1.1-3.3.1.5 apply throughout the country and across the sectors of the economy. The same holds true for the description of the factors of production as set out above in Sections 3.3.1.6-3.3.1.8 above.

(141) The Commission recalls that in order to produce ACF products, a range of inputs are needed. There is no evidence in the investigation file that those inputs are not sourced in the PRC. When the producers of ACF products purchase/contract these inputs, the prices they pay (and which are recorded as their costs) are clearly exposed to the same systemic distortions mentioned before. For instance, suppliers of inputs employ labour that is subject to the distortions. They may borrow money that is subject to the distortions on the financial sector/capital allocation. In addition, they are subject to the planning system that applies across all levels of government and sectors.

(142) As a consequence, not only the domestic sales prices of ACF products are not appropriate for use within the meaning of Article 2(6a)(a) of the basic Regulation, but all the input costs (including raw materials, energy, land, financing, labour, etc.) are also affected because their price formation is affected by substantial government intervention, as described in Parts A and B of the Report. Indeed, the government interventions described in relation to the allocation of capital, land, labour, energy and raw materials are present throughout the PRC. This means, for instance, that an input that in itself was produced in the PRC by combining a range of factors of production is exposed to significant distortions. The same applies for the input to the input and so forth. The arguments and evidence adduced by the exporting producers in this regard are addressed in the next section.

3.3.1.10. Conclusion

(143) The preceding analysis, which includes an examination of all the available evidence relating to public interventions in the Chinese economy in general as well as in the aluminium sector (including the product concerned), showed that prices or costs of the product concerned, including the costs of raw materials, energy and labour, are not the result of free market forces because they are affected by substantial government intervention within the meaning of Article 2(6a)(b) of the basic Regulation as shown by the actual or potential impact of one or more of the relevant elements listed therein. On that basis, and in the absence of any cooperation from the GOC, the Commission concluded that it is not appropriate to use domestic prices and costs to establish normal value in this case.

3.3.1.11. Comments by interested parties

(144) Xiamen claimed in response to the Second Note that there is no need for recourse to benchmarks, if the factors of production are sourced by Xiamen at arm's length. In particular, Xiamen argued that benchmark prices and the prices settled by Xiamen for ingots and slabs were comparable, which appears to rebut allegations of material distortions. Furthermore, Zhongji argued that it purchased the raw materials and energy on a commercial basis at arm's length.

(145) The Commission noted that once it is determined that due to the existence of significant distortions in the exporting country in accordance with Article 2(6a)(b) of the basic Regulation it is not appropriate to use domestic prices and costs in the exporting country, the normal value is constructed by reference to undistorted prices or benchmarks in an appropriate representative country for each exporting producer according to Article 2(6a)(a) of the basic Regulation. The same provision of the basic Regulation allows for the use of domestic costs if they are positively established not to be distorted, based on accurate and appropriate evidence. However, in the present case, Xiamen as well as Zhongji failed to produce any such accurate and appropriate evidence. Similar price levels of certain raw materials in the exporting country and the representative country are in itself not indicative of the absence of significant distortions under Article 2(6a) of the basic Regulation, because prices may happen to fluctuate and be aligned over a certain period for a number of other reasons. On the contrary, there is a host of other factors contributing to the finding of significant distortions as evidenced in sections 3.3.1.2 to 3.3.1.9. Consequently, a mere reference to comparability of domestic prices of certain raw materials with benchmark values in the representative country cannot satisfy the condition of adducing accurate and appropriate evidence. Therefore, Xiamen's and Zhongji's claims had to be rejected.

(146) Furthermore, in its comments on initiation, Xiamen, firstly alleged that Article 2(6a) is inconsistent with the WTO Anti-Dumping Agreement ('ADA'). This is because, first, Article 2.2 ADA recognizes three scenarios, which allow for the normal value construction: (i) sales are not made in the ordinary course of trade; (ii) there is a particular market situation; or (iii) because of the low volume of sales on the domestic market, such sales are not representative. Xiamen submitted that significant distortions meet none of the three criteria. It further submitted that even if the concept of significant distortions could possibly be considered to fall under the second of the above criteria, the Panel in WTO DS529 Australia – Anti-Dumping Measures on A4 Copy Paper confirmed that the fact that the domestic price of the product concerned and its inputs are affected by governmental distortions was not enough to consider that the proper comparison between domestic market sales and export sales is affected 'because of the particular market situation'. In addition, Xiamen commented that the Commission applied the construction of normal value systematically, while it should be checking on a case by case basis if the conditions of Article 2.2 ADA are met. Xiamen further submitted that Article 2.2 ADA requires that the construction of the normal value must reflect 'a cost in the country of origin', as confirmed in the cases WTO DS529 Australia – Anti-Dumping Measures on A4 Copy Paper and WTO DS473 European Union – Anti-Dumping Measures on Biodiesel from Argentina. Furthermore, Xiamen argued that the normal value should be constructed in accordance with the requirements of Article 2.2.1.1 ADA, and it added that the findings in the above mentioned report DS473 and in case WTO DS427 China – Anti-Dumping and Countervailing Duty Measures on Broiler Products from the United States required the investigating authorities to take into account the recorded costs of the exporting producers unless they are not in accordance with the generally accepted accounting principles or do not reasonably reflect the costs associated with the production and sale of the product under consideration. Even if the recorded costs satisfied those two conditions, Article 2(6a) of the basic Regulation is according to Xiamen inconsistent with Article 2.2.1.1 WTO ADA because the costs of the exporting producer are disregarded systematically.

(147) The Commission considered that the provisions of Article 2(6a) of the basic Regulation are fully consistent with the European Union's WTO obligations. As explicitly clarified by the WTO Appellate Body in DS473 European Union – Anti-Dumping Measures on Biodiesel from Argentina, WTO law permits the use of data from a third country, duly adjusted when such adjustment is necessary and substantiated. The Commission recalled that the cases DS529 Australia – Anti-Dumping Measures on A4 Copy Paper and DS427 China – Broiler Products did not concern the interpretation of Article 2(6a) of the basic Regulation and the conditions for its application. Furthermore, the underlying factual situations in those cases was different from the underlying situation and criteria giving rise to the application of the methodology under this provision of the basic Regulation, which concerns the existence of significant distortions in the exporting country. Under Article 2(6a) it is only when significant distortions are found to be present and to affect costs and prices that normal value is constructed by reference to undistorted costs and prices sourced in a representative country or by reference to an international benchmark. In any event, Article 2(6a) second subparagraph, third indent of the basic Regulation provides for the possibility to use domestic costs to the extent they are established not to be distorted. The Commission therefore rejected these claims.

(148) Second, Xiamen submitted that Article 2(6a) of the basic Regulation is inconsistent with Article 2.2.2 ADA. It further submitted that the Appellate Body in DS219 EC – Tube or Pipe Fittings confirmed that the investigating authority is obliged to use the actual SG&A and profit of the exporting producers, as long as such data exists. Xiamen therefore submitted that the Article 2(6a) of the basic Regulation was incompatible with Article 2.2.2 ADA.

(149) The Commission noted that once it is determined that due to the existence significant distortions in the exporting country in accordance with Article 2(6a)(b) of the basic Regulation it is not appropriate to use domestic prices and costs in the exporting country, the normal value is constructed by reference to undistorted prices or benchmarks in an appropriate representative country for each exporting producer according to Article 2(6a)(a) of the basic Regulation. As explained above in recital (147), the same provision of the basic Regulation also allows the use of domestic costs if they are positively established not to be distorted. In that context, the exporting producers had the possibility to provide evidence that their individual SG&A costs and/or other input costs were actually undistorted. However, as evidenced in Sections 3.3.1.2 to 3.3.1.9, the Commission established the existence of distortions in the Chinese aluminium industry and there was no positive evidence as to the factors of production of individual exporting producers being undistorted. Therefore, these claims were rejected.

(150) Third, Xiamen submitted that according to the provisions of Article 2(6a) of the basic Regulation, the Commission may use domestic costs, and that it is obliged to conduct a company-specific and cost-specific analysis in this respect. Therefore, there should have been a specific analysis of Xiamen based on the questionnaire it submitted.

(151) The Commission noted that the existence of significant distortions giving rise to the application of Article 2(6a) of the basic Regulation is established on a country-wide level. If the existence of significant distortions is established, then the provisions of Article 2(6a) apply, *a priori*, to all exporting producers in the PRC and concern all costs relating to their factors of production. In any event, the same provision of the basic Regulation provides for the use of domestic costs which are positively established not to be affected by significant distortions. If this is the case with regard to one or more exporting producers, then Article 2(6a) third subparagraph requires a separate assessment of these claims for each exporter and producer individually, without prejudice to the sampling provisions.

(152) The calculations concerning Xiamen's anti-dumping rate reflect the data submitted by the company itself, calculated in accordance with the provisions of the basic Regulation, in particular Article 2(6a). There was no evidence that Xiamen's domestic prices and costs were not distorted by the pervasive distortions established on the basis of the evidence available, except for titanium boron aluminium rod as specified in recital (161). Therefore, the provisional margins of dumping reflect the specific situation of the company, including the factors of production and amounts as reported by the company in the questionnaire reply, but duly taking into account the existence and impact of significant distortions in the PRC. These claims were therefore rejected.

(153) With regard to the individual situation of the company, Xiamen submitted that the company was a privately owned company and that there was no evidence that it was subject to the same ownership, control or policy supervision and guidance by the Chinese authorities as an SOE and was not subject to policy supervision and guidance through State presence interfering with respect to prices and costs. It thus claimed that it did not 'operate under the ownership, control or policy supervision or guidance of the authorities of the exporting country' as referred to in Article 2(6a)(b), first indent, of the basic Regulation.

(154) The Commission reiterated that once the significant distortions are established, the methodology under Article 2(6a) of the basic Regulation applies country-wide unless it is positively established that certain costs are not affected by distortions. Xiamen did not provide any such evidence, but only generic arguments concerning certain criteria listed in Article 2(6a)(b) of the basic Regulation on the existence of significant distortions in the exporting country as a whole and not linked to their specific costs being undistorted. The claim by Xiamen to be independent from State control cannot call into question the substantial body of evidence and the conclusions in Sections 3.3.1.3 to 3.3.1.5 which show the extent and pervasiveness of the influence of the government and of the CCP in the Chinese economy, including in the aluminium sector. Moreover, as indicated in Section 3.3.1.8, the government disposes of a vast number of instruments and financial incentives to steer the companies, including the privately owned ones, to follow its guidance. As described in the same section, financial institutions, including the private ones have incentives to facilitate access to finance for projects in line with the governmental plans, which has a substantial impact on the privately owned companies which need to comply with the governmental directives to ensure financial liquidity. Therefore, the argument of Xiamen that it is free from any government influence, including ownership, control or policy supervision and guidance by Chinese authorities, should be rejected.

(155) More specifically, the Commission noted that Xiamen is formally recognised as: a National Level Key High-Tech Enterprise by the State Council; Fujian Province's Backbone Enterprise for Strategic and Emerging Industries by the Fujian Province Economic and IT Commission; a Fujian Province Innovative Enterprise by the Fujian Province Science and Technology Bureau, the Fujian Province Economic and IT Commission, the Fujian Provincial Federation of Trade Unions and by the Fujian Province People's Government State-owned Asset Supervision and Administration Commission ([88]). In order to receive these formal recognitions, the company must have fulfilled the relevant eligibility requirements, which include, among others, following the official line of the GOC and complying with the official governmental strategies and policies. This is also necessary to be able to retain such recognitions and further benefit from the direct or indirect governmental support attached to them. As an example, some of the specific policies, objectives and benefits linked to the recognition as Strategic and Emerging Industries backbone enterprises in Fujian province, a title held by Xiamen, include: 'Involve backbone enterprises as leaders and examples, foster the leapfrog scientific development of strategic emerging industries in Fujian, and achieve the goals and tasks set in the "Implementation Plan for Accelerating the Development of Strategic Emerging Industries in the Fujian Province"'; 'Support Fujian's various types of venture capital funds for strategic emerging industries to carry out equity investment to develop key projects of backbone enterprises'; 'Encourage and support the provincial strategic emerging industries backbone enterprises to go public for financing and to issue corporate bonds, short-term financing bills, etc., and provide relevant support and services for corporate financing'; 'Together with economic and trade departments of districts, cities, of Pingtan Comprehensive Experimental Zone and with provincial group (holding) companies, the Provincial Economic and Trade Committee has established a working and contact system with emerging industry backbone enterprises to help coordinate and solve the difficulties and problems encountered in the development of enterprises, and to ensure monitoring and analysis the development of backbone enterprises' ([89]). The Commission thus did not accept the company specific defence that Xiamen would be free from control or policy supervision or guidance of the authorities of the PRC.

(156) Furthermore, Xiamen submitted that it was a wholly owned foreign enterprise (a 'WOFE') and subject to Chinese laws. Its shareholder was Daching Enterprises Limited, a company incorporated in Hong Kong. It further submitted that its financial statements were audited under the international accounting standards as it is part of an international group and that it was formed based on the Foreign Trade Law of the People's Republic of China, the Foreign Investment Law of the People's Republic of China, the Company Law of the People's Republic of China and was subject to the Enterprise Bankruptcy Law of the People's Republic of China. Pursuant to those laws, it was protected by the bankruptcy law and its capital could be freely remitted inward or outward in accordance with the law. It further argued that its financial statements were audited under the international accounting standards, by Ernst & Young and if its financial health was in jeopardy, it would have to follow international standards and possibly be put in bankruptcy.

(157) The Commission recalled, that, as described in Section 3.3.1.6, the distortions in the PRC in the domain of law do not stem from the fact that the Chinese laws are inadequate for their purpose. On the contrary, the Chinese laws are modelled on similar laws in other countries and hence there is no quality problem with the laws as such. The problem lies in inadequate enforcement of those laws and the role the state holds in the insolvency proceedings. Based on the findings in Section 3.3.1.6 and in absence of evidence that Xiamen would not be subject to the country-wide distortions in respect to bankruptcy proceedings, this claim was rejected.

(158) Xiamen further commented that it conducted independent price negotiations with its customers in the EU or elsewhere based on the cost of production and the prevailing market conditions. It added that when selling to its customers in the EU, its price was based on a conversion premium plus aluminium price quoted, for sales to the EU, in the London Metal Exchange (LME).

([88]) See Xiamen's website: http://www.xiashun.com/about/awards.htm

([89]) See 2012 Fujian Province Notice on developing the recognition of Strategic and Emerging industry backbone enterprises, Sections II and VI: http://www.fjmtxh.com/NewsInfo.aspx?Id=11101

(159) According to Article 2(6a)(a) of the basic Regulation, the normal value must be constructed on the basis of undistorted prices or benchmarks if it is determined that it is not appropriate to use domestic prices and costs in the exporting country due to the existence in that country of significant distortions. The claims summarised in the previous recital concerns the export price to the EU (or elsewhere) and not the normal value. The Commission thus rejected this claim.

(160) With regard to raw materials, Xiamen submitted that there are no public policies or measures discriminating in favour of domestic suppliers or otherwise influencing free market forces in the PRC. In its view, it has a free choice of selecting its own suppliers, whether producers or distributors, at freely negotiated prices. It added that the purchase price of the raw materials and other inputs was determined through negotiation and bidding among several suppliers. Xiamen further added that it purchased some of its raw materials overseas. In particular, this is the case for Titanium Boron Aluminium Rod, which it buys entirely from the United Kingdom.

(161) In this respect, the Commission recalled that Xiamen did not provide evidence positively establishing that its costs regarding domestically sourced inputs were not affected by the substantial government intervention according to the findings made in Sections 3.3.1.2 to 3.3.1.9. The investigation established distortions in the entire chain of the aluminium sector. Those distortions also concern the suppliers of raw materials, who are subject to all types of distortions found in the PRC, including the cost of electricity, labour, access to finance etc. In contrast, in the case of Xiamen's purchases overseas, on the basis of the evidence submitted and subsequently remotely cross-checked, including the questionnaire reply, a price analysis of these purchases (showing prices similar to the ones used from the representative country), and absent any evidence of distortions for this input in the United Kingdom, it was positively established that the purchase price of Titanium Boron Aluminium Rod from the United Kingdom (which represents a small part of the overall costs of raw materials of this company) is non-distorted and does not have to be replaced with data from a representative country.

(162) Furthermore, the investigation revealed that Xiamen established jointly with Yunnan Yunlv Yongxin Metal Processing Co., Ltd (a SOE) an enterprise incorporated under the name of Yunnan Yongshun Aluminium Co., Ltd in Jianshui County, Yunnan Province. That company's main business is the production of large aluminium alloy slabs and it is a supplier of Xiamen. This shows that first, Xiamen is closely cooperating with the Chinese state, by creating a joint-venture with a SOE, and secondly, that the country-wide distortions also concern its suppliers.

(163) Xiamen further submitted that the government had no influence over its ability to access credit or the terms of credit that the company was granted and that the terms of credit, such as the interest rate, are determined by the pertinent prevailing market rate. Also, Xiamen submitted that its SG&A expenses were undistorted and reasonable and should be taken into account.

(164) The Commission recalled that for the purpose of establishing the existence of significant distortions under Article 2(6a)(b) of the basic Regulation, the potential impact of one or more of the distortive elements listed in that provision is analysed with regard to prices and costs in the exporting country. Even if the exporting producer did not benefit from any significant state financing directly, *quod non*, Xiamen was eligible for financial support as described in Sections 3.3.1.8 coupled with 3.3.1.5 above. This is because, as explained in Section 3.3.1.5, the exporting producer was subject, as all companies in the aluminium sector, to Chinese State planning and guidance documents and enjoyed access to financing, through the Chinese financial system described in Section 3.3.1.8. In this respect, banks and other financing institutions, following the guidance of the GOC, facilitate access to finance for market players, including producers of aluminium products, hence creating a financial safety net for those enterprises, and giving them an advantage compared to their counterparts located outside the PRC. Furthermore, as explained in recital (118), Xiamen, having the status of a Strategic Emerging Industry ('SEI'), is eligible for the financial support made available to the companies having the SEI status, as described in the mentioned recital.

(165) Regarding labour, Xiamen submitted that it followed a sound and normal wage cost system. It negotiated independently with its employees for the individual wages based on the market rates and their personal expertise and achievements. It added that there is no state mandate regarding wage controls in the PRC.

(166) The Commission recalled that distortions on the labour market were established at the country-wide level in Section 3.3.1.7. The issues inherent to the Chinese labour market, including the lack of labour unions independent from the government and the workforce mobility restrictions due to the household registration system as described in recital (130) have a distortive impact on the wage creation in the PRC. In this respect, there is no evidence establishing that the distortive effects of the country-wide lack of independent trade unions and the issue of household registration system are not applicable to Xiamen. The claim was therefore rejected.

(167) Finally, Xiamen submitted that, for all the reasons mentioned above, its SG&A and profits were undistorted and also reasonable and should be taken into account in the calculations.

(168) As for the claim concerning SG&A and profits, the Commission first noted that it was generic and unsubstantiated, as it simply referred to the other claims by this exporting producer which have all been rejected. Furthermore, Article 2(6a)(a) of the basic Regulation specifically requires that if there is a finding of significant distortions, the constructed normal value must include an undistorted and reasonable amount for SG&A costs and for profits. Since this is the case in this investigation and the exporting producer as well as its suppliers are affected by these distortions, these claims were rejected.

(169) Consequently, and taking due account of the exception as regards titanium boron aluminium rod, the Commission proceeded to construct the normal value on the basis of costs of production and sale reflecting undistorted prices or benchmarks, that is, in this case, on the basis of corresponding costs of production and sale in an appropriate representative country, in accordance with Article 2(6a)(a) of the basic Regulation, as discussed in the following section.

3.4. **Representative country**

3.4.1. *General remarks*

(170) The choice of the representative country was based on the following criteria pursuant to Article 2(6a) of the basic Regulation:

— A level of economic development similar to the PRC. For this purpose, the Commission used countries with a gross national income per capita similar to the PRC on the basis of the database of the World Bank ([90]);

— Production of the product under investigation in that country;

— Availability of relevant public data in the representative country.

— Should there be more than one possible representative country, preference would be given, where appropriate, to the country with an adequate level of social and environmental protection.

(171) As explained in recitals (70)-(71), the Commission issued and placed on the file two notes on the sources for the determination of the normal value. The Notes described the facts and evidence underlying the relevant criteria and addressed the comments received by the parties on these elements and on the relevant sources. In the Second Note, the Commission informed interested parties of its intention to consider Turkey as an appropriate representative country in the present case if the existence of significant distortions pursuant to Article 2(6a) of the basic Regulation would be confirmed. The Commission's assessment can be summarised as follows.

3.4.2. *A level of economic development similar to China and production of the product under investigation*

(172) In the First Note, the Commission identified 55 countries with a similar level of economic development as China. In the investigation period, the World Bank classified these countries as 'upper-middle income' countries on a gross national income basis. However, a sizeable production of the product under investigation was found to exist only in five of these countries, namely in Armenia, Brazil, Indonesia, Russian Federation and Turkey.

([90]) World Bank Open Data – Upper Middle Income, https://data.worldbank.org/income-level/upper-middle-income.

(173) Given the unavailability of meaningful data on imports/exports and/or financial data of ACF producers in Armenia and Indonesia, the said countries were not examined further as potential representative countries.

(174) Following the First Note, Xiamen claimed that the Commission should consider Malaysia as a possible representative country. This exporting producer submitted that sufficiently representative quantities of aluminium foil are produced in Malaysia and referred to two companies producing the product concerned, namely Alcom and UACJ Foil Malaysia. Xiamen reiterated its claim following the Second Note.

(175) First, the Commission noted that trade export restrictions in the form of licensing requirements and export taxes related to aluminium scrap are in place in Malaysia. This factor of production accounts for approximatively between 5 % and 10 % of cost of manufacturing. Second, Alcom did not appear to be producing ACF, and UACJ Foil Malaysia was loss-making based on the latest financial data available for 2019 (period partially overlapping with IP) in the Dun&Bradstreet ("D&B") database ([91]). Lastly, the Notes contain a specific annex to guide parties in submitting information on possible additional representative countries and/or companies for the purpose of Article 2(6a)(a) of the basic Regulation. Xiamen failed to provide the information to the requisite standard and level of detail prescribed by the said annex. For the above reasons, Xiamen's claim had to be rejected.

(176) Moreover, for Russia, export restrictions in the form of an export tax were found to be in place with respect to aluminium scrap ([92]), a significant by-product that to a certain extent can be re-used in the ACF production process. Furthermore, the majority of foil stock (which is a key input for ACF production, representing more than 90 % of the production cost, depending on the production process) is imported from China or from countries listed in Annex I of Regulation (EU) 2015/755 ([93]) ("Regulation 2015/755"). The Commission therefore ruled out Russia from its consideration set and analysed in the Notes in more detail Brazil and Turkey as potential representative countries.

3.4.3. *Availability of relevant public data in the representative country*

(177) Following the First Note, all sampled exporting producers argued that Brazil was not an appropriate representative country, given the existence of various distortions on the Brazilian aluminium market. They also claimed that Novelis do Brasil Ltda, the company proposed by the Commission as a representative producer, was unsuitable, notably in view of an uncharacteristically high level of profit reported, which was considered to be unrepresentative of the industrial sector concerned and inappropriate for use in the present case.

(178) The Commission is aware that the Brazilian authorities opened, on 29 July 2020, an anti-dumping investigation on Chinese imports of aluminium products into Brazil (Circular No 46 of 28 July 2020 – 'Circular 46' – of the Brazilian Secretariat of Foreign Trade –'SECEX') ([94]). The product scope of the investigation mentioned in Circular 46 largely overlapped with the scope of the product concerned in the current investigation, defined in Section 2 above. Circular 46 also published, in an index format, operational results of the complainants (three companies including Novelis do Brasil) that showed that throughout the period 2015 – 2019, the complainants registered losses.

(179) Based on this evidence, the Commission considered it unlikely that Novelis do Brasil's reported profit (19,4 % in the latest financial period) had been achieved in relation to the product concerned. In this respect, given that the company produces a large scope of products, the Commission considered that such a profit was most likely, and to a large extent, achieved in relation to other products manufactured by Novelis do Brasil, such as products for the aerospace or automotive industry and beverage cans.

(180) The Commission therefore considered that data of Novelis do Brasil did not constitute an appropriate benchmark to establish a reasonable SG&A and profit for the product under investigation. Thus, the Commission dismissed, at the stage of the Second Note, Brazil as a choice for an appropriate representative country and focused its analysis on Turkey.

([91]) https://dnb.onelogin.com/portal/ (https://globalfinancials.com/index-admin.html).
([92]) HS code 7602 00.
([93]) Regulation (EU) 2015/755 of the European Parliament and of the Council of 29 April 2015 on common rules for imports from certain third countries OJ L 123, 19.5.2015, p. 33 as amended by Commission delegated regulation (EU) 2017/749 of 24 February 2017 (OJ L 113, 29.4.2017, p. 11).
([94]) Circular No 46 of 28 July 2020, of the Brazilian Secretariat of Foreign Trade, http://www.in.gov.br/en/web/dou/-/circular-n-46-de-28-de-julho-de-2020-269159613

(181) The analysis of imports of the main factors of production into Turkey showed that the imports of foil stock into Turkey were not materially affected by imports from China or any of the countries listed in Annex I to Regulation 2015/755. Furthermore, it was established that more precise import data for major inputs (including foil stock) were available for Turkey in comparison to Brazil.

(182) In the present case, the Commission identified two Turkish producers of ACF, i.e. Assan Aluminyum and Asaş Aluminyum. While Assan Aluminyum was loss-making in the financial year 2019 (overlapping partially with the IP), Asaş Aluminyum's profit in 2019 was close to break-even. The Commission notes in this respect that, as set out in Article 2(6a)(a) of the basic Regulation, *"the constructed normal value shall include an undistorted and reasonable amount for administrative, selling and general costs and for profits*". A profit close to break-even cannot be considered reasonable, in particular considering the level of profit achieved by other Turkish companies in the aluminium industry ([95]). Hence the data for Asaş Aluminyum as an ACF producer was provisionally not deemed an appropriate benchmark.

(183) In the absence of an appropriate benchmark to establish a reasonable SG&A and profit for the product under investigation in Turkey, the Commission provisionally considered that data of companies in a sector producing a similar product could be appropriate in these circumstances. More specifically, the Commission considered that data of Turkish companies active in the sector of aluminium extrusion would be appropriate for use. The Commission based its conclusion on the knowledge and information already available in another recent anti-dumping investigation ([96]), in the same (aluminium) sector and covering a similar product and a similar period, namely aluminium extrusions. This was further complemented by additional research.

(184) Aluminium extrusions are products having similar source material composition as ACF. In terms of production process, aluminium can be formed into a variety of products by extruding, rolling or casting. Extrusions are, together with ACF, considered semi-finished aluminium products, thus pertaining to the same general category of products. Moreover, companies producing extrusions in some instances also make other aluminium products, including rolled products covering also ACF (see recital (193) for more details). This justifies the choice of extrusion producers for the establishment of profit and SG&A in the representative country.

(185) For the purposes of the present case, availability of the companies' data for the financial year 2019, covering half of the investigation period, was first determined. No financial data were available for 2020. Subsequently, companies profitable ([97]) in the said financial period were selected. Out of the companies identified, three companies ([98]) were found to show a reasonable level of profitability based on the data in the D&B database in 2019.

(186) Moreover, based on supplementary research conducted by the Commission, it is observed that Asaş Aluminyum (the ACF producer) as well as two other companies identified by Zhongji in its comments in response to the First Note (P. M.S. Metal Profil Aluminyum Sanayi Ve Ticaret Anonim Sirketi and Cansan Aluminyum Profil Sanayi Ve Ticaret Anonim Sirketi), are involved, apart from production of other semi-finished aluminium products, in the manufacturing of aluminium extrusions ([99]). Furthermore, financial data for P.M.S. Metal and Cansan Aluminyum is readily available in the D&B database and, unlike Asaş Aluminyum, the said companies also posted reasonable profit levels in 2019. Therefore, the said two companies are also considered by the Commission as representative producers in Turkey for the purposes of this case (see recital (223) for a complete list of the companies selected).

([95]) See Commission Implementing Regulation (EU) 2021/582 of 9 April 2021 imposing a provisional anti-dumping duty on imports of aluminium flat-rolled products originating in the People's Republic of China, OJ 2021 (L 124), p. 40–115, recitals 266-267.

([96]) See Commission Implementing Regulation (EU) 2021/546 of 29 March 2021 imposing a definitive anti-dumping duty and definitively collecting the provisional duty imposed on imports of aluminium extrusions originating in the People's Republic of China, L 109, p. 1.

([97]) Reasonable profit had to be achieved by the companies, i.e. companies that were loss-making or had a very low profit (close to break-even) were excluded from consideration.

([98]) The fourth company provisionally selected in the Second Note (Emek Kablo Sanayi Ve Ticaret Anonim Sirketi) was ultimately found not to be producing aluminium extrusions and hence excluded from consideration.

([99]) See https://www.asastr.com/production-facilities/, http://www.cansan.com.tr/EN/Production/Extrusion/ and https://www.turkishexportal.com/PMS-Metal-Profile-Aluminum-Industry-Trade-Inc_SHC13B_3f52c050b5a442608328416c31ac84bd?lang=en for more details.

(187) In response to the Second Note, all sampled exporting producers opposed the use of SG&A and profit data for companies from the extrusion sector, calling instead for the use of the corresponding data of either Turkish ACF producers (using either actual or adjusted figures), or producers of other aluminium products, such as aluminium foil. The companies argued that extrusions and ACF do not pertain to the same general category of products and/or sectors and that there is no correspondence between the two products, be it in terms of physical or technical characteristics, end-uses, production process or production cost.

(188) First, it is recalled that the Commission seeks to identify actual, reasonable and undistorted profit and SG&A figures in the representative country. As outlined in the Second Note, in search of such appropriate benchmarks, the Commission may, if necessary, consider also producers manufacturing a product in the same general category and/or sector of the product under investigation in the absence of a representative ACF producer. Although certain characteristics, end-uses, production processes and production cost for ACF and aluminium extrusions may not be identical, these aspects cannot be considered dispositive in the present case. In addition to the reasons already given in recital (184), the aluminium extrusion industry falls under the same general category of economic activity and industry as ACF production based on the statistical classification of economic activities in the Union ([100]).

(189) With regard to the claim that the Commission should use producers of other aluminium products namely aluminium foil (other than ACF), that party did not explain how this product and its characteristics and use were more appropriate than aluminium extrusion and how they compared to it. Furthermore, the exporting producers failed to propose aluminium foil producers with available financial data and reasonable profit from the potential representative country. In any event, as specified below at recital (190), the companies provisionally used in this investigation are representative of a broader aluminium product group, including rolled products.

(190) Second, companies considered suitable in the context of Article 2(6a)(a) of the basic Regulation frequently produce more than one product. It is likewise common that the level of detail of publicly available financial data of suitable companies in the representative country does not permit a more granular analysis of the SG&A and profit at the level of individual products. Similarly, in this case, financial data of the extrusion producers identified is only available at an aggregate level in the D&B database while, as outlined in recital (186) above, some of the extrusion producers also make other semi-finished aluminium products. Therefore, the available financial data for aluminium extrusion companies is representative not only strictly of the situation in the extrusion market, but also as concerns the market for a broader product group, including rolled products. The request to use alternative financial data was therefore rejected.

(191) Furthermore, all sampled exporting producers took issue with the fact that the Commission disregarded Asaş Aluminyum (the ACF producer) for having too low a profit, while considering all profitable aluminium extrusion companies, irrespective of their individual profit levels, as potentially representative producers. Zhongji further submitted that the profitability of Asaş Aluminyum was not unreasonable for the ACF industry.

(192) The Commission observed that the use of pooled and weighted financial data of a basket of companies with reasonable profit figures (beyond negative or break-even profit levels) is more adequate than examining the performance of a single producer for the purposes of finding a reasonable amount for SG&A and profit. As set out in recital (177) as well as the notes to the file, in this case, a profit close to break-even, based solely on the data of a single company, cannot be considered reasonable within the meaning of Article 2(6a)(a) of the basic Regulation.

(193) Zhongji further argued that the Commission's findings on financial data to be used for representative producers must be revisited after data for 2020 is made available. According to Zhongji, the data for 2019 had been largely unaffected by the COVID-19 pandemic for both Chinese as well as other producers in potential representative countries, while data for 2020 had been fully affected by the pandemic.

([100]) Class 24.42 – Aluminium Production, covering semi-manufacturing of aluminium and production of aluminium wrapping foil (see https://ec.europa.eu/eurostat/documents/3859598/5902521/KS-RA-07-015-EN.PDF (p. 156)).

(194) In response, the Commission noted that, first, the COVID-19 pandemic was declared only in March 2020 ([101]), hence overlapping with the IP only by one quarter. Second, the IP covered the period July 2019-June 2020, which means that data for 2019 as well as 2020 are equally relevant for the Commission assessment. In any event, the Commission has not identified any available financial data, relevant to this case, for 2020. Moreover, Zhongji's claim concerning the impact of the COVID-19 pandemic on producers is unsubstantiated and, given the performance of the sampled exporting producers in the IP compared to 2019, appears implausible.

(195) In conclusion, financial data for a representative pool of aluminium extrusion producers deemed indicative of the situation and profit levels in the semi-finished aluminium segment (including ACF) is available and considered adequate for establishing normal value in accordance with Article 2(6a)(a) of the basic Regulation.

3.4.4. *Level of social and environmental protection*

(196) Having established that Turkey was the appropriate representative country at this stage of the investigation, based on all of the above elements, there was no need to carry out an assessment of the level of social and environmental protection in accordance with the last sentence of Article 2(6a)(a) first indent of the basic Regulation.

3.4.5. *Conclusion*

(197) In view of the above analysis and in accordance with Article 2(6a)(a) of the basic Regulation, the Commission intends (in line with the Second Note) to use Turkey as an appropriate representative country and use the financial data of aluminium extrusion producers as listed in recital (223).

3.5. **Sources used to establish undistorted costs for factors of production**

(198) On the basis of the information submitted by interested parties and other relevant information available on the file, the Commission established, in the First Note, an initial list of factors of production ('FOP') such as materials, energy and labour, used for the production of the product under investigation.

(199) In accordance with Article 2(6a)(a) of the basic Regulation, the Commission also identified sources to be used for establishing undistorted prices and benchmarks. The main source that the Commission proposed to use included the Global Trade Atlas ('GTA'). Finally, the Commission identified the Harmonised System ('HS') codes of the FOPs which in the First Note were initially considered to be used for the GTA analysis on the basis of information provided by the interested parties.

(200) The Commission invited the interested parties to comment and propose publicly available information on undistorted values for each of the FOP mentioned in the First Note. Subsequently, in the Second Note, the Commission updated information for a number of FOPs based on the comments received from the interested parties.

(201) It was further established by the Commission that numerous FOPs listed initially in the Notes shall be disregarded for the purposes of constructing the normal value, as they were in fact not used by any of the sampled exporting producers in the ACF production process (see also recitals (230)-(231) for more details).

([101]) See https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19—11-march-2020 (last accessed on 21 April 2021).

(202) In view of the above, the following FOPs and their sources were identified with regard to Turkey, in order to determine the normal value in accordance with Article 2(6a)(a) of the basic Regulation:

Table 2

Factors of production of ACF

Factor of Production	Commodity Code	Undistorted value	Unit of measurement
Raw materials			
Aluminium Ingots	7601 10	12,73	CNY/KG
Aluminium slabs	7601 20 20	13,91	CNY/KG
Aluminium foil stock	7606 12 92	26,06	CNY/KG
Rolling oil ('white spirit')	2710 12 21	5,92	CNY/KG
Rolling oil additives	2710 12 21	5,92	CNY/KG
Aluminium scrap	7602 00 19	11,01	CNY/KG
Labour			
Labour costs in manufacturing sector	NACE C.24	59,97	CNY/hour
Energy			
Electricity	Turkish Statistical Institute consumption band 70 000 MWh<consumption<150 000 MWh	0,51	CNY/KWh
Electricity	Turkish Statistical Institute consumption band 150 000 MWh< consumption	0,48	CNY/KWh

3.5.1. *Raw materials used in the production process*

(203) In order to establish the undistorted price of raw materials the Commission used as a basis the weighted average import price (CIF) to the representative country, as reported in the GTA, from all third countries excluding the PRC and countries that are not members of the WTO and listed in Annex I of Regulation 2015/755. The Commission decided to exclude imports from China as it concluded that it is not appropriate to use domestic prices and costs in China due to the existence of significant distortions in accordance with Article 2(6a)(b) of the basic Regulation (see Section 3.3.1 above). Absent any evidence showing that the same distortions do not equally affect products intended for export, the Commission considered that the same distortions affected exports. The weighted average import price was adjusted for import duties, where applicable.

(204) The Commission expressed the transport cost incurred by the cooperating exporting producers for the supply of raw materials as a percentage of the actual cost of such raw materials and then applied the same percentage to the undistorted cost of the same raw materials in order to obtain the undistorted transport costs. The Commission considered that, in the context of this investigation, the ratio between the exporting producer's raw material and the reported transport costs could be reasonably used as an indication to estimate the undistorted transport costs of raw materials when delivered to the company's factory.

(205) For a small number of FOP, the actual costs incurred by the cooperating exporting producers represented a negligible share of total raw material costs in the investigation period. As the value used for those had no appreciable impact on the dumping margin calculations, regardless of the source used, the Commission treated those FOPs as consumables, as explained in recital (227).

(206) In response to the Second Note, Zhongji argued that the databases relied on by the Commission (notably GTA and D&B) are not generally available and only accessible to subscribers and that in the absence of a subscription, parties cannot exercise their rights of defence appropriately. Furthermore, Zhongji expressed its concerns about the reliability of the data included in the D&B database, referring to inaccuracies detected in data entered in the database for Zhongji's Hong Kong affiliate. Lastly, Zhongji claimed that the Commission failed to disclose in the Second Note updated values intended to be used for each FOP as well as the underlying source data and calculations performed.

(207) First, the Commission noted that, according to Article 2(6a) of the basic Regulation, the data does not have to be 'publicly available' but 'readily available'. The Commission noted that 'publicly available' means available to the public at large whereas 'readily available' means available to everyone, provided that certain conditions, such as a payment of a fee, have been fulfilled. Second, D&B database is a comprehensive and widely used and recognized business directory, which the Commission indiscriminately used to identify producers in potential representative countries. Any potential inaccuracies entered in the database for the Hong Kong affiliate of Zhongji were not substantiated. Records for this company are not even available in the D&B database ([102]) and moreover the excerpt provided by Zhongji includes modelled rather than actual revenues. In any event, the alleged inaccuracies would not be liable to undermine reliability of the data used by the Commission in this case, as the data for Zhongji affiliate in Hong Kong has not been used in any way for the purposes of applying Article 2(6a) of the basic Regulation. Third, all the relevant information used to construct the normal value for exporting producers, including all the underlying data and detailed calculations was made available to the producers by means of general or company-specific disclosures, thus enabling the said companies to duly exercise their rights of defence. This claim was therefore rejected.

(208) In response to the Second Note, Donghai as well as Zhongji repeatedly challenged the inclusion of the import duty paid in the representative country for each raw material input used in the construction of the normal value. According to Zhongji, by including the import duties in the cost, the Commission is distorting this cost and is not arriving at the undistorted cost of production in China. Zhongji further argued that the corresponding costs in China, in line with Article 2(6a) of the basic Regulation, do not include import duties since the inputs are produced domestically. Furthermore and along similar lines, Donghai submitted that, since in accordance with Article 2(6a) of the basic Regulation the assessment shall be done for each exporter and producer separately, the inclusion of import duties for raw materials that Chinese companies purchased domestically could not be considered reasonable.

(209) It is noted that for the purposes of applying Article 2(6a)(a) of the basic Regulation, the objective is to determine undistorted prices of inputs in the representative markets. In the absence of availability of data on domestic prices in the possible representative countries (which is the case here as well), data on import prices which are readily available to the Commission are applied. In order to arrive at a reasonable proxy representing an undistorted domestic price in the domestic market of the selected representative country, the import prices identified need to be adjusted by adding the relevant import duties, because these also affect the actual price on the domestic market. In the absence of import duties, the price would not be representative of the market price in the representative country. Moreover, this assessment was carried out for each sampled exporting producer separately in the establishment of their separate dumping margins. The parties' claims therefore had to be rejected.

(210) In response to the Second Note, Donghai as well as Zhongji submitted that the aluminium scrap they generate throughout the ACF production process had equal or similar purity to aluminium ingot and that the scrap was used in the same manner as aluminium ingots in the casting stage. Consequently, according to those companies, the HS code reported by the Commission in the Notes (7602 00) or even the 8-digit code 7602 00 90 would refer to a different product, namely to aluminium scrap with various sources, less purity and different alloy composition, not corresponding to the quality of scrap actually produced by the companies.

(211) First, the Commission observed based on the evidence brought by both Donghai and Zhongji during the RCC process, that the aluminium scrap used (and sold) by these exporting producers was not priced at the same level as aluminium ingots, but that a price reduction was made depending on its grade, to reflect the scrap purity. Therefore, it was confirmed that the price of the aluminium ingot was higher than the price of the aluminium scrap generated.

([102]) https://globalfinancials.com/index-admin.html

(212) Second, the Commission established that the relevant commodity code under the Turkish nomenclature distinguishes between so-called manufacturing scrap under 8-digit commodity code 7602 00 19 and scrap under 8-digit commodity code 7602 00 90. Based on the Commission's review of the respective codes and arguments presented by the parties, commodity code 7602 00 19 appears to reflect better the type of scrap consumed and produced by both Donghai and Zhongji. Therefore, the Commission decided to use as the benchmark the import price under commodity code 7602 00 19 and not an import price for an ingot as suggested by the companies.

(213) In response to the Second Note, Zhongji claimed that reliance on Turkish GTA import data using 8 digit commodity code for foil stock (7606 12 92) was not representative, nor corresponding to Zhongji's costs for foil stock. More specifically, Zhongji argued that the Turkish GTA prices are higher than the prices in the Union. Furthermore, according to the company, import data for commodity code 7606 12 92 also covers imports of foil stock used for aircraft parts and the automotive industry, allegedly resulting in a significant inflation of prices. Zhongji further submitted that the GTA data does not distinguish between the types of alloys. While Zhongji only uses certain cheaper alloy types in its foil stock, GTA data relied on by the Commission covered all alloys. Zhongji therefore requested to adjust the GTA data based on the price of a specific alloy similar in terms of chemical and metal components to grades used by Zhongji in the CRU report ([103]). Zhongji claimed that the Complaint also relied on CRU data, specifically in the context of Turkey as a representative country. Donghai submitted a claim along similar lines, arguing that CRU data is more appropriate for use as it allows products to be distinguished based on specific alloy types. Finally, Zhongji claimed that several import transactions included in the GTA for imports of foil stock showed abnormally high unit prices and should be excluded.

(214) As a preliminary remark, it is recalled that in line with Article 2(6a) of the basic Regulation, the Commission aimed at identifying corresponding costs of production in an appropriate representative country with a similar level of economic development as the exporting country or, if it considered appropriate, undistorted international prices, costs, or benchmarks ([104]).

(215) In the present case, import prices into Turkey are available in the GTA database ([105]). With respect to the foil stock, the data in GTA is available at an 8-digit level, thus enabling the Commission to capture specifically imports of foil stock of the thickness used by the ACF manufacturers (thickness of less than 3mm). The 8-digit code equally excludes foil stock that is thicker and foil designed for other end uses such as beverage can stock or coated foil stock. Therefore, the GTA data at 8-digit level not only captures all foil stock types used in production of ACF, but also excludes to a considerable degree foil stock types used in other applications. Hence, such data is appropriate for the purposes of applying Article 2(6a) of the basic Regulation.

(216) Furthermore, in contrast to the GTA data, which reliably covers foil stock used by the ACF producers, the data stemming from the CRU report has numerous properties which make it less appropriate for use. First, the CRU data relied on by Donghai and Zhongji only concern prices for foil stock made from the specific alloy type 1050. The sampled exporting producers on the other hand not only used different 1xxx series alloys, but they also used 8xxx series alloys in material quantities, which are known to be of superior quality (as also confirmed during RCC with Zhongji) and hence pricier than 1xxx series alloys. Therefore, the price for 1050 alloy cannot be considered representative of prices for foil stock actually used by ACF producers in the production process. Moreover, the CRU prices proposed by the parties related to prices in several Union Member States (Germany, Italy, France) and the UK and they therefore neither reflected the situation in a representative country with a similar level of economic development nor international benchmarks. Furthermore, while the CRU data was used in the Complaint, it was for the purpose of determining production capacity and consumption of ACF in Turkey rather than for identifying benchmark values for factors of production.

([103]) CRU International Ltd is a commodity research company that issues a.o. Aluminium Products Monitor Data.

([104]) Alternatively, domestic costs can be used, but only to the extent that they are positively established not to be distorted, on the basis of accurate and appropriate evidence.

([105]) http://www.gtis.com/gta/secure/default.cfm

(217) Lastly, the Commission considered the available import data for foil stock as a whole. The use of an average price reduces the impact of any potentially abnormal prices at the lower and higher end of the range and equally reflects a mix of different qualities of the raw material used (in this case e.g. alloy types 1xxx and 8xxx series) in the representative market concerned.

3.5.2. *Labour*

(218) To establish the benchmark for labour costs the Commission used the most recent statistics published by the Turkish Statistical Institute ([106]). This institute publishes detailed information on labour costs in different economic sectors in Turkey. The Commission established the benchmark based on hourly labour costs for 2016 for the economic activity C.24 (Manufacture of basic metals) ([107]). The values were further adjusted for inflation using the domestic producer price index ([108]) published by the Turkish Statistical Institute to reflect the costs for the investigation period.

(219) Donghai as well as Zhongji argued that in terms of benchmark used for labour, production of ACF is closer to activities under code 25 (Manufacture of fabricated metal products, except machinery and equipment), namely Class 25.50 (Forging, pressing, stamping and roll-forming of metal; powder metallurgy) or Class 25.92 (Manufacture of light metal packaging), rather than activities under code C.24. Furthermore, Zhongji argued that some of the Union producers (Amcor and Carcano Antonio) are classified under NACE class 25.92.

(220) The Commission noted that based on the statistical classification of economic activities in the Union (which is in line with the international, UN classification), production of aluminium falls under division 24, more specifically under group 24.4 (Manufacture of basic precious and other non-ferrous metals) and class 24.42 ([109]). The said class covers aluminium production including activities such as semi-manufacturing of aluminium and production of aluminium wrapping foil. The fact that some of the ACF producers might be classified under a different NACE class (such as 25.92) simply means that those companies produce, among other things, also metal packaging, which is not considered to be ACF. Hence the Commission maintained that it had correctly established the benchmark using labour costs for the economic activity C.24 (manufacture of basic metals) as a basis, and the claims of the parties had to be rejected.

3.5.3. *Electricity*

(221) To establish the benchmark price for electricity, the Commission used prices of electricity for companies (industrial users) in Turkey published by the Turkish Statistical Institute ([110]). The benchmark was established based on the price for electricity published on 23 September 2020. The price referred to is the average for the 2nd semester of 2019 and 1st semester of 2020. The Commission used the data on the industrial electricity prices in the consumption band that is respectively 70 000 ≤ T < 150 000 MWh and > 150 000 MWh. The Commission used prices at net level (without VAT).

3.5.4. *SG&A and profits*

(222) According to Article 2(6a)(a) of the basic Regulation, "*the constructed normal* value *shall include an undistorted and reasonable amount for administrative, selling and general costs and for profits*". In addition, a value for manufacturing overhead costs needs to be established to cover costs not included in the factors of production referred to above.

([106]) The labour costs are available at http://www.turkstat.gov.tr/PreIstatistikTablo.do?istab_id=2088

([107]) The category 'basic metals' includes aluminium under code C24.42.

([108]) https://data.tuik.gov.tr/Bulten/DownloadIstatistikselTablo?p=RQJc6lWaNMpivNV6h1MxkWk9ycHqk1cNqZM2UJkJfMUYAmenKIIz/lKzy74RY7Y2

([109]) See https://ec.europa.eu/eurostat/documents/3859598/5902521/KS-RA-07-015-EN.PDF, p. 156; see also UN International Standard Industrial Classification of All Economic Activities https://unstats.un.org/unsd/classifications/Econ/Download/In%20Text/ISIC_Rev_4_publication_English.pdf , p. 122-123.

([110]) https://data.tuik.gov.tr/Bulten/Index?p=Electricity-and-Natural-Gas-Period-I:-January-June,-2020-33647

(223) For establishing an undistorted and reasonable amount for SG&A and profits, the Commission used the SG&A and profit of the five companies in Turkey, which had been identified as producing the similar product (among other semi-finished aluminium products), i.e. aluminium extrusion products as explained in recitals (190)-(196). As outlined in those recitals, the Commission used the figures relating to 2019 financial data as those were the most recent available data, which moreover overlap with the IP by half a year. The data for the following five companies was used:

(1) Eksal Aluminyum Kalip Sanayi Ve Ticaret Limited Sirketi,

(2) Okyanus Aluminyum Sanayi Ticaret Anonim Sirketi,

(3) Cuhadaroglu Metal Sanayi Ve Pazarlama Anonim Sirketi

(4) P.M.S. Metal Profil Aluminyum Sanayi Ve Ticaret Anonim Sirketi

(5) Cansan Aluminyum Profil Sanayi Ve Ticaret Anonim Sirketi

3.6. **Calculation of normal value**

(224) Based on the undistorted prices and benchmarks described above, the Commission constructed the normal value per product type on an ex-works basis in accordance with Article 2(6a)(a) of the basic Regulation.

(225) To establish the undistorted costs of manufacturing for each legal entity manufacturing and exporting the product concerned, the Commission replaced, for each exporting producer, factors of production purchased both from related and unrelated parties by the factors of production identified in Table 2.

(226) First, the Commission established the undistorted costs of manufacturing based on the factors of production purchased by each of the companies. It then applied the undistorted unit costs to the actual consumption of the individual factors of production of each of the cooperating exporting producers. The Commission reduced the costs of manufacturing by the undistorted costs of by-products re-used in the production process.

(227) Second, to arrive at a total undistorted cost of manufacturing, the Commission added manufacturing overheads. Manufacturing overheads incurred by the cooperating exporting producers were increased by the costs of consumables referred to in recital (205) and subsequently expressed as a share of the costs of manufacturing actually incurred by each of the exporting producers. This percentage was applied to the undistorted costs of manufacturing.

(228) Finally, the Commission added SG&A and profit, determined on the basis of the five Turkish companies (see recital (223)). SG&A, expressed as a percentage of the cost of goods sold and applied to the undistorted total cost of manufacturing, amounted to 8,7 %. The profit, expressed as a percentage of the cost of goods sold and applied to the total undistorted costs of manufacturing, amounted to 7,5 %.

(229) On that basis, the Commission constructed the normal value per product type on an ex-works basis in accordance with Article 2(6a)(a) of the basic Regulation.

(230) Donghai claimed that its ACF producing entity should be treated, together with other entities pertaining to the same corporate group ('the Nanshan Group'), in a consolidated way as far as the calculation of the normal value is concerned, i.e. the Commission should only consider replacing the prices of factors of production that the Nanshan Group was buying at the beginning of the production process from an unrelated party with the benchmark prices. Donghai referred in this context to the Commission's practice regarding the concept of a 'single economic entity' applied for the purpose of establishing the export price. Similarly, Zhongji argued that its ACF producing entity sourced the majority of the foil stock from affiliated companies and that the Commission should take into account cost components (for production of foil stock) of these affiliated companies for the construction of normal value of Zhongji's producing entity. According to Zhongji, the fact that Zhongji's producing entity was a part of an integrated group of companies and sourced raw materials from the related entities should be duly reflected and treated differently from a scenario where raw materials are supplied by unrelated suppliers.

(231) First, the Commission observed that the concept of 'single economic entity' applies to the establishment of the export or domestic price, insofar as it informs the identification of the relevant price to independent customers, and the possible adjustments to such prices, when domestic or export sales are effected via a related trader. By contrast, the question raised by Donghai and Zhongji relates to the production process followed by and the relevant inputs used by the producing entities when manufacturing the product concerned. In that respect, it is the Commission's consistent practice (applied also in the present case) to construct a normal value for each individual exporting producer entity based on the specific production process and the inputs as purchased by each legal entity manufacturing the product concerned. The request to have the production process established on a consolidated basis and using factors of production of affiliated producers for upstream products other than ACF would obfuscate the industrial and economic reality of the ACF producing entities by unjustifiably assuming that the group of related companies constitutes a single integrated producer entity. The claims submitted by Donghai and Zhongji were therefore rejected.

3.7. **Export price**

(232) The first of the sampled exporting producers, Donghai, exported the product concerned to the Union through a related company located in China and the export price was the price actually paid or payable for the product concerned when sold for export to the Union, in accordance with Article 2(8) of the basic Regulation.

(233) Furthermore, Donghai also sold the product concerned to the Union through an additional related company established in the Union, acting as an importer. For these sales, the export price was constructed on the basis of the price at which the imported product was first resold to independent customers in the Union in accordance with Article 2(9) of the basic Regulation. The adjustments made related to all costs incurred between importation and resale, including SG&A expenses and profits, in order to establish a reliable export price at the Union frontier level.

(234) The second sampled company, Zhongji, exported the products concerned directly to independent customers in the Union as well as through a related company located in Hong Kong. The export price for Zhongji was the price actually paid or payable for the product concerned when sold for export to the Union, in accordance with Article 2(8) of the basic Regulation.

(235) Finally, the third sampled producer, Xiamen exported the product concerned through a related company located in Hong Kong and, in minor quantities, directly to independent customers in the Union. The export price for Xiamen was the price actually paid or payable for the product concerned when sold for export to the Union, in accordance with Article 2(8) of the basic Regulation.

3.8. **Comparison**

(236) The Commission compared the normal value and the export price of the sampled exporting producers on an ex-works basis.

(237) In order to ensure a fair comparison, the Commission adjusted the normal value and/or the export price for differences affecting prices and price comparability, in accordance with Article 2(10) of the basic Regulation. Adjustments to the export price were made for transport, insurance, handling and loading, packaging, commission, discounts, credits costs, bank charges, year-end rebates and customs duties.

(238) All export sales of the product concerned by Donghai were made via a related domestic trader in China, which sold ACF either directly to independent customers in the Union or via a related trading company in Germany. According to Donghai, the domestic trader acted as an internal sales department of the production companies. Based on an assessment of the evidence available, the Commission provisionally accepted the claim and no adjustment was made under Article 2(10)(i) for the domestic trader.

(239) Furthermore, during the investigation period, both Zhongji and Xiamen exported ACF to the Union through related traders located outside the Union, in Hong Kong. The Commission found that the functions of these traders were similar to those of an agent as they received mark-up for their services.

(240) In this context, Xiamen requested the application of a 'single economic entity' status to its trader located in Hong Kong. It is observed that: (i) Xiamen's trader was not located at the premises or near the producers and kept its accounting records at its own premises; (ii) in addition to its trading activities, the trader is also acting as a purchasing entity for certain auxiliary materials for the group, and it is also engaged in hedging and financial operations as the group's holding company; (iii) based on the verified profit and loss sheet, the related trader's own profit covered its office expenditures; (iv) the trader assumed the customer default risk; (v) the trader was paying sea freight and bank charges in export sales of the product concerned to the Union; (vi) not all goods produced by Xiamen are sold via the related trader - about [20 % - 30 %] of sales of the product concerned to the EU and 100 % of the sales of other products to the EU and to other third countries are made directly by Xiamen. In view of the above, Xiamen's argument had to be rejected.

(241) Consequently, an adjustment under Article 2(10)(i) was made for sales through the related trading companies of Xiamen and Zhongji. Applying Article 2(9) by analogy, the adjustment consisted of the deduction of SG&A of the respective trading companies and a notional profit based on the profit margin for the sole cooperating unrelated importer in this case.

3.9. **Dumping margins**

(242) For the sampled cooperating exporting producers, the Commission compared the weighted average normal value of each type of the like product with the weighted average export price of the corresponding type of the product concerned to calculate the dumping margin, in accordance with Article 2(11) and (12) of the basic Regulation.

(243) For the cooperating exporting producers outside the sample, the Commission calculated the weighted average dumping margin, in accordance with Article 9(6) of the basic Regulation. Therefore, that margin was established on the basis of the margins of the sampled exporting producers.

(244) On this basis, the provisional dumping margin of the cooperating exporting producers outside the sample is 69,6 %.

(245) For all other exporting producers in China, the Commission established the dumping margin on the basis of the facts available, in accordance with Article 18 of the basic Regulation. To this end, the Commission determined the level of cooperation of the exporting producers. The level of cooperation is determined based on the volume of exports of the cooperating exporting producers to the Union, expressed as a proportion of the total export volume — as reported in Eurostat import statistics — from the country concerned to the Union.

(246) The level of cooperation in this case is considered high as the exports of the cooperating exporting producers constituted over 90 % of the total exports to the Union during the investigation period. Therefore, the Commission considered it appropriate to set the country-wide dumping margin applicable to all other non-cooperating exporting producers at the level of the highest dumping margin found for the sampled exporting producers, namely Donghai. The dumping margin thus established was 98,9 %.

(247) The provisional dumping margins, expressed as a percentage of the CIF Union frontier price, duty unpaid, are as follows:

Company	Provisional dumping margin
Yantai Donghai Aluminum Foil Co., Ltd	98,9 %
Jiangsu Zhongji Lamination Materials Co., Ltd	81,5 %
Xiamen Xiashun Aluminium Foil Co., Ltd	16,1 %
Other cooperating companies	69,6 %
All other companies	98,9 %

4. INJURY

4.1. Definition of the Union industry and Union production

(248) As indicated in recital (39), the transition period for the UK withdrawal from the EU ended on 31 December 2020 and the UK ceased to be subject to Union law as of 1 January 2021. Consequently, the Commission requested the interested parties to provide updated information on EU27 basis. The indicators below as well as undercutting and underselling margins were consequently calculated exclusively based on EU27 data.

(249) The like product was manufactured by eleven producers in the Union during the investigation period. They constitute the 'Union industry' within the meaning of Article 4(1) of the basic Regulation.

(250) The total Union production during the investigation period was established at around 209 000 tonnes. The Commission established this figure on the basis of all the available information concerning the Union industry, such as the replies to the anti-dumping questionnaires by the sampled Union producers as well as the replies to the macro questionnaire by non-sampled Union producers. This data was cross-checked with the figures in the complaint for reliability and completeness. As indicated in recital (27), the three sampled Union producers represented above 50 % of the total Union production of the like product.

4.2. Determination of the relevant Union market

(251) To establish whether the Union industry suffered injury and to determine consumption and the various economic indicators related to the situation of the Union industry, the Commission examined whether and to what extent the subsequent use of the Union industry's production of the like product had to be taken into account in the analysis.

(252) In doing so, and to provide a picture of the Union industry that was as complete as possible, the Commission obtained data for the entire ACF activity and determined whether the production was destined for captive use or for the free market.

(253) The Commission found that a part of the total Union producers' production was destined for the captive market, as shown in Table 3 below. The captive market increased over the period considered but remained at a relatively low level of around 15 % of consumption in the IP. However, the Commission has no conclusive evidence at this stage of the investigation whether the companies using ACF for downstream production have a free choice of supplier or not, as the information on captive sales and production is based on data collected from companies outside the sample. The Commission provisionally considered that there might be competition between them, and consequently all the market shares are calculated on the basis of total EU consumption. At this stage, this is the most conservative approach and in any event, it does not alter the findings on injury.

(254) The Commission examined certain economic indicators relating to the Union industry exclusively on the basis of data for the free market. These indicators are: sales volume and sales prices on the Union market, growth, export volume and prices, profitability, return on investment, and cash flow. Where possible and justified, the findings of the examination were compared with the data for the captive market in order to provide a complete picture of the situation of the Union industry.

(255) However, other economic indicators could meaningfully be examined only by referring to the whole activity, including the captive use of the Union industry. These are: production, production capacity, capacity utilisation, investments, stocks, employment, productivity, wages, and ability to raise capital. These indicators depend on the whole activity, whether the production is captive or sold on the free market.

4.3. Union consumption

(256) The Commission established the Union consumption on the basis of the Union producer's replies to the anti-dumping questionnaire, the macro questionnaire as well as the imports based on the Eurostat data.

(257) Union consumption developed as follows over the period considered:

Table 3

Union consumption (tonnes)

	2017	2018	2019	IP
Total Union consumption	201 282	201 696	191 085	189 149
Index	*100*	*100*	*95*	*94*
Captive market	27 209	27 340	28 727	29 128
Index	*100*	*100*	*106*	*107*
Free market	174 073	174 356	162 358	160 021
Index	*100*	*100*	*93*	*92*

Source: sampled and non-sampled Union producers as well as Eurostat.

(258) During the period considered, consumption first increased slightly by less than 1 % in 2018 before dropping by 5 % in 2019 and then by a further 1 % in the IP. As a result, consumption decreased by 6 % during the period considered. The decrease is at least partially caused by the general guidelines announced by the EU in 2019 for a Circular Economy including recyclability targets for basic materials such as aluminium, steel, glass etc. The laminates for which light gauge foils are used in combination with other basic materials like plastic films, paper, etc. are under severe scrutiny since they can hardly be recycled with the existing technologies. This had a negative effect on the demand for light gauge aluminium foil.

(259) It appears that the consumption was not affected by the COVID-19 pandemic. According to the information supplied by the Union producers, food products stockpiling at the beginning of the pandemic actually initially increased the consumption, but then these products were consumed over the next months slightly decreasing the sales of the food packing.

4.4. **Imports from the country concerned**

4.4.1. *Volume and market share of the imports from the country concerned*

(260) The Commission established the volume of imports on the basis of two TARIC codes ([111]) extracted from Eurostat database. The market share of the imports was established on the basis of import volume from the country concerned as compared to the volume of total Union consumption as shown in Table 3.

(261) Imports from the country concerned developed as follows over the period considered:

Table 4

Import volume and market share

	2017	2018	2019	IP
Volume of imports from the country concerned (tonnes)	36 660	42 343	46 595	44 276
Index	*100*	*115*	*127*	*121*
Market share	18 %	21 %	24 %	23 %
Index	*100*	*115*	*134*	*129*

Source: Eurostat.

([111]) TARIC codes 7607 11 19 60 and 7607 11 19 93 (which was numbered 7607 11 19 95 until 17 February 2017).

(262) The volume of imports from the PRC increased by 21 % over the period considered and their market share increased by 5 percentage points, reaching 23 % in the IP. Prior to the pandemic, i.e. in 2019, the market share of Chinese imports even reached 24 %.

4.4.2. *Prices of the imports from the country concerned and price undercutting*

(263) The Commission established the prices of imports on the basis of Eurostat data, using the TARIC codes indicated in recital (260).

(264) The weighted average price of imports from the country concerned developed as follows during the period considered:

Table 5

Import prices (EUR/ tonne)

	2017	2018	2019	IP
Import price	2 869	2 893	2 801	2 782
Index	*100*	*101*	*98*	*97*

Source: Eurostat.

(265) Average import prices from China decreased by 3 % over the period considered from 2 869 EUR/tonne to 2 782 EUR/tonne. Those prices remained significantly below the sampled Union producers' sales prices and cost of production during the period considered, as shown in Table 9.

(266) The Commission determined the price undercutting during the investigation period by comparing:

— the weighted average sales prices per product type of the sampled Union producers charged to unrelated customers on the Union market, adjusted to an ex-works level; and

— the corresponding weighted average prices per product type of the imports from the sampled cooperating Chinese producers to the first independent customer on the Union market, established on a cost, insurance, freight (CIF) basis, with appropriate adjustments for customs duties and post-importation costs.

(267) The price comparison was made on a type-by-type basis for transactions at the same level of trade, duly adjusted where necessary, and after deduction of rebates and discounts. The result of the comparison was expressed as a percentage of the sampled Union producers' theoretical turnover during the investigation period. It showed a undercutting margins of between 3,9 % and 14,2 % by the imports from the country concerned on the Union market. The weighted average undercutting found was 10,8 %.

4.5. **Economic situation of the Union industry**

4.5.1. *General remarks*

(268) In accordance with Article 3(5) of the basic Regulation, the examination of the impact of the dumped imports on the Union industry included an evaluation of all economic indicators having a bearing on the state of the Union industry during the period considered.

(269) As mentioned in recital (27), sampling was used for the determination of possible injury suffered by the Union industry.

(270) For the injury determination, the Commission distinguished between macroeconomic and microeconomic injury indicators. The Commission evaluated the macroeconomic indicators on the basis of data contained in the replies to the anti-dumping questionnaire by the sampled producers as well as the replies to the macro questionnaire by non-sampled producers, crosschecked with the data in the complaint. The Commission evaluated the microeconomic indicators on the basis of data contained in the questionnaire replies from the sampled Union producers. Both sets of data were found to be representative of the economic situation of the Union industry.

(271) The macroeconomic indicators are: production, production capacity, capacity utilisation, sales volume, market share, growth, employment, productivity, magnitude of the dumping margin, and recovery from past dumping.

(272) The microeconomic indicators are: average unit prices, unit cost, labour costs, inventories, profitability, cash flow, investments, return on investments, and ability to raise capital.

4.5.2. *Macroeconomic indicators*

4.5.2.1. Production, production capacity and capacity utilisation

(273) The total Union production, production capacity and capacity utilisation developed over the period considered as follows:

Table 6

Production, production capacity and capacity utilisation

	2017	2018	2019	IP
Production volume (tonnes)	240 005	240 349	212 713	208 976
Index	*100*	*100*	*89*	*87*
Production capacity (tonnes)	296 161	283 091	281 091	278 319
Index	*100*	*96*	*95*	*94*
Capacity utilisation	81 %	85 %	76 %	75 %
Index	*100*	*105*	*93*	*93*

Source: sampled and non-sampled Union producers.

(274) The production volume remained almost unchanged between 2017 and 2018 then it went down in 2019 and then further in the IP. The overall production volume decreased over the period considered by 13 %. Considering the situation on the free market and diminishing sales (see Table 7), in order to maintain production and dilute fixed costs, the Union producers increased their captive sales (see Table 7), as well as their export sales (see Table 14). Despite these efforts, the production volume still went down.

(275) Production capacity decreased over the period considered by 6 %. This was a measured response to limit the injury when faced with the diminishing sales on the free market that pulled down the production over the period considered. As production decreased more sharply than production capacity, capacity utilisation dropped by 7 % over the period considered reaching 75 % in the IP.

4.5.2.2. Sales volume and market share

(276) The Union industry's sales volume and market share developed over the period considered as follows:

Table 7

Sales volume and market share

	2017	2018	2019	IP
Total Sales volume on the Union market (tonnes)	148 840	144 726	130 060	132 227
Index	*100*	*97*	*87*	*89*
Market share	74 %	72 %	68 %	70 %
Index	*100*	*97*	*92*	*95*

Captive market sales (tonnes)	22 378	22 392	23 972	25 106
Index	*100*	*100*	*107*	*112*
Market share of captive market sales	11 %	11 %	13 %	13 %
Index	*100*	*100*	*113*	*119*
Free market sales (tonnes)	126 462	122 334	106 087	107 120
Index	*100*	*97*	*84*	*85*
Market share of free market sales	63 %	61 %	56 %	57 %
Index	*100*	*97*	*88*	*90*

Source: sampled and non-sampled Union producers.

(277) Total sales in the EU followed a downward trend over the period considered reaching (-11 %). Between 2018 and 2019 the drop was most significant (–10 %), followed by a slight increase by 2 %, which coincided with global supply chain disruptions due to the outbreak of the COVID-19 pandemic in the PRC.

(278) As mentioned in recital (253), a part of the total Union producers' production was destined for the captive market. That part accounted for 15 % of the Union consumption during the IP and increased over the period considered by 12 %. The growth occurred mainly between 2018 and 2019 and during the IP.

(279) Total sales on the free market by the Union industry decreased by 15 % during the period considered. As a result, the market share of free market sales of the Union industry decreased from 63 % in 2017 to 57 % in the investigation period. After dropping by 5 percentage points in 2018-2019, it increased by 1 percentage point by the end of the IP.

4.5.2.3. Growth

(280) In a context of decreasing consumption, the Union industry not only lost sales volumes in the EU but also market share on the free market as demonstrated in section 4.5.2.2.

4.5.2.4. Employment and productivity

(281) Employment and productivity developed over the period considered as follows:

Table 8

Employment and productivity

	2017	2018	2019	IP
Number of employees	2 220	2 151	2 072	2 003
Index	*100*	*97*	*93*	*90*
Productivity (tonne/FTE)	108	112	103	104
Index	*100*	*103*	*95*	*97*

Source: sampled and non-sampled Union producers.

(282) Employment decreased by 10 % over the period considered as the Union industry tried to ensure its sustainability and align with the demand in the domestic market.

(283) Consequently, its productivity first improved in 2018 from 108 to 112 tonnes/FTE before decreasing following the reduction of the production volume. Overall productivity thus deteriorated by 3 %. This is because in 2018 the employment was reduced whilst the production remained relatively stable. From 2019 to the end of the IP, however, production dropped quicker than employment due to the lower sales, which resulted in a corresponding decrease in productivity.

4.5.2.5. Magnitude of the dumping margin and recovery from past dumping

(284) All dumping margins were significantly above the *de minimis* level. The impact of the magnitude of the actual margins of dumping on the Union industry was substantial, given the volume and prices of imports from the country concerned.

(285) This is the first anti-dumping investigation regarding the product concerned. Therefore, no data were available to assess the effects of possible past dumping.

4.5.3. *Microeconomic indicators*

4.5.3.1. Prices and factors affecting prices

(286) The weighted average unit sales prices of the sampled Union producers to unrelated customers in the Union developed over the period considered as follows:

Table 9

Sales prices in the Union

	2017	2018	2019	IP
Average unit sales price on the free market (EUR/ tonne)	3 396	3 557	3 408	3 359
Index	*100*	*105*	*100*	*99*
Unit cost of production (EUR/ tonne)	3 423	3 642	3 733	3 687
Index	*100*	*106*	*109*	*108*

Source: sampled Union producers.

(287) Sales prices on the free market first increased from 3 396 to 3 557 EUR/tonne in 2018. Subsequently, they decreased to 3 408 in 2019 before dropping further to 3 359 EUR/tonne in the investigation period.

(288) The unit cost of production of the sampled producers increased from 3 423 EUR/tonne by 6 % in 2018 and then further by 3 % in 2019, reaching 3 733 EUR/tonne. This figure remained more or less stable during the IP. One of the sampled Union producers incurred costs related to restructuring (mainly redundancy packages), which had an impact on cost of production in the IP. However, even without these costs, the unit cost of production of the sampled Union producers would be 3 % higher in the IP than in 2017.

(289) The overall increase of the unit cost of production over the period considered was mainly caused by the drop in the production volume by 13 % (15 % for the sampled Union producers). Extraordinary restructuring costs aside, this is particularly visible in 2019, where these costs were minor but a production drop was very significant for the sampled Union producers (-19 %). Afterwards, all sampled Union producers started adapting, which resulted in the sales and production volume during the IP improving slightly also due to lower imports from the PRC following the outbreak of the pandemic. This elimination and dilution of some of the fixed costs resulted in lowering of unit cost of production in the IP (if the restructuring costs are not taken into consideration).

4.5.3.2. Labour costs

(290) The average labour costs of the sampled Union producers developed over the period considered as follows:

Table 10

Average labour costs per employee

	2017	2018	2019	IP
Average labour costs per employee (EUR)	75 686	80 542	74 897	94 489
Index	*100*	*106*	*99*	*125*

Source: Sampled Union producers.

(291) The average labour costs per employee increased by 6 % in 2018 and then decreased by 7 % in 2019. It then increased by 26 % in the IP, which is a factor of the restructuring costs a Union producer incurred. If these extraordinary costs are disregarded, the figure in the IP would be [77 000 – 81 000], which is a [2 – 7] % increase from 2017.

4.5.3.3. Inventories

(292) Stock levels of the sampled Union producers developed over the period considered as follows:

Table 11

Inventories

	2017	2018	2019	IP
Closing stocks (tonnes)	8 745	8 598	6 664	7 491
Index	*100*	*98*	*76*	*86*
Closing stocks as a percentage of production	7,9 %	7,9 %	7,3 %	8,2 %
Index	*100*	*99*	*92*	*103*

Source: sampled Union producers.

(293) Closing stocks remained at a reasonable level throughout the period considered. Since the ACF industry generally operates on a production to order basis, this indicator is of a lesser importance in the overall injury analysis.

(294) The percentage of closing stocks expressed on production shows a slight decrease in 2019 and a slight increase in the IP. These are however not extraordinary stock variations.

4.5.3.4. Profitability, cash flow, investments, return on investments and ability to raise capital

(295) Profitability, cash flow, investments and return on investments of the sampled Union producers developed over the period considered as follows:

Table 12

Profitability, cash flow, investments and return on investments

	2017	2018	2019	IP
Profitability of sales in the Union to unrelated customers (% of sales turnover)	-1,9 %	-1,0 %	-8,1 %	-9,6 %
Cash flow (EUR)	1 714 095	12 673 563	2 805 796	- 11 241 877
Index	*100*	*739*	*164*	*- 656*

Investments (EUR)	21 447 204	19 751 766	19 457 392	16 592 531
Index	*100*	*92*	*91*	*77*
Return on investments	- 2 %	- 5 %	- 19 %	- 24 %
Index	*- 100*	*- 210*	*- 769*	*- 997*

Source: sampled Union producers.

(296) The Commission established the profitability of the sampled Union producers by expressing the pre-tax net profit of the sales of the like product to unrelated customers in the Union as a percentage of the turnover of those sales.

(297) The sales of the Union industry to unrelated customers turned from loss making in 2017 to slightly less loss making in 2018, to significantly loss making in 2019 and even more loss making in the IP (-9,6 %). It is of note that one of the sampled Union producers started restructuring during the IP. The cost of this restructuring, including severance payments negatively impacted the second part of the IP. However, even without these extraordinary expenses, the sampled producers would still be loss making at the rate of -5,6 % in the IP.

(298) It is clear that the Union industry was already injured in 2017. This is not surprising considering the market share of the Chinese imports (18 % in 2017) at prices not only below the Union industry's prices but also below its costs of production. As explained in recitals (260) and (261), the costs of the Union producers increased more than their prices, which led to the decrease in profitability of the Union industry. The Union industry was unable to raise prices at the same rate as costs were increasing because of the downward pressure caused by imports from the PRC (both in terms of volumes and low prices). Indeed, throughout the period considered, Chinese prices were consistently low and significantly below Union industry prices (see Tables 5 and 9), limiting price increases. This resulted in price suppression and decreasing profitability. which continued during the IP. Indeed, following a slight increase of 1 % in 2018, Chinese prices decreased by 3 % in 2019 and then 0,7 % in the IP. They remained far below the price level achieved by the Union industry. This is also evidenced by the significant undercutting margins stated in recital (224).

(299) The net cash flow is the ability of the Union producers to self-finance their activities. The trend in net cash flow developed negatively over the period considered in line with the evolution of the profitability.

(300) Investment decreased over the period considered by 23 %. Ambitious investment plans were halted due to the insufficient profitability. Less ambitious plans were implemented in their stead.

(301) The return on investments is the profit in percentage of the net book value of investments. It developed negatively over the period considered from -2 % in 2017 to -24 % in the IP. Such development follows the decreasing profitability of the Union industry.

(302) As stated in recital (256), it is becoming increasingly difficult for the sampled Union producers to raise capital for investment. With returns on investments falling so quickly, the sampled producers' ability to raise capital in the future is in even greater jeopardy.

4.5.4. *Conclusion on injury*

(303) During the period considered, imports of ACF from the PRC, which were already significant in 2017, increased significantly both in absolute (+21 %) and relative terms (+5 percentage points in market share) while consumption in the EU decreased by 6 %. During the investigation period, the import prices of the sampled exporting producers undercut Union prices by 10,8 % on average. Regardless of the specific undercutting found, as regards the sampled exporting producers, the Commission also observed that Chinese prices were consistently low and significantly below Union industry prices during the entire period considered (see Tables 5 and 9). The Union industry was unable to raise prices to the same extent as costs were increasing because of the downward pressure caused by imports from the PRC (both in terms of volumes and low prices).

(304) Already at the beginning of the period considered, the Union industry showed signs of injury. This not surprising, considering the market share of Chinese imports of 18 % in 2017 and their price being significantly below the price of the Union industry (see Tables 5 and 9).

(305) All macroeconomic indicators, such as production, capacity, capacity utilization, sales volume in the EU market, market share, employment and productivity, showed a negative trend over the period considered. Similarly, virtually all microeconomic indicators, such as sales prices in the EU free market, cost of production, labour costs, profitability, closing stocks, cash flow, investment and return on investments, showed a negative trend over the period considered. The same injury indicators also developed negatively when looking at the period 2017-2019, that is, before the start of the COVID-19 pandemic. For many indicators the situation in the IP was better than in 2019. This is mainly due to the lower level of imports from the PRC, that was caused by the pandemic outbreak at the end of 2019 and beginning of 2020. This further emphasises the impact these imports have on the overall situation of the Union industry.

(306) On the basis of the above, the Commission provisionally concluded that the Union industry suffered material injury within the meaning of Article 3(5) of the basic Regulation.

5. **CAUSATION**

(307) In accordance with Article 3(6) of the basic Regulation, the Commission examined whether the dumped imports from the country concerned caused material injury to the Union industry. In accordance with Article 3(7) of the basic Regulation, the Commission also examined whether other known factors could at the same time have injured the Union industry and ensured that any possible injury caused by factors other than the dumped imports from the country concerned was not attributed to the dumped imports. The following potential factors were identified: consumption; COVID-19 pandemic; alleged lack of investment; restructuring of the Union industry; high production costs in the Union; imports from third countries; export performance of the Union industry.

5.1. **Effects of the dumped imports**

(308) The deterioration in the situation of the Union industry coincided with the significant penetration by imports from China, which consistently undercut the Union industry's prices and suppressed Union market price. As mentioned in recital (224), the import prices of the sampled exporting producers undercut Union prices by 10,8 % on average.

(309) The volume of imports from the PRC increased (as shown in Table 4) from 36 660 tonnes in 2017 to 44 276 in the investigation period, an increase of 21 %. In turn, the market share increased by 29 %, i.e. from 18 % to 23 %. Over the same period (as shown in Table 7), the Union industry sales on the free market decreased by 15 % and its market share on the free market fell from 63 % to 57 %, a decrease by 10 %.

(310) The situation in the period 2017-2019 is even more telling as Chinese imports increased by 27 % (from 36 660 tonnes to 46 595 tonnes) reaching a 24 % market share while the free market share of the Union industry dropped to 56 % (a fall of 12 %). Indeed, despite a decrease in consumption between 2018 and 2019, Chinese imports continued to increase and gain market share from the Union industry.

(311) The prices of the dumped imports decreased by 3 % over the period considered (as shown in Table 5) from 2 869 to 2 781 EUR/tonne. In comparison, the Union industry prices decreased only by 1 % over the same period, from 3 396 EUR/tonne in 2017 to 3 359 EUR/tonne in the investigation period. Hence, although starting from a lower price level in 2017, Chinese prices decreased more (-88 EUR/tonne) than Union industry prices (-37 EUR/tonne) over the period considered. Also, in the period 2017-2019, the decrease in Chinese prices amounted to 2 % while the Union industry prices increased by less than 1 % (12 EUR/tonne).

(312) The pressure exerted by the dumped imports thereby caused significant price suppression to the Union industry. The Union industry was unable to raise prices at the same rate as costs were increasing because of the downward pressure caused by imports from China (both in terms of volumes and low prices). Indeed, the degree of such downward pressure is, to the least, apparent from the fact that throughout the period considered, Chinese prices were consistently low and significantly below Union industry prices and cost of production, limiting the possibility of increasing prices (see recital (265)). This resulted in a drop of the profitability of the Union industry.

(313) The difference between 2019 and the IP is particularly telling in terms of the nexus between the imports from the PRC and the situation of the Union industry. When the imports diminished following to the disruption of production and exports in the PRC due to the pandemic, production of the sampled Union procures, sales, unit cost of production and profitability of the Union industry improved slightly (disregarding extraordinary restructuring costs).

(314) On the basis of the above, the Commission provisionally concluded that the imports from China caused material injury to the Union industry. Such injury had both volume and price effects.

5.2. **Effects of other factors**

5.2.1. *Consumption*

(315) One exporting producer argued that ACF being replaced in certain segments by other products could be the source of injury of the Union industry.

(316) Indeed, as indicated in recital (258), the Union consumption contracted in 2019 and in the IP. Nevertheless, imports from the PRC increased throughout the period considered, whilst consumption decreased. Indeed, when demand is decreasing, one would normally expect all producers to be affected in a similar way or even exports to decrease more in comparison to domestic (Union) sales in view of the proximity between domestic producers and customers. Still, throughout the period considered, the imports from the PRC increased by 21 % (27 % in 2019) whilst the Union sales to the free market decreased by 15 % (16 % in 2019). Furthermore the slight improvement of some indicators discussed in recital (284) coincided with the continuous consumption contraction as seen in Table 4. The only significant difference between these two periods were lower levels of cheap imports from the PRC due to the pandemic.

5.2.2. *COVID-19 pandemic*

(317) The COVID-19 pandemic that started in the first half of 2020 affected the situation on the EU market in various ways. As mentioned in recital (259), as the overall consumption was not affected while there was a slight decrease in the imports from the PRC.

(318) As explained in recital (262), the dumped Chinese imports had already increased steadily on a year-on-year basis in the period 2017-2019 leading to an increase of over 27 % until the start of the COVID-19 pandemic in the first half of 2020. In other words, the material injury caused to the Union industry by the dumped imports had already materialised as evidenced by the negative development of all macro- and microeconomic indicators in the period 2017-2019 before COVID-19 came into the equation. Furthermore, as discussed in recital (284), lower volume of imports from the PRC due to the pandemic at the beginning of 2020 had positive impact on some of the injury indicators. This further exemplifies a strong nexus between the imports and the injurious situation of the Union industry.

(319) In view of the above, the Commission provisionally concluded that the COVID-19 pandemic did not contribute to the material injury suffered by the Union industry.

5.2.3. *Lack of investment*

(320) One exporting producer and two users argued that lack of investment by the Union industry in their production facilities is one of the reasons for the injury.

(321) It is true that, as mentioned in recital (256), some ambitious investments of the sampled Union producers were halted. However, this was the result of the injurious situation of the Union industry, not its cause. Despite the dire situation of the Union industry throughout the period considered, the investigation has shown investments into inline quality control mechanisms and other upgrades to the existing machine park. Furthermore, several companies invested into R&D to produce thinner ACF and ACF for electric car battery production. This demonstrates that the Union industry adapted to market requirements, within their financial possibilities.

(322) While it cannot be excluded that additional investments in the latest technology may be needed to ensure the long-term sustainability of the Union industry, the Commission concluded that the state of the Union industry's production equipment and the development of its operating costs do not attenuate the causal link established between the dumped imports and the material injury suffered by the Union industry.

(323) In view of the above, the Commission provisionally concluded that limited investment did not contribute to the material injury suffered by the Union industry.

5.2.4. *Restructuring of the Union industry*

(324) One user pointed to Union producers exiting the market and restructuring as a reason for the Union industry's injurious situation.

(325) Most of the market exits noted by the user took place before the period considered. There were no reasons indicating that these closures would occur under fair market conditions. If anything, similarly to the situation regarding investments explained in recital (271), closures of production facilities and business are a result of the injurious situation of the Union industry, not its cause. As part of restructuring and adaptation, such closures usually alleviate, not worsen the injury.

(326) As mentioned in recital (253) it is true that cost of restructuring of one of the sampled Union producers in the second half of the IP may have had an impact on some indicators, such as cost of production, cost of employment and profitability. This is why in recitals (260)-(261), (263) and (268) the Commission also considered the injury picture disregarding those costs. Even without those cost elements, it is clear that the Union industry suffered injury throughout the period considered including in the IP. These claims were therefore rejected.

(327) In view of the above, the Commission provisionally concluded that restructuring of the Union industry did not contribute to the material injury suffered by the Union industry.

5.2.5. *High wages, energy costs and lack of vertical integration*

(328) One user argued that high wages and energy prices are the reasons for the injurious situation of the Union industry.

(329) The Union producers reduced from 2017 to the IP the number of employees in production and administration, decreasing their overall labour cost substantially, to maintain competitiveness with a smaller market share. As demonstrated in Table 10, the average cost per employee increased in the IP, but this was mainly due to the restructuring of one of the sampled producers. Disregarding these extraordinary expenses, the average cost per employee remains relatively stable throughout the period considered whilst the sampled Union producers are still loss making at the rate of -5,6 % (see recital (268)).

(330) As to the costs of energy, they represent a relatively low portion of the cost of production (around 3 %) and as such do not have a significant impact on the increase of cost of production indicated in Table 9. Whilst energy cost per tonne of ACF produced by the sampled Union producers increased by 12 % throughout the period considered, they are partly due to the decreased volume of production and in any case, considering the potion of energy cost in the cost of production, cannot be responsible for the cost of production increase in Table 9.

(331) One user argued that the lack of vertical integration is a source of material injury to the Union industry.

(332) The Commission noted that lack of vertical integration does not break the chain of causation as this factor has not changed throughout the period considered. Furthermore, not all Chinese exporting producers are vertically integrated either. This claim was therefore rejected.

(333) In view of the above, the Commission provisionally concluded that wages, energy costs and lack of vertical integration did not contribute to the material injury suffered by the Union industry.

5.2.6. *Imports from third countries*

(334) The volume of imports from other third countries developed over the period considered as follows:

Table 13

Imports from third countries

Country		2017	2018	2019	IP
Total of all third countries except the country concerned	Volume (tonnes)	10 950	9 680	9 675	8 625
	Index	*100*	*88*	*88*	*79*
	Market share	5 %	5 %	5 %	5 %
	Average price (EUR/tonne)	3 192	3 386	3 474	3 575
	Index	*100*	*106*	*109*	*112*

Source: Eurostat.

(335) Imports from third countries were relatively limited. Average prices of imports from third countries were consistently above the Chinese prices throughout the period considered. They were only slightly below the Union prices in 2017 and 2018 and then surpassed them in 2019 and the IP. Their volumes decreased (-21 %) over the period considered. Considering the contraction of the consumption, their market share remained at around 5 % throughout the period considered. Their prices increased by 12 % during the period considered.

(336) On this basis, the Commission concluded that the evolution of imports from other countries over the period considered did not contribute to the material injury suffered by the Union industry.

5.2.7. *Export performance of the Union industry*

(337) The volume of exports of the sampled Union producers developed over the period considered as follows:

Table 14

Export performance of the sampled Union producers

	2017	2018	2019	IP
Export volume (tonnes)	57 956	74 277	69 027	61 811
Index	*100*	*128*	*119*	*107*
Average price (EUR/tonne)	3 498	3 632	3 475	3 400
Index	*100*	*104*	*99*	*97*

Source: sampled and non-sampled Union industry.

(338) Exports of the Union industry increased by 7 % over the period considered from 57 356 tonnes in 2017 to around 61 811 tonnes in the investigation period.

(339) The average price of these exports first increased by 4 % in 2018 before progressively decreasing to a lower level than in 2017 (-3 %) in the IP. The average price of these exports remained consistently above the price that the Union industry could achieve on the EU market.

(340) In view of the price levels of the Union industry exports to third countries, the Commission provisionally concluded that the export performance did not contribute to the material injury suffered by the Union industry.

5.3. **Conclusion on causation**

(341) There is a clear nexus between the deterioration of the situation of the Union industry and the increase of imports from the PRC.

(342) The Commission distinguished and separated the effects of all known factors on the situation of the Union industry from the injurious effects of the dumped imports. None of the factors contributed, alone or in combination, to the negative developments of the injury indicators observed in the period considered.

(343) On the basis of the above, the Commission concluded at this stage that the dumped imports from the country concerned caused material injury to the Union industry and that the other factors, considered individually or collectively, did not attenuate the causal link between the dumped imports and the material injury.

6. **UNION INTEREST**

6.1. **Interest of the Union industry and suppliers**

(344) There are eleven known groups of companies producing ACF in the Union. The Union industry employs over 2 000 workers directly with many more relying on it indirectly. The producers are widely spread throughout the Union.

(345) The absence of measures is likely to have a significant negative effect on the Union industry in terms of further price suppression, lower sales and further deterioration of the profitability. The measures will allow the Union industry to reach its potential on the Union market, recover lost market share, and improve profitability to levels to be expected under normal conditions of competition.

(346) Consequently, the Commission concluded that the imposition of measures is in the interest of the Union industry and its upstream suppliers.

6.2. **Interest of users**

(347) As mentioned in recital (36), nine users representing the flexible packaging industry, as well as construction material industry replied to the questionnaire. The nine companies account for around 27 % of the Chinese imports during the IP. Two other users provided comments, but did not provide questionnaire replies. Based on these replies, the Commission did not find a significant dependency on ACF imported from the PRC. For most of the cooperating users, ACF from the PRC represented between zero and 7 % of the costs of production of the products that consumed ACF. The exception to this were two users (one in the construction and another in the packaging sector), who import [80 - 95] % and [85 - 100] % of their ACF from the PRC, representing, respectively, [15 - 25] % and [20 – 30] % of their cost of the relevant production. At this stage of the investigation, their replies contain gaps in the information provided and their ability to pass on or absorb the additional costs cannot be reliably assessed. This aspect will be investigated further.

(348) Four users argued that the Union producers could not provide the same quality ACF as the Chinese producers due to a lack of investment in new machinery and in-line quality check equipment. While it is true that Union producers in general have an older machine park than Chinese producers, the Union producers have made investments and also apply in-line quality detection tools. As export figures of the Union industry show, Union producers are also able to compete successfully in third country markets, proving that their product is generally not inferior when compared to the global standard. Whilst some Chinese market leaders have facilities capable of producing efficiently high quality product, the quality analysis provided by a user has shown that this is not true for all of the ACF industry in the PRC and all its exporting producers.

(349) Three users argued that Union producers would not supply large widths or at least would have supply constraints for specific dimensions. The investigation found that Union producers could provide all widths requested by the market. Specific widths might be more cost efficient than others, depending on the maximum width of the rolling mill, which is then reflected in the price negotiations, however this is normal business practice.

(350) Three users argued that Union producers would not be able to provide quality ACF with a gauge below 6 microns. As explained in recital (50), the Commission found that the Union industry not only has existing capacity and made commercial sales in this segment, but that it also invests in the production of gauges below 6 microns, which was a developing market segment with a relatively low consumption during the IP.

(351) Two users argued that anti-dumping duties would cause supply chain interruptions. While peak demand in specific situations can cause higher lead times and Chinese producers can have more financial flexibility for stocking raw materials, it is important to note that interruptions in the supply chain from the PRC can equally occur, as has been the case due to COVID 19, which makes the survival of the Union producers an important factor for supply stability in Europe. In any event, as indicated in Table 6, there is a substantial spare production capacity in the Union available to the users.

(352) Two users argued that anti-dumping duties would jeopardise the competitiveness of the converter industry on the Union market, competing against producers from countries outside the Union, as cost increases could not be passed on to their customers. European converters could therefore shift production to outside of the Union. However, no specific evidence of inability to pass on the additional costs to the converters was provided.

(353) Two users argued that the duties would contravene the European sustainability goal as the use of thinner ACF would help to reach these goals. However, while the Commission already concluded above (see recital (50)) that the Union industry is perfectly in position to produce thinner ACF, it should be noted that the European Union cannot build a sustainable green policy, of which greener insulation materials for construction represent an element, on heavily dumped and injurious imports from the PRC.

(354) One user argued that duties would distort the market as two of the largest ACF producers, who are also converters, would have a captive consumption greater than 70 % of their production. In view of the number of Union producers, it is highly unlikely that the captive consumption of two integrated ACF producers, who are also converters, would distort the market. Moreover, there is significant spare ACF capacity available in the EU. Finally, not imposing anti-dumping measures for this reason would mean favouring one business model (non-integrated production) over the other.

(355) One user argued that instead of imposing anti-dumping duties, state-aid could be offered to the Union industry. The Commission noted that financial aid is, however, not the right instrument to counter injurious dumping.

(356) In light of the above, the Commission concluded that there is no uniform interest of users either in favour or against the imposition of the measures. Those users, who argued against the imposition of the measures, and in particular the two mentioned in recital (339) may face certain negative consequences.

6.3. **Interest of importers**

(357) A consortium of five unrelated importers provided comments on initiation. However, only one unrelated importer, representing [15 – 25 %] of the imports from the PRC, submitted a reply to the importers' questionnaire. At this stage of the investigation, its reply contain gaps in the information provided and its ability to pass on or absorb the additional costs cannot be reliably assessed. This aspect will be investigated further.

(358) The consortium argued that the Union producers are not able to manufacture the full spectrum of ACF in the required quality and volume due to technical constraints originating in a lack of vertical integration of most Union producers. This would cause higher costs of production, lower quality, dependency on the raw material (foil stock) market and longer lead times due to a longer supply chain. They further claimed that a lack of investment, especially on in-line detection systems, has led to quality issues. Therefore, the consortium expects a supply shortage, especially for thin gauge ACF, if measures were imposed. This, together with higher prices, would undermine the competitiveness of the Union converters (users).

(359) As discussed in Section 4.6.2.1, the Union industry appears to have sufficient spare capacity, even taking into account the high level of captive use of two big Union producers. Contrary to the claim of the consortium of importers, investments in in-line quality control have been made and the data does not consistently demonstrate a higher quality of Chinese ACF.

(360) In light of the above, the Commission concluded at this stage that the imposition of measures would not necessarily be in the interest of importers. However, it further assessed their likely effects when weighing the different interests at stake (see Section 6.4).

6.4. **Weighing of the competing interests**

(361) In line with Article 21(1) of the basic Regulation, the Commission assessed the competing interests and gave special consideration to the need to eliminate the trade distorting effects of injurious dumping and to restore effective competition.

(362) As far as an increase in prices is concerned, the investigation revealed that Chinese prices were undercutting Union prices on average by 10,8 % and that the price suppression lead to a deterioration of the situation of the Union industry. Should prices rise again to sustainable levels, the Commission considered that such increase would be limited in view of the level of competition on the Union market. As already mentioned in Section 4.6.2.1, the Union industry has sufficient spare capacity. Accordingly, the negative effect on users would also remain limited. None of the specific arguments raised by the users and importers and discussed in recitals (340) to (348) and (350) to (351) change this conclusion.

(363) When assessing the significance of negative effects for the importers, the Commission first noted that the level of cooperation was relatively low as only one out of the five cooperating importers submitted a questionnaire reply. As mentioned in recital (349), at this stage of the investigation it is impossible to establish whether the importer would be able to absorb the price increase, as it did not provide the relevant data.

6.5. **Conclusion on Union interest**

(364) On the basis of the above, the Commission provisionally concluded that there were no compelling reasons to conclude that it is not in the Union interest to impose provisional measures on imports of ACF originating in China.

7. **LEVEL OF MEASURES**

(365) In order to determine the level of the measures, the Commission examined whether a duty lower than the margin of dumping would be sufficient to remove the injury caused by dumped imports to the Union industry.

(366) In the present case, the complainants claimed the existence of raw material distortions within the meaning of Article 7(2a) of the basic Regulation. Thus, in order to conduct the assessment on the appropriate level of measures, the Commission first established the amount of duty necessary to eliminate the injury suffered by the Union industry in the absence of distortions under Article 7(2a) of the basic Regulation. Then it examined whether the dumping margin of the sampled exporting producers would be higher than their underselling margin (see recital (380) below).

7.1. **Injury margin**

(367) The Commission first established the amount of duty necessary to eliminate the injury suffered by the Union industry in the absence of distortions under Article 7(2a) of the basic Regulation. In this case, the injury would be eliminated if the Union industry was able to cover its costs of production, including those costs '*resulting from Multilateral Environmental Agreements, and protocols thereunder, to which the Union is a party, and of ILO Conventions listed in Annex Ia*' (Article 7(2d) of the basic Regulation), and to obtain a reasonable profit ('target profit').

(368) In accordance with Article 7(2c) of the basic Regulation, for establishing the target profit, the Commission took into account the following factors:

— the level of profitability before the increase of imports from the country concerned,

— the level of profitability needed to cover full costs and investments, research and development (R&D) and innovation, and

— the level of profitability to be expected under normal conditions of competition.

(369) Such profit margin should not be lower than 6 %.

(370) Over the period considered, only one sampled company could achieve a profit higher than 6 % in 2017. The two other sampled companies, which together represented [65 – 85] % of the sales of all sampled companies in the Union, were loss-making during the entire period considered. The consolidated profit margin of the Union industry, taking into account the highest profit margin of each sampled company over the period considered was a loss of 1 %.

(371) In view of the above considerations, the profit margin was established at 6 % in accordance with the provisions of Article 7(2c).

(372) In accordance with article 7(2d) of the basic Regulation, as a final step, the Commission assessed the future costs resulting from Multilateral Environmental Agreements, and protocols thereunder, to which the Union is a party, and of ILO Conventions listed in Annex Ia to the basic Regulation that the Union industry will incur during the period of the application of the measure pursuant to Article 11(2). The Commission established an additional cost ranging from 9,93 to 15,64 EUR/tonne which was added to the non-injurious price for the sampled Union producers concerned. A note to the file on how the Commission established this additional cost is available in the file for inspection by interested parties.

(373) These costs comprised the additional future costs to ensure compliance with the EU Emissions Trading System (EU ETS). The EU ETS is a cornerstone of the EU's policy to comply with Multilateral Environmental Agreements. Such additional costs were calculated on the basis of the average estimated additional EU Allowances (EUA) which will have to be purchased during the period of the application of the measures (2021 to 2025). The EUAs used in the calculation were net of free allowances receivable and were adjusted to ensure they related solely to the like product. The additional costs also took account of indirect CO_2 costs stemming from an increase in electricity prices over the period 2021 to 2025 linked to the EU ETS. Such indirect CO_2 costs were also based on the EUA and net of any compensation received from national authorities.

(374) The costs of the EUAs were extrapolated to account for the expected price variation during the lifespan of the measures. The source for these projected prices is a Bloomberg New Energy Finance extraction dated 2 March 2021. The average projected price for EUAs for this period is 35,50 EUR/tonne of CO_2 emitted.

(375) On this basis, the Commission calculated a non-injurious price of the like product for the Union industry.

(376) The Commission then determined the injury elimination level on the basis of a comparison of the weighted average import price of the cooperating exporting producers, as established for the price undercutting calculations, with the weighted average non-injurious price of the like product sold by the sampled Union producers on the Union market during the investigation period. Any difference resulting from this comparison was expressed as a percentage of the weighted average import CIF value.

(377) In terms of the residual margin, considering that co-operation of the Chinese exporters was high, and other considerations explained in recital (289) above, the Commission set the residual margin at the level of the highest underselling margin established for the product types sold in representative quantities, on the basis of the data of the cooperating exporting producers. The residual underselling margin so calculated was set at a level of 29,1 %.

(378) The result of these calculations is shown in the table below.

Company	Dumping margin	Injury margin	Provisional anti-dumping duty
Jiangsu Zhongji Lamination Materials Co., Ltd	81,5 %	29,1 %	29,1 %
Xiamen Xiashun Aluminium Foil Co., Ltd	16,1 %	16,0 %	16,0 %
Yantai Donghai Aluminum Foil Co., Ltd	98,9 %	25,2 %	25,2 %
Other cooperating companies	69,6 %	24,2 %	24,2 %
All other companies	98,9 %	29,1 %	29,1 %

7.2. **Raw material distortions**

(379) As explained in the Notice of Initiation, the complainant provided the Commission sufficient evidence that there are raw material distortions in the country concerned regarding the product under investigation. Therefore, in accordance with Article 7(2a) of the basic Regulation, this investigation examined the alleged distortions to assess whether, if relevant, a duty lower than the margin of dumping would be sufficient to remove injury.

(380) The complainant alleged that in the PRC, one of the raw materials used to produce the product concerned was subject to an export tax and therefore, distorted. The distorted raw material was aluminium ingots, which according to the complainant accounted for more than 17 % of the cost of production of the product concerned.

(381) The investigation confirmed that the PRC had, in the IP, an export tax on aluminium ingots. This tax amounts to 15 % of the export price of the ingots. The Commission therefore concluded that this measure falls under the list of measures amounting to a distortion of raw materials in the sense of Article 7(2a) of the basic Regulation.

(382) The Commission confirmed that aluminium ingots accounted for more than 17 % of the cost of production of the product concerned. The Commission further examined whether the price of this raw material was significantly lower as compared to prices in the representative international markets, in accordance with Article 7(2a), second paragraph. For the purpose of this comparison, the Commission provisionally used the benchmark price established to calculate the normal value, namely the import price of aluminium ingots into Turkey as indicated in Table 2 at recital (208), as in this case this price was also considered to constitute a price of representative international markets. The Commission compared the benchmark price with the price of the aluminium ingots actually paid by the sampled exporting producers, and established on that basis that the purchase price of this raw material in the PRC by the sampled exporting producers was not significantly below the benchmark price in the representative country, namely in a range of [0 % - 5 %] on average. Evidence on file also showed that domestic prices for aluminium ingots fluctuated above and below international prices.

(383) The Commission thus provisionally concluded that the price of aluminium ingots was not significantly lower as compared to prices in the representative international markets. Therefore, the Commission considered at this stage that the conditions of Article 7(2a) of the basic Regulation were not met, and as a result, the provisions of Article 7(2) were applicable to set the level of the provisional duty.

8. **PROVISIONAL ANTI-DUMPING MEASURES**

(384) On the basis of the conclusions reached by the Commission on dumping, injury, causation, Union interest and the level of measures, provisional measures should be imposed to prevent further injury being caused to the Union industry by the dumped imports.

(385) Provisional anti-dumping measures should be imposed on imports of ACF products originating in the People's Republic of China, in accordance with the lesser duty rule in Article 7(2) of the basic Regulation following the provisional conclusion at recital (383) concerning the possible application of Article 7(2a) of the basic Regulation.

(386) The Commission compared the underselling margins and the dumping margins (recital (377) above). The amount of the duties was set at the level of the lower of the dumping and the underselling margins.

(387) On the basis of the above, the provisional anti-dumping duty rates, expressed on the CIF Union border price, customs duty unpaid, should be as follows:

Company	Provisional anti-dumping duty
Jiangsu Zhongji Lamination Materials Co., Ltd	29,1 %
Xiamen Xiashun Aluminium Foil Co., Ltd	16,0 %
Yantai Donghai Aluminum Foil Co., Ltd	25,2 %
Other cooperating companies	24,2 %
All other companies	29,1 %

(388) The individual company anti-dumping duty rates specified in this Regulation were established on the basis of the findings of this investigation. Therefore, they reflected the situation found during this investigation with respect to these companies. These duty rates are exclusively applicable to imports of the product concerned originating in the country concerned and produced by the named legal entities. Imports of product concerned produced by any other company not specifically mentioned in the operative part of this Regulation, including entities related to those specifically mentioned, should be subject to the duty rate applicable to 'all other companies'. They should not be subject to any of the individual anti-dumping duty rates.

(389) To minimise the risks of circumvention due to the difference in duty rates, special measures are needed to ensure the application of the individual anti-dumping duties. The companies with individual anti-dumping duties must present a valid commercial invoice to the customs authorities of the Member States. The invoice must conform to the requirements set out in Article 1(4) of this Regulation. Imports not accompanied by that invoice should be subject to the anti-dumping duty applicable to 'all other companies'.

(390) While presentation of this invoice is necessary for the customs authorities of the Member States to apply the individual rates of anti-dumping duty to imports, it is not the only element to be taken into account by the customs authorities. Indeed, even if presented with an invoice meeting all the requirements set out in Article 1(4) of this Regulation, the customs authorities of Member States must carry out their usual checks and may, like in all other cases, require additional documents (shipping documents, etc.) for the purpose of verifying the accuracy of the particulars contained in the declaration and ensure that the subsequent application of the lower rate of duty is justified, in compliance with customs law.

(391) Should the exports by one of the companies benefiting from lower individual duty rates increase significantly in volume after the imposition of the measures concerned, such an increase in volume could be considered as constituting in itself a change in the pattern of trade due to the imposition of measures within the meaning of Article 13(1) of the basic Regulation. In such circumstances and provided the conditions are met an anti-circumvention investigation may be initiated. This investigation may, inter alia, examine the need for the removal of individual duty rate(s) and the consequent imposition of a country-wide duty.

(392) To ensure a proper enforcement of the anti-dumping duties, the anti-dumping duty for all other companies should apply not only to the non-cooperating exporting producers in this investigation, but also to the producers which did not have exports to the Union during the investigation period.

9. **INFORMATION AT PROVISIONAL STAGE**

(393) In accordance with Article 19a of the basic Regulation, the Commission informed interested parties about the planned imposition of provisional duties. This information was also made available to the general public via DG TRADE's website. Interested parties were given three working days to provide comments on the accuracy of the calculations specifically disclosed to them.

(394) Following the pre-disclosure, comments were received from two exporting producers (Xiamen and Donghai) as well as from one user (Manreal). None of them related to clerical errors and were therefore not within the scope of the pre-disclosure.

10. **FINAL PROVISIONS**

(395) In the interests of sound administration, the Commission will invite the interested parties to submit written comments and/or to request a hearing with the Commission and/or the Hearing Officer in trade proceedings within a fixed deadline.

(396) The findings concerning the imposition of provisional duties are provisional and may be amended at the definitive stage of the investigation,

HAS ADOPTED THIS REGULATION:

Article 1

1. A provisional anti-dumping duty is imposed on imports of aluminium converter foil of a thickness of less than 0,021 mm, not backed, not further worked than rolled, in rolls of a weight exceeding 10 kg, currently falling under CN code ex 7607 11 19 (TARIC codes 7607 11 19 60 and 7607 11 19 91) and originating in People's Republic of China.

2. The following products shall be excluded from the product described in paragraph 1:

— Aluminium household foil of a thickness of not less than 0,008 mm and not more than 0,018 mm, not backed, not further worked than rolled, in rolls of a width not exceeding 650 mm and of a weight exceeding 10 kg.

— Aluminium household foil of a thickness of not less than 0,007 mm and less than 0,008 mm, regardless of the width of the rolls, whether or not annealed.

— Aluminium household foil of a thickness of not less than 0,008 mm and not more than 0,018 mm and in rolls of a width exceeding 650 mm, whether or not annealed.

— Aluminium household foil of a thickness of more than 0,018 mm and less than 0,021 mm, regardless of the width of the rolls, whether or not annealed.

3. The rates of the provisional anti-dumping duty applicable to the net, free-at-Union-frontier price, before duty, of the product described in paragraph 1 and produced by the companies listed below shall be as follows:

Company	Provisional anti-dumping duty (%)	TARIC additional code
Jiangsu Zhongji Lamination Materials Co., Ltd	29,1 %	C686
Xiamen Xiashun Aluminium Foil Co., Ltd	16,0 %	C687
Yantai Donghai Aluminum Foil Co., Ltd	25,2 %	C688
Other cooperating companies (Annex)	24,2 %	
All other companies	29,1 %	C999

4. The application of the individual duty rates specified for the companies mentioned in paragraph 3 shall be conditional upon presentation to the Member States' customs authorities of a valid commercial invoice, on which shall appear a declaration dated and signed by an official of the entity issuing such invoice, identified by his/her name and function, drafted as follows: *'I, the undersigned, certify that the (volume) of (product concerned) sold for export to the European Union covered by this invoice was manufactured by (company name and address) (TARIC additional code) in [country concerned]. I declare that the information provided in this invoice is complete and correct.'* If no such invoice is presented, the duty applicable to all other companies shall apply.

5. The release for free circulation in the Union of the product referred to in paragraph 1 shall be subject to the provision of a security deposit equivalent to the amount of the provisional duty.

6. Unless otherwise specified, the provisions in force concerning customs duties shall apply.

Article 2

1. Interested parties shall submit their written comments on this regulation to the Commission within 15 calendar days of the date of entry into force of this Regulation.

2. Interested parties wishing to request a hearing with the Commission shall do so within 5 calendar days of the date of entry into force of this Regulation.

3. Interested parties wishing to request a hearing with the Hearing Officer in trade proceedings are invited to do so within 5 calendar days of the date of entry into force of this Regulation. The Hearing Officer shall examine requests submitted outside this time limit and may decide whether to accept to such requests if appropriate.

Article 3

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

Article 1 shall apply for a period of six months.

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

Done at Brussels, 17 June 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Cooperating exporting producers not sampled

Country	Name	TARIC additional code
People's Republic of China	Zhangjiagang Fineness Aluminum Foil Co., Ltd	C689
People's Republic of China	Kunshan Aluminium Co., Ltd	C690
People's Republic of China	Suntown Technology Group Corporation Limited	C691
People's Republic of China	Luoyang Wanji Aluminium Processing Co., Ltd	C692
People's Republic of China	Shanghai Sunho Aluminum Foil Co., Ltd	C693
People's Republic of China	Binzhou Hongbo Aluminium Foil Technology Co. Ltd	C694

COMMISSION IMPLEMENTING REGULATION (EU) 2021/984

of 17 June 2021

amending Implementing Regulation (EU) 2020/466 as regards the period of application of temporary measures

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) ([1]), and in particular Article 141(1) thereof,

Whereas:

(1) Regulation (EU) 2017/625 lays down rules for, inter alia, the performance of official controls and of other official activities by the competent authorities of Member States. It also empowers the Commission to adopt, by means of an implementing act, appropriate temporary measures necessary to contain risks to human, animal and plant health and animal welfare, if it has evidence of a serious disruption in a Member State's control system.

(2) In order to address the specific circumstances due to the ongoing crisis related to coronavirus disease (COVID-19), Commission Implementing Regulation (EU) 2020/466 ([2]) allows Member States to apply temporary measures in relation to official controls and other official activities.

(3) Member States have informed the Commission that, in view of the crisis linked to COVID-19, certain serious disruptions in the functioning of their control systems, in particular due to difficulties to perform official controls and other official activities on official certificates and official attestations with respect to movements of animals and goods into the Union and within the Union, will persist beyond 1 July 2021.

(4) In order to address these serious disruptions, which are likely to persist in the coming months, and to facilitate the planning and the performance of official controls and other official activities during the crisis linked to COVID-19, the period of application of Implementing Regulation (EU) 2020/466 should be prolonged until 1 September 2021.

(5) Implementing Regulation (EU) 2020/466 should therefore be amended accordingly.

(6) 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

In Article 6, second paragraph, of Implementing Regulation (EU) 2020/466, the date '1 July 2021' is replaced by the date '1 September 2021'.

([1]) OJ L 95, 7.4.2017, p. 1.

([2]) Commission Implementing Regulation (EU) 2020/466 of 30 March 2020 on temporary measures to contain risks to human, animal and plant health and animal welfare during certain serious disruptions of Member States' control systems due to coronavirus disease (COVID-19) (OJ L 98, 31.3.2020, p. 30).

Article 2

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

It shall apply from 2 July 2021.

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

Done at Brussels, 17 June 2021.

For the Commission
The President
Ursula VON DER LEYEN

DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2021/985

of 3 June 2021

correcting the Spanish language version of Decision 2004/842/EC concerning implementing rules whereby Member States may authorise the placing on the market of seed belonging to varieties for which an application for entry in the national catalogue of varieties of agricultural plant species or vegetable species has been submitted

(notified under document C(2021) 3869)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 2002/55/EC of 13 June 2002 on the marketing of vegetable seed ([1]), and in particular Article 23(2) thereof,

Whereas:

(1) The Spanish language version of Commission Decision 2004/842/EC ([2]) contains an error in Article 31(1) as regards the renewal of authorisations concerning vegetable species.

(2) The Spanish language version of Decision 2004/842/EC should therefore be corrected accordingly. The other language versions are not affected.

(3) 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

(does not concern the English language)

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 3 June 2021.

For the Commission
Johannes HAHN
Member of the Commission

([1]) OJ L 193, 20.7.2002, p. 33.
([2]) Commission Decision 2004/842/EC of 1 December 2004 concerning implementing rules whereby Member States may authorise the placing on the market of seed belonging to varieties for which an application for entry in the national catalogue of varieties of agricultural plant species or vegetable species has been submitted (OJ L 362, 9.12.2004, p. 21).

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