Official Journal

L 147

of the European Union



English edition

Legislation

Volume 66

27

7 June 2023

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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.

⁽¹⁾ Text with EEA relevance.

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⁽¹⁾ Text with EEA relevance.

II

(Non-legislative acts)

INTERNATIONAL AGREEMENTS

Notification to the Joint Sectoral Committee by the European Union under Article 7 of the Sectoral Annex on Pharmaceutical Good Manufacturing Practices (GMPs) of the Agreement on Mutual Recognition between the European Community and the United States of America

THE EUROPEAN UNION,

Having regard to the Agreement on Mutual Recognition between the European Community and the United States of America done in 1998, and in particular Article 7 of the Sectoral Annex on Pharmaceutical Good Manufacturing Practices (GMPs Annex) as amended on 1 March 2017.

NOTIFIES THE JOINT SECTORAL COMMITTEE THAT:

The European Union has determined that, for the product scope indicated in Article 4 and Appendix 3 to the GMPs Annex, the Food and Drug Administration of the United States of America has the capability, capacity and procedures in place to carry out GMP inspections at a level equivalent to the EU and enforce compliance with GMP and therefore, shall be added to the list of recognised authorities for veterinary products under the GMPs Annex.

This determination is without prejudice to any future decisions of the Joint Sectoral Committee with respect to the inclusion of vaccines for human use, plasma derived pharmaceuticals and investigational products in the operational scope of the GMPs Annex.

This notification shall be effective from the date of its publication in the Official Journal of the European Union.

Signed in Brussels, on 30 May 2023.

For the European Union Stella KYRIAKIDES

REGULATIONS

COMMISSION REGULATION (EU) 2023/1101

of 6 June 2023

refusing to authorise a health claim made on foods and referring to children's development and health

(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 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods (1), and in particular Article 17(3) thereof,

Whereas:

- (1) Pursuant to Regulation (EC) No 1924/2006 health claims made on foods are prohibited unless they are authorised by the Commission in accordance with that Regulation and included in the Union list of permitted claims.
- (2) Regulation (EC) No 1924/2006 also provides that applications for authorisation of health claims may be submitted by food business operators to the national competent authority of a Member State. The national competent authority is to forward valid applications to the European Food Safety Authority ('the Authority').
- (3) Following the receipt of an application, the Authority is to inform without delay the other Member States and the Commission, and to deliver an opinion on the health claim concerned.
- (4) The Commission is to decide on the authorisation of the health claim taking into account the opinion delivered by the Authority.
- (5) Following an application from the Cyprus International Institute for Environmental and Public Health, Cyprus University of Technology, submitted pursuant to Article 14(1), point (b), of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on the scientific substantiation of a health claim related to organic foods and their contribution to the protection of body cells and molecules (lipids and DNA) from oxidative damage, and whose target population are healthy children 3 to 15 years old (Question No EFSA-Q-2021-00055). The claim proposed by the applicant was worded as follows: 'Organic food (lower levels of pesticide residues than those in conventional food) contributes to the protection of body cells and molecules (lipids and DNA) from oxidative damage'.
- (6) On 20 October 2021, the Commission and the Member States received the Authority's scientific opinion (²) on that claim. In that opinion, the Authority noted that the level of pesticide residues required to characterise foods as 'organic' has not been specified either in the application or in the human studies submitted for the substantiation of the health claim, and concluded that, on the basis of the data presented, the food/constituent 'organic foods', which is the subject of the health claim, is not sufficiently characterised and therefore a cause and effect relationship cannot be established between the consumption of organic foods and the protection of body cells and molecules (lipids and DNA) from oxidative damage. Accordingly, as the health claim does not comply with the requirements of Regulation (EC) No 1924/2006 for the inclusion in the Union list of permitted health claims, it should not be authorised.

⁽¹⁾ OJ L 404, 30.12.2006, p. 9.

⁽²⁾ EFSA Journal 2021;19(10):6847.

- (7) Upon the publication of that Opinion, the Commission did not receive any comments pursuant to Article 16(6) of Regulation (EC) No 1924/2006.
- (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 health claim set out in the Annex to this Regulation shall not be included in the Union list of permitted health claims as provided for in Article 14(1) of Regulation (EC) No 1924/2006.

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, 6 June 2023.

For the Commission The President Ursula VON DER LEYEN

ANNEX

Rejected health claim

Application – Relevant provisions of Regulation (EC) No 1924/2006	Nutrient, substance, food or food category	Claim	EFSA opinion reference
Article 14(1), point (b), health claim referring to children's development and health		Organic food (lower levels of pesticide residues than those in conventional food) contributes to the protection of body cells and molecules (lipids and DNA) from oxidative damage	

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1102

of 6 June 2023

imposing a definitive anti-dumping duty on imports of certain graphite electrode systems originating in India following an expiry review pursuant to Article 11(2) of Regulation (EU) 2016/1036 of the European Parliament and of the Council

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 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 (¹) ('the basic Regulation'), and in particular Article 11(2) thereof,

Whereas:

1. PROCEDURE

1.1. Previous investigations and measures in force

- (1) Following an anti-dumping investigation, the Council imposed a definitive anti-dumping duty on imports of certain graphite electrodes systems originating in India ('the original investigation') by Regulation (EC) No 1629/2004 ('). The Council, following an anti-subsidy investigation, by Regulation (EC) No 1628/2004 ('), also imposed definitive countervailing duties on imports of certain graphite electrodes systems originating in India.
- (2) Following an ex-officio partial interim review of the countervailing measures, the Council by Regulation (EC) No 1354/2008 (4) amended Regulation (EC) No 1628/2004 and Regulation (EC) No 1629/2004.
- (3) Further to an expiry review pursuant to Article 11(2) of the basic Regulation, the Council by Implementing Regulation (EU) No 1186/2010 (5) extended the anti-dumping measures. Further to an expiry review of the countervailing measures, the Council by Implementing Regulation (EU) No 1185/2010 (6) extended the countervailing measures.

⁽¹⁾ OJ L 176, 30.6.2016, p. 21.

^(*) Council Regulation (EC) No 1629/2004 of 13 September 2004 imposing a definitive anti-dumping duty and collecting definitively the provisional duty imposed on imports of certain graphite electrode systems originating in India (OJ L 295, 18.9.2004, p. 10).

⁽³⁾ Council Regulation (EC) No 1628/2004 of 13 September 2004 imposing a definitive countervailing duty and collecting definitively the provisional duty imposed on imports of certain graphite electrode systems originating in India (OJ L 295, 18.9.2004, p. 4).

⁽⁴⁾ Council Regulation (EC) No 1354/2008 of 18 December 2008 amending Regulation (EC) No 1628/2004 imposing a definitive countervailing duty on imports of certain graphite electrode systems originating in India and Regulation (EC) No 1629/2004 imposing a definitive anti-dumping duty on imports of certain graphite electrode systems originating in India (OJ L 350, 30.12.2008, p. 24).

⁽⁵⁾ Council Implementing Regulation (EU) No 1186/2010 of 13 December 2010 imposing a definitive anti-dumping duty on imports of certain graphite electrode systems originating in India following an expiry review pursuant to Article 11(2) of Regulation (EC) No 1225/2009 (OJ L 332, 16.12.2010, p. 17).

⁽⁶⁾ Council Implementing Regulation (EU) No 1185/2010 of 13 December 2010 imposing a definitive countervailing duty on imports of certain graphite electrode systems originating in India following an expiry review pursuant to Article 18 of Regulation (EC) No 597/2009(OJ L 332, 16.12.2010, p. 1).

- (4) Following the expiry review pursuant to Article 11(2) of the basic Regulation, the European Commission ('Commission') extended the anti-dumping measures by the Implementing Regulation (EU) 2017/422 ('). Following the expiry review of the countervailing measures, the Commission extended the countervailing measures by the Implementing Regulation (EU) 2017/421 (8).
- (5) The anti-dumping measures currently in force are 9,4 % and 0 % on imports from individually named exporters, and a duty rate of 8,5 % on imports from all other companies from India.

1.2. Request for an expiry review

- (6) Following the publication of a Notice of impending expiry (°), the Commission received a request for review pursuant to Article 11(2) of the basic Regulation.
- (7) The request for review was submitted on 9 December 2021 by the Union producers, representing around 90 % of the total Union production of certain graphite electrodes systems ('the applicants'). The request for review was based on the grounds that the expiry of the measures would be likely to result in continuation of dumping and recurrence of injury to the Union industry.

1.3. Initiation of an expiry review

(8) Having determined, after consulting the Committee established by Article 15(1) of the basic Regulation, that sufficient evidence existed for the initiation of an expiry review, the Commission, on 9 March 2022, by Notice published in the Official Journal of the European Union (10) ('the Notice of Initiation'), initiated an expiry review with regard to imports of certain graphite electrode systems originating in India ('the country concerned') on the basis of Article 11(2) of the basic Regulation.

1.4. Separate investigation concerning anti-subsidy measures imposed on imports of the product under review

(9) By a notice published in the Official Journal of the European Union on 9 March 2022 (11), the Commission also initiated an expiry review pursuant to Article 18 of Regulation (EU) 2016/1037 (12), of the definitive anti-subsidy measures in force with regard to imports into the Union of certain graphite electrode systems originating in India.

1.5. Review investigation period and period considered

(10) The investigation of a likelihood of continuation or recurrence of dumping covered the period from 1 January 2021 to 31 December 2021 ('the review investigation period' or 'RIP'). The examination of trends relevant for the assessment of a likelihood of continuation or recurrence of injury covered the period from 1 January 2018 to the end of the review investigation period ('the period considered').

- (7) Commission Implementing Regulation (EU) 2017/422 of 09 March 2017 imposing a definitive anti-dumping duty on imports of certain graphite electrode systems originating in India following an expiry review pursuant to Article 11(2) of Regulation (EU) 2016/1036 of the European Parliament and of the Council (OJ L 64, 10.3.2017, p. 46).
- (8) Commission Implementing Regulation (EU) 2017/421 of 09 March 2017 imposing a definitive countervailing duty on imports of certain graphite electrode systems originating in India following an expiry review pursuant to Article 18 of Regulation (EU) 2016/1037 of the European Parliament and of the Council (OJ L 64, 10.3.2017, p. 10).

(9) OJ C 226, 14.6.2021, p. 3.

- (10) Notice of initiation of an expiry review of the anti-dumping measures applicable to imports of certain graphite electrode systems originating in India, OJ C 113, 9.3.2022, p. 3.
- (11) Notice of initiation of an expiry review of the anti-subsidy measures applicable to imports of certain graphite electrode systems originating in India, OJ C 113, 9.3.2022, p. 13.
- (12) Regulation (EU) 2016/1037 of the European Parliament and of the Council of 8 June 2016 on protection against subsidized imports from countries not members of the European Union, OJ L 176, 30.6.2016, p. 55.

1.6. Interested parties

- (11) In the Notice of Initiation, the Commission invited interested parties to contact it in order to participate in the investigation. In addition, the Commission specifically informed the applicants, other known Union producers, the known exporting producers and the Indian authorities, known importers, suppliers and users, traders, as well as associations known to be concerned about the initiation of the investigation and invited them to participate.
- (12) 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.

1.7. Sampling

(13) In the Notice of Initiation, the Commission stated that it might sample the interested parties in accordance with Article 17 of the basic Regulation.

1.7.1. Sampling of Union producers

(14) In the Notice of Initiation, the Commission stated that it had provisionally selected a sample of Union producers. The Commission selected the sample on the basis of production and sales volumes of the like product in the Union. This sample consisted of three Union producers. The sampled Union producers accounted for around 61 % of the estimated total Union production and 64 % of the estimated sales volume of the like product in the Union. The Commission invited interested parties to comment on the provisional sample. The Commission received no comments. The sample is representative of the Union industry.

1.7.2. Sampling of importers

- (15) To decide whether sampling is necessary and, if so, to select a sample, the Commission asked unrelated importers to provide the information specified in the Notice of Initiation.
- (16) No importers came forward.
 - 1.7.3. Sampling of exporting producers in India
- (17) To decide whether sampling is necessary and, if so, to select a sample, the Commission asked all exporting producers in India to provide the information specified in the Notice of Initiation. The Commission has received in due time a sampling response from two graphite electrode systems producers in India: HEG Limited and Graphite India Limited, therefore, sampling was not necessary. The Commission decided to investigate the two exporting producers that provided the requested information.

1.8. Questionnaire replies and remote cross-checking

- (18) At the initiation the questionnaires were made available in the file for inspection by interested parties and on DG Trade's website (13).
- (19) Questionnaire replies were received from the three sampled Union producers. None of the exporting producers provided a questionnaire reply. None of the users provided a questionnaire or came forward during the investigation.
- (20) The Commission sought and verified all the information it deemed necessary for the determination of the likelihood of continuation or recurrence of dumping and resulting injury and for the determination of the Union interest. Verification visits pursuant to Article 16 of the basic Regulation were carried out at the premises of the following companies:

Union producers

— GrafTech Iberica S.L., Navarra, Spain

⁽¹³⁾ https://tron.trade.ec.europa.eu/investigations/case-view?caseId=2585.

- Showa Denko Carbon Spain S.A., A Coruna, Spain
- Tokai Erftcarbon GmbH, Grevenbroich, Germany

2. PRODUCT UNDER REVIEW AND LIKE PRODUCT

2.1. Product under review

(21) The product under review is graphite electrodes of a kind used for electric furnaces, with an apparent density of 1,65 g/cm3 or more and an electrical resistance of 6,0 μ . Ω .m or less, and nipples used for such electrodes, whether imported together or separately ('the product under review'), currently falling under CN codes ex 8545 11 00 and ex 8545 90 90 (TARIC codes 8545 11 00 10 and 8545 90 90 10) 'the product under review', or 'GES').

2.2. Like product

- (22) As established in the original investigation as well as in the previous expiry reviews, this expiry review investigation confirmed that the following products have the same basic physical, chemical and technical characteristics as well as the same basic uses:
 - the product under review;
 - the product produced and sold on the domestic market of the country concerned, and
 - the product produced and sold in the Union by the Union industry.
- (23) The Commission decided that those products are therefore like products within the meaning of Article 1(4) of the basic Regulation.

3. **DUMPING**

(24) In accordance with Article 11(2) of the basic Regulation, the Commission examined whether the expiry of the measure in force would be likely to lead to a continuation or recurrence of dumping from India.

3.1. Preliminary remarks

- (25) In accordance with Article 11(2) of the basic Regulation, it was examined whether the expiry of the existing measures would be likely to lead to a continuation or recurrence of dumping.
- (26) As mentioned above in recital (19), none of the exporting producers provided a questionnaire reply. Due to the lack of cooperation from the cooperating exporting producers, and in accordance with Article 18 of the basic Regulation, the Commission's analysis had to be made of facts available in accordance with Article 18 of the basic Regulation.
- (27) The Indian authorities were duly informed that due to the non-cooperation of the Indian exporting producers, the Commission may apply Article 18 of the basic Regulation. No comments were received in this respect.
- (28) The findings in Section 3 and 4 were thus based on facts available. For this purpose, the information provided in the request for expiry review and the statistics available in Eurostat and the Global Trade Atlas (14) ('GTA') databases as well as other publicly available sources were used.

3.2. Normal value

(29) On the basis of the above, the Commission constructed the normal value on an ex-works basis in accordance with Article 2 of the basic Regulation.

⁽¹⁴⁾ https://www.gtis.com/gta/

- (30) The normal value was based on the data provided by the applicants, from (i) Mordor Intelligence (15) and (ii) Valuates Reports (16). The two sources indicated a similar average domestic price of GES in India of 3 788 EUR per tonne at ex-works level in the review investigation period. This price was cross-checked and was in line with the estimates made, based on the publicly available price charts published by SteelMint.com (17) during the same period, indicating an average price of EUR 3 630 per tonne.
- (31) The Commission used the average price of the two sources provided by the applicants to establish a normal value at 3 788 EUR per tonne.

3.3. Export price

(32) In the absence of cooperation by the exporting producers from India, the export price was determined based on CIF prices in Eurostat data corrected to ex-works level. As seen in recital (44), the import volumes from India in the review investigation period were significant and thus the prices were considered as representative. The CIF price of 2 747 EUR per tonne (18) was adjusted for the sea freight and insurance cost, domestic transport costs in India and EU customs handling to arrive at 2 558 EUR per tonne at the ex-works level. The adjustments were based on OECD data (19) and information provided in the review request.

3.4. Comparison and dumping margin

(33) The Commission compared the normal value and the export price on an ex-work basis as established above.

3.5. Dumping margin

(34) On this basis, the weighted average dumping margins expressed as a percentage of the CIF Union frontier price, duty unpaid, was 44,7 % for India. It was therefore concluded that dumping continued during the review investigation period.

4. LIKELIHOOD OF CONTINUATION OF DUMPING

- (35) Further to the finding of the existence of dumping during the review investigation period, the Commission investigated, in accordance with Article 11(2) of the basic Regulation, the likelihood of continuation of dumping, should the measures be allowed to lapse.
- (36) The investigation showed that during the RIP Indian imports continued to enter the Union market at significantly dumped prices and maintained their quantities and market shares as in the last two review investigations. Furthermore, the analysis of production volume and spare capacity in India, export volumes and prices from India to the other third country markets, existing measures in the other third countries, and attractiveness of the Union market provided in recitals (107) (115) also shows that it is likely that the dumped exports would further increase their already substantial presence in the Union market should the current measures be allowed to lapse. Consequently, it is concluded that there is a likelihood of continuation of dumping should measures be allowed to lapse.
- (15) https://www.mordorintelligence.com/
- (16) https://reports.valuates.com/
- (12) A market data provider for steel producers and steel users: https://www.steelmint.com/intel/india-graphite-electrode-prices-inch-up-6-for-oct-dec-21-quarter-8571 and https://twitter.com/SteelMint/status/1400101045217357835, the publicly available information consists of charts providing monthly domestic sales prices for GES in India; however, the Commission could only estimate these prices and not precisely define them.
- (18) Import price without the customs and AD/AS duties. Source: Comext.
- (19) Dataset: International transport and insurance costs of merchandise trade OECD.

5. INJURY

5.1. Definition of the Union industry and Union production

- (37) The like product was manufactured by seven producers in the Union during the review investigation period. They constitute the 'Union industry' within the meaning of Article 4(1) of the basic Regulation.
- (38) The total Union production during the review investigation period was established at 219 330 tonnes. The Commission established the figure on the basis of the verified questionnaire replies of the sampled Union producers and the data provided by the non-sampled producers and the applicants (20). As indicated in recital (14) the three sampled Union producers represented more than 61 % of the total Union production of the like product.

5.2. Union consumption

- (39) The Commission established Union consumption on the basis of the sales volumes of the Union industry's own production destined for the Union market and the import volumes obtained from Eurostat statistics.
- (40) On this basis, Union consumption developed as follows:

Table 1
Union consumption (tonnes) (21)

	2018	2019	2020	Review investigation period
Total Union consumption	152 612	120 169	99 873	137 279
Index	100	79	65	90

Source: Eurostat, information provided by the sampled and non-sampled Union producers, information provided by the applicants.

- (41) The Union consumption of GES decreased by 10 % over the period considered. The year 2018 showed a high consumption driven by high demand of the EU steel industry, which was in the process of recovering from the steel crisis. In addition, in a situation of a sudden GES price increase, steelmakers were building up stocks of GES in the expectation of an additional increase.
- (42) In 2019, the production of steel from electric arc furnaces decreased, as compared to 2018 (by 6,6 % according to Eurofer figures). Consequently, the demand for GES dropped. As the price of GES went down significantly, building up stocks was no longer considered necessary for the downstream industry as users were not anymore concerned by a further price increase. As a consequence, steel producers started destocking their GES inventories. Moreover, demand dropped further but this time on a temporary basis in 2020, following the COVID-19 outbreak.

5.3. Imports from India

- 5.3.1. Volume and market share of the imports from India
- (43) As mentioned in recital (39), the Commission established the volume of imports from India on the basis of Eurostat statistics. The market share was established based on of the Union consumption as set out in recital (40).

⁽²⁰⁾ The production volume is based on EU-27 data as the United Kingdom ceased to be part of the European Union as from 1 February 2020 and the transition period for the United Kingdom's withdrawal ended on 31 December 2020.

⁽²¹⁾ The consumption is based on EU-27 data, excluding data related to the United Kingdom.

(44) Imports from India developed as follows:

Table 2

Import volume (tonnes) and market share

	2018	2019	2020	Review investigation period
Volume of imports from India (tonnes)	5 802	3 369	2 154	6 540
Index	100	58	37	113
Market share (%)	4	3	2	5
Index	100	74	57	125

Source: Eurostat and 14.6 database

- (45) Imports of the product under review from the country concerned had decreased in 2019 and 2020, following the decrease of EU consumption, and recovered during the review investigation period. Overall, during the period considered the volume of imports increased from 5 802 tonnes in 2018 to 6 540 tonnes in the review investigation period, i.e. by 13 %. Imports of GES from India represented around 16 % of total GES imports to the Union during the review investigation period corresponding to a market share of 5 %.
- (46) Overall, the imports from India and their market share increased over the period considered. Despite the Union consumption decrease, the volume of dumped imports from India kept increasing during the period considered (by 13 %), whereas the Union industry's sales decreased.
 - 5.3.2. Prices of the imports from India and price undercutting
- (47) The average price of imports from India developed as follows:

Import prices (EUR/tonne)

Table 3

	2018	2019	2020	Review investigation period
Import prices from India	13 756	10 211	4 1 2 0	2 747
Index	100	74	30	20

Source: Eurostat

- (48) The average import price (22) of GES from India went down by 80 % throughout the period considered, from 13 756 EUR/tonne in 2018 to 2 747 EUR/tonne in the review investigation period.
- (49) Due to the high global demand for GES, the Indian prices surpassed the Union industry prices in the first half of the period considered, but then dropped by 60 % between 2018 and 2020 and remained consistently lower than the Union prices in 2020 and in the review investigation period.
- (50) In view of the non-cooperation of the Indian exporting producers, the Commission determined the price undercutting in the review investigation period by comparing:
 - (1) the weighted average sales price of the Union producers charged to unrelated customers on the Union market, adjusted to an ex-works level; and

⁽²²⁾ Import price without the customs and AD/AS duties. Source: Eurostat.

- (2) the corresponding weighted average import prices of the product under review from India from Eurostat, established on a CIF basis, excluding the anti-dumping and countervailing duties, with appropriate adjustments for customs duties and post-importation costs. In the absence of any other information, these costs were estimated at 1 % of the CIF value.
- (51) This resulted in the average undercutting margin of 33,2 %. These prices were also considered as a reasonable indicator of future possible price levels should measures be repealed.
- (52) After disclosure the Government of India (GOI), argued that the undercutting margin calculated by the Commission is not representative as it is not based on actual market prices in the Union. In GOI's view the fact that sales sourced from GrafTech Iberica were made pursuant to long-term contracts ('LTAs') have resulted in an artificially high selling price which is not indicative of the market price of GES in the Union.
- (53) The Commission disagrees with this assessment. LTAs are not an uncommon commercial practice and a business decision in which a customer accepts to tie itself to a particular price level in exchange for a security of supply. Considering that LTAs were being used in dealings on the relevant market their presence in the sample does not render the sample not representative. Moreover, Only part of the sales made by GrafTech were covered by LTAs while the sales of the other two sampled Union producers in the review investigation period were not covered by similar LTAs. Therefore, in the Commission's view, whilst representative of a part of the market, overall the LTAs used by GrafTech Iberica did not significantly affected the undercutting calculation. Therefore, this claim was dismissed.
 - 5.3.3. Imports from third countries other than India
- (54) The imports of the product under review from other third countries were mainly from China, Mexico and Russia.
- (55) The volume of imports from other third countries, as well as the market share and price trends developed over the period considered as follows:

Table 4

Imports from third countries other than India

Country		2018	2019	2020	Review investigation period
PRC	Volume (tonnes)	22 054	19 284	20 074	26 065
	Index	100	87	91	118
	Market share (%)	14	16	20	19
	Index	100	111	139	131
	Average price	10 875	5 253	2 337	2 614
	Index	100	48	21	24
Russia	Volume (tonnes)	1 076	3 229	780	3 371
	Index	100	300	72	313
	Market share (%)	1	3	1	2
	Index	100	381	111	348

	Average price	9 623	5 771	4 898	2 851
	Index	100	60	51	30
Mexico	Volume (tonnes)	1 374	12	896	1 437
	Index	100	1	65	105
	Market share (%)	1	0	1	1
	Index	100	1	100	116
	Average price	2 5 3 0	3 264	3 976	3 435
	Index	100	129	157	136
Rest of the world	Volume (tonnes)	4 482	2 471	2 616	3 621
	Index	100	55	58	81
	Market share (%)	3	2	3	3
	Index	100	70	89	90
	Average price	8 253	10 648	5 7 3 7	3 979
	Index	100	129	70	48
Total third	Volume (tonnes)	28 987	24 996	24 366	34 494
countries except India	Index	100	86	84	119
	Market share (%)	19	21	24	25
	Index	100	110	128	132
	Average price	10 027	5 852	2 844	2 814
	Index	100	58	28	28

Source: Eurostat

- (56) The impact of imports from other third countries has been analysed since they represented around 84 % of total GES imports to the Union during the RIP. Despite the decreasing consumption, volume of imports from other third countries increased by 19 % from almost 29 000 tonnes in 2018 to around 35 000 tonnes in the RIP.
- (57) Imports from third countries followed partially the decrease in consumption in 2019 and 2020 yet rapidly recovered and reached the highest level in the RIP, with 19 % increase compared to 2018. The average price of imports from other third countries followed the global trend, decreasing by 72 % between 2018 and the RIP.
- (58) The large majority of these imports in the RIP, 76 %, were imports from China. The import volumes from the other third countries except China and India increased over the period considered by 22 %. Import volume of GES from India increased from 5 800 tonnes in 2018 to 6 500 tonnes during the RIP, while China increased from 22 054 tonnes in 2018 to 26 065 tonnes during the RIP, with a market share gain of 25 % and 31 %, respectively.
- (59) Over the same period import prices from China were lower than the prices of both the Indian exporters and the prices of the Union producers (except in 2018).

(60) Furthermore, as of 7 April 2022 (23) the Commission made the imports of GES from China subject to anti-dumping duty (ranging from 23 % to 74,9 %) (24).

5.4. Economic situation of the Union industry

5.4.1. General remarks

- (61) The assessment of the economic situation of the Union industry included an evaluation of all economic indicators having a bearing on the state of the Union industry during the period considered.
- (62) As mentioned in recital (14), sampling was used for the assessment of the economic situation of the Union industry.
- (63) For the injury determination, the Commission distinguished between macroeconomic and microeconomic injury indicators. The Commission evaluated the macroeconomic indicators based on data contained in the replies to the anti-dumping questionnaire by the sampled producers as well as macroeconomic data provided by the non-sampled producers and the applicants, crosschecked with the data in the review request. The data related to all Union producers. The Commission evaluated the microeconomic indicators based on 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.
- (64) 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.
- (65) The microeconomic indicators are: average unit prices, unit cost, labour costs, inventories, profitability, cash flow, investments, return on investments, and ability to raise capital.

5.4.2. Macroeconomic indicators

5.4.2.1. Production, production capacity and capacity utilisation

(66) The total Union production, production capacity and capacity utilisation developed over the period considered as follows:

Table 5

Production, production capacity and capacity utilisation

	2018	2019	2020	Review investigation period
Production volume (tonnes)	251 009	219 744	164 413	219 330
Index	100	88	66	87
Production capacity (tonnes)	283 500	294 900	294 900	285 235
Index	100	104	104	101
Capacity utilisation (%)	89	75	56	77
Index	100	84	63	87

Source: Information provided by the sampled and non-sampled Union producers, information provided by the applicants.

⁽²³⁾ Commission Implementing Regulation (EU) 2022/558 of 6 April 2022 imposing a definitive anti-dumping duty and definitively collecting the provisional duty imposed on imports of certain graphite electrode systems originating in the People's Republic of China (OJ L 108, 7.4.2022, p. 20).

⁽²⁴⁾ The scope of the Chinese regulation is slightly different than the scope of the present regulation, as it does not include nipples and it also includes graphite electrodes of a kind used for electric furnaces, with an apparent density of 1,5 g/cm³ or more but less than 1,65 g/cm³ and an electrical resistance of 6,0 μΩ.m or less, or with an apparent density of 1,5 g/cm³ or more and an electrical resistance of more than 6,0 μΩ.m but not more than 7,0 μΩ.m, (TARIC codes 8545 11 00 10 and 8545 11 00 15).

- (67) Following the decrease in consumption, the production volume of the Union industry dropped by 34 % between 2018 and 2020, and partially recovered in the RIP, remaining below the 2018 level. Overall, the production volume decreased by 13 % during the period considered.
- (68) The decrease of the production volume is due to the decrease in consumption coupled with the loss in sales quantity suffered by the Union industry, as explained below in recital (70).
 - 5.4.2.2. Sales volume and market share
- (69) The Union industry's sales volume and market share developed over the period considered as follows:

Table 6

Sales volume and market share

	2018	2019	2020	Review investigation period
Total sales volume on the Union market (tonnes)	117 824	91 804	73 352	96 245
Index	100	78	62	82
Market share (%)	77	76	73	70
Index	100	99	95	91

Source:Information provided by the applicants, information provided by the sampled and non-sampled Union producers.

- (70) Sales volume of the Union industry decreased by 18 % during the period considered. It decreased steadily up to 2020 (by 38 %) and recovered only partially during the review investigation period. However, this increase was not in line with the similar trend followed by the Union consumption which resulted overall in a loss of market share of the Union industry from 77 % in 2018 to 70 % in the review investigation period (minus 9 %), while the market share of the imports from India increased by 25 % during the same period.
- (71) During the period considered, the EU consumption of GES decreased by 10 %. This decrease of 15 000 tonnes in consumption hit only the Union industry, that lost 21 000 tonnes of sales. Over the same period the volume of dumped imports from India, China and other third countries kept increasing during the period considered, by 13 %, 18 % and 19 % respectively.

5.4.2.3. Growth

(72) As explained above, during the period considered, the sales volume of the Union industry lost 21 000 tonnes of sales while imports increased by more than 6 200 tonnes. This resulted in a 9 % market share loss for the Union industry over the period considered. Consequently, there was no growth for the Union industry during the period considered.

5.4.2.4. Employment and productivity

(73) Employment and productivity developed over the period considered as follows:

Table 7

Employment and productivity

	2018	2019	2020	Review investigation period
Number of employees (FTE)	1 165	1 148	1 102	1 143
Index	100	99	95	98

Productivity (unit/employee)	215	191	149	192
Index	100	89	69	89

Source: Information provided by the applicants, information provided by the sampled and non-sampled Union producers

- (74) The number of employees of the Union industry remained relatively stable over the period considered (decreased by 2 % over the period considered). Therefore, given the drop in production explained in section 5.4.2.1, the productivity of the Union industry's workforce, measured as output (tonnes) per employee, followed the same trend dropping by 11 % over the same period.
 - 5.4.2.5. Magnitude of the dumping margin and recovery from past dumping
- (75) The Commission concluded in recital (34) that dumping from India continued during the review investigation period. The Commission also concluded that there was a strong likelihood of continuation of dumping from India if the measures were allowed to lapse.
- (76) Despite the anti-dumping measures in force since 2009, the Union industry has lost substantial sales volume which is reflected in a loss of market share of 9 percentage points over the period considered. Thus, no full recovery from the past dumping could be established and the Union industry remains highly vulnerable to the injurious effects of any dumped imports in the Union market.
 - 5.4.3. Microeconomic indicators
 - 5.4.3.1. Prices and factors affecting prices
- (77) The weighted average unit sales prices of the sampled Union producers to unrelated customers in the Union developed over the period considered as follows:

Sales prices in the Union

Table 8

	2018	2019	2020	Review investigation period
Average unit sales price in the Union on the total market (EUR/tonne)	8 483	9 578	5 870	4 682
Index	100	113	69	55
Unit cost of production (EUR/tonne)	3 696	4 685	4 864	3 556
Index	100	127	132	96

Source: Questionnaire replies of the sampled Union producers

- (78) The sales prices increased between 2018 and 2019 by 13 % before decreasing steeply in 2020 and in the review investigation period to the level by 45 % lower than in 2018.
- (79) Cost of production increased, reached its highest point in 2020 and started decreasing during the review investigation period. This trend is due to the substantial increase of the price of the main raw material, that is needle coke. The price of needle coke, due to the increased demand driven by the lithium-ion battery industry, increased steadily and significantly up to 2019 and only as of 2020 it started decreasing.

- (80) Considering the sales prices of the Union industry, the Commission noted that a part of the Union production (in particular produced by GrafTech Iberica and GrafTech France) representing around 50 % of the total Union sales and production, was to some extent temporarily shielded from direct market competition, whereas the other part (the other two sampled Union producers) was directly exposed to the dumped Indian imports.
- (81) This situation was due to the existence of LTAs covering sales of GES sourced from GrafTech Iberica. These LTAs were concluded in the wake of a period of unusually high prices in the years 2017–2018. These contracts are 'take or pay' purchase contracts with a guaranteed level of supplies at set prices and the buyer committed to buy the agreed volumes at the pre-determined and fixed price, subject to various contractual rights and obligations. The duration of these contracts was three to five years. It appeared that a very large portion of sales sourced from GrafTech Iberica during the review investigation period were made under these LTAs. The investigation did not reveal that any other Union producer would covered by similar LTAs in the period considered. In view of the LTAs' limited duration, the Commission noted that the impact of the contracts is of a temporary nature.
- (82) The origin of these LTAs is to be found in the period of high price volatility in the years 2017-2018 that stretched up to 2019. In these years, globally prices of graphite electrodes increased significantly. This was due to many factors, including increased global demand. The key reason for the rise in demand cited by the Union industry was to be the global shift in the steel industry, from blast furnaces to the electric arc furnaces, which use graphite electrodes. In addition, as explained in recital (79), the new competition for needle coke (the main raw material used in the production of graphite electrodes) with the lithium-ion battery industry drove an increase of raw material cost that contributed to the price volatility. To address this issue of price volatility, the LTAs for the supply of the product under review sourced from GrafTech Iberica were negotiated with a duration between three to five years. The principle was to obtain more stable prices in exchange for a stable supply as requested by clients.
- (83) Therefore, thanks to the existing LTAs, sales of GrafTech Iberica could be made at a stable price level ([25–50] % above the average unit sales price in the Union) during the review investigation period despite the general fall in prices from which the remainder of the Union industry was not covered by LTAs. Based on the information available, such as sales volumes of the product under review not subject to LTAs and sourced from GrafTech Iberica as well as the sales of the other two sampled Union producers, the Commission estimated that the average price on the market not covered by the terms of the LTAs was around [25–50] % lower than the average unit sales price in the Union on the total market. Accordingly, the average Union sales price during the review investigation period does not accurately reflect the competitive price situation on the Union market, which was significantly affected by low-priced and dumped imports from both India and China.

5.4.3.2. Labour costs

(84) The average labour costs of the sampled Union producers developed over the period considered as follows:

Average labour costs per employee

Table 9

	2018	2019	2020	Review investigation period
Average labour costs per employee (EUR)	91 856	87 714	84 993	87 519
Index	100	95	93	95

Source: Questionnaire replies of the sampled Union producers

(85) The average labour cost slightly decreased over the period considered. Overall, the average labour cost per employee decreased by 5 %. This trend was mostly influenced by the limited reduction in employment figures as explained in recital (74).

5.4.3.3. Inventories

(86) Stock levels of the sampled Union producers developed over the period considered as follows:

Table 10

Inventories

	2018	2019	2020	Review investigation period
Closing stocks (tonnes)	7 026	9 447	8 172	8 812
Index	100	134	116	125
Closing stocks as a percentage of production (%)	3	4	5	4
Index	100	154	178	144

Source: Questionnaire replies of the sampled Union producers

- (87) Inventories cannot be considered as a relevant injury indicator in this sector, as production and sales are mainly based on orders and, accordingly, producers tend to hold limited stocks. Therefore, the trends on inventories are given for information only.
- (88) Overall, inventories were influenced by the decreasing trends of production and sales of the Union industry. Closing stocks as a percentage of production increased significantly in 2019 and 2020 (by 54 % and 78 % respectively) partially decreasing during the review investigation period. Overall, during the period considered closing stocks in tonnes increased by 25 %.
- (89) However, when looking at the data of the two Union producers that did not conclude LTAs. Over the same period their stocks increased by [35 45] %.
 - 5.4.3.4. Profitability, cash flow, investments, return on investments and ability to raise capital
- (90) Profitability, cash flow, investments and return on investments of the sampled Union producers developed over the period considered as follows:

Table 11

Profitability, cash flow, investments and return on investments

	2018	2019	2020	Review investigation period
Profitability of sales in the Union to unrelated customers (% of sales turnover)	75	62	2	31
Index	100	82	2	42
Cash flow (EUR)	659 909 270	475 537 375	120 592 009	210 732 326
Index	100	72	18	32
Investments (EUR)	23 523 042	28 065 231	21 574 327	29 396 885
Index	100	119	92	125

Return on investments (%)	722	467	35	154
Index	100	65	5	21

Source: Questionnaire replies of the sampled Union producers

- (91) 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.
- (92) After the previous expiry review investigation mentioned in recital (1), where the anti-dumping measures were imposed, the situation of the Union industry improved and its profit margin, due to the increase in prices mentioned above in section 5.4.3.1, reached 75 % in 2018. However, the situation deteriorated subsequently and profit margins declined as from 2018 reaching its bottom point in 2020 (2 %) and partially recovering in the review investigation period (31 %), corresponding to a decrease of 58 % over the period considered.
- (93) The cause for this decreasing trend is the significant reduction in Union consumption and in sales volume suffered by the Union industry at the advantage of the dumped Indian and Chinese imports that exerted significant price pressure entering into the Union undercutting those of the Union industry and forcing the part of the Union industry not covered by the LTAs to reduce their prices levels, as explained above in recital (83).
- (94) As mentioned above, one of the sampled Union producers, Graftech Iberica, sold the majority of its volume under LTAs. Therefore, products were sold at stable prices and, during the RIP (until expiry of the LTAs; a significant part expired by the end of 2021, another part by the end of 2022), these sales were still considered partially shielded from external factors such as the general price decrease.
- (95) However, the situation is different for the other two sampled Union producers. Excluding GrafTech Iberica the micro-indicators show a different picture, with profitability of sales in the Union dropping from [+70 +80] % in 2018 to [0 +10] % in the review investigation period.
- (96) The net cash flow is the Union industry's ability to self-finance their activities. Given the decreasing trend of Union industry's profit the cash flow dropped by 68 % over the period considered.
- (97) Investments, thanks to a still positive cash flow, increased by 25 % in the period considered, which is mainly due to the efforts made by the Union industry to rationalize its production and increase efficiency and productivity to face the increasing low-priced imports. However, in the same period, the return on investments, which is expressed as the profit in percentage of the net book value of investments dropped by 79 % and therefore followed the same trend as the profitability.
- (98) A picture similar to the one explained above can be observed when looking at the data of the two Union producers that did not sell under LTAs during the review investigation period. Over the same period return on investment and cash flow dropped to [0 + 10]%.
- (99) The decreasing profitability and return on investment will made it increasingly difficult for the sampled Union producers to raise capital for future investment. With return on investments falling so quickly, the sampled producers' ability to raise capital in the future is in greater jeopardy.

5.4.4. Conclusion on injury

(100) The investigation showed that the measures allowed the Union industry to maintain, at least partially, a significant market shares throughout the period considered. Most of injury indicators showed that the economic situation of the Union industry was difficult. As explained above, these negative developments are explained by the decrease in consumption coupled with the consequence of the COVID-19 outbreak and dumped imports from China and India which during the same period gained market share to the detriment of Union industry whose market share decreased. The situation was further aggravated by the sharp increase of the dumped imports from China and India. The Union industry has responded to these challenges by decreasing its prices and reducing profit, which, nevertheless, remained positive during the period considered.

- (101) In particular, production, sales volumes and market shares decreased, as well as sales prices which had a negative effect on productivity as well as on profitability. The increased price pressure from the dumped imports coming from India and China forced the Union industry to reduce its sales prices with negative effects on its profitability which decreased substantially over the period considered. Finally, the rapidly decreasing returns on investments has a negative impact on the Union industry's ability to raise capital and investments.
- (102) On the other hand, despite the declining trends, the Union industry still managed to maintain large sales volume and considerable market share. Likewise, despite the negative trend, profitability remained positive throughout the period considered. Therefore, the Commission concluded that the Union industry was subject to some negative trends over the period considered which resulted in an overall vulnerable situation in 2021 but did not suffer material injury within the meaning of Article 3(5) of the basic Regulation during the review investigation period.
- (103) After disclosure, the GOI claimed that the increased prices of raw materials, following the military aggression by the Russian Federation against Ukraine, is one of the main factors for the reduced profitability of the Union industry.
- (104) This claim is not supported by any evidence. The military aggression and the underlying geopolitical situation developed after the review investigation period, as of February 2022, and therefore had no influence on the situation of the Union industry over the period considered. Therefore, this claim was deemed as unfounded.

6. LIKELIHOOD OF RECURRENCE OF INJURY

- (105) The Commission concluded in recital (102) that the Union industry did not suffer material injury during the review investigation period. Therefore, the Commission assessed, in accordance with Article 11(2) of the basic Regulation, whether there would be a likelihood of recurrence of injury originally caused by the dumped imports from India if the measures were allowed to lapse.
- (106) In order to establish whether there is likelihood of recurrence of injury originally caused by the dumped imports from India, the Commission considered the following elements: (i) production volume and spare capacity in India, (ii) export volumes and prices from India to the other third country markets, (iii) existing measures in the other third countries, (iv) attractiveness of the Union market, and, (v) likely price levels of imports from India and their impact on the Union industry's situation, should the measures allowed to lapse.

6.1. Production capacity and spare capacity

- (107) Based on the information provided in the request for expiry review (25), the total Indian production capacity of GES was estimated at around 160 000 tonnes, the production at around 121 000 tonnes and the spare capacity at around 39 000 tonnes in the review investigation period. The estimated spare capacity represented around 29 % of the Union consumption during the review investigation period.
- (108) In addition, the information provided in the request (26) indicated that one Indian producer is expected to continue to increase its capacity by additional 20 000 tonnes by early 2023, increasing the spare capacity to 59 000 tonnes (43 % of the Union consumption during the review investigation period). Therefore, the capacity to significantly increase export quantities to the Union exists, in particular because there are no indications that third country markets or the domestic market could absorb any additional production.

6.2. Export volumes and prices from India to the other third country markets

(109) In the absence of cooperation and consequently of any other more reliable source for establishing the Indian exports of GES from India to the other third countries except the Union, the analysis was based on the GTA data of HS code 8545 11. This HS code covered around 82 % of the Indian exports to the Union (compared to Eurostat TARIC data), while almost no imports into the Union from India were made under HS code 8545 90. The GTA data for HS 8545 11 was therefore considered the most reliable source for third country market analysis.

⁽²⁵⁾ Publicly available annual report of HEG in 2021 and GIL Corporate Presentation of 2021.

⁽²⁶⁾ HEG, Annual Report 2021, p. 2, 11.

- (110) Both GIL and HEG were, the two known producers of GES in India, found to be highly export oriented, exporting above 60 % of their production in 2021. Turkey, the United States, the Union and Egypt were its their main export markets. Overall, worldwide export volumes from India decreased by 14 % from 2018 to the RIP, while it increased by 16 % to the top three export markets (Turkey, United States and Egypt).
- (111) The export prices analysis to India's top ten export countries during the RIP indicated that the export price to the Union at FOB Indian border level (2 727 EUR/tonne) was higher than to Egypt, South Korea, South Africa, Mexico and United Arab Emirates, while lower than to Turkey, United States, Saudi Arabia and Indonesia. However, given the export restrictions the Indian industry is facing, as explained below in section 6.3, and taking into account the current Indian spare capacity, it was considered that,, Indian exporters would have an incentive to shift significant quantities of exports from third countries to the more attractive Union market should measures be allowed to lapse.

6.3. Existing measures in the other third countries

- (112) Following the US sanctions against Iran in August 2018, India lost its largest export destination for GES (²⁷). Before the sanctions, Iran was among the top three export destinations of GES for India with export volumes of around 9 000 tonnes/year. In 2019, following the sanctions, export volumes from India to Iran decreased to nearly zero tonnes and remained so in the following years.
- (113) In addition, the Eurasian Economic Commission extended the anti-dumping measures on imports of GES from India until September 2023 at the rate of 16,04 % for HEG and 32,83 % for GIL and other Indian manufactures. The Russian Federation, one of the members of the Eurasian Economic Union, was an important consumer of GES with its annual electric arc furnaces steelmaking of 24 million tonnes in 2019. India's GES exports to Russia decreased from around 840 tonnes in 2018 to zero tonnes in 2020 and 2021. Therefore, with the already available spare capacity this will restrict the potentially available export markets for the Indian producers, increasing even further the attractiveness of the Union market, should the measures allowed to lapse.

6.4. Attractiveness of the Union market

- (114) The attractiveness of the Union market was demonstrated by the fact that despite the anti-dumping and countervailing duties in force, Indian GES continued to enter the Union market. During the period considered, India continued to be the second largest exporting country to the Union after China. Despite a decrease between 2019 and 2020 due to the COVID-19 pandemic, India maintained and increased its exports to the Union, between 5 800 tonnes in 2018 and to 6 500 tonnes in the review investigation period, and market shares, between 4 % in 2018 and 5 % in the review investigation period. This is in the same range of the export volumes and market shares observed in the Union during the review investigation period of the two previous expiry reviews. As provided in the recital (51), the Indian export price to the Union was significantly undercutting the prices on the Union market during the review investigation period.
- (115) In addition, according to the public statements of HEG, the producer considers the Union an important export market to increase their presence if the anti-dumping/subsidy measures are lifted (28).

6.5. Likely price levels of imports from India and their impact on the Union industry's situation should the measures lapse

(116) To assess the impact of future imports on the situation of the Union industry, the Commission considered that price levels of the Indian exports without the anti-dumping duties would be a reasonable indicator of future price levels to the Union market. On this basis, as set out in (51), the average undercutting margin for the product under review was found to be 33,2 %, therefore is considered the best indicator of the likely price levels in the absence of anti-dumping measures.

⁽²⁷⁾ Non-US companies can no longer use US dollars for transactions with Iran. Moreover, if sanctioned for violating the US sanctions it may result for foreign companies not being permitted to open new US bank accounts and facing restrictions on loans, licences and Ex-Im credit.

⁽²⁸⁾ Publicly available HEG, Conference Call Transcript 2021 provided by the applicants. https://hegltd.com/wp-content/uploads/2021/06/ConferenceCallTranscript08062021.pdf;

- (117) Given its intense use and rapid replacement, users of the product under review tend to maintain substantial stocks as for commodities. Therefore, the product under review is price sensitive. A surge in imports at low prices would force the Union industry to further reduce their prices as it has already been done to compete with the imports from India and China, as explained above in section 5.4.3.1.
- (118) In addition, as of April 2022 imports of certain GES from China are subject to the anti-dumping duty mentioned in recital (58). The scope of the product concerned by these duties covers, to a large extent, the scope of the product concerned by the present investigation, namely TARIC code 8545 11 00 10. It is therefore expected that the Chinese market share will decrease (from 20 %, in the review investigation period). This will further increase the attractiveness of the Union market for the dumped/subsidised imports from India. With the current or even likely increased spare capacity mentioned above in recital (108), and without the competition of the Chinese exporting producers, there is a strong likelihood that Indian exporting producers will significantly increase their imports of the product under review to the Union market should measures be allowed to lapse.
- (119) Moreover, as explained above in recitals (81) to (83) the global situation of the Union industry is affected by the particular situation of GrafTech Iberica that is temporary. The LTAs came to an end (to a large extent the large majority of the LTAs in force already expired in 2022) Some of the existing LTAs sourced from GrafTech Iberica were extended for one or two years beyond 2022. However, the extended LTAs covered only a minor part of total sales sourced from GrafTech Iberica. Even including the extended LTAs, the vast majority of the sales volume sourced from GrafTech Iberica will, at the end of 2023 no longer be covered by the current LTAs. This proportion will further increase at the end of 2024. Moreover, the Commission noted that the average sales prices for products sourced from GrafTech Iberica for the IP declined compared to 2020 (even including the sales under the LTAs), which indicated that sales sourced from GrafTech Iberica were impacted by the imports of graphite electrodes from India and China at low prices. Therefore, by the end of 2023 at the latest, Graftech Iberica will be in the same situation as the other producers and will be fully exposed to the impact of increasing volumes of dumped imports from India. This means that the economic situation of the Union industry would further deteriorate should measures be allowed to lapse.
- (120) With a loss of profitability, the Union industry would not be able to carry out necessary investments. Ultimately, this would also lead to an employment loss and risk of production lines closures.
- (121) After disclosure the GOI argued that there is no likelihood of recurrence of injury in the present case, primarily because the market share of the imports from India into the Union is merely 5 % and that any injury to the Union industry is on account of imports from China and not imports from India. Furthermore, the GOI argued that the low import prices from India is a reaction to the low-priced imports from China.
- (122) When establishing whether there is a likelihood of recurrence of injury originally caused by the dumped imports from India, as explained in recital (106), the Commission considered several elements such as production volume and spare capacity in India, export volumes and prices from India to the other third country markets, existing measures in the other third countries, attractiveness of the Union market, and likely price levels of imports from India and their impact on the Union industry's situation, should the measures be allowed to lapse. In its comments GOI did not question the Commission's analysis or conclusion on any of these elements other than the one addressed in recital (125). Contrary to what the GOI suggested in its comments, the Commission did not base its finding with regards to the likelihood of recurrence of injury on the market share of imports of the GES from India to the Union observed during the review investigation period.
- (123) The claim was therefore dismissed.
- (124) Furthermore, the GOI claimed that the Union market is not a price attractive market for the Indian exporting producers as its export prices to the Union are lower that the export price of GES to other third countries.
- (125) The Commission acknowledged, in recital (111) above that Indian export prices to some third countries are above the export prices to the Union. Nevertheless, prices to some other export markets, that are important to the Indian exporting producers, are lower than the prices to the Union. Moreover, as explained in sections 6.1 to 6.5 above, the Indian exports gained market share in the Union over the period considered. Therefore, for the reasons set out above, the Commission concluded that this claim was unfounded.

6.6. Conclusion

(126) In view of the above, the Commission concluded that the expiry of the measures would in all likelihood result in a significant increase of dumped imports from India at prices undercutting the Union industry prices, and therefore would aggravate the economic situation of the Union industry. It is highly likely that this would lead to a recurrence of material injury and as a consequence, the viability of the Union industry would be at serious risk.

7. UNION INTEREST

- (127) In accordance with Article 21 of the basic Regulation, the Commission examined whether maintaining the existing anti-dumping measures would be against the interest of the Union as whole. The determination of the Union interest was based on an appreciation of all the various interests involved, including those of the Union industry, importers, distributors and users.
- (128) All interested parties were given the opportunity to make their views known pursuant to Article 21(2) of the basic Regulation.

7.1. Interest of the Union industry

- (129) The Union industry is composed of five groups producing graphite electrodes in the Union. All groups cooperated fully in the investigation. As mentioned in recital (14), the Commission selected a sample of Union producers. The sample consisted of 3 Union producers that provided a reply to the questionnaire. The sample was considered representative for the Union industry.
- (130) As set out above, the Union industry did not suffer material injury during the period considered but it is in a fragile situation, as confirmed by the negative trends of the injury indicators. Removing the anti-dumping duties would lead to a likely recurrence of material injury which would be translated in a loss of sales and production volume, as well as market share leading to a loss of profitability and employment.
- (131) On the other hand, the Union industry has proven to be a viable industry. After the last expiry review it managed to improve its situation in the fair conditions on the Union market, invest and operating at a profit above the target profit established in the original investigation. The continuation of the measures would prevent the low priced imports from India to flood the Union market and therefore would allow the Union industry to maintain sustainable prices and profitability levels necessary for future investments.
- (132) On this basis, the Commission thus concluded that the maintenance of the anti-dumping measures is in the interest of the Union industry.

7.2. Interest of unrelated importers, traders, and users

- (133) The Commission contacted all known unrelated importers, traders, and users. No interested party came forward.
- (134) Given the non-cooperation of any importers, traders or users, no information was available on the impact of the duties on these parties. The original investigation revealed, however, that any impact on other interested parties was not as such that measures had to be considered to be against the Union interest and likewise, the previous expiry review investigation established that the maintenance of the measures would not have a significant negative impact on the situation these parties.
- (135) On the basis of the above, the Commission concluded that the maintenance of the anti-dumping measures in force would not have any significant adverse effects on importers, traders or users.

- (136) After disclosure the GOI claimed that the maintenance of the anti-dumping measures in force is not in the interest of the Union. The GOI argued that the fact that sales sourced from GrafTech Iberica were made pursuant to LTAs resulted in an artificially and anti-competitive high selling price which is not indicative of the market price of GES in the Union. The consequences of these artificially high-priced sales would be faced by the downstream users in the Union.
- (137) As explained above in recital (53) LTAs are a not uncommon freely entered into commercial practice in which both parties agrees on the terms as they assume they will be beneficial. Therefore, in the Commission's view the LTAs and the resulting prices cannot be deemed as anti-competitive. Moreover, as explained in recital (119) by the end of 2023 the majority of the LTAs signed by GrafTech Iberica will come to an end and GrafTech Iberica will be in the same situation as the other producers and will be fully exposed to the impact of increasing volumes of dumped imports from India.
- (138) Therefore, this claim was dismissed.
- (139) Furthermore, the GOI argued that the continuation of duties would not be in interest of the Union as the impact of such duties will be passed down to the customers.
- (140) This argument was deemed as unfounded. The interest of the users was assessed, by the Commission, in recitals (134) and (135) and it was concluded that the maintenance of the anti-dumping measures in force would not have any significant adverse effects on the users.

7.3. Conclusion on Union interest

(141) On the basis of the above, the Commission concluded that there were no compelling reasons of the Union interest against the maintenance of the existing measures on imports of the product under review originating in India.

8. ANTI-DUMPING MEASURES

- (142) Based on the conclusions reached by the Commission concerning the continuation of dumping from India, the likelihood of recurrence of injury caused by dumped imports from India, and the Union interest, the Commission finds that the anti-dumping measures on imports of certain graphite electrode systems originating in India should be maintained.
- (143) 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(3) of this regulation. Imports not accompanied by that invoice should be subject to the anti-dumping duty applicable to 'all other companies'.
- (144) 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(3) 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.
- (145) 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 anticircumvention 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.

- (146) The individual company anti-dumping duty rates specified in this Regulation are exclusively applicable to imports of the product under review originating in India and produced by the named legal entities. Imports of the product under review 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.
- (147) A company may request the application of these individual anti-dumping duty rates if it changes subsequently the name of its entity. The request must be addressed to the Commission (29). The request must contain all the relevant information enabling to demonstrate that the change does not affect the right of the company to benefit from the duty rate which applies to it. If the change of name of the company does not affect its right to benefit from the duty rate which applies to it, a regulation about the change of name will be published in the Official Journal of the European Union.
- (148) All interested parties were informed of the essential facts and considerations on the basis of which it was intended to recommend that the existing measures be maintained. They were also granted a period to make representations subsequent to this disclosure. No comments were received.
- (149) In view of Article 109 of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council (30), when an amount is to be reimbursed following a judgment of the Court of Justice of the European Union, the interest to be paid should be the rate applied by the European Central Bank to its principal refinancing operations, as published in the C series of the Official Journal of the European Union on the first calendar day of each month.
- (150) The measures provided for in this regulation are in accordance with the opinion of the Committee established by Article 15(1) of Regulation (EU) 2016/1036.

HAS ADOPTED THIS REGULATION:

Article 1

- 1. A definitive anti-dumping duty is hereby imposed on imports of graphite electrodes of a kind used for electric furnaces, with an apparent density of 1,65 g/cm3 or more and an electrical resistance of 6,0 μ . Ω .m or less, and nipples used for such electrodes, whether imported together or separately, currently falling under CN codes ex 8545 11 00 and ex 8545 90 90 (TARIC codes 8545 11 00 10 and 8545 90 90 10) and originating in India.
- 2. The rates of the definitive 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	Anti-dumping duty	TARIC additional code
Graphite India Limited (GIL), 31 Chowringhee Road, Kolkatta – 700016, West Bengal	9,4	A530
HEG Limited, Bhilwara Towers, A-12, Sector-1, Noida – 201301, Uttar Pradesh	0	A531
All other companies	8,5	A999

⁽²⁹⁾ European Commission, Directorate-General for Trade, Directorate G, Rue de la Loi 170, 1040 Brussels, Belgium.

⁽²⁰⁾ Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 (OJ L 193, 30.7.2018, p. 1).

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- 3. The application of the individual duty rates specified for the companies mentioned in paragraph 2 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 India. 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.
- 4. Unless otherwise specified, the provisions in force concerning customs duties shall apply.

Article 2

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

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

Done at Brussels, 6 June 2023.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1103

of 6 June 2023

imposing a definitive countervailing duty on imports of certain graphite electrode systems originating in India following an expiry review pursuant to Article 18 of Regulation (EU) 2016/1037 of the European Parliament and of the Council

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2016/1037 of the European Parliament and of the Council of 8 June 2016 on protection against subsidised imports from countries not members of the European Union (¹) ('the basic Regulation'), and in particular Article 18 thereof,

Whereas:

1. PROCEDURE

1.1. Previous investigations and measures in force

- (1) Following an anti-subsidy investigation, by Regulation (EC) No 1628/2004 (²), the Council imposed definitive countervailing duties on imports of certain graphite electrodes systems originating in India. The Council, following an anti-dumping investigation with Regulation (EC) No 1629/2004 (³), also imposed a definitive anti-dumping duty on imports of certain graphite electrodes systems originating in India ('the original investigation')
- (2) Following an *ex officio* partial interim review of the countervailing measures, the Council by Regulation (EC) No 1354/2008 (4) amended Regulations (EC) No 1628/2004 and (EC) No 1629/2004.
- (3) Further to an expiry review of the countervailing measures, the Council by Implementing Regulation (EU) No 1185/2010 (3) extended the countervailing measures.
- (4) Further to an expiry review of the countervailing measures, the European Commission ('the Commission') with Implementing Regulation (EU) 2017/421 (') extended the countervailing measures.
- (5) The countervailing measures took the form of an *ad valorem* duty rate of 6,3 % and 7,0 % for imports from individually named exporters, and a duty rate of 7,2 % on imports from all other companies in India.

⁽¹⁾ OJ L 176, 30.6.2016, p. 55.

^(*) Council Regulation (EC) No 1628/2004 of 13 September 2004 imposing a definitive countervailing duty and collecting definitively the provisional duty imposed on imports of certain graphite electrode systems originating in India (OJ L 295, 18.9.2004, p. 4).

⁽³⁾ Council Regulation (EC) No 1629/2004 of 13 September 2004 imposing a definitive anti-dumping duty and collecting definitively the provisional duty imposed on imports of certain graphite electrode systems originating in India (OJ L 295, 18.9.2004, p. 10).

^(*) Council Regulation (EC) No 1354/2008 of 18 December 2008 amending Regulation (EC) No 1628/2004 imposing a definitive countervailing duty on imports of certain graphite electrode systems originating in India and Regulation (EC) No 1629/2004 imposing a definitive anti-dumping duty on imports of certain graphite electrode systems originating in India (OJ L 350, 30.12.2008, p. 24).

⁽⁵⁾ Council Implementing Regulation (EU) No 1185/2010 of 13 December 2010 imposing a definitive countervailing duty on imports of certain graphite electrode systems originating in India following an expiry review pursuant to Article 18 of Regulation (EC) No 597/2009(OJ L 332, 16.12.2010, p. 1).

^(°) Commission Implementing Regulation (EU) 2017/421 of 9 March 2017 imposing a definitive countervailing duty on imports of certain graphite electrode systems originating in India following an expiry review pursuant to Article 18 of Regulation (EU) 2016/1037 of the European Parliament and of the Council (OJ L 64, 10.3.2017, p. 10).

1.2. Request for an expiry review

- (6) Following the publication of a Notice of impending expiry (7), the Commission received a request for a review pursuant to Article 18 of the basic Regulation.
- (7) The request for review was submitted on 9 December 2021 by Union producers, representing around 90 % of the total Union production of certain graphite electrodes systems ('the applicants'). The request for review was based on the grounds that the expiry of the measures would be likely to result in continuation of subsidisation and or recurrence of injury to the Union industry. Some of the alleged subsidy practices were already countervailed in the original investigation while some others are additional or new subsidies, which were not examined in the original investigation. In view of Article 18(2) of the basic Regulation, the Commission prepared a memorandum on sufficiency of evidence containing the Commission's assessment on all the evidence at its disposal concerning the country concerned and on the basis of which the Commission initiates this investigation. That memorandum can be found in the file for inspection by interested parties.
- (8) In accordance with Article 10(7) the basic Regulation, the Commission notified the Government of India ('GOI') prior to the initiation of the proceeding that it had received a properly documented review request. The Commission invited India for consultations with the aim of clarifying the situation as regards the contents of the review request and arriving at a mutually agreed solution. The GOI accepted the offer of consultations that were subsequently held on 3 March 2022. During the consultations, no mutually agreed solution could be arrived at.

1.3. Initiation of an expiry review

(9) Having determined, after consulting the Committee established by Article 25(1) of the basic Regulation, that sufficient evidence existed for the initiation of an expiry review, the Commission, on 9 March 2022, by Notice, published in the Official Journal of the European Union (8) ('the Notice of Initiation'), initiated an expiry review with regard to imports of certain graphite electrode systems originating in India ('India' or 'the country concerned') on the basis of Article 18 of the basic Regulation.

1.4. Separate investigation concerning anti-dumping measures imposed on imports of the product under review

(10) By a notice published in the Official Journal of the European Union on 9 March 2022 (9), the Commission also announced the initiation of an expiry review pursuant to Article 11(2) of Regulation (EU) 2016/1036 of the European Parliament and of the Council (10), of the definitive anti-dumping measures in force with regard to imports into the Union of certain graphite electrode systems originating in India

1.5. Review investigation period and period considered

(11) The investigation of a likelihood of continuation or recurrence of subsidisation covered the period from 1 January 2021 to 31 December 2021 ('the review investigation period' or 'RIP'). The examination of trends relevant for the assessment of a likelihood of continuation or recurrence of injury covered the period from 1 January 2018 to the end of the review investigation period ('the period considered').

⁽⁷⁾ OJ C 222, 11.6.2021, p. 24.

⁽⁸⁾ Notice of initiation of an expiry review of the anti-subsidy measures applicable to imports of certain graphite electrode systems originating in India (OJ C 113, 9.3.2022, p. 13).

⁽⁹⁾ Notice of initiation of an expiry review of the anti-dumping measures applicable to imports of certain graphite electrode systems originating in India (OJ C 113, 9.3.2022, p. 3).

⁽¹⁰⁾ 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 (OJ L 176, 30.6.2016, p. 21).

1.6. Interested parties

- (12) In the Notice of Initiation, the Commission invited interested parties to contact it, in order to participate in the investigation. In addition, the Commission specifically informed the applicants, other known Union producers, the known exporting producers and the Indian authorities, known importers, suppliers and users, traders, as well as associations known to be concerned about the initiation of the investigation and invited them to participate.
- (13) 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.

1.7. Sampling

(14) In the Notice of Initiation, the Commission stated that it might sample the interested parties in accordance with Article 17 of the basic Regulation.

1.7.1. Sampling of Union producers

(15) In its Notice of Initiation, the Commission stated that it had provisionally selected a sample of Union producers. The Commission selected the sample on the basis of production and sales volumes of the like product in the Union. This sample consisted of three Union producers. The sampled Union producers accounted for around 61 % of the estimated total Union production and 64 % of the estimated sales volume of the like product in the Union. The Commission invited interested parties to comment on the provisional sample. The Commission received no comments. The sample was therefore considered representative of the Union industry.

1.7.2. Sampling of importers

- (16) To decide whether sampling is necessary and, if so, to select a sample, the Commission asked unrelated importers to provide the information specified in the Notice of Initiation.
- (17) No importers came forward and provided the requested information.

1.8. Questionnaire replies and remote cross-checking

- (18) At the initiation the questionnaires were made available in the file for inspection by interested parties and on DG Trade's website (11).
- (19) Questionnaire replies were received from the three sampled Union producers, the Government of the Republic of India ('GOI') and one Indian exporting producer. None of the users provided a questionnaire or came forward during the investigation.
- (20) The Commission sought and verified all the information it deemed necessary for the determination of the likelihood of continuation or recurrence of subsidisation and resulting injury and for the determination of the Union interest. Verification visits pursuant to Article 26 of the basic Regulation were carried out at the premises of the GOI and of the following companies:
 - (a) Union producers
 - GrafTech Iberica S.L., Navarra, Spain
 - Showa Denko Carbon Spain S.A., A Coruna, Spain
 - Tokai Erftcarbon GmbH, Grevenbroich, Germany
 - (b) Exporting producer in India:
 - HEG Limited, Bhopal ('HEG')

⁽¹¹⁾ https://tron.trade.ec.europa.eu/investigations/case-view?caseId=2586

2. PRODUCT UNDER REVIEW AND LIKE PRODUCT

2.1. Product under review

(21) The product under review is graphite electrodes of a kind used for electric furnaces, with an apparent density of 1,65 g/cm3 or more and an electrical resistance of 6,0 $\mu\Omega$.m or less, and nipples used for such electrodes, whether imported together or separately ('the product under review'), currently falling under CN codes ex 8545 11 00 and ex 8545 90 90 (TARIC codes 8545 11 00 10 and 8545 90 90 10). 'the product under review' or 'GES').

2.2. Like product

- (22) As established in the original investigation as well as in the previous expiry reviews, this expiry review investigation confirmed that the following products have the same basic physical, chemical and technical characteristics as well as the same basic uses:
 - the product under review;
 - the product produced and sold on the domestic market of the country concerned, and
 - the product produced and sold in the Union by the Union industry.
- (23) The Commission decided that those products are therefore like products within the meaning of Article 1(4) of the basic Regulation.

3. LIKELIHOOD OF CONTINUATION OR RECURRENCE OF SUBSIDISATION

(24) In accordance with Article 18 of the basic Regulation, and as stated in the Notice of Initiation, the Commission examined whether the expiry of the existing measures would be likely to lead to a continuation or recurrence of subsidisation.

3.1. Subsidies and subsidy programmes within the scope of the investigation

On the basis of the information contained in the review request, as well as the information submitted by the GOI and the cooperating exporting producer, the following schemes, which allegedly involve the granting of subsidies, were investigated:

Schemes originally investigated and confirmed during the last expiry review

- (a) Advance Authorisation Scheme ('AAS');
- (b) Merchandise Export from India Scheme ('MEIS');
- (c) Export Promotion Capital Goods Scheme ('EPCGS');
- (d) Duty Drawback Scheme ('DDS')
- (e) Regional Schemes: electricity duty exemption and fiscal assistance;

Additional schemes

- (f) Remission of Duties and Taxes on Exported Products ('RODTEP');
- (g) Pre-shipment and Post-shipment Export Financing, Interest Equalization scheme ('IES'),
- (h) Duty Free Import Authorisation Scheme ('DFIA');
- (i) Regional schemes: electricity rebates and reduced rates;
- (j) Gold Card Scheme, Status Holder Scheme;
- (k) Market Access Initiative ('MAI').

3.2. Schemes originally investigated and confirmed in the last expiry review

- 3.2.1. Duty exemption and remission schemes
- (26) The AAS, EPCGS and MEIS schemes are based on the Foreign Trade (Development and Regulation) Act 1992 (No 22 of 1992) which entered into force on 7 August 1992 (Foreign Trade Act'). The Foreign Trade Act authorises the GOI to issue notifications regarding the export and import policy. These are summarised in 'Foreign Trade Policy' documents, which are normally issued by the Ministry of Commerce every five years and updated regularly.
- (27) The Foreign Trade Policy document relevant for the RIP is Foreign Trade Policy 2015-20 ('FTP 2015-20'). The FTP 2015-20 entered into force in April 2015 and was originally set to expire on 31 March 2020. However, due to the Covid-19 pandemic FTP 2015-20 was extended several times, the latest extension was until 31 March 2023. The GOI also sets out the procedures governing FTP 2015-20 in a 'Handbook of Procedures, 2015-20' ('HOP 2015-20').
 - 3.2.2. Advanced Authorisation Scheme ('AAS')
- (28) The Commission established that HEG used AAS during the RIP.
 - 3.2.2.1. Legal basis
- (29) The detailed description of the scheme is contained in paragraphs 4.03 to 4.24 of the FTP 2015-20 and chapters 4.04 to 4.52 of the HOP 2015-20 and the updated HOP 2015-20.
 - 3.2.2.2. Eligibility
- (30) AAS consists of six sub-schemes, i.e. physical exports, annual requirement, intermediate supplies, deemed exports, advance release order, or back to back inland letter of credit. Those sub-schemes differ, inter alia, in the scope of eligibility. Manufacturer-exporters and merchant-exporters 'tied to' supporting manufacturers are eligible for the AAS physical exports and for the AAS annual requirement sub-schemes. Manufacturer-exporters supplying the ultimate exporter are eligible for AAS for intermediate supplies. Main contractors which supply to the 'deemed export' categories mentioned in paragraph 7.02 of the FTP 2015-20, such as suppliers of an Export Oriented Unit ('EOU'), are eligible for the AAS deemed export sub-scheme. Eventually, intermediate suppliers to manufacturer exporters are eligible for 'deemed export' benefits under the sub-schemes Advance Release Order and Back to back inland letter of credit.
 - 3.2.2.3. Practical implementation
- (31) The AAS can be issued for:
 - (a) Physical exports: This is the main sub-scheme. It allows for duty-free import of input materials for the production of a specific resulting export product. 'Physical' in this context means that the export product has to leave Indian territory. An import allowance and export obligation including the type of export product are specified in the licence;
 - (b) Annual requirement: Such an authorisation is not linked to a specific export product, but to a wider product group (e.g. chemical and allied products). The licence holder can up to a certain value threshold set by its past export performance import duty-free any input to be used in manufacturing any of the items falling under such a product group. It can choose to export any resulting product falling under the product group using such duty-exempt material;
 - (c) Intermediate supplies: This sub-scheme covers cases where two manufacturers intend to produce a single export product and divide the production process. The manufacturer-exporter who produces the intermediate product can import duty-free input materials and can obtain for this purpose an AAS for intermediate supplies. The ultimate exporter finalises the production and is obliged to export the finished product;

- (d) Deemed exports: This sub-scheme allows a main contractor to import inputs free of duty which are required in manufacturing goods to be sold as 'deemed exports' to the categories of customers mentioned in paragraph 8.2 (b) to (f), (g), (i) and (j) of the FTP 15-20. According to the GOI, deemed exports refer to those transactions in which the goods supplied do not leave the country. A number of categories of supply is regarded as deemed exports provided the goods are manufactured in India, e.g. supply of goods to an export-oriented unit (EOU') or to a company situated in a special economic zone ('SEZ');
- (e) Advance Release Order ('ARO'): The AAS holder intending to source the inputs from indigenous sources, in lieu of direct import, has the option to source them against AROs. In such cases the Advance Authorisations are validated as AROs and are endorsed to the indigenous supplier upon delivery of the items specified therein. The endorsement of the ARO entitles the indigenous supplier to the benefits of deemed exports as set out in paragraph 8.3 of the FTP 15-20 (i.e. AAS for intermediate supplies/deemed export, deemed export drawback and refund of terminal excise duty). The ARO mechanism refunds taxes and duties to the supplier instead of refunding the same to the ultimate exporter in the form of drawback/refund of duties. The refund of taxes/duties is available both for indigenous inputs as well as imported inputs;
- (f) Back to back inland letter of credit: This sub-scheme again covers indigenous supplies to an Advance Authorisation holder. The holder of an Advance Authorisation can approach a bank for opening an inland letter of credit in favour of an indigenous supplier. The authorisation will be validated by the bank for direct import only in respect of the value and volume of items being sourced indigenously instead of importation. The indigenous supplier will be entitled to deemed export benefits as set out in paragraph 8.3 of the FTP 15-20 (i.e. AAS for intermediate supplies/deemed export, deemed export drawback and refund of terminal excise duty).
- (32) It was found that HEG obtained concessions under the first sub-scheme i.e. AAS physical exports during the RIP. It is therefore not necessary to establish the countervailability of the remaining unused sub-schemes. This is the main sub-scheme. It allows for duty-free import of input materials for the production of a specific resulting export product. 'Physical' in this context means that the export product has to leave Indian territory. An import allowance and export obligation including the type of export product are specified in the licence.
- (33) For verification purposes by the Indian authorities, an Advance Authorisation holder is legally obliged to maintain 'a true and proper account of consumption and utilisation of duty-free imported/domestically procured goods' in a specified format (chapters 4.51 and Appendix 4H or 4I HOP I 15-2020 (12)), i.e. an actual consumption register. This register has to be verified by an external chartered accountant/cost and works accountant who issues a certificate stating that the prescribed registers and relevant records have been examined and the information furnished under Appendix 4H is true and correct in all respects.
- (34) With regard to the sub-scheme used during the RIP by the company concerned, i.e. physical exports, the import allowance and the export obligation are fixed in volume and value by the GOI and are documented on the Authorisation. In addition, at the time of import and of export, the corresponding transactions are to be documented by Government officials on the Authorisation. The volume of imports allowed under the AAS is determined by the GOI on the basis of Standard Input Output Norms ('SIONs') which exist for most products including the product under review.
- (35) Imported input materials are not transferable and have to be used to produce the resultant export product. The export obligation must be fulfilled within a prescribed time frame after issuance of the licence (18 months with two possible extensions of 6 months each).
- (36) The SION applicable to the product under review was established by the GOI in 1998 and was not revised or adjusted until the RIP. Therefore, the SION is insufficient to effectively monitor the actual consumption. The GOI did also not carry out further examination based on actual input. For the main raw material Needle coke (also named 'calcined petroleum coke' or 'CPC') the Commission found an important discrepancy between the SION and the actual raw material consumption of the company. The SION allows a ratio of 1.3 of Needle coke per exported ton, whereas the actual ratio needed for production is substantially lower.

⁽¹²⁾ Handbook of Procedures (1st April, 2015 – 31st March, 2020) Updated up to 4.8.2015: https://www.mofpi.gov.in/sites/default/files/updated_hbp_2015-2020.pdf

- (37) The investigation therefore established that the verification requirements stipulated by the Indian authorities were not sufficient to prevent a benefit.
- (38) The cooperating exporting producer maintained a certain production and consumption register. It was however not possible to verify which inputs (including their origin) were consumed in the production of the exported product and in what amounts. In particular with the system put in place it was not possible to identify and measure with precision whether there was an excess remission because, the raw material is stored in silos, which contain needle coke imported duty free together with needle coke imported with duties, without any local separation. As soon as imported needle coke is stored, a specific charge of imports could thereby no longer be traced.
- (39) HEG confirmed that its consumption register does not allow to establish the actual consumption of duty free imported raw materials and linking it with produced and exported final products. As a result, the sub-scheme used in the present case cannot be considered a permissible duty drawback system.

3.2.2.4. Conclusion on the AAS

- (40) The exemption from import duties is a subsidy within the meaning of Article 3(1)(a)(ii) and Article 3(2) of the basic Regulation, namely it constitutes a financial contribution of the GOI since it foregoes duty revenue which would otherwise be due and it confers a benefit upon the investigated exporter since it improves its liquidity.
- (41) In addition, AAS physical exports are contingent in law upon export performance, and therefore deemed to be specific and countervailable under Article 4(4), first subparagraph, point (a) of the basic Regulation. Without an export commitment, a company cannot obtain benefits under this scheme.
- (42) The sub-scheme used in the present case cannot be considered a permissible duty drawback system or substitution drawback system within the meaning of Article 3(1)(a)(ii) of the basic Regulation. It does not conform to the rules laid down in Annex I item (i), Annex II (definition and rules for drawback) and Annex III (definition and rules for substitution drawback) of the basic Regulation. The GOI did not effectively apply a verification system or a procedure to confirm whether and in what amounts inputs were consumed in the production of the exported product (Annex II(4) of the basic Regulation and, in the case of substitution drawback schemes, Annex III(II)(2) of the basic Regulation). It is also considered that the SIONs for the product under review were not sufficiently precise and that, in themselves, those SIONs cannot constitute a verification system of actual consumption because the design of those standard norms does not enable the GOI to verify with sufficient precision what amounts of inputs were consumed in the export production. In addition, the GOI did not carry out a further examination based on actual inputs involved, although this would need to be carried out in the absence of an effectively applied verification system (Annex II(5) and Annex III(II)(3) to the basic Regulation). This also manifested in the fact that since its establishment in 1998 the SION has never been revised.
- (43) The sub-scheme is therefore countervailable.
- (44) Following the final disclosure, the GOI commented that there is a verification mechanism in place and the same had been duly demonstrated in the verification process.
- (45) The Commission rejected this argument. As explained in recital (36), the SION that determines the amount of tax free imported raw materials has never been revised since its imposition and the Commission found an important discrepancy between the SION and the actual consumption. The Commission concluded that the monitoring of the application of the SION cannot ensure that the benefits are not granted in excess, if the underlying SION, that determines the amount of tax free imported raw materials, is not sufficiently precise and this fact is not monitored. In addition, the Commission found that at HEG it was not possible to trace the imported raw materials to the finished goods.
- (46) Following the final disclosure, the GOI commented that it follows from Paragraph 2 of Section I under Annex II of the WTO's SCM Agreement ('ASCM') that indirect taxes rebate schemes are countervailable only if it provides remissions over and above the import duty on inputs consumed in production of the exported product.

- (47) The GOI further argued that the AAS is not a countervailable program since it does not provide excess remission of import duties over the number of duties accrued on the imported inputs. This followed from Section II of Annex II of the ASCM, which provides guidelines for determining whether inputs are consumed in the production of the exported product. Further the panel report in European Union countervailing Measures on Certain Polyethylene Terephthalated from Pakistan (WT/DS/486) stated that 'the excess remission principle' provides a legal standard which determine whether the remissions of import duties obtained under the duty drawback scheme constitute a financial contribution.
- (48) The Commission explained in recital (36) the Commission found a substantial discrepancy between the SION and the actual consumption. As explained in Recital (38) the cooperating exporting producer maintained a certain production and consumption register. It was however not possible to verify which inputs (including their origin) were consumed in the production of the exported product and in what amounts. In particular, with the system put in place it was not possible to identify and measure with precision whether there was an excess remission. It was also found that no records kept by the companies would enable the calculation of excess remission, thereby making any future certification by an external chartered accountant/cost and works accountant impossible. The GOI has not elaborated in which aspect this lack of possibility to verify does not meet the standard of the quoted Sections of the ASCM.
- (49) The Commission therefore rejected this claim.
 - 3.2.2.5. Calculation of the subsidy amount
- (50) In the absence of permitted duty drawback systems and lack of the possibility of verification of the actual consumption rate of the relevant inputs, and since there was no reliable evidence showing otherwise, the total amount of custom duties foregone (basic custom duty and custom cess) is considered an excess remission that would constitute a countervailable subsidy in accordance with Article 3(1)(a)(ii) of the basic Regulation. The application fees paid by the company have been deducted.
- (51) In accordance with Article 7(2) of the basic Regulation, the Commission allocated these subsidy amounts over the total export turnover of the company during RIP as appropriate denominator, because the subsidy is contingent upon export performance and it was not granted by reference to the quantities manufactured, produced, exported or transported.
- (52) The subsidy rate established with regard to this scheme totalled 1,66 % for HEG during the RIP.
- (53) Following the final disclosure, the GOI claimed that, if the Commission decides to countervail the AAS, only the amount, in excess of the duties, that has been remitted, can be countervailed. The GOI claimed that this follows from the WTO Panel Report on India-Export Related Measures [WT/DS541/R], which stated that any exemption of indirect taxes not in excess of duties levied on imported inputs consumed in production of exported product shall not be regarded as countervailable. The GOI further argues that the panel report (WT/DS/486) provided the legal standard to support this determination.
- (54) As explained in recital (50), in the absence of permitted duty drawback systems and lack of the possibility of verification of the actual consumption rate of the relevant inputs, and since there was no reliable evidence showing otherwise, the total amount of custom duties foregone (basic custom duty and custom cess) is considered an excess remission. The WTO Panel Report on India-Export Related Measures [WT/DS541/R] does not contain a definition that contradicts this consideration.
- (55) The Commission therefore rejected this claim.
 - 3.2.3. Merchandise Export from India Scheme ('MEIS')
- (56) The Commission established that HEG used MEIS during the RIP.

3.2.3.1. Legal basis

(57) The detailed description of the MEIS is contained in chapter 3 of FTP 2015-20 and updated FTP 2015-20 and in chapter 3 of the updated HOP 2015-20 (¹³).

3.2.3.2. Eligibility

(58) Any manufacturer-exporter or merchant-exporter is eligible for this scheme.

3.2.3.3. Practical implementation

- (59) Eligible companies can benefit from the MEIS by exporting specific products to specific countries which are categorised into Group A ('Traditional Markets' including all EU Member States), Group B ('Emerging and Focus Markets') and Group C ('Other Markets'). The countries falling under each group and the list of products with corresponding reward rates are listed in Appendix 3B of the updated HOP 2015-20.
- (60) The benefit takes the form of a duty credit equivalent to a percentage of the FOB value of the export. The MEIS rate for export of GES to Group A countries during the RIP amounted to 2 %.
- (61) Pursuant to para 3.06 of the FTP 2015-20 certain types of exports are excluded from the scheme, e.g. exports of imported goods or transhipped goods, deemed exports, service exports and export turnover of units operating under special economic zones/export operating units.
- (62) The duty credits under the MEIS are freely transferable and valid for a period of 18 months from the date of issue while the duty credit scrips issued on or after 1 January 2016 shall be valid for a period of 24 months from the date of issue as per paragraph 3.13 of the updated HOP 2015-20.
- (63) They can be used for: (i) payment of custom duties on imports of inputs or goods including capital goods, (ii) payment of excise duties on domestic procurement of inputs or goods including capital goods and payment, (iii) payment of service tax on procurement of services.
- (64) An application for claiming benefits under the MEIS must be filed online on the Directorate-General of Foreign Trade website. Relevant documentation (shipping bills, bank realisation certificate and proof of landing) must be linked with the online application. The relevant Regional Authority ('RA') of the GOI issues the duty credit after scrutiny of the documents. As long as the exporter provides the relevant documentation, the RA has no discretion over the granting of the duty credits.
- (65) The MEIS scheme was discontinued from 1 January 2021. However, it was found that benefits were awarded to HEG under the MEIS scheme during the RIP, as the scheme allowed to retroactively claim benefits for previous periods until end of 2021.

3.2.3.4. Conclusion on MEIS

- (66) The MEIS provides subsidies within the meaning of Article 3(1)(a)(ii) and Article 3(2) of the basic Regulation. MEIS duty credit is a financial contribution by the GOI, since the credit will eventually be used to offset import duties paid on capital goods, thus decreasing the GOI's duty revenue which would be otherwise due. In addition, MEIS duty credit confers a benefit upon the exporter who is not subject to the payment of those import duties.
- (67) Furthermore, the MEIS is contingent in law upon export performance, and therefore deemed to be specific and countervailable under Article 4(4), first subparagraph, point (a) of the basic Regulation.

⁽¹³⁾ https://www.mofpi.gov.in/sites/default/files/updated_hbp_2015-2020.pdf

- (68) This scheme cannot be considered a permissible duty drawback system or substitution drawback system within the meaning of Article 3(1)(a)(ii) of the basic Regulation. It does not conform to the strict rules laid down in Annex I point (i), Annex II (definition and rules for drawback) and Annex III (definition and rules for substitution drawback) of the basic Regulation. An exporter is under no obligation to actually consume the goods imported free of duty in the production process and the amount of credit is not calculated in relation to actual inputs used. There is no system or procedure in place to confirm which inputs are consumed in the production process of the exported product or whether an excess payment of import duties occurred within the meaning of point (i) of Annex I and Annexes II and III of the basic Regulation. An exporter is eligible for MEIS benefits regardless of whether it imports any inputs at all. In order to obtain the benefit, it is sufficient for an exporter to simply export goods without having to demonstrate that any input material was imported. Thus, even exporters which procure all of their inputs locally and do not import any goods which can be used as inputs are still entitled to benefit from MEIS. Moreover, an exporter can use MEIS duty credits in order to import capital goods although capital goods are not covered by the scope of permissible duty drawback systems, as set out in Annex I point (i) of the basic Regulation, because they are not consumed in the production of the exported products. Moreover, no further examination by the GOI was conducted on the basis of actual inputs and transactions in order to determining whether an excess payment occurred.
- (69) It is noted that the MEIS expired as of 1 January 2021 (14). However, until the end of 2021, the companies could still apply for the MEIS scripts for the export transactions made in 2020. Furthermore, the companies are still able to use the MEIS script obtained in 2021 to balance import duties due, until 15 September 2023. Thus, benefits under this scheme were received during the RIP and will continue even after the end of the investigation.
- (70) Following the final disclosure, the GOI commented that MEIS is not a countervailable program since it is merely intended to refund indirect taxes paid on inputs consumed in the production of exported goods. Further, the value of the duty credit scripts (that are awarded as benefits under the MEIS) is not in excess of indirect taxes incurred by the exporter. Thus, the MEIS program is in accordance with the provisions of paragraphs (g) and (h) of Annex I read with Footnote 1 of the WTO's ASCM.
- (71) Contrary to what the GOI argues, MEIS provides an excess remission of duties. As demonstrated in recital (68) an exporter is under no obligation to actually consume the goods imported free of duty in the production process and the amount of credit is not calculated in relation to actual inputs used. There is no system or procedure in place to confirm which inputs are consumed in the production process of the exported product. The mere intention to refund indirect taxes paid on inputs consumed does not replace the need for a monitoring, if these are actually consumed.
- (72) The GOI further commented that MEIS has been terminated by the GOI with effect from 1 January 2021 and the extension of the duty would result in countervailing a program under which no assistance would be conferred to any exporter. The GOI pointed to the fact that in previous investigations the Commission has refrained from countervailing schemes which have been revoked by the GOI.
- (73) In recital (69) the Commission demonstrated that despite the termination of the scheme, HEG received benefits during the RIP, following the termination of the scheme. The Commission also demonstrated that these benefits continue even after the end of the investigation. None of those facts were disputed by the GOI.
- (74) The Commission therefore rejected this claim.
 - 3.2.3.5. Calculation of the subsidy amount
- (75) In accordance with Article 3(2) and Article 5 of the basic Regulation, the Commission calculated the amount of countervailable subsidies in terms of the benefit conferred on the recipient, which was found to exist during the RIP. In this regard, the Commission established that the benefit is conferred on the recipient at the time when the company receives the benefit under this scheme, following the company's application. At this moment, the GOI issues a duty credit which is booked by the exporting producer as an account receivable which can be offset by the

⁽¹⁴⁾ To be noted that this scheme was replaced by a new scheme, the RODTEP, which is described in section 3.2.5 below.

exporting producer at any moment. This constitutes a financial contribution within the meaning of Article 3(1)(a)(ii) of the basic Regulation. Once the customs authorities issue an export shipping bill, the GOI has no discretion as to whether or not to grant the subsidy. In the light of the above, and since there was no reliable evidence showing otherwise, the Commission considered appropriate to assess the benefit under the MEIS as being the sum of the amounts received under this scheme during the RIP. The Commission took into account MEIS amounts earned on all the export transactions of HEG, as the company exports only product under review.

- (76) In accordance with Article 7(1)(a) of the basic Regulation, fees incurred by the company to obtain the subsidy were deducted from the total subsidy amount where claimed.
- (77) In accordance with Article 7(2) and (3) of the basic Regulation, the Commission allocated this subsidy amount over the export turnover of HEG during the RIP as appropriate denominator, because the subsidy is contingent upon export performance, and it was not granted by reference to the quantities manufactured, produced, exported or transported.
- (78) The subsidy rate established with regard to this scheme totalled 0,87 % for HEG during the RIP.
 - 3.2.4. Export Promotion Capital Goods Scheme ('EPCGS')
- (79) Like in the original investigation and the last review, the Commission established that HEG received concessions under the EPCGS which could be allocated to the product under review originating in India during the RIP.
 - 3.2.4.1. Legal basis
- (80) The detailed description of the EPCGS is contained in chapter 5 of the FTP 2015-20 as well as in chapter 5 of HOP 2015-20.
 - 3.2.4.2. Eligibility
- (81) Manufacturer-exporters, merchant-exporters 'tied to' supporting manufacturers and service providers are eligible for this scheme.
 - 3.2.4.3. Practical implementation
- (82) Under the condition of an export obligation, a company is allowed to import capital goods (new and second-hand capital goods up to 10 years old) at a reduced duty rate. To this end, the GOI issues, upon application and payment of a fee, an EPCGS licence. The scheme provides for a reduced import duty rate applicable to all capital goods imported under the scheme. In order to meet the export obligation, the imported capital goods must be used to produce a certain amount of goods deemed for export during a certain period. Under the FTP 2015-20 and updated FTP 2015-20 the capital goods can be imported with a 0 % duty rate under the EPCGS. The export obligation, which amounts to six times the duty saved, must be fulfilled within a period of maximum six years.
- (83) The EPCGS licence holder can also source the capital goods indigenously. In such case, the indigenous manufacturer of capital goods may avail itself of the benefit for duty free import of components required to manufacture such capital goods. Alternatively, the indigenous manufacturer can claim the benefit of deemed export in respect of supply of capital goods to an EPCGS licence holder.
 - 3.2.4.4. Conclusion on the EPCGS
- (84) The EPCGS provides subsidies within the meaning of Article 3(1)(a)(ii) and Article 3(2) of the basic Regulation. The duty reduction constitutes a financial contribution by the GOI, since this concession decreases the GOI's duty revenue which would be otherwise due. In addition, the duty reduction confers a benefit upon the exporter, because the duties saved upon importation improve the company's liquidity.

- (85) Furthermore, the EPCGS is contingent in law upon export performance, since such licences cannot be obtained without a commitment to export. Therefore, it is deemed to be specific and countervailable under Article 4(4), first subparagraph, point (a) of the basic Regulation.
- (86) The EPCGS cannot be considered a permissible duty drawback system or substitution drawback system within the meaning of Article 3(1)(a)(ii) of the basic Regulation. Capital goods are not covered by the scope of such permissible systems, as set out in Annex I point (I), of the basic Regulation, because they are not consumed in the production of the exported products.
 - 3.2.4.5. Calculation of the subsidy amount
- (87) The amount of countervailable subsidies was calculated, in accordance with Article 7(3) of the basic Regulation, on the basis of the unpaid customs duty on imported capital goods spread across a period which reflects the normal depreciation period of such capital goods in the industry concerned. The amount so calculated, which is attributable to the RIP, has been adjusted by adding interest during this period in order to reflect the full-time value of the money. The commercial interest rate during the investigation period in India was considered appropriate for this purpose.
- (88) In accordance with Article 7(1)(a) of the basic Regulation, fees incurred by HEG to obtain the subsidy were deducted from the total subsidy amount where claimed.
- (89) In accordance with Article 7(2) and 7(3) of the basic Regulation, this subsidy amount has been allocated over the export turnover of the product under review during the RIP as the appropriate denominator as the company used machines purchased under the EPCGS only for the production of the product under review, because the subsidy is contingent upon export performance and was not granted by reference to the quantities manufactured, produced, exported or transported.
- (90) The subsidy rate established with regard to this scheme totalled 0,31 % for HEG during the RIP.
 - 3.2.5. Direct transfer of funds
- (91) The Commission analysed a direct transfer of funds within the DDS scheme. The DDS scheme is based on section 75 of the Customs Act of 1962, on section 37 of the Central Excise Act of 1944, on sections 93A and 94 of the Financial Act of 1994, and on the Customs, Central Excise Duties and Service Tax Drawback Rules of 1995. The drawback rates are published on a regular basis.
 - 3.2.6. Duty Drawback Scheme ('DDS')
- (92) The Commission established that HEG used the DDS during the RIP.
 - 3.2.6.1. Legal Basis
- (93) The legal basis applicable during the RIP was the Custom & Central Excise Duties Drawback Rules 1995 ('the 1995 DDS Rules'), as amended in 2006 (15) and then replaced by Customs and Central Excise Duties Drawback Rules, 2017 (16) ('the 2017 Rules') which entered into force on 1 October 2017. Rule 3(2) of the 1995 DDS Rules governs the method of calculation of this duty drawback scheme. Rule 12(1)(a)(ii) of the said DDS Rules governs the Declaration that the exporting producers need to file in order to benefit from the scheme. These Rules have remained identical in the 2017 DDS Rules and correspond to Rule 3(2) and Rule 13(1)(a)(ii) respectively.

(15) http://www.cbic.gov.in/htdocs-cbec/customs/cs-act/formatted-htmls/cs-rulee

⁽¹⁶⁾ Notification No 88/2017-CUSTOMS (N.T.) New Delhi, the 21st September, 2017. http://www.cbic.gov.in/resources//htdocs-cbec/customs/cs-act/notifications/notfns-2017/cs-nt2017/csnt88-2017.pdf

- (94) In addition, Circular No 24/2001 (17) contains specific instructions how to implement the Rule 3(2) and the Declaration that exporters need to produce under the Rule 12(1)(a)(ii).
- (95) The Rule 4 of the 1995 DDS Rules stipulates that the Central Government may revise amount or rates determined under the rule 3. The Government has made a number of modifications, the last ones revising the rates being Notification No 95/2018 CUSTOMS and Notification No 07/2020 CUSTOMS. As a result, for the product under review, the DDS rate was 1,6 % of the FOB value of the exported products. The same DDS rate is applied to GES exported by HEG.

3.2.6.2. Eligibility

(96) Any manufacturer-exporter or merchant-exporter is eligible for this scheme.

3.2.6.3. Practical implementation

- (97) Under this scheme, any company exporting eligible products is entitled to receive an amount corresponding to a percentage of the declared FOB value of the exported product. According to Rule 3(2) of Custom & Central Excise Duties Drawback Rules, the GOI bases the refundable amount on industry-wide average values of relevant customs duties paid on imported raw materials and an average industry consumption ratio collected from what the GOI considers as being representative manufacturers of the eligible export products. The GOI then expresses the amount to be refunded as a percentage of the average export value of the eligible exported products.
- (98) In order to be eligible to benefit from this scheme, a company must export. At the moment when shipment details are entered in the Customs server (ICEGATE), it is indicated that the export is taking place under the DDS and the DDS amount is fixed irrevocably. After the shipping company has filed the Export General Manifest and the customs office has satisfactorily compared that document with the shipping bill data, all conditions are fulfilled to authorise the payment of the drawback amount by either direct payment on the exporter's bank account or by draft.
- (99) The exporter also has to produce evidence of realisation of export proceeds by means of a Bank Realisation Certificate ('BRC'). This document can be provided after the drawback amount has been paid but the GOI will recover the paid amount if the exporter fails to submit the BRC within a given deadline.
- (100) The drawback amount can be used for any purpose and, in accordance with Indian accounting standards, the amount can be booked on an accrual basis as income in the commercial accounts, upon fulfilment of the export obligation.
- (101) The relevant legislation and administrative instructions stipulate that the Indian customs administration should require no evidence that the exporter requesting the duty drawback must have incurred or will incur a customs duty liability for imports of the raw materials needed for the manufacture of the exported product. In addition, during the verification visit, the GOI confirmed that companies that would source domestically all the raw materials would still benefit from the full rate calculated under Rule 3(2) mentioned above HEG exercised DDS with the All Industry Rate, where no proof of actually paid duties is necessary.

3.2.6.4. Conclusion on the DDS

(102) The DDS provides subsidies within the meaning of Article 3(1)(a)(i) and Article 3(2) of the basic Regulation. The so-called duty drawback amount is a financial contribution by the GOI as it takes form of a direct transfer of funds by the GOI. There are no restrictions as to the use of these funds. In addition, the duty drawback amount confers a benefit upon the exporter, because it improves its liquidity.

⁽¹⁷⁾ Cus. 20th April, 2001F.NO.605/47/2001-DBK, Government of India, Ministry of Finance, Department of Revenue, Declaration under Rule 12(1)(a)(ii) of Drawback Rule for availing AIR of Drawback. See in particular Sections 2 and 3 of the Declaration under Rule 12(1)(a)(ii) of Drawback Rule for availing AIR of Drawback; available at: http://www.cbic.gov.in/htdocs-cbec/customs/cs-circulars/cscirculars-2001/24-2001-cus

- (103) The rate of duty drawback for exports is determined by the GOI on a product-by-product basis. However, although the subsidy is referred to as a duty drawback, the scheme does not have all the characteristics of a permissible duty drawback system or substitution drawback system within the meaning of Article 3(1)(a)(ii) of the basic Regulation; nor does the scheme conform to the rules laid down in Annex I item (I), Annex II (definition and rules for drawback) and Annex III (definition and rules for substitution drawback) of the basic Regulation. The cash payment to the exporter is not necessarily linked to actual payments of import duties on raw materials and is not a duty credit to offset import duties on past or future imports of raw materials. In addition, there is no system or procedure in place to confirm which inputs are consumed in the production of the exported products and in what amounts. In addition, the GOI did not carry out a further examination based on actual inputs involved, although this would need to be carried out in the absence of an effectively applied verification system (Annex II(5) and Annex III(II)(3) to the basic Regulation). No evidence was provided of the existence of a link between the drawback rates and duties paid on raw materials.
- (104) Consequently, the payment which takes form of a direct transfer of funds by the GOI subsequent to exports made by exporters is contingent upon export performance and therefore this scheme is deemed to be specific and countervailable under Article 4(4)(a) of the basic Regulation.
- (105) In view of the above, it is concluded that the DDS is countervailable.
- (106) Following the final disclosure, the GOI claimed that the DDS is not countervailable since it is intended to implement the principle that taxes should not be exported. The said schemes is in accordance with Paragraph 2 of Section I under Annex II of the WTO's Agreement on Subsidies and Countervailing Measures ('SCM Agreement'). The drawback of indirect taxes or import charges is not in excess of the amount of such taxes or charges actually levied on inputs that are consumed in the production of the exported product. DDS is merely a program, which reimburses taxes paid on the importation of inputs used in the production of goods exported. The return of values would be calculated from a percentage of the FOB value exported, variable according to the exported goods.
- (107) The GOI also argued that its databases are used for appropriate cross-checks. A Committee also visits manufacturer exporter units for first-hand knowledge of the manufacturing process and observes the nature of inputs ordinarily used and the amount of wastage. The Committee also takes into account the industry experience and broad technical factors, as appropriate. The refund is the average amount of duty paid on materials of any particular class or description of goods used in the manufacture of export goods of specified goods.
- (108) The Commission, however, did not consider that the alleged link between the drawback rates and the duties paid on raw materials is sufficient in order for the scheme to conform to the rules laid down in Annex I item (I), Annex II (definition and rules for drawback) and Annex III (definition and rules for substitution drawback) of the basic Regulation. In particular, the amount of credit was not calculated in relation to actual inputs used. Moreover, there was no system or procedure in place to confirm which inputs (including their amounts and origin) were consumed in the production process of the exported product or whether an excess payment of import duties occurred within the meaning of item (I) of Annex I, and Annexes II and III of the basic Regulation. Moreover, no further examination by the GOI was conducted on the basis of actual inputs and transactions in order to determine whether an excess payment occurred.
- (109) The Commission therefore rejected this claim.
 - 3.2.6.5. Calculation of the subsidy amount
- (110) In accordance with Article 3(2) and Article 5 of the basic Regulation, the Commission established that the benefit is conferred on the recipient at the time when an export transaction is made under this scheme. At this moment, the GOI is liable to the payment of the drawback amount, which constitutes a financial contribution within the meaning of Article 3(1)(a)(I) of the basic Regulation. Once the customs authorities issue an export shipping bill which shows, inter alia, the amount of drawback which is to be granted for that export transaction, the GOI has no discretion as to whether or not to grant the subsidy.

- (111) In the light of the above, and since there is no reliable evidence showing otherwise, the Commission considered appropriate to assess the benefit under the DDS as being the sum of the drawback amounts earned on export transactions made under this scheme during the RIP. The Commission took into account duty drawback amounts earned on all the export transactions of HEG as the company exports only the product under review.
- (112) In accordance with Article 7(2) of the basic Regulation, the Commission allocated these subsidy amounts over the total export turnover of the company during RIP as appropriate denominator, because the subsidy is contingent upon export performance and it was not granted by reference to the quantities manufactured, produced, exported or transported.
- (113) The subsidy rate established with regard to this scheme totalled 1,27 % for HEG during the RIP.
- (114) Following the final disclosure, the GOI argued that, if there is any excess drawback, only the excess drawback can be countervailed. The GOI argued this would be supported by the Panel Report, European Union -Countervailing Measures on Certain Polyethylene Terephthalate from Pakistan, WT/DS486/R. From this Panel report the GOI quoted a section that contains the statement: 'Consistent with this observation, Annex III (II) provides guidance for investigating authorities that are designed to allow investigating authorities to identify excess remissions.'
- (115) The Panel Report does not contain findings that would contradict the Commission's conclusion on how to define the excess benefit in this case. As described in recital (111), since there was no evidence of an actual verification process showing otherwise, but only general descriptions of how the Committee works and establishes the DDS ratio, the Commission considered appropriate to assess the benefit under the DDS as being the sum of the drawback amounts earned on export transactions made under this scheme during the RIP.
- (116) The Commission therefore rejected the claim.
 - 3.3. Additional schemes used to determine the continuation of subsidisation
 - 3.3.1. Duty exemption and remission schemes
- (117) Similar to MEIS, also the RODTEP scheme is based on the Foreign Trade (Development and Regulation) Act 1992 (No 22 of 1992) which entered into force on 7 August 1992 ('Foreign Trade Act'). RODTEP was designed as a successor of the MEIS scheme, but due to differences between these schemes on how the benefits are awarded, there is an overlap in the period in which the two schemes were applied.
 - 3.3.2. Remission of Duties and Taxes on Exported Products ('RODTEP')
- (118) The Commission established that HEG used RODTEP during the RIP.
 - 3.3.2.1. Legal basis
- (119) The detailed description of RODTEP is contained in chapter 4 of FTP 2015-20 and updated FTP 2015-20 and in chapter 4 of updated HOP 2015-20. It can also be found in the Notification introducing RODTEP into the FTP 2015-20 (18).
 - 3.3.2.2. Eligibility
- (120) Any manufacturer-exporter or merchant-exporter is eligible for this scheme.

⁽¹⁸⁾ https://content.dgft.gov.in/Website/dgftprod/8c25b521-147e-40e4-afa4-416eafdf3df6/RoDTEP%20Scheme%20Guidelines%20Notification%2019%20dated%2017%20Aug%202021.pdf

3.3.2.3. Practical implementation

- (121) Eligible companies can benefit from RODTEP by exporting products, which are not excluded according to the list of section 4.55 of FTP 2015-20 as Ineligible Supplies/Items/Categories under the Scheme. GES was not excluded according to this list.
- (122) Under the Scheme a rebate is granted at a notified percentage of FOB value with a value cap per unit of the exported product. The Scheme is implemented by issuance of rebate amount in form of a transferable duty credit/electronic script (e-scrip), which is maintained in an electronic ledger by the Central Board of Indirect Taxes & Customs (CBIC).
- (123) The e-scripts can be used for payment of custom duties on imports of inputs or goods including capital goods under the First Schedule to the Customs Tariff Act, 1975 viz. Basic Customs Duty.

3.3.2.4. Conclusion on RODTEP

- (124) RODTEP provides subsidies within the meaning of Article 3(1)(a)(ii) and Article 3(2) of the basic Regulation. RODTEP duty credit is a financial contribution by the GOI, since the credit will eventually be used to offset import duties paid on capital goods, thus decreasing the GOI's duty revenue which would be otherwise due. In addition, RODTEP duty credit confers a benefit upon the exporter who is not subject to the payment of those import duties.
- (125) Furthermore, RODTEP is contingent in law upon export performance, and therefore deemed to be specific and countervailable under Article 4(4), first subparagraph, point (a) of the basic Regulation.
- (126) This scheme cannot be considered a permissible duty drawback system or substitution drawback system within the meaning of Article 3(1)(a)(ii) of the basic Regulation. It does not conform to the strict rules laid down in Annex I point (i), Annex II (definition and rules for drawback) and Annex III (definition and rules for substitution drawback) of the basic Regulation. An exporter is under no obligation to actually consume any goods imported free of duty in the production process and the amount of credit is not calculated in relation to actual inputs used. There is no system or procedure in place to confirm which inputs are consumed in the production process of the exported product or whether an excess payment of import duties occurred within the meaning of point (i) of Annex I and Annexes II and III of the basic Regulation. Moreover, no further examination by the GOI was conducted on the basis of actual inputs and transactions in order to determining whether an excess payment occurred.
- (127) Following the final disclosure, the GOI argued that an expiry review is limited to the extension of the duty that is already in force. Therefore, new subsidy schemes such as RODTEP must remain outside the scope of the present review.
- (128) The fact that an expiry review is limited to the extension of a duty already in force, does not limit the Commission in only investigating subsidy schemes that existed in the investigation period of the original investigation. For the purpose of determining, whether a subsidisation above the de minimis level continued during the RIP, the Commission took into account RODTEP since it was included in the review request and it was a follow-up scheme to MEIS.
- (129) The GOI further claimed, that the RODTEP is not countervailable since it is intended to implement the principle that taxes should not be exported. The said schemes is in accordance with Paragraph 2 of Section I under Annex II of the WTO's Agreement on Subsidies and Countervailing Measures ('SCM Agreement'). The drawback of indirect taxes or import charges is not in excess of the amount of such taxes or charges actually levied on inputs that are consumed in the production of the exported product. DDS is merely a program, which reimburse taxes paid on the importation of inputs used in the production of goods exported. The reimbursed values would be calculated from a percentage of the FOB value exported, variable according to the exported goods.
- (130) The GOI databases are used for appropriate cross-checks. A Committee also visits manufacturer exporter units for first-hand knowledge of the manufacturing process and observe the nature of inputs ordinarily used and the amount of wastage. The Committee also takes into account the industry experience and broad technical factors, as appropriate. The refund is of the average amount of duty paid on materials of any particular class or description of goods used in the manufacture of export goods of specified goods.

- (131) Contrary to what the GOI argued, the RODTEP is not merely a program, which reimbursed taxes paid on the importation of inputs used in the production of goods exported. As described in recital (126), an exporter is under no obligation to actually consume any goods imported free of duty in the production process and the amount of credit is not calculated in relation to actual inputs used. There is no system or procedure in place to confirm which inputs are consumed in the production process of the exported product or whether an excess payment of import duties occurred within the meaning of point (i) of Annex I and Annexes II and III of the basic Regulation. Therefore, the details that the GOI described on how the rate for the RODTEP scheme is determined by the Committee and cross-checks with its data banks are not relevant as this does not prevent the excess benefit.
- (132) The Commission therefore rejected the claim.
 - 3.3.2.5. Calculation of the subsidy amount
- (133) In accordance with Article 3(2) and Article 5 of the basic Regulation, the Commission calculated the amount of countervailable subsidies in terms of the benefit conferred on the recipient, which was found to exist during the RIP. In this regard, the Commission established that the benefit is conferred on the recipient at the time when the company receives the benefit under this scheme. At that moment, the GOI issued a duty credit which was booked by HEG as an account receivable which can be offset by HEG at any moment. This constitutes a financial contribution within the meaning of Article 3(1)(a)(ii) of the basic Regulation. Once the customs authorities issue an export shipping bill, the GOI has no discretion as to whether or not to grant the subsidy. In the light of the above, and since there was no reliable evidence showing otherwise, the Commission considered appropriate to assess the benefit under the RODTEP as being the sum of the amounts earned on export transactions made under this scheme during the RIP by the cooperating exporting producer HEG. The Commission took into account RODTEP amounts earned on all the export transactions of HEG, as the company exports only product under review.
- (134) In accordance with Article 7(1)(a) of the basic Regulation, fees incurred by the coopering exporting producer HEG to obtain the subsidy were deducted from the total subsidy amount where claimed.
- (135) In accordance with Article 7(2) and (3) of the basic Regulation, the Commission allocated this subsidy amount over the export turnover of HEG during the RIP as appropriate denominator, because the subsidy is contingent upon export performance, and it was not granted by reference to the quantities manufactured, produced, exported or transported.
- (136) The subsidy rate established with regard to this scheme amounted to 0,59 % for HEG during the RIP.
- (137) Following the final disclosure, the GOI argued that, if there is any excess drawback, only the excess drawback can be countervailed. The GOI argued this would be supported by the Panel Report, European Union -Countervailing Measures on Certain Polyethylene Terephthalate from Pakistan, WT/DS486/R. From this Panel report the GOI quoted a section that contains the statement: 'Consistent with this observation, Annex III (II) provides guidance for investigating authorities that are designed to allow investigating authorities to identify excess remissions.'
- (138) The Panel Report does not contain conclusions that prevent the Commission from its conclusion on how to define the excess benefit. As described in recital (133), since there is no evidence an actual verification process showing otherwise, but only general descriptions of how the Committee works and establishes the RODTEP ratio, the Commission considered appropriate to assess the benefit under the RODTEP as being the sum of the drawback amounts earned on export transactions made under this scheme during the RIP.
- (139) The Commission therefore rejected the claim.

- 3.3.3. Preferential financing: Interest Equalization scheme ('IES')
- (140) The Commission established that HEG received benefits under the IES which could be allocated to the product under review during the RIP.

3.3.3.1. Legal basis

(141) The Reserve bank of India ('RBI') announced the 'Interest Equalisation Scheme on Pre and Post Shipment Rupee Export Credit' in Master Circular DBR.Dir.BC.No 62/04.02.001/2015-16 dated 4 December 2015. The IES was originally set to expire in September 2021. However, in March 2022, RBI notified the banks about the retroactive extension of the scheme until 2024, but at the lower rate of 2 %.

3.3.3.2. Eligibility

(142) The IES is available to exports of a wide range of products, including GES, irrespective of the size of the exporting producer and to any export for Micro, Small and Medium Enterprises.

3.3.3. Practical implementation

- (143) The IES is a scheme administered by the DGFT. It originally provided a 3-5 % interest offset for loans availed in respect of exports under 416 tariff lines as per Annexure A and exports made by Micro, Small & Medium Enterprises (MSMEs) across all ITC(HS) codes.
- (144) The Master Circular dated 4 December 2015 stipulated that from the month of December 2015 onwards, banks shall reduce the interest rate charged to the eligible exporters as per the guidelines on interest rates on advances by the rate of interest equalisation provided by Government of India. The local banks received compensation from the Reserve Bank of India so that the lower interests are provided to the eligible companies. The interest equalisation benefit is available from the date of disbursement up to the date of repayment or up to the date beyond which the outstanding export credit becomes overdue. However, the interest equalisation is available to the eligible exporters only during the period the scheme is in force.
- (145) When in March 2022, RBI notified the banks about the retroactive extension of the scheme until 2024 at the lower rate of 2 %, it also allowed the private banks to retroactively reimburse to the eligible exporting producers the respective offset amount for the period between October 2021 and March 2022.

3.3.3.4. Conclusion on the IES

- (146) The IES provides subsidies within the meaning of Article 3(1)(a)(iv) and Article 3(2) of the basic Regulation. Private banks are directly by law to provide interest offsets to eligible companies.
- (147) Furthermore, the IES is contingent in law upon export performance, since such loan interest offset cannot be obtained without a commitment to export. Therefore, it is deemed to be specific and countervailable under Article 4(4), first subparagraph, point (a) of the basic Regulation.

3.3.3.5. Calculation of the subsidy amount

(148) According to Article 6(b) of the basic Regulation, the benefit conferred on the recipient is the difference between the amount of interest that the company pays on the preferential loan and the amount that the company would pay for a comparable commercial loan obtainable on the Indian financial market (namely, the interest offset provided by the law). The amount of countervailable subsidies was therefore considered to be equal to the amount of interest relating to the RIP offset by the RBI and thus saved by HEG. This also includes the amounts that were retroactively reimbursed by the banks with respect to the RIP, due to the retroactive prolongation of the scheme in March 2022.

- (149) In accordance with Article 7(2) of the basic Regulation, the Commission allocated this subsidy amount over the export turnover of HEG during the RIP as appropriate denominator, because the subsidy is contingent upon export performance, and it was not granted by reference to the quantities manufactured, produced, exported or transported.
- (150) The subsidy rate established with regard to this scheme amounted to 0,71 % for HEG during the RIP.

3.4. Other additional schemes

3.4.1. National schemes

- (151) Duty Free Import Authorisation Scheme ('DFIA') is a duty exemption scheme for imports that are incorporated in exports, regulated under Chapter 4 of the FTP 2015-20. The scheme continued under the updated FTP 2015-20. For exports that benefit from AAS, a company cannot claim benefits under DFIA at the same time. No benefit for HEG has been found during the RIP.
- (152) Pursuant to Article 8.1.3 of the Master Circular, creditworthy exporters with good track record are granted an easy access to export credit on best terms through the Gold Card Scheme. The Commission has not found specific benefits for HEG during the RIP that could be linked to the Gold Card Scheme.
- (153) The Status Holder scheme grants benefits to business leaders who have excelled in international trade and have successfully contributed to country's foreign trade. All exporters with an import-export code number are eligible for the scheme provided that they achieve a defined threshold of export performance levels in the current and previous three financial years. The Commission has not found specific benefits for HEG during the RIP that could be linked to the Status Holder scheme.
- (154) During the RIP, HEG availed itself of Pre-shipment and Post-shipment Export Financing. However, apart from the interest rebate under the Interest Equalization Scheme already discussed in section 3.3 above, the Commission has not found specific benefits for HEG linked to pre-and post-shipment export financing.
- (155) The Market Access Initiative ('MAI') is a general export promotion scheme, which however only targets implementing agencies to promote exports and facilitate Market Access. It involves no direct interaction with the exporting Producers but with the Export Promotion Council under the supervision of the Ministry of Commerce. Exporting producers can indirectly benefit from reimbursement of costs for activities linked to export promotion. However, no benefit for HEG has been found during the RIP.

3.4.2. Regional schemes

- (156) There was no cooperation in this investigation from exporters with production in Karnataka and Maharashtra. Therefore, the Commission would need to base its conclusions on facts available.
- (157) Following the final disclosure, the GOI commented that the Commission countervailed programs from Karnataka and Maharashtra and submitted that there are no producers of the product under review in Maharashtra.
- (158) Contrary to the understanding of the GOI, for the purpose of this investigation the Commission did not make any findings on regional schemes in Karnataka and Maharashtra.
- (159) During the last expiry review, HEG benefited from an exemption of electricity duty provided by the State of Madhya Pradesh to industrial companies investing in electricity generation for captive consumption. HEG's eligibility to benefit from this scheme expired as of 2016.
- (160) Regarding purchased electricity, the complaint mentioned a rebate of 2 RS as a possible benefit under regional schemes. Electricity invoices reviewed at the company showed differences with regular industrial electricity tariff, including a rebate mentioned in the invoices. As a result, the Commission collected documents from the company and the GOI related to the energy tariffs applicable to HEG in Madhya Pradesh.

- (161) The documents and other information available showed that the Madhya Pradesh Electricity Regulatory Commission was constituted by Government of Madhya Pradesh via Gazette Notification dated 20th August, 1998. The Electricity Act 2003 (No 36 of 2003) enacted by the regional parliament has come into force w.e.f. 10 June 2003 and the Commission is now deemed to have been constituted and functioning under the provisions of Electricity Act 2003. Section 86 of the Electricity Act, 2003 prescribed the functions of that State Commission include:
 - '(a) determine the tariff for generation, supply, transmission and wheeling of electricity, wholesale, bulk or retail, as the case may be, within the State:
 - Provided that where open access has been permitted to a category of consumers under section 42, the State Commission shall determine only the wheeling charges and surcharge thereon, if any, for the said category of consumers;
 - (b) regulate electricity purchase and procurement process of distribution licensees including the price at which electricity shall be procured from the generating companies or licensees or from other sources through agreements for purchase of power for distribution and supply within the State;'
- (162) In its Retail Supply Tariff Orders, the Madhya Pradesh Electricity Regulatory Commission established a rebate for industrial consumers with captive power plants. The rebate was created initially for a period of 5 years starting from the financial year 2016/2017, but it was prolonged to be applicable up to the financial year 2022/2023. During the RIP, the Retail Supply Tariff Order FY 2020-21 indicated that a rebate of Rs 2 per unit shall be applicable on the regular price of incremental electricity units purchased by the consumer from the grid, subject to a reduction in its consumption of power captively generated.
- (163) In addition, the Retail Supply Tariff Orders further indicate a special Tariff for a specific category of industrial users, called 'Power Intensive industries', which is below the regular rate for industrial users (the 'reduced electricity rate').
- (164) The captive power plant rebate is available to companies located in the State of Madhya Pradesh who have fully or partially met their energy demand in one financial year between 2016 and 2020 through captive power plants and are now selling their own energy to the grid and subsequently repurchasing their energy demand via the grid.
- (165) The reduced electricity rates for power intensive industries is available only to companies located in the State of Madhya Pradesh who are active as Mini Steel Plants ('MSP'), MSP with rolling mills/sponge iron plants in the same premises, electro chemical/electro thermal industry, or ferro alloy industry.
- (166) Rebates and reduced electricity rates are set by the Madhya Pradesh Electricity Regulatory Commission in its yearly Retail Supply Tariff Order. The fully government-owned grid operator, Madhya Pradesh Madhya Kshetra Vidyut Vitaran Co. Ltd (one of the four publicly owned providers of electricity in the State), then applies these orders in its respective energy bills. Apart from captive power plants, there are no private actors operating on the electricity market in Madhya Pradesh.
- (167) Due to the findings on the schemes described in sections 3.2 and 3.3, which already confirm continuation of subsidisation at a level well above the de minimis threshold, the Commission concluded that in the context of this expiry review it was not necessary to further analyse the two schemes (electricity rebate and reduced electricity rate for certain industrial sectors) to make a determination on the continuation of subsidisation, which was already established.
- (168) However, on basis of the documents collected, and in view of the fact that the application of both the electricity rebate and the reduced electricity rate lead to a reduction of the price by 50 % in comparison with the regular electricity rate for large industrial users in the State of Madhya Pradesh, it cannot be excluded that the cooperating exporting producer received a significant benefit under these schemes.
- (169) Following the final disclosure, the GOI commented that that an investigation into this scheme was not covered neither in the Notice of Initiation, nor in the consultations with the GOI as required under the ASCM.

(170) In line with recitals (159) and (160) the Commission considered that the scheme was covered by the review request and possibly constituted a continuation of the previous electricity scheme. However, the Commission also confirmed its position described in recital (168) that for the purpose of this expiry review it is not necessary to fully analyse the two schemes. Therefore, no determination of subsidisation was made concerning these schemes.

3.5. Amount of countervailable subsidies

(171) The amounts of countervailable subsidies in accordance with the provisions of the basic Regulation, expressed ad valorem, for the cooperating exporting producer were as follows:

Schemes	DDS	AAS	MEIS	RODTEP	EPCGS	IES	Total
HEG	1,27 %	1,66 %	0,87 %	0,59 %	0,31 %	0,71 %	5,41 %

(172) The total amount of subsidisation exceeds the de minimis threshold mentioned in Article 14(5) of the basic Regulation.

3.6. Conclusions on the likelihood of a continuation of subsidisation

- (173) It was established that the cooperating exporting producer continued to benefit from countervailable subsidisation by the Indian authorities during the RIP. It was established that subsidisation continued at country-level as well, since most schemes are available nation-wide to exporters of GES.
- (174) The countervailable subsidy schemes give recurring benefits and there is no indication that these schemes will be phased out in the foreseeable future or that HEG would stop obtaining benefits under these schemes. To the contrary, the national tax-related schemes were renewed during the RIP as part of the Foreign Trade Policy 2015-2020 which will remain in force until March 2023. In addition, it is reminded that the application of the Foreign Trade Policy 2015-2020 was prolonged multiple times, which indicates that the follow-up Foreign Trade Policy is likely to continue the subsidisation. Moreover, each exporter is eligible to several of the subsidy schemes. The only exception concerns MEIS, which has expired in January 2021. However, this scheme has been replaced by a similar scheme, the RODTEP, for which the company accrued benefits, as highlighted in section 3.2.5 above.
- (175) Similarly, the Commission found that the preferential financing under the IES scheme has been extended until 2024 at least.
- (176) The investigation also showed that during the RIP Indian imports continued to enter the Union market and maintained their quantities and market shares as in the last two review investigations. Furthermore, the analysis of production volume and spare capacity in India, export volumes and prices from India to the other third country markets, existing measures in the other third countries, and attractiveness of the Union market provided in recitals (250) to (270) also shows that it is likely that the subsidised exports would further increase their already substantial presence in the Union market should the current measures be allowed to lapse.
- (177) In view of the above, in accordance with Article 18(3) of the basic Regulation, the Commission concluded that there was a likelihood of continuation of subsidisation should the measures in force be allowed to lapse.

4. INJURY

4.1. Definition of the Union industry and Union production

(178) The like product was manufactured by seven producers in the Union during the review investigation period. They constitute the 'Union industry' within the meaning of Article 4(1) of the basic Regulation.

(179) The total Union production during the review investigation period was established at 219 330 tonnes. The Commission established the figure on the basis of the verified questionnaire replies of the sampled Union producers and the data provided by the non-sampled producers and the applicants (19). As indicated in recital (15) the three sampled Union producers represented more than 61 % of the total Union production of the like product.

4.2. Union consumption

- (180) The Commission established Union consumption on the basis of the sales volumes of the Union industry's own production destined for the Union market and the import volumes obtained from Eurostat statistics.
- (181) On this basis, Union consumption developed as follows:

Table 1

Union consumption (tonnes) (20)

	2018	2019	2020	Review investigation period
Total Union consumption	152 612	120 169	99 873	137 279
Index	100	79	65	90

Source: Eurostat, information provided by the sampled and non-sampled Union producers, information provided by the applicants.

- (182) The Union consumption of GES decreased by 10 % over the period considered. The year 2018 showed a high consumption driven by high demand of the EU steel industry, which was in the process of recovering from the steel crisis. In addition, in a situation of a sudden GES price increase, steelmakers were building up stocks of GES in the expectation of an additional increase.
- (183) In 2019, the production of steel from electric arc furnaces decreased, as compared to 2018 (by 6,6 % according to Eurofer figures). Consequently, the demand for GES dropped. As the price of GES went down significantly, building up stocks was no longer considered necessary for the downstream industry as users were not anymore concerned by a further price increase. As a consequence, steel producers started destocking their GES inventories. Moreover, demand dropped further but this time on a temporary basis in 2020, following the COVID-19 outbreak.

4.3. Imports from India

- 4.3.1. Volume and market share of the imports from India
- (184) As mentioned in recital (180), the Commission established the volume of imports from India on the basis of Eurostat statistics. The market share was established based on of the Union consumption as set out in recital (181).
- (185) Imports from India developed as follows:

⁽¹⁹⁾ The production volume is based on EU-27 data as the United Kingdom ceased to be part of the European Union as from 1 February 2020 and the transition period for the United Kingdom's withdrawal ended on 31 December 2020.

⁽²⁰⁾ The consumption is based on EU-27 data, excluding data related to the United Kingdom.

Table 2

Import volume (tonnes) and market share

	2018	2019	2020	Review investigation period
Volume of imports from India (tonnes)	5 802	3 369	2 154	6 540
Index	100	58	37	113
Market share (%)	4	3	2	5
Index	100	74	57	125

Source: Eurostat and 14.6 database.

- (186) Imports of the product under review from the country concerned had decreased in 2019 and 2020, following the decrease of EU consumption, and recovered during the review investigation period. Overall, during the period considered the volume of imports increased from 5 802 tonnes in 2018 to 6 540 tonnes in the review investigation period, i.e. by 13 %. Imports of GES from India represented around 16 % of total GES imports to the Union during the review investigation period corresponding to a market share of 5 %.
- (187) Overall, the imports from India and their market share increased over the period considered. Despite the Union consumption decrease, the volume of dumped and subsidised imports from India kept increasing during the period considered (by 13 %), whereas the Union industry's sales decreased.
 - 4.3.2. Prices of the imports from India and price undercutting
- (188) The average price of imports from India developed as follows:

Import prices (EUR/tonne)

Table 3

	2018	2019	2020	Review investigation period
Import prices from India	13 756	10 211	4 1 2 0	2 747
Index	100	74	30	20

- (189) The average import price (21) of GES from India went down by 80 % throughout the period considered, from 13 756 EUR/tonne in 2018 to 2 747 EUR/tonne in the review investigation period.
- (190) Due to the high global demand for GES, the Indian prices surpassed the Union industry prices in the first half of the period considered, but then dropped by 60 % between 2018 and 2020 and remained consistently lower than the Union prices in 2020 and in the review investigation period.
- (191) The Commission determined the price undercutting in the review investigation period by comparing:
 - (a) the weighted average sales price of the Union producers charged to unrelated customers on the Union market, adjusted to an ex-works level; and

⁽²¹⁾ Import price without the customs and AD/AS duties. Source: Eurostat.

- (b) the corresponding weighted average import prices of the product under review from India from the cooperating Indian exporting producer, established on a CIF basis, excluding the anti-dumping and countervailing duties, with appropriate adjustments for customs duties and post-importation costs. In the absence of any other information, these costs were estimated at 1 % of the CIF value.
- (192) This resulted in the average undercutting margin of 41,1 %.
- (193) After disclosure the Government of India (GOI), argued that the undercutting margin calculated by the Commission is not representative as it is not based on actual market prices in the Union. In GOI's view the fact that sales sourced from GrafTech Iberica were made pursuant to long-term contracts ('LTAs') have resulted in an artificially high selling price which is not indicative of the market price of GES in the Union.
- (194) The Commission disagrees with this assessment. LTAs are not an uncommon commercial practice and a business decision in which a customer accepts to tie itself to a particular price level in exchange for a security of supply. Considering that LTAs were being used in dealings on the relevant market their presence in the sample does not render the sample not representative. Moreover, only part of the sales made by GrafTech were covered by LTAs while the sales of the other two sampled Union producers in the review investigation period were not covered by similar LTAs. Therefore, in the Commission's view, whilst representative of a part of the market, overall the LTAs used by GrafTech Iberica did not significantly affected the undercutting calculation. Therefore, this claim was dismissed.
 - 4.3.3. Imports from third countries other than India
- (195) The imports of the product under review from other third countries were mainly from China, Mexico and Russia.
- (196) The volume of imports from other third countries, as well as the market share and price trends developed over the period considered as follows:

Table 4

Imports from third countries other than India

Country		2018	2019	2020	Review investigation period
PRC	Volume (tonnes)	22 054	19 284	20 074	26 065
	Index	100	87	91	118
	Market share (%)	14	16	20	19
	Index	100	111	139	131
	Average price	10 875	5 253	2 337	2 614
	Index	100	48	21	24
Russia	Volume (tonnes)	1 076	3 229	780	3 371
	Index	100	300	72	313
	Market share (%)	1	3	1	2
	Index	100	381	111	348
	Average price	9 623	5 771	4 898	2 851
	Index	100	60	51	30

Source: Eurostat.

Mexico	Volume (tonnes)	1 374	12	896	1 437
	Index	100	1	65	105
	Market share (%)	1	0	1	1
	Index	100	1	100	116
	Average price	2 5 3 0	3 264	3 976	3 435
	Index	100	129	157	136
Rest of the world	Volume (tonnes)	4 482	2 471	2 616	3 621
	Index	100	55	58	81
	Market share (%)	3	2	3	3
	Index	100	70	89	90
	Average price	8 253	10 648	5 737	3 979
	Index	100	129	70	48
Total third	Volume (tonnes)	28 987	24 996	24 366	34 494
countries except India	Index	100	86	84	119
	Market share (%)	19	21	24	25
	Index	100	110	128	132
	Average price	10 027	5 852	2 844	2 814
	Index	100	58	28	28

(197) The impact of imports from other third countries has been analysed since they represented around 84 % of total GES imports to the Union during the RIP. Despite the decreasing consumption, volume of imports from other third countries increased by 19 % from almost 29 000 tonnes in 2018 to around 35 000 tonnes in the RIP.

(198) Imports from third countries followed partially the decrease in consumption in 2019 and 2020 yet rapidly recovered and reached the highest level in the RIP, with 19 % increase compared to 2018. The average price of imports from other third countries followed the global trend, decreasing by 72 % between 2018 and the RIP.

(199) The large majority of these imports in the RIP, 76 %, were imports from China. The import volumes from the other third countries except China and India increased over the period considered by 22 %. Import volume of GES from India increased from 5 800 tonnes in 2018 to 6 500 tonnes during the RIP, while China increased from 22 054 tonnes in 2018 to 26 065 tonnes during the RIP, with a market share gain of 25 % and 31 %, respectively.

(200) Over the same period import prices from China were lower than the prices of both the Indian exporters and the prices of the Union producers (except in 2018).

(201) Furthermore, as of 7 April 2022 (²²) the Commission made the imports of GES from China subject to anti-dumping duty (ranging from 23 % to 74,9 %) (²³).

4.4. Economic situation of the Union industry

4.4.1. General remarks

- (202) The assessment of the economic situation of the Union industry included an evaluation of all economic indicators having a bearing on the state of the Union industry during the period considered.
- (203) As mentioned in recital (15), sampling was used for the assessment of the economic situation of the Union industry.
- (204) For the injury determination, the Commission distinguished between macroeconomic and microeconomic injury indicators. The Commission evaluated the macroeconomic indicators based on data contained in the replies to the anti-dumping questionnaire by the sampled producers as well as macroeconomic data provided by the non-sampled producers and the applicants, crosschecked with the data in the review request. The data related to all Union producers. The Commission evaluated the microeconomic indicators based on 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.
- (205) 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.
- (206) The microeconomic indicators are: average unit prices, unit cost, labour costs, inventories, profitability, cash flow, investments, return on investments, and ability to raise capital.

4.4.2. Macroeconomic indicators

- 4.4.2.1. Production, production capacity and capacity utilisation
- (207) The total Union production, production capacity and capacity utilisation developed over the period considered as follows:

Table 5

Production, production capacity and capacity utilisation

	2018	2019	2020	Review investigation period
Production volume (tonnes)	251 009	219 744	164 413	219 330
Index	100	88	66	87
Production capacity (tonnes)	283 500	294 900	294 900	285 235

⁽²²⁾ Commission Implementing Regulation (EU) 2022/558 imposing a definitive anti-dumping duty and definitively collecting the provisional duty imposed on imports of certain graphite electrode systems originating in the People's Republic of China (OJ L 108, 7, 4, 2022, p. 20)

⁽²³⁾ The scope of the Chinese regulation is slightly different than the scope of the present regulation, as it does not include nipples and it also includes graphite electrodes of a kind used for electric furnaces, with an apparent density of 1,5 g/cm³ or more but less than 1,65 g/cm³ and an electrical resistance of 6,0 $\mu\Omega$.m or less, or with an apparent density of 1,5 g/cm³ or more and an electrical resistance of more than 6,0 $\mu\Omega$.m but not more than 7,0 $\mu\Omega$.m, (TARIC codes 8545 11 00 10 and 8545 11 00 15).

Index	100	104	104	101
Capacity utilisation (%)	89	75	56	77
Index	100	84	63	87

Source:information provided by the sampled and non-sampled Union producers, information provided by the applicants.

- (208) Following the decrease in consumption, the production volume of the Union industry dropped by 34 % between 2018 and 2020, and partially recovered in the RIP, remaining below the 2018 level. Overall, the production volume decreased by 13 % during the period considered.
- (209) The decrease of the production volume is due to the decrease in consumption coupled with the loss in sales quantity suffered by the Union industry, as explained below in recital (211).
 - 4.4.2.2. Sales volume and market share
- (210) The Union industry's sales volume and market share developed over the period considered as follows:

77

Sales volume and market share

Table 6

	2018	2019	2020	Review investigation period
Total sales volume on the Union market (tonnes)	117 824	91 804	73 352	96 245
Index	100	78	62	82

Index 100 99 95 91

Source: Information provided by the applicants, information provided by the sampled and non-sampled Union producers.

76

73

70

- (211) Sales volume of the Union industry decreased by 18 % during the period considered. It decreased steadily up to 2020 (by 38 %) and recovered only partially during the review investigation period. However, this increase was not in line with the similar trend followed by the Union consumption which resulted overall in a loss of market share of the Union industry from 77 % in 2018 to 70 % in the review investigation period (minus 9 %), while the market share of the imports from India increased by 25 % during the same period.
- (212) During the period considered, the EU consumption of GES decreased by 10 %. This decrease of 15 000 tonnes in consumption hit only the Union industry, that lost 21 000 tonnes of sales. Over the same period the volume of dumped imports from India, China and other third countries kept increasing during the period considered, by 13 %, 18 % and 19 % respectively.

4.4.2.3. Growth

Market share (%)

(213) As explained above, during the period considered, the sales volume of the Union industry lost 21 000 tonnes of sales while imports increased by more than 6 200 tonnes. This resulted in a 9 % market share loss for the Union industry over the period considered. Consequently, there was no growth for the Union industry during the period considered.

4.4.2.4. Employment and productivity

(214) Employment and productivity developed over the period considered as follows:

Table 7

Employment and productivity

	2018	2019	2020	Review investigation period
Number of employees (FTE)	1 165	1 148	1 102	1 143
Index	100	99	95	98
Productivity (unit/employee)	215	191	149	192
Index	100	89	69	89

Source: Information provided by the applicants, information provided by the sampled and non-sampled Union producers.

- (215) The number of employees of the Union industry remained relatively stable over the period considered (decreased by 2 % over the period considered). Therefore, given the drop in production explained in section 4.4.2.1, the productivity of the Union industry's workforce, measured as output (tonnes) per employee, followed the same trend dropping by 11 % over the same period.
 - 4.4.2.5. Magnitude of the subsidy margin and recovery from past subsidization
- (216) The Commission concluded in recital (177) that Indian imports continued to enter the Union market at subsidised prices during the review investigation period. The Commission also found evidence that subsidisation will likely continue should the measures lapse.
- (217) Despite the countervailing measures in force since 2009, the Union industry has lost substantial sales volume which is reflected in a loss of market share of 9 percentage points over the period considered. Thus, no full recovery from the past subsidy could be established and the Union industry remains highly vulnerable to the injurious effects of any subsidized imports in the Union market.
 - 4.4.3. Microeconomic indicators
 - 4.4.3.1. Prices and factors affecting prices
- (218) 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 8

Sales prices in the Union

	2018	2019	2020	Review investigation period
Average unit sales price in the Union on the total market (EUR/tonne)	8 483	9 578	5 870	4 682
Index	100	113	69	55

Unit cost of production (EUR/tonne)	3 696	4 685	4 864	3 5 5 6
Index	100	127	132	96

Source: Questionnaire replies of the sampled Union producers.

- (219) The sales prices increased between 2018 and 2019 by 13 % before decreasing steeply in 2020 and in the review investigation period to the level by 45 % lower than in 2018.
- (220) Cost of production increased, reached its highest point in 2020 and started decreasing during the review investigation period. This trend is due to the substantial increase of the price of the main raw material, that is needle coke. The price of needle coke, due to the increased demand driven by the lithium-ion battery industry, increased steadily and significantly up to 2019 and only as of 2020 it started decreasing.
- (221) Considering the sales prices of the Union industry, the Commission noted that a part of the Union production (in particular produced by GrafTech Iberica and GrafTech France) representing around 50 % of the total Union sales and production, was to some extent temporarily shielded from direct market competition, whereas the other part (the other two sampled Union producers) was directly exposed to the dumped Indian imports.
- (222) This situation was due to the existence of LTAs covering sales of GES sourced from GrafTech Iberica. These LTAs were concluded in the wake of a period of unusually high prices in the years 2017–2018. These contracts are 'take or pay' purchase contracts with a guaranteed level of supplies at set prices and the buyer committed to buy the agreed volumes at the pre-determined and fixed price, subject to various contractual rights and obligations. The duration of these contracts was three to five years. It appeared that a very large portion of sales sourced from GrafTech Iberica during the review investigation period were made under these LTAs. The investigation did not reveal that any other Union producer would be covered by similar LTAs in the period considered. In view of the LTAs' limited duration, the Commission noted that the impact of the contracts is of a temporary nature.
- (223) The origin of these LTAs is to be found in the period of high price volatility in the years 2017-2018 that stretched up to 2019. In these years, globally prices of graphite electrodes increased significantly. This was due to many factors, including increased global demand. The key reason for the rise in demand cited by the Union industry was to be the global shift in the steel industry, from blast furnaces to the electric arc furnaces, which use graphite electrodes. In addition, as explained in recital (220), the new competition for needle coke (the main raw material used in the production of graphite electrodes) with the lithium-ion battery industry drove an increase of raw material cost that contributed to the price volatility. To address this issue of price volatility, the LTAs for the supply of the product under review sourced from GrafTech Iberica were negotiated with a duration between three to five years. The principle was to obtain more stable prices in exchange for a stable supply as requested by clients.
- (224) Therefore, thanks to the existing LTAs, sales of GrafTech Iberica could be at a stable price level ([25–50] % above the average unit sales price in the Union) during the review investigation period despite the general fall in prices from which the remainder of the Union industry was not covered by LTA. Based on the information available, such as sales volumes of the product under review not subject to LTAs and sourced from GrafTech Iberica as well as the sales of the other two sampled Union producers, the Commission estimated that the average price on the market not covered by the terms of the LTAs was around [25–50] % lower than the average unit sales price in the Union on the total market. Accordingly, the average Union sales price during the review investigation period does not accurately reflect the competitive price situation on the Union market, which was significantly affected by low-priced and dumped imports from both India and China.

4.4.3.2. Labour costs

(225) The average labour costs of the sampled Union producers developed over the period considered as follows:

Table 9 Average labour costs per employee

	2018	2019	2020	Review investigation period
Average labour costs per employee (EUR)	91 856	87 714	84 993	87 519
Index	100	95	93	95

Source: Questionnaire replies of the sampled Union producers.

(226) The average labour cost slightly decreased over the period considered. Overall, the average labour cost per employee decreased by 5 %. This trend was mostly influenced by the limited reduction in employment figures as explained in recital (215).

4.4.3.3. Inventories

(227) Stock levels of the sampled Union producers developed over the period considered as follows:

Table 10

Inventories

	2018	2019	2020	Review investigation period
Closing stocks (tonnes)	7 026	9 447	8 172	8 812
Index	100	134	116	125
Closing stocks as a percentage of production	3	4	5	4
Index	100	154	178	144

Source: Questionnaire replies of the sampled Union producers.

- (228) Inventories cannot be considered as a relevant injury indicator in this sector, as production and sales are mainly based on orders and, accordingly, producers tend to hold limited stocks. Therefore, the trends on inventories are given for information only.
- (229) Overall, inventories were influenced by the decreasing trends of production and sales of the Union industry. Closing stocks as a percentage of production increased significantly in 2019 and 2020 (by 54 % and 78 % respectively) partially decreasing during the review investigation period. Overall, during the period considered closing stocks in tonnes increased by 25 %.
- (230) However, when looking at the data of the two Union producers that did not conclude LTAs. Over the same period their stocks increased by [35 45] %.
 - 4.4.3.4. Profitability, cash flow, investments, return on investments and ability to raise capital
- (231) Profitability, cash flow, investments and return on investments of the sampled Union producers developed over the period considered as follows:

Table 11

Profitability, cash flow, investments and return on investments

	2018	2019	2020	Review investigation period
Profitability of sales in the Union to unrelated customers (% of sales turnover)	75	62	2	31
Index	100	82	2	42
Cash flow (EUR)	659 909 270	475 537 375	120 592 009	210 732 326
Index	100	72	18	32
Investments (EUR)	23 523 042	28 065 231	21 574 327	29 396 885
Index	100	119	92	125
Return on investments (%)	722	467	35	154
Index	100	65	5	21

Source: Questionnaire replies of the sampled Union producers.

- (232) 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.
- (233) After the previous expiry review investigation mentioned in recital (1), where the countervailing measures were imposed, the situation of the Union industry improved and its profit margin, due to the increase in prices mentioned above in section 4.4.3.1, reached 75 % in 2018. However, the situation deteriorated subsequently and profit margins declined as from 2018 reaching its bottom point in 2020 (2 %) and partially recovering in the review investigation period (31 %), corresponding to a decrease of 58 % over the period considered.
- (234) The cause for this decreasing trend is the significant reduction in Union consumption and in sales volume suffered by the Union industry at the advantage of the dumped and subsidized Indian and dumped Chinese imports that exerted significant price pressure entering into the Union undercutting those of the Union industry and forcing the part of the Union industry not covered by the LTAs to reduce their prices levels, as explained above in recital (224).
- (235) As mentioned above, one of the sampled Union producers, GrafTech Iberica, sold the majority of its volumes under LTAs. Therefore, products were sold at stable prices and, during the RIP (until expiry of the LTAs; a significant part expired by the end of 2021, another part by the end of 2022), these sales were still considered partially shielded from external factors such as the general price decrease.
- (236) However, the situation is different for the other two sampled Union producers. Excluding GrafTech Iberica the micro-indicators show a different picture, with profitability of sales in the Union dropping from [+70 +80] % in 2018 to [0 +10] % in the review investigation period.
- (237) The net cash flow is the Union industry's ability to self-finance their activities. Given the decreasing trend of Union industry's profit the cash flow dropped by 68 % over the period considered.

- (238) Investments, thanks to a still positive cash flow, increased by 25 % in the period considered, which is mainly due to the efforts made by the Union industry to rationalize its production and increase efficiency and productivity to face the increasing low-priced imports. However, in the same period, the return on investments, which is expressed as the profit in percentage of the net book value of investments dropped by 79 % and therefore followed the same trend as the profitability.
- (239) A picture similar to the one explained above can be observed when looking at the data of the two Union producers that did not sell under LTAs during the review investigation period. Over the same period return on investment and cash flow dropped to [0 + 10]%.
- (240) The decreasing profitability and return on investment will made it increasingly difficult for the sampled Union producers to raise capital for future investment. With return on investments falling so quickly, the sampled producers' ability to raise capital in the future is in greater jeopardy.

4.4.4. Conclusion on injury

- (241) The investigation showed that the measures allowed the Union industry to maintain, at least partially, a significant market shares throughout the period considered. Most of injury indicators showed that the economic situation of the Union industry was difficult. As explained above, these negative developments are explained by the decrease in consumption coupled with the consequence of the COVID-19 outbreak and dumped imports from China and dumped and subsidized imports from India which during the same period gained market share to the detriment of Union industry whose market share decreased. The situation was further aggravated by the sharp increase of the dumped imports from China and India. The Union industry has responded to these challenges by decreasing its prices and reducing profit, which, nevertheless, remained positive during the period considered.
- (242) In particular, production, sales volumes and market shares decreased, as well as sales prices which had a negative effect on productivity as well as on profitability. The increased price pressure from the dumped imports coming from India and China forced the Union industry to reduce its sales prices with negative effects on its profitability which decreased substantially over the period considered. Finally, the rapidly decreasing returns on investments has a negative impact on the Union industry's ability to raise capital and investments.
- (243) On the other hand, despite the declining trends, the Union industry still managed to maintain large sales volume and considerable market share. Likewise, despite the negative trend, profitability remained positive throughout the period considered. Therefore, the Commission concluded that the Union industry was subject to some negative trends over the period considered which resulted in an overall vulnerable situation in 2021 but did not suffer material injury within the meaning of Article 3(5) of the basic Regulation during the review investigation period.
- (244) After disclosure, the GOI claimed that the increased prices of raw materials, following the military aggression by the Russian Federation against Ukraine, is one of the main factors for the reduced profitability of the Union industry.
- (245) This claim is not supported by any evidence. The military aggression and the underlying geopolitical situation developed after the review investigation period, as of February 2022, and therefore had no influence on the situation of the Union industry over the period considered. Therefore, this claim was deemed as unfounded.

5. LIKELIHOOD OF RECURRENCE OF INJURY

(246) The Commission concluded in recital (243) that the Union industry did not suffer material injury during the review investigation period. Therefore, the Commission assessed, in accordance with Article 11(2) of the basic Regulation, whether there would be a likelihood of recurrence of injury originally caused by the dumped and subsidized imports from India if the measures were allowed to lapse.

(247) In order to establish whether there is likelihood of recurrence of injury originally caused by the dumped and subsidized imports from India, the Commission considered the following elements: (i) production volume and spare capacity in India, (ii) export volumes and prices from India to the other third country markets, (iii) existing measures in the other third countries, (iv) attractiveness of the Union market, and, (v) likely price levels of imports from India and their impact on the Union industry's situation, should the measures allowed to lapse.

5.1. Production capacity and spare capacity

- (248) Based on the information provided in the request for expiry review (24), the total Indian production capacity of GES was estimated at around 160 000 tonnes, the production at around 121 000 tonnes and the spare capacity at around 39 000 tonnes in the review investigation period. The estimated spare capacity represented around 29 % of the Union consumption during the review investigation period.
- (249) In addition, the information provided in the request (25) indicated that one Indian producer is expected to continue to increase its capacity by additional 20 000 tonnes by early 2023, increasing the spare capacity to 59 000 tonnes (43 % of the Union consumption during the review investigation period). Therefore, the capacity to significantly increase export quantities to the Union exists, in particular because there are no indications that third country markets or the domestic market could absorb any additional production.

5.2. Export volumes and prices from India to the other third country markets

- (250) In the absence of cooperation and consequently of any other more reliable source for establishing the Indian exports of GES from India to the other third countries except the Union, the analysis was based on the GTA data of HS code 8545 11. This HS code covered around 82 % of the Indian exports to the Union (compared to Eurostat TARIC data), while almost no imports into the Union from India were made under HS code 8545 90. The GTA data for HS 8545 11 was therefore considered the most reliable source for third country market analysis.
- (251) Both GIL and HEG were, the two known producers of GES in India, found to be highly export oriented, exporting above 60 % of their production in 2021. Turkey, the United States, the Union and Egypt were its their main export markets. Overall, worldwide export volumes from India decreased by 14 % from 2018 to the RIP, while it increased by 16 % to the top three export markets (Turkey, United States and Egypt).
- (252) The export prices analysis to India's top ten export countries during the RIP indicated that the export price to the Union at FOB Indian border level (2 727 EUR/tonne) was higher than to Egypt, South Korea, South Africa, Mexico and United Arab Emirates, while lower than to Turkey, United States, Saudi Arabia and Indonesia. However, given the export restrictions the Indian industry is facing, as explained below in section 5.3, and taking into account the current Indian spare capacity, it was considered that,, Indian exporters would have an incentive to shift significant quantities of exports from third countries to the more attractive Union market should measures be allowed to lapse.

5.3. Existing measures in the other third countries

(253) Following the US sanctions against Iran in August 2018, India lost its largest export destination for GES (26). Before the sanctions, Iran was among the top tree export destination of GES for India with export volumes of around 9 000 tonnes/year. In 2019, following the sanctions, export volumes from India to Iran decreased to nearly zero tonnes and remained so in the following years.

⁽²⁴⁾ Publicly available annual report of HEG in 2021 and GIL Corporate Presentation of 2021.

⁽²⁵⁾ HEG, Annual Report 2021, p. 2, 11.

⁽²⁶⁾ Non-US companies can no longer use US dollars for transactions with Iran. Moreover, if sanctioned for violating the US sanctions it may result for foreign companies not being permitted to open new US bank accounts and facing restrictions on loans, licences and Ex-Im credit.

(254) In addition, the Eurasian Economic Commission extended the anti-dumping measures on imports of GES from India until September 2023 at the rate of 16,04 % for HEG and 32,83 % for GIL and other Indian manufactures. The Russian Federation, one of the members of the Eurasian Economic Union, was an important consumer of GES with its annual electric arc furnaces steelmaking of 24 million tonnes in 2019. India's GES exports to Russia decreased from around 840 tonnes in 2018 to zero tonnes in 2020 and 2021. Therefore, with the already available spare capacity this will restrict the potentially available export markets for the Indian producers, increasing even further the attractiveness of the Union market, should the measures allowed to lapse.

5.4. Attractiveness of the Union market

- (255) The attractiveness of the Union market was demonstrated by the fact that despite the anti-dumping and countervailing duties in force, Indian GES continued to enter the Union market. During the period considered, India continued to be the second largest exporting country to the Union after China. Despite a decrease between 2019 and 2020 due to the COVID-19 pandemic, India maintained and increased its exports to the Union, between 5 800 tonnes in 2018 and to 6 500 tonnes in the review investigation period, and market shares, between 4 % in 2018 and 5 % in the review investigation period. This is in the same range of the export volumes and market shares observed in the Union during the review investigation period of the two previous expiry reviews. As provided in the recital (192), the Indian export price to the Union was significantly undercutting the prices on the Union market during the review investigation period.
- (256) In addition, according to the public statements of HEG, the producer considers the Union an important export market to increase their presence if the anti-dumping/subsidy measures are lifted (²⁷).

5.5. Likely price levels of imports from India and their impact on the Union industry's situation should the measures lapse

- (257) To assess the impact of future imports on the situation of the Union industry, the Commission considered that price levels of the Indian exports without the anti-dumping duties would be a reasonable indicator of future price levels to the Union market. On this basis, the average undercutting margin for the product under review was found to be, without anti-dumping and countervailing duties included, 41,1 %, therefore is considered the best indicator of the likely price levels in the absence of anti-subsidy measures.
- (258) Given its intense use and rapid replacement, users of the product under review tend to maintain substantial stocks as for commodities. Therefore, the product under review is price sensitive. A surge in imports at low prices would force the Union industry to further reduce their prices as it has already been done to compete with the imports from India and China, as explained above in section 4.4.3.1.
- (259) In addition, as of April 2022 imports of certain GES from China, are subject to the anti-dumping duty mentioned in recital (199). The scope of the product concerned by these duties covers, to a large extent, the scope of the product concerned by the present investigation, namely TARIC codes 8545 11 00 10. It is therefore expected that the Chinese market share will decrease (from 20 %, in the review investigation period). This will further increase the attractiveness of the Union market for the dumped/subsidised imports from India. With the current or even likely increased spare capacity mentioned above in recital (249), and without the competition of the Chinese exporting producers, there is a strong likelihood that Indian exporting producers will significantly increase their imports of the product under review to the Union market should measures be allowed to lapse.
- (260) Moreover, as explained above in recitals (221) to (224) the global situation of the Union industry is affected by the particular situation of GrafTech Iberica that is temporary. The LTAs came to an end (to a large extent the large majority of the LTAs in force already expired in 2022) Some of the existing LTAs sourced from GrafTech Iberica were extended for one or two years beyond 2022. However, the extended LTAs covered only a minor part of total sales sourced from GrafTech Iberica. Even including the extended LTAs, the vast majority of the sales volume

⁽²⁷⁾ Publicly available HEG, Conference Call Transcript 2021 provided by the applicants. https://hegltd.com/wp-content/uploads/2021/06/ConferenceCallTranscript08062021.pdf

sourced from GrafTech Iberica will, at the end of 2023 no longer be covered by the current LTAs. This proportion will further increase at the end of 2024. Moreover, the Commission noted that the average sales prices for products sourced from GrafTech Iberica for the IP declined compared to 2020 (even including the sales under the LTAs), which indicated that sales sourced from GrafTech Iberica were impacted by the imports of graphite electrodes from India and China at low prices. Therefore, by the end of 2023 at the latest, GrafTech Iberica will be in the same situation as the other producers and will be fully exposed to the impact of increasing volumes of dumped and subsidized imports from India. This means that the economic situation of the Union industry would further deteriorate should measures be allowed to lapse.

- (261) With a loss of profitability, the Union industry would not be able to carry out necessary investments. Ultimately, this would also lead to an employment loss and risk of production lines closures.
- (262) After disclosure the GOI argued that there is no likelihood of recurrence of injury in the present case, primarily because the market share of the imports from India into the Union is merely 5 % and that any injury to the Union industry is on account of imports from China and not imports from India. Furthermore, the GOI argued that the low import prices from India is a reaction to the low-priced imports from China.
- (263) When establishing whether there is a likelihood of recurrence of injury originally caused by the dumped imports from India, as explained in recital (247), the Commission considered several elements such as production volume and spare capacity in India, export volumes and prices from India to the other third country markets, existing measures in the other third countries, attractiveness of the Union market, and likely price levels of imports from India and their impact on the Union industry's situation, should the measures be allowed to lapse. In its comments GOI did not question the Commission's analysis or conclusion on any of these elements other than the one addressed in recital (127). Contrary to what the GOI suggested in its comments, the Commission did not base its finding with regard to the likelihood of recurrence of injury on the market share of imports of the GES from India to the Union observed during the review investigation period.
- (264) The claim was therefore dismissed.
- (265) Furthermore, the GOI claimed that the Union market is not a price attractive market for the Indian exporting producers as its export prices to the Union are lower that the export price of GES to other third countries.
- (266) The Commission acknowledged, in recital (252) above that Indian export prices to some third countries are above the export prices to the Union. Nevertheless, prices to some other export markets, that are important to the Indian exporting producers, are lower than the prices to the Union. Moreover, as explained in section 4.3.1 above, the Indian exports gained market share in the Union over the period considered. Therefore, for the reasons set out above, the Commission concluded that this claim was unfounded.

5.6. Conclusion

(267) In view of the above, the Commission concluded that the expiry of the measures would in all likelihood result in a significant increase of dumped and subsidized imports from India at prices undercutting the Union industry prices, and therefore would aggravate the economic situation of the Union industry. It is highly likely that this would lead to a recurrence of material injury and as a consequence, the viability of the Union industry would be at serious risk.

6. UNION INTEREST

- (268) In accordance with Article 21 of the basic Regulation, the Commission examined whether maintaining the existing anti-dumping measures would be against the interest of the Union as whole. The determination of the Union interest was based on an appreciation of all the various interests involved, including those of the Union industry, importers, distributors and users.
- (269) All interested parties were given the opportunity to make their views known pursuant to Article 21(2) of the basic Regulation.

6.1. Interest of the Union industry

- (270) The Union industry is composed of five groups producing graphite electrodes in the Union. All groups cooperated fully in the investigation. As mentioned in recital (15), the Commission selected a sample of Union producers. The sample consisted of 3 Union producers that provided a reply to the questionnaire. The sample was considered representative for the Union industry.
- (271) As set out above, the Union industry did not suffer material injury during the period considered but it is in a fragile situation, as confirmed by the negative trends of the injury indicators. Removing the anti-dumping duties would lead to a likely recurrence of material injury which would be translated in a loss of sales and production volume, as well as market share leading to a loss of profitability and employment.
- (272) On the other hand, the Union industry has proven to be a viable industry. After the last expiry review it managed to improve its situation in the fair conditions on the Union market, invest and operating at a profit above the target profit established in the original investigation. The continuation of the measures would prevent the low priced imports from India to flood the Union market and therefore would allow the Union industry to maintain sustainable prices and profitability levels necessary for future investments.
- (273) On this basis, the Commission thus concluded that the maintenance of the countervailing measures is in the interest of the Union industry.
- (274) Following the final disclosure, the GOI commented that since the anti-subsidy duties already were in place for almost 20 years, the further continuation of the duties would lead to overprotection and would stifle the competition on the EU market. There was no justification for the continuation of the duties for more than 20 years.
- (275) The Commission has found evidence that the subsidisation of the Indian exports continued in the RIP. Therefore, even if the measures are in place for a long time, the prolongation of the duties is in line with the rule for protection against subsidized imports. There is also no risk for a negative influence on the competition on the EU market as the duties only counterbalance the subsidisation and restore a fair international competition.

6.2. Interest of unrelated importers, traders, and users

- (276) The Commission contacted all known unrelated importers, traders, and users. No interested party came forward.
- (277) Given the non-cooperation of any importers, traders or users, no information was available on the impact of the duties on these parties. The original investigation revealed, however, that any impact on other interested parties was not as such that measures had to be considered to be against the Union interest and likewise, the previous expiry review investigation established that the maintenance of the measures would not have a significant negative impact on the situation these parties.
- (278) On the basis of the above, the Commission concluded that the maintenance of the countervailing measures in force would not have any significant adverse effects on importers, traders or users.
- (279) After disclosure the GOI claimed that the maintenance of the anti-dumping measures in force is not in the interest of the Union. The GOI argued that the fact that sales sourced from GrafTech Iberica were made pursuant to LTAs resulted in an artificially and anti-competitive high selling price which is not indicative of the market price of GES in the Union. The consequences of these artificially high-priced sales would be faced by the downstream users in the Union.
- (280) As explained above in recital (194) LTAs are a not uncommon freely entered into commercial practice in which both parties agrees on the terms as they assume they will be beneficial. Therefore, in the Commission's view the LTAs and the resulting prices cannot be deemed as anti-competitive. Moreover, as explained in recital (235) by the end of 2023 the majority of the LTAs signed by GrafTech Iberica will come to an end and GrafTech Iberica will be in the same situation as the other producers and will be fully exposed to the impact of increasing volumes of dumped imports from India.

- (281) Therefore, this claim was dismissed.
- (282) Furthermore, the GOI argued that the continuation of duties would not be in interest of the Union as the impact of such duties will be passed down to the customers.
- (283) This argument was deemed as unfounded. The interest of the users was assessed, by the Commission, in recitals (276) to (278) and it was concluded that the maintenance of the anti-dumping measures in force would not have any significant adverse effects on users.

6.3. Conclusion on Union interest

(284) On the basis of the above, the Commission concluded that there were no compelling reasons of the Union interest against the maintenance of the existing measures on imports of the product under review originating in India.

7. ANTI-SUBSIDY MEASURES

- (285) Based on the conclusions reached by the Commission concerning the continuation of subsidisation from India, the likelihood of recurrence of injury caused by subsidised imports from India, and the Union interest, the Commission finds that the countervailing measures on imports of certain graphite electrode systems originating in India should be maintained.
- (286) The individual company countervailing duty rates specified in this Regulation are exclusively applicable to imports of the product under review originating in India and produced by the named legal entities. Imports of the product under review 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 countervailing duty rates.
- (287) A company may request the application of these individual countervailing duty rates if it changes subsequently the name of its entity. The request must be addressed to the Commission (28). The request must contain all the relevant information enabling to demonstrate that the change does not affect the right of the company to benefit from the duty rate which applies to it. If the change of name of the company does not affect its right to benefit from the duty rate which applies to it, a regulation about the change of name will be published in the Official Journal of the European Union.
- (288) All interested parties were informed of the essential facts and considerations on the basis of which it was intended to recommend that the existing measures be maintained. They were also granted a period to make representations subsequent to this disclosure.
- (289) In view of Article 109 of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council (29), when an amount is to be reimbursed following a judgment of the Court of Justice of the European Union, the interest to be paid should be the rate applied by the European Central Bank to its principal refinancing operations, as published in the C series of the Official Journal of the European Union on the first calendar day of each month.
- (290) The measures provided for in this regulation are in accordance with the opinion of the Committee established by Article 15(1) of Regulation (EU) 2016/1036,

(28) European Commission, Directorate-General for Trade, Directorate G, Rue de la Loi 170, 1040 Brussels, Belgium.

⁽²⁹⁾ Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 (OJ L 193, 30.7.2018, p. 1).

HAS ADOPTED THIS REGULATION:

Article 1

- 1. A definitive countervailing duty is hereby imposed on imports of graphite electrodes of a kind used for electric furnaces, with an apparent density of 1,65 g/cm3 or more and an electrical resistance of 6,0 $\mu\Omega$.m or less, and nipples used for such electrodes, whether imported together or separately, currently falling under CN codes ex 8545 11 00 and ex 8545 90 90 (TARIC codes 8545 11 00 10 and 8545 90 90 10) and originating in India.
- 2. The rates of the definitive countervailing 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	Countervailing duty (%)	TARIC additional code
Graphite India Limited (GIL), 31 Chowringhee Road, Kolkatta – 700016, West Bengal	6,3	A530
HEG Limited, Bhilwara Towers, A-12, Sector-1, Noida – 201301, Uttar Pradesh	7,0	A531
All other companies	7,2	A999

- 3. The application of the individual duty rates specified for the companies mentioned in paragraph 2 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.
- 4. Unless otherwise specified, the provisions in force concerning customs duties shall apply.

Article 2

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

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

Done at Brussels, 6 June 2023.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1104

of 6 June 2023

amending Regulation (EC) No 1238/95 as regards the fees payable to the Community Plant Variety Office

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 2100/94 of 27 July 1994 on Community Plant Variety Rights (¹), and in particular Article 113 thereof,

After consulting the Administrative Council of the Community Plant Variety Office,

Whereas:

- (1) Article 9(1) of Commission Regulation (EC) No 1238/95 (²) sets out the level of the fee payable to the Community Plant Variety Office ('the Office'), for each year of the duration of a Community plant variety right as provided for in Article 113(2), point (d), of Regulation (EC) No 2100/94.
- (2) In order to reflect the potential for inflation on all budget lines and to continue to increase the free reserve to the minimum level to ensure the operation of the office, the annual fee paid by a holder of a Community plant variety right should be raised to EUR 380.
- (3) The complexity of appeal cases has been rising and the current appeal fee established in Article 11 of Regulation (EC) No 1238/95 does not cover the real costs. This appeal fee should therefore be raised to EUR 2 100.
- (4) Experience has shown that there is a need to cover the administrative costs concerning the declaration of Community plant variety right null and void, as referred to in Article 20 of Regulation (EC) No 2100/94, and the administrative fee concerning a written objection to granting a Community plant variety right, as referred to in Article 59 of that Regulation.
- (5) Annex I to Regulation (EC) No 1238/95 sets out the level of fees for arranging and carrying out the technical examination of a variety which is the subject of an application for a Community plant variety right, payable to the Office.
- (6) On the basis of a survey on the costs of the Examination offices carried out by the Office, the fees charged by the Office should be updated, taking into account the inflation rate. Oil seed rape should be included in the group of other agricultural species and strawberry in the group of other fruits species as the level of fees in those groups are more appropriate for those species. Therefore, fees set out in Annex I to Regulation (EC) No 1238/95 should be modified for all the cost groups concerned.
- (7) According to Article 83 Regulation (EC) No 2100/94 the Office shall charge fees for its official acts provided for under the Regulation. Therefore, fees should be laid down for the declaration of Community plant variety right null and void and for a written objection to granting a Community plant variety right in order to cover costs of these increased activities.
- (8) Regulation (EC) No 1238/95 should therefore be amended accordingly.
- (9) This Regulation should apply from 1 July 2023 in order to allow sufficient time for the Office and the stakeholders to adapt to those amendments.
- (10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Community Plant Variety Rights,

⁽¹⁾ OJ L 227, 1.9.1994, p. 1.

⁽²⁾ Commission Regulation (EC) No 1238/95 of 31 May 1995 establishing implementing rules for the application of Council Regulation (EC) No 2100/94 as regards the fees payable to the Community Plant Variety Office (OJ L 121, 1.6.1995, p. 31).

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 1238/95 is amended as follows:

- (1) in Article 9, paragraph 1 is replaced by the following:
 - '1. The Office shall charge a holder of a Community plant variety right ('the holder') a fee of EUR 380 for each year of the duration of a Community plant variety right ('annual fee'), as referred to in Article 113(2), point (d), of the Basic Regulation.';
- (2) in Article 11, paragraph 1 is replaced by the following:
 - '1. The appellant shall pay an appeal fee of EUR 2 100 for the processing of an appeal, as provided for in Article 113(2), point (c), of the Basic Regulation.';
- (3) in Article 12, paragraph 1 is replaced by the following:
 - '1. The President of the Office shall fix the fees for the following matters:
 - (a) the administrative fee referred to in Article 8(5);
 - (b) fees for issuing certified copies of documents;
 - (c) the administrative fee referred to in Article 82(2) of the Proceedings Regulation;
 - (d) the administrative fee concerning the declaration of Community plant variety right null and void, as referred to in Article 20 of the Basic Regulation;
 - (e) the administrative fee concerning a written objection to granting a Community plant variety right, as referred to in Article 59 of the Basic Regulation.'
- (4) in Article 12, paragraph 2 is replaced by the following:
 - '2. The President of the Office may decide to make the services mentioned under paragraph (1(a) to (e) dependent on an advance payment.'
- (5) Annex I is replaced by the text in 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 1 July 2023.

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

Done at Brussels, 6 June 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

'ANNEX I

Fees relating to technical examination as referred to in Article 8

The fee to be paid for the technical examination of a variety shall be determined in accordance with the table:

(in EUR) Cost group Fee Agricultural group 1 Potato 2 580 2 Grasses 3 6 5 0 3 Other agricultural species 1 980 Fruit group Apple 4 1 3 0 5 Other fruit species 4 1 3 0 Ornamental group 6 Ornamental living greenhouse 2 3 9 0 7 Ornamental living outdoor 30708 Ornamental non-living greenhouse 27609 Ornamental non-living outdoor 2890 10 3 5 5 0 Ornamental special Vegetable group Vegetable greenhouse 3 570 11 12 Vegetable outdoor 3 280'

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1105

of 6 June 2023

granting a Union authorisation for the single biocidal product 'Superficid express WIPES' in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(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 Article 44(5), first subparagraph, thereof,

Whereas:

- (1) On 23 April 2019, Lysoform Dr. Hans Rosemann 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 single biocidal product, as referred to in Article 1 of Implementing Regulation (EU) No 414/2013, named 'Superficid express WIPES', 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-RL051111-45 in the Register for Biocidal Products ('the Register'). The application also indicated the application number of the related reference biocidal product family 'Knieler & Team Propanol Family', recorded in the Register under case number BC-AQ050985-22.
- (2) The same single biocidal product 'Superficid express WIPES' contains propan-1-ol and propan-2-ol as the active substances, which are included in the Union list of approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012 for product-types 2 and 4.
- (3) On 8 December 2021, the Agency submitted to the Commission an opinion (3) and the draft summary of the biocidal product characteristics ('SPC') of 'Superficid express WIPES' in accordance with Article 6 of Implementing Regulation (EU) No 414/2013.
- (4) The opinion concludes that the proposed differences between the same single biocidal product and the related reference biocidal product are limited to information which can be the subject of an administrative change in accordance with Commission Implementing Regulation (EU) No 354/2013 (4), and that based on the assessment of the related reference biocidal product family 'Knieler & Team Propanol Family' and subject to compliance with the draft SPC, the same single biocidal product meets the conditions laid down in Article 19(1) of Regulation (EU) No 528/2012.
- (5) On 24 October 2022, 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 single biocidal product 'Superficid express WIPES'.

⁽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 for 'Superficid express WIPES' of 8 December 2021, https://echa.europa.eu/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 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-0027676-0000 is granted to Lysoform Dr. Hans Rosemann GmbH for the making available on the market and use of the same single biocidal product 'Superficid express WIPES' in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 27 June 2023 until 31 July 2032.

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, 6 June 2023.

For the Commission The President Ursula VON DER LEYEN

ANNEX

Summary of product characteristics for a biocidal product

Superficid express WIPES

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-0027676-0000

R4BP asset number: EU-0027676-0000

1. **ADMINISTRATIVE INFORMATION**

1.1. Trade name(s) of the product

Trade name(s)	Superficid express WIPES Bactesil Wipes IPA Express Wipes Twoalko Express Wipes MicrobaX Express Wipes Alkodes Express Wipes Septokil Express Wipes Mastersept Express Wipes Descoficid Wipes Bactoficid Express Wipes Supergerm Express Wipes Superdes Express Wipes Superdes Express Wipes
	Superdes Express Wipes APESIN express F wipes

1.2. Authorisation holder

Name and address of the authorisation	Name	Lysoform Dr. Hans Rosemann GmbH
holder	Address	Kaiser-Wilhelm-Str. 133, 12247 Berlin Germany
Authorisation number	EU-0027676-0000	
R4BP asset number	EU-0027676-0000	
Date of the authorisation	27 June 2023	
Expiry date of the authorisation	31 July 2032	

1.3. Manufacturer(s) of the product

Name of manufacturer	Lysoform Dr. Hans Rosemann GmbH,
Address of manufacturer	Kaiser-Wilhelm-Str. 133, 12247 Berlin Germany
Location of manufacturing sites	Lysoform Dr. Hans Rosemann GmbH, Kaiser-Wilhelm-Str. 133, 12247 Berlin Germany A.F.P. Antiseptica Forschungs- und Produktionsgesellschaft mbH, Otto- Brenner-Straße 16-18, 21337 Lüneburg Germany Sterisol AB, Kronoängsgatan 3, S 59223 Vadstena Sweden

1.4. Manufacturer(s) of the active substance(s)

Active substance	Propan-1-ol	
Name of manufacturer	OQ Chemicals GmbH (formerly Oxea GmbH)	
Address of manufacturer	Rheinpromenade 4a, 40789 Monheim am Rhein Germany	
Location of manufacturing sites	OQ Chemicals Corperation (formerly Oxea Coperation), 2001 FM 3057 TX, 77414 Bay City United States	
Active substance	Propan-1-ol	
Name of manufacturer	BASF SE	
Address of manufacturer	Carl-Bosch-Str. 38, 67056 Ludwigshafen Germany	
Location of manufacturing sites	BASF SE, Carl-Bosch-Str. 38, 67056 Ludwigshafen Germany	
Active substance	Propan-2-ol	
Name of manufacturer	INEOS Solvent Germany GmbH	
Address of manufacturer	Römerstrasse 733, 47443 Moers Germany	
Location of manufacturing sites	INEOS Solvent Germany GmbH, Römerstrasse 733, 47443 Moers Germany INEOS Solvent Germany GmbH, Shamrockstrasse 88, 44623 Herne Germany	

2. PRODUCT COMPOSITION AND FORMULATION

2.1. Qualitative and quantitative information on the composition of the product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active Substance	71-23-8	200-746-9	14,3
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,14

2.2. Type of formulation

AL - Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	Highly flammable liquid and vapour. Causes serious eye damage. 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.

Avoid breathing vapours. 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. Immediately call a POISON CENTER/doctor. Store in a well-ventilated place.Keep cool. Store locked up. Dispose of contents to an authorised waste collection point.

4. AUTHORISED USE(S)

4.1. Use description

Use # 1 – hard non-porous small surface disinfection RTU wipes

Table 1

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	Not relevant
Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data Scientific name: no data Common name: Yeasts Development stage: no data Scientific name: no data Common name: Enveloped viruses Development stage: no data
Field(s) of use	Indoor Health care facilities and pharmaceutical and cosmetic industry, for example patient-near surrounding, working areas/desks, general equipment (excluding food contact surfaces): disinfection of small hard/non-porous surfaces For professional use only.
Application method(s)	Method: Manual application Detailed description: Ready-to-use disinfectant wipes at room temperature (20±2 °C). The surface to be disinfected is wiped and wetted with a sufficient amount of the product, ensuring complete Coverage.
Application rate(s) and frequency	Application Rate: Minimum exposure time: for the control of bacteria, yeasts and enveloped viruses: 60 sec; Make the surface completely wet. Dilution (%): Ready-to-use product Number and timing of application: A reasonable frequency of disinfection in a patient's room is 1-2 per day. Maximum number of applications is 6 per day. No safety intervals need to be considered between the application phases.

Category(ies) of users	Industrial Professional
Pack sizes and packaging material	Dispenser of PE composite foil with screwed-in PE cap, containing 100 PP/PE wipes.

4.1.1. Use-specific instructions for use

Surfaces should always be visibly clean prior to disinfection. Maximum number of applications is 6 per day.

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 See general directions for use.
- 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

Use # 2 – hard non-porous small surface disinfection RTU wipes

Table 2

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data Scientific name: no data Common name: Yeasts Development stage: no data
Field(s) of use	Indoor Health care facilities and food industry, for example patient-near surrounding, food preparation and handling in kitchens/restaurants): disinfection of small hard/non-porous surfaces. For professional use only.
Application method(s)	Method: Manual application Detailed description: Ready-to-use disinfectant wipes at room temperature (20±2 °C). The surface to be disinfected is wetted with a sufficient amount of the product by wiping, ensuring complete coverage.

Application rate(s) and frequency	Application Rate: Minimum exposure time: for the control of bacteria and yeasts at 20°C: 60 sec; Make the surface completely wet. Dilution (%): Ready-to-use product Number and timing of application: The product can be used as often as necessary. A reasonable frequency of disinfection in kitchens is 1-2 per day. No safety intervals need to be considered between the application phases.
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	Dispenser of PE composite foil with screwed-in PE cap, containing 100 PP/PE wipes.

4.2.1. Use-specific instructions for use

Surfaces should always be visibly clean prior to disinfection.

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

See general directions for use.

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** (1)

5.1. **Instructions for use**

For professional use only.

For wipes reseal the package after opening.

5.2. Risk mitigation measures

Avoid contact with eyes.

Keep out of reach of children

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

First-aid measures general: Move the affected person away from the contaminated area. Get medical advice/attention if you feel unwell. If possible, show this sheet.

IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTRE or a doctor.

IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor.

⁽¹⁾ Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses.

IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance.

Information to Healthcare personnel/doctor:

The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid.

IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.

Accidental release measures: Stop leak if safe to do so. Remove ignition sources. Use special care to avoid static electric charges. No open flames. No smoking. Prevent entry to sewers and public waters. Wipe up with absorbent material (for example cloth). Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Take up mechanically (sweeping, shovelling). Dispose of in accordance with relevant local regulations.

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

Disposal must be done according to official regulations. Do not empty into drains. Do not dispose of with domestic waste. Dispose of contents/container to an authorised waste collection point. Empty the packaging completely prior to disposal. When totally empty, containers are recyclable like any other packing.

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

Shelf-life: 24 months

Store in dry, cool, well-ventilated area. Keep container tightly closed. Keep out of direct sunlight.

Recommended storage temperature: 0-30°C

Do not store at temperatures below 0°C

Do not store near food, drink and animal feedingstuff. Keep away from combustible material.

6. OTHER INFORMATION

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1106

of 6 June 2023

granting a Union authorisation for the single biocidal product 'Manorapid express GEL' in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(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 Article 44(5), first subparagraph, thereof,

Whereas:

- (1) On 23 April 2019, Lysoform Dr. Hans Rosemann 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 Union authorisation of the same single biocidal product, as referred to in Article 1 of Implementing Regulation (EU) No 414/2013, named 'Manorapid express GEL', of product-type 1, as described in Annex V to Regulation (EU) No 528/2012. The application was recorded under case number BC-SV051112-22 in the Register for Biocidal Products ('the Register'). The application also indicated the application number of the related reference biocidal product family 'Knieler & Team Propanol Family', recorded in the Register under case number BC-AQ050985-22.
- (2) The same single biocidal product 'Manorapid express GEL' contains propan-1-ol and propan-2-ol as the active substances, which are included in the Union list of approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012 for product-type 1.
- (3) On 8 December 2021, the Agency submitted to the Commission an opinion (3) and the draft summary of the biocidal product characteristics (SPC) of Manorapid express GEL in accordance with Article 6 of Implementing Regulation (EU) No 414/2013.
- (4) The opinion concludes that the proposed differences between the same single biocidal product and the related reference biocidal product are limited to information which can be the subject of an administrative change in accordance with Commission Implementing Regulation (EU) No 354/2013 (4), and that based on the assessment of the related reference biocidal product family 'Knieler & Team Propanol Family' and subject to compliance with the draft SPC, the same single biocidal product meets the conditions laid down in Article 19(1) of Regulation (EU) No 528/2012.
- (5) On 11 January 2023, 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 single biocidal product 'Manorapid express GEL'.

⁽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 for 'Manorapid express GEL' of 8 December 2021, https://echa.europa.eu/opinions-on-union-authorisation.

^(*) 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 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-0027675-0000 is granted to Lysoform Dr. Hans Rosemann GmbH for the making available on the market and use of the same single biocidal product 'Manorapid express GEL' in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 27 June 2023 until 31 July 2032.

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, 6 June 2023.

For the Commission The President Ursula VON DER LEYEN

ANNEX

Summary of product characteristics for a biocidal product

Manorapid express GEL

Product type 1 - Human hygiene (Disinfectants)

Authorisation number: EU-0027675-0000

R4BP asset number: EU-0027675-0000

1. **ADMINISTRATIVE INFORMATION**

1.1. Trade name(s) of the product

Trade name(s)	Manorapid express GEL
	Bactesil Gel
	IPA Hands Gel
	Twoalko Gel
	MicrobaX Gel
	Alkodes Gel
	Septokil Gel
	Mastersept Gel
	Bactoficid Gel
	Supergerm Gel
	Superdes Gel

1.2. Authorisation holder

Name and address of the authorisation holder	Name	Lysoform Dr. Hans Rosemann GmbH
	Address	Kaiser-Wilhelm-Str. 133, 12247 Berlin Germany
Authorisation number	EU-0027675-0000	
R4BP asset number	EU-0027675-0000	
Date of the authorisation	27 June 2023	
Expiry date of the authorisation	31 July 2032	

1.3. Manufacturer(s) of the product

Name of manufacturer	Lysoform Dr. Hans Rosemann GmbH
Address of manufacturer	Kaiser-Wilhelm-Str. 133, 12247 Berlin Germany
Location of manufacturing sites	Lysoform Dr. Hans Rosemann GmbH, Kaiser-Wilhelm-Str. 133, 12247 Berlin Germany Sterisol AB Kronoängsgatan 3, S 59223 Vadstena Sweden A.F.P. Antiseptica Forschungs- und Produktionsgesellschaft mbH, Otto- Brenner-Straße 16-18, 21337 Lüneburg Germany

1.4. Manufacturer(s) of the active substance(s)

Active substance	Propan-1-ol	
Name of manufacturer	OQ Chemicals GmbH (formerly Oxea GmbH)	
Address of manufacturer	Rheinpromenade 4a, 40789 Monheim am Rhein Germany	
Location of manufacturing sites	OQ Chemicals Corperation (formerly Oxea Coperation), 2001 FM 3057 TX, 77414 Bay City United States	
Active substance	Propan-1-ol	
Name of manufacturer	BASF SE	
Address of manufacturer	Carl-Bosch-Str. 38, 67056 Ludwigshafen Germany	
Location of manufacturing sites	BASF SE, Carl-Bosch-Str. 38, 67056 Ludwigshafen Germany	
Active substance	Propan-2-ol	
Name of manufacturer	INEOS Solvent Germany GmbH	
Address of manufacturer	Römerstrasse 733, 47443 Moers Germany	
Location of manufacturing sites	INEOS Solvent Germany GmbH, Römerstrasse 733, 47443 Moers Germany INEOS Solvent Germany GmbH, Shamrockstrasse 88, 44623 Herne Germany	

2. PRODUCT COMPOSITION AND FORMULATION

2.1. Qualitative and quantitative information on the composition of the product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active Substance	71-23-8	200-746-9	14,3
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,14

2.2. Type of formulation

AL - Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS

Precautionary statements	Keep away from heat, hot surfaces, sparks, open flames and other ignition
	sources No smoking.
	Keep container tightly closed.
	Avoid breathing vapours.
	Use only outdoors or in a well-ventilated area.
	IF INHÁLED: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.
	Immediately call a POISON CENTER/doctor.
	Store in a well-ventilated place. Keep cool.
	Store locked up.
	Dispose of container to an authorised waste collection point.

4. AUTHORISED USE(S)

4.1. Use description

Table 1. Use # 1 – hygienic handrub, gel

Product type	PT01 - Human hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data
	Scientific name: no data Common name: Tuberculosis bacilli Development stage: no data
	Scientific name: no data Common name: Yeasts Development stage: no data
	Scientific name: no data Common name: Enveloped viruses Development stage: no data
Field(s) of use	 Indoor hospitals and other health care institutions, ambulances, surgeries, nursing homes (including home-care of patients) hospital canteens, large kitchens, pharmaceutical industries, production sites, laboratories: hygienic handrub onto visibly clean and dry hands. For professional use only.
Application method(s)	Method: Manual application
	Detailed description: Rubbing
Application rate(s) and frequency	Application Rate: Dosage: At least 3 ml (use dispensers: for example set to 1,5 ml per stroke, 2 strokes per 3 ml). Contact time: 30 s
	Dilution (%): Ready-to-use product

	Number and timing of application: There is no restriction in the number and timing of applications. No safety intervals need to be considered between the application phases.			
	The product may be used at any time and as often as required.			
Category(ies) of users	Industrial Professional			
Pack sizes and packaging material				
1 0 0	125, 150, 500, 1 000 ml in transparent/white high-density polypropylene (HDPE) bottles with polypropylene (PP) flip top caps;			
	5 000 ml transparent/white HDPE canister with HDPE screwed cap.			
	700 ml pouch of transparent PE composite foil with integrated PP pump; 75 ml transparent HDPE bottle with PP flip top cap.			

4.1.1. Use-specific instructions for use

The products can be applied directly or the products can be used in a dispenser or with a pump.

For hygienic handrub use 3 ml of product and keep hands wet for 30 seconds.

Do not refill.

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

See general directions for use

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 – surgical handrub, gel

Product type	PT01 - Human hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant

Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data		
	Scientific name: no data Common name: Tuberculosis bacilli Development stage: no data		
	Scientific name: no data Common name: Yeasts Development stage: no data		
	Scientific name: no data Common name: Enveloped viruses Development stage: no data		
Field(s) of use	Indoor Hospitals and other health care institutions: surgical handrub onto visibly clean and dry hands and forearms. For professional use only.		
Application method(s)	Method: Manual application		
	Detailed description: Rubbing		
Application rate(s) and frequency	Application Rate: Dosage: Rub sufficient amount in portions of 3 ml (use dispensers: for example set to 1,5 ml per stroke, 2 strokes per 3 ml). Contact time: 90 s		
	Dilution (%): Ready-to-use product		
	Number and timing of application:		
	There is no restriction in the number and timing of applications. No safety intervals need to be considered between the application phases.		
	The product may be used at any time and as often as required.		
Category(ies) of users	Professional		
Pack sizes and packaging material	125, 150, 500, 1 000 ml in transparent/white high-density polypropylene (HDPE) bottles with polypropylene (PP) flip top caps;		
	5 000 ml transparent/white HDPE canister with HDPE screwed cap.		
	700 ml pouch of transparent PE composite foil with integrated PP pump; 75 ml transparent HDPE bottle with PP flip top cap.		

4.2.1. Use-specific instructions for use

For surgical handrub use as many portions of 3 ml as necessary to keep hands wet for 90 seconds.

Do not refill.

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

See general directions for use

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** (1)

5.1. Instructions for use

For professional use only.

5.2. Risk mitigation measures

Avoid contact with eyes.

Keep out of reach of children.

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

First-aid measures general: Move the affected person away from the contaminated area. Get medical advice/attention if you feel unwell. If possible, show this sheet.

IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTRE or a doctor.

IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor.

IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance.

Information to Healthcare personnel/doctor:

The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid.

IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.

Accidental release measures:

Stop leak if safe to do so. Remove ignition sources. Use special care to avoid static electric charges. No open flames. No smoking.

⁽¹⁾ Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses.

Prevent entry to sewers and public waters.

Wipe up with absorbent material (for example cloth). Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Take up mechanically (sweeping, shovelling). Dispose of in accordance with relevant local regulations.

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

Disposal must be done according to official regulations. Do not empty into drains. Do not dispose of with domestic waste. Dispose of contents/container to an authorised waste collection point. Empty the packaging completely prior to disposal. When totally empty, containers are recyclable like any other packing.

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

Shelf-life: 24 months

Store in dry, cool, well-ventilated area. Keep container tightly closed. Keep out of direct sunlight.

Recommended storage temperature: 0-30°C

Do not store at temperatures below 0°C

Do not store near food, drink and animal feedingstuff. Keep away from combustible material.

6. **OTHER INFORMATION**

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1107

of 6 June 2023

granting a Union authorisation for the single biocidal product 'Manorapid express' in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(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 Article 44(5), first subparagraph, thereof,

Whereas:

- (1) On 23 April 2019, Lysoform Dr. Hans Rosemann 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 Union authorisation of the same single biocidal product, as referred to in Article 1 of Implementing Regulation (EU) No 414/2013, named 'Manorapid express', of product-type 1, as described in Annex V to Regulation (EU) No 528/2012. The application was recorded under case number BC-GD051113-68 in the Register for Biocidal Products ('the Register'). The application also indicated the application number of the related reference biocidal product family 'Knieler & Team Propanol Family', recorded in the Register under case number BC-AQ050985-22.
- (2) The same single biocidal product 'Manorapid express' contains propan-1-ol and propan-2-ol as the active substances, which are included in the Union list of approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012 for product-type 1.
- (3) On 8 December 2021, the Agency submitted to the Commission an opinion (3) and the draft summary of the biocidal product characteristics ('SPC') of 'Manorapid express' in accordance with Article 6 of Implementing Regulation (EU) No 414/2013.
- (4) The opinion concludes that the proposed differences between the same single biocidal product and the related reference biocidal product are limited to information which can be the subject of an administrative change in accordance with Commission Implementing Regulation (EU) No 354/2013 (4), and that based on the assessment of the related reference biocidal product family 'Knieler & Team Propanol Family' and subject to compliance with the draft SPC, the same single biocidal product meets the conditions laid down in Article 19(1) of Regulation (EU) No 528/2012.
- (5) On 24 October 2022, 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 single biocidal product 'Manorapid express'.

⁽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 for 'Manorapid express' of 8 December 2021, https://echa.europa.eu/opinions-on-union-authorisation.

^(*) 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 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-0027674-0000 is granted to Lysoform Dr. Hans Rosemann GmbH for the making available on the market and use of the same single biocidal product 'Manorapid express' in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 27 June 2023 until 31 July 2032.

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, 6 June 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Summary of product characteristics for a biocidal product

Manorapid express

Product type 1 - Human hygiene (Disinfectants)

Authorisation number: EU-0027674-0000

R4BP asset number: EU-0027674-0000

1. **ADMINISTRATIVE INFORMATION**

1.1. Trade name(s) of the product

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Trade name(s)	Manorapid express
	Bactesil
	IPA Hands
	Twoalko
	MicrobaX
	Alkodes
	Septokil
	Mastersept
	Bactoficid
	Supergerm
	Superdes
	Soft Care Man HD Biocide

1.2. Authorisation holder

Name and address of the authorisation	Name	Lysoform Dr. Hans Rosemann GmbH	
holder	Address	Kaiser-Wilhelm-Str. 133, 12247 Berlin Germany	
Authorisation number	EU-0027674	-0000	
R4BP asset number	EU-0027674-0000		
Date of the authorisation 27 June 2023			
Expiry date of the authorisation	31 July 2032		

1.3. Manufacturer(s) of the product

Name of manufacturer	Lysoform Dr. Hans Rosemann GmbH		
Address of manufacturer	Kaiser-Wilhelm-Str. 133, 12247 Berlin Germany		
Location of manufacturing sites	Lysoform Dr. Hans Rosemann GmbH, Kaiser-Wilhelm-Str. 133, 12247 Berlin Germany Sterisol AB Kronoängsgatan 3, S 59223 Vadstena Sweden A.F.P. Antiseptica Forschungs- und Produktionsgesellschaft mbH, Otto-Brenner-Straße 16-18, 21337 Lüneburg Germany		

1.4. Manufacturer(s) of the active substance(s)

Active substance	Propan-1-ol		
Name of manufacturer	OQ Chemicals GmbH (formerly Oxea GmbH)		
Address of manufacturer	Rheinpromenade 4a, 40789 Monheim am Rhein Germany		
Location of manufacturing sites	OQ Chemicals Corperation (formerly Oxea Coperation), 2001 FM 3057 TX, 77414 Bay City United States		
Active substance	Propan-1-ol		
Name of manufacturer	BASF SE		
Address of manufacturer	Carl-Bosch-Str. 38, 67056 Ludwigshafen Germany		
Location of manufacturing sites	BASF SE, Carl-Bosch-Str. 38, 67056 Ludwigshafen Germany		
Active substance	Propan-2-ol		
Name of manufacturer	INEOS Solvent Germany GmbH		
Address of manufacturer	Römerstrasse 733, 47443 Moers Germany		
Location of manufacturing sites	INEOS Solvent Germany GmbH, Römerstrasse 733, 47443 Moers Germany INEOS Solvent Germany GmbH, Shamrockstrasse 88, 44623 Herne Germany		

2. PRODUCT COMPOSITION AND FORMULATION

2.1. Qualitative and quantitative information on the composition of the product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active Substance	71-23-8	200-746-9	14,3
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,14

2.2. Type of formulation

AL - Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	Highly flammable liquid and vapour. Causes serious eye damage. May cause drowsiness or dizziness. Repeated exposure may cause skin dryness or cracking.
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Precautionary statements	Keep away from heat, hot surfaces, sparks, open flames and other
	ignition sources No smoking.
	Keep container tightly closed.
	Avoid breathing vapours.
	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.
	Immediately call a POISON CENTER/doctor.
	Store in a well-ventilated place.Keep cool.
	Store locked up.
	Dispose of container to an authorised waste collection point.

4. **AUTHORISED USE(S)**

4.1. Use description

Table 1. Use # 1 – hygienic handrub, liquid

Product type	PT01 - Human hygiene (Disinfectants)			
Where relevant, an exact description of the authorised use	Not relevant			
Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data			
	Scientific name: no data Common name: Tuberculosis bacilli Development stage: no data			
	Scientific name: no data Common name: Yeasts Development stage: no data			
	Scientific name: no data Common name: Enveloped viruses Development stage: no data			
Field(s) of use	 Indoor hospitals and other health care institutions, ambulances, so geries, nursing homes (including home-care of patients) hospital canteens, large kitchens, pharmaceutical industries, puduction sites, laboratories: hygienic handrub onto visibly cleand dry hands For professional use only. 			
Application method(s)	Method: Manual application			
	Detailed description: Rubbing			
Application rate(s) and frequency	Application Rate: Dosage: At least 3 ml (use dispensers: for example set to 1,5 ml per stroke, 2 strokes per 3 ml). Contact time: 30 s			
	Dilution (%): Ready-to-use product			

	Number and timing of application: There is no restriction in the number and timing of applications. No safety intervals need to be considered between the application phases. The product may be used at any time and as often as required.
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	100, 125, 150, 500, 1 000 ml in transparent/white high-density polyethylene (HDPE) bottles with polyethylene (PP) flip top caps; 5 000 ml transparent/white HDPE canister with HDPE screwed cap. 700 ml Pouch of transparent PE composite foil with integrated PP pump; 75 ml transparent/white HDPE bottle with PP flip top cap.

4.1.1. Use-specific instructions for use

The products can be applied directly or the products can be used in a dispenser or with a pump.

For hygienic handrub use 3 ml of product and keep hands wet for 30 seconds.

Do not refill.

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

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

See general directions for use

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

See general directions for use

4.2. Use description

Table 2. Use # 2 – surgical handrub, liquid

Product type	PT01 - Human hygiene (Disinfectants)	
Where relevant, an exact description of the authorised use	Not relevant.	
Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data	
	Scientific name: no data Common name: Tuberculosis bacilli Development stage: no data	

	Scientific name: no data Common name: Yeasts Development stage: no data
	Scientific name: no data Common name: enveloped viruses Development stage: no data
Field(s) of use	Indoor Hospitals and other health care institutions: surgical handrub onto visibly clean and dry hands and forearms. For professional use only.
Application method(s)	Method: Manual application
	Detailed description: Rubbing
Application rate(s) and frequency	Application Rate: Dosage: Rub sufficient amount in portions of 3 ml (use dispensers: for example set to 1,5 ml per stroke, 2 strokes per 3 ml). Contact time: 90 s
	Dilution (%): Ready-to-use product
	Number and timing of application: There is no restriction in the number and timing of applications. No safety intervals need to be considered between the application phases. The product may be used at any time and as often as required.
Category(ies) of users	Professional
Pack sizes and packaging material	100, 125, 150, 500, 1 000 ml in transparent/white high-density polyethylene (HDPE) bottles with polyethylene (PP) flip top caps;
	5 000 ml transparent/white HDPE canister with HDPE screwed cap.
	700 ml Pouch of transparent PE composite foil with integrated PP pump; 75 ml transparent/white HDPE bottle with PP flip top cap.

4.2.1. Use-specific instructions for use

The products can be applied directly or the products can be used in a dispenser or with a pump.

For surgical handrub use as many portions of 3 ml as necessary to keep hands wet for 90 seconds.

Do not refill.

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

See general directions for use

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** (1)

5.1. **Instructions for use**

For professional use only.

5.2. Risk mitigation measures

Avoid contact with eyes.

Keep out of reach of children.

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

First-aid measures general: Move the affected person away from the contaminated area. Get medical advice/attention if you feel unwell. If possible, show this sheet.

IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTRE or a doctor.

IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor.

IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance.

Information to Healthcare personnel/doctor:

The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid.

IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.

Accidental release measures:

Stop leak if safe to do so. Remove ignition sources. Use special care to avoid static electric charges. No open flames. No smoking.

Prevent entry to sewers and public waters.

Wipe up with absorbent material (for example cloth). Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Take up mechanically (sweeping, shovelling). Dispose of in accordance with relevant local regulations.

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

Disposal must be done according to official regulations. Do not empty into drains. Do not dispose of with domestic waste. Dispose of contents/container to an authorised waste collection point. Empty the packaging completely prior to disposal. When totally empty, containers are recyclable like any other packing.

⁽¹⁾ Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses.

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

Shelf-life: 24 months

Store in dry, cool, well-ventilated area. Keep container tightly closed. Keep out of direct sunlight.

Recommended storage temperature: 0-30°C

Do not store at temperatures below 0°C

Do not store near food, drink and animal feedingstuff. Keep away from combustible material.

6. **OTHER INFORMATION**

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1108

of 6 June 2023

granting a Union authorisation for the single biocidal product 'OP Plus' in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(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 Article 44(5), first subparagraph, thereof.

Whereas:

- (1) On 23 April 2019, Laboratorium Dr. Deppe 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 Union authorisation of the same single biocidal product, as referred to in Article 1 of that Regulation, named 'OP Plus', of product-type 1, as described in Annex V to Regulation (EU) No 528/2012. The application was recorded under case number BC-JN051117-37 in the Register for Biocidal Products ('the Register'). The application also indicated the application number of the related reference biocidal product family 'Knieler & Team Propanol Family', recorded in the Register under case number BC-AQ050985-22.
- (2) The same single biocidal product 'OP Plus' contains propan-1-ol and propan-2-ol as the active substances, which are included in the Union list of approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012 for product-type 1.
- (3) On 8 December 2021, the Agency submitted to the Commission an opinion (3) and the draft summary of the biocidal product characteristics ('SPC') of 'OP Plus' in accordance with Article 6 of Implementing Regulation (EU) No 414/2013.
- (4) The opinion concludes that the proposed differences between the same single biocidal product and the related reference biocidal product are limited to information which can be the subject of an administrative change in accordance with Commission Implementing Regulation (EU) No 354/2013 (4), and that based on the assessment of the related reference biocidal product family 'Knieler & Team Propanol Family' and subject to compliance with the draft SPC, the same single biocidal product meets the conditions laid down in Article 19(1) of Regulation (EU) No 528/2012.
- (5) On 20 October 2022, 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 single biocidal product 'OP Plus'.
- (7) 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) 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 for 'OP Plus', 8 December 2021, https://echa.europa.eu/opinions-on-union-authorisation

^(*) 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).

HAS ADOPTED THIS REGULATION:

Article 1

A Union authorisation with authorisation number EU-0027670-0000 is granted to Laboratorium Dr. Deppe GmbH for the making available on the market and use of the same single biocidal product 'OP Plus' in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 27 June 2023 until 31 July 2032.

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, 6 June 2023.

For the Commission The President Ursula VON DER LEYEN

ANNEX

Summary of product characteristics for a biocidal product

OP Plus

Product type 1 - Human hygiene (Disinfectants)

Authorisation number: EU-0027670-0000

R4BP asset number: EU-0027670-0000

1. **ADMINISTRATIVE INFORMATION**

1.1. Trade name(s) of the product

Trade name(s)	OP Plus Nextsept MyClean HB plus MyClean HB basic Bavicid Hand
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1.2. Authorisation holder

Name and address of the authorisation holder	Name	Laboratorium Dr. Deppe GmbH	
	Address	Hooghe Weg 35, 47906 Kempen Germany	
Authorisation number	EU-0027670-0000		
R4BP asset number	EU-0027670-0000		
Date of the authorisation	27 June 2023		
Expiry date of the authorisation	31 July 2032		

1.3. Manufacturer(s) of the product

Name of manufacturer	Laboratorium Dr. Deppe GmbH		
Address of manufacturer	Hooghe Weg 35, 47906 Kempen Germany		
Location of manufacturing sites	Laboratorium Dr. Deppe GmbH, Hooghe Weg 35, 47906 Kempen Germany		

1.4. Manufacturer(s) of the active substance(s)

Active substance	Propan-1-ol		
Name of manufacturer	OQ Chemicals GmbH (formerly Oxea GmbH)		
Address of manufacturer	Rheinpromenade 4a, 40789 Monheim am Rhein Germany		
Location of manufacturing sites	OQ Chemicals Corperation (formerly Oxea Coperation), 2001 FM 3057 TX, 77414 Bay City United States		

Carl-Bosch-Str. 38, 67056 Ludwigshafen Germany			
hafen Germany			
Secunda Chemical Operations, Sasol Place, 50 Katherine Street, 2090 Sandton South Africa			
Secunda Chemical Operations, PDP Kruger Street, 2302 Secunda South Africa			
se 733, 47443 Moers			
Stinnes-Platz 1, 45472 Mülheim an der Ruhr Germany			
Shell Nederland Raffinaderij B.V., 3196 KK Rotterdam-Pernis Netherlands Exxon Mobil, LA 70805 Baton Rouge United States			

2. PRODUCT COMPOSITION AND FORMULATION

2.1. Qualitative and quantitative information on the composition of the product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active Substance	71-23-8	200-746-9	12,229
Propan-2-ol		Active Substance	67-63-0	200-661-7	62,751

2.2. **Type of formulation**

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	Highly flammable liquid and vapour. Causes serious eye damage. 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. Avoid breathing vapours. 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. Immediately call a POISON CENTER/doctor. Store in a well-ventilated place.Keep cool. Store locked up. Dispose of container to an authorised waste collection point.

4. AUTHORISED USE(S)

4.1. Use description

Table 1. Use # 1 – hygienic handrub, liquid

Product type	PT01 - Human hygiene (Disinfectants)		
Where relevant, an exact description of the authorised use	Not relevant		
Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data		
	Scientific name: no data Common name: Tuberculosis bacilli Development stage: no data		
	Scientific name: no data Common name: Yeasts Development stage: no data		
	Scientific name: no data Common name: Enveloped viruses Development stage: no data		
Field(s) of use	 Indoor hospitals and other health care institutions, ambulances, surgeries, nursing homes (including home-care of patients) hospital canteens, large kitchens, pharmaceutical industries, production sites, laboratories: hygienic handrub onto visibly clean and dry hands For professional use only. 		
Application method(s)	Method: Manual application Detailed description: Rubbing		

Application rate(s) and frequency	Application Rate: Dosage: At least 3 ml (use dispensers: for example set to 1,5 ml per stroke, 2 strokes per 3 ml). Contact time: 30 s	
	Dilution (%): Ready-to-use product	
	Number and timing of application: There is no restriction in the number and timing of applications. No safety intervals need to be considered between the application phases. The product may be used at any time and as often as required.	
Category(ies) of users	Industrial Professional	
Pack sizes and packaging material	100, 125, 150, 500, 1 000 ml in white HDPE bottles with PP flip top caps; 5 000 ml white HDPE canister with HDPE screwed cap.	

4.1.1. Use-specific instructions for use

The products can be applied directly or the products can be used in a dispenser or with a pump.

For hygienic handrub use 3 ml of product and keep hands wet for 30 seconds.

Do not refill.

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

See general directions for use

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 – surgical handrub, liquid

Product type	PT01 - Human hygiene (Disinfectants)	
Where relevant, an exact description of the authorised use	Not relevant.	
Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data	

	Scientific name: no data Common name: Tuberculosis bacilli Development stage: no data		
	Scientific name: no data Common name: Yeasts Development stage: no data		
	Scientific name: no data Common name: enveloped viruses Development stage: no data		
Field(s) of use	Indoor Hospitals and other health care institutions: surgical handrub onto visibly clean and dry hands and forearms. For professional use only.		
Application method(s)	Method: Manual application		
	Detailed description: Rubbing		
Application rate(s) and frequency	Application Rate: Dosage: Rub sufficient amount in portions of 3 ml (use dispensers: for example set to 1,5 ml per stroke, 2 strokes per 3 ml). Contact time: 90 s		
	Dilution (%): Ready-to-use product		
	Number and timing of application: There is no restriction in the number and timing of applications. No safety intervals need to be considered between the application phases. The product may be used at any time and as often as required.		
Category(ies) of users	Professional		
Pack sizes and packaging material	100, 125, 150, 500, 1 000 ml in white HDPE bottles with PP flip to caps; 5 000 ml white HDPE canister with HDPE screwed cap.		

4.2.1. Use-specific instructions for use

The products can be applied directly or the products can be used in a dispenser or with a pump.

For surgical handrub use as many portions of 3 ml as necessary to keep hands wet for 90 seconds.

Do not refill.

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

See general directions for use

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 (1)

5.1. Instructions for use

For professional use only.

5.2. Risk mitigation measures

Avoid contact with eyes.

Keep out of reach of children.

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

First-aid measures general: Move the affected person away from the contaminated area. Get medical advice/attention if you feel unwell. If possible, show this sheet.

IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTRE or a doctor.

IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor.

IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance.

Information to Healthcare personnel/doctor:

The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid.

IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.

Accidental release measures:

Stop leak if safe to do so. Remove ignition sources. Use special care to avoid static electric charges. No open flames. No smoking.

Prevent entry to sewers and public waters.

Wipe up with absorbent material (for example cloth). Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Take up mechanically (sweeping, shovelling). Dispose of in accordance with relevant local regulations.

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

Disposal must be done according to official regulations. Do not empty into drains. Do not dispose of with domestic waste. Dispose of contents/container to an authorised waste collection point. Empty the packaging completely prior to disposal. When totally empty, containers are recyclable like any other packing.

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

Shelf-life: 24 months

⁽¹⁾ Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses.

Store in dry, cool, well-ventilated area. Keep container tightly closed. Keep out of direct sunlight.

Recommended storage temperature: 0-30°C

Do not store at temperatures below 0°C

Do not store near food, drink and animal feedingstuff. Keep away from combustible material.

6. **OTHER INFORMATION**

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1109

of 6 June 2023

granting a Union authorisation for the single biocidal product 'APESIN Spray' in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(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 Article 44(5), first subparagraph, thereof,

Whereas:

- (1) On 23 April 2019, Tana-Chemie 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 Union authorisation of the same single biocidal product, as referred to in Article 1 of that Regulation, named 'APESIN Spray', 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-PT051116-21 in the Register for Biocidal Products ('the Register'). The application also indicated the application number of the related reference biocidal product family 'Knieler & Team Propanol Family', recorded in the Register under case number BC-AQ050985-22.
- (2) The same single biocidal product 'APESIN Spray' contains propan-1-ol and propan-2-ol as the active substances, which are included in the Union list of approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012 for product-types 2 and 4.
- (3) On 8 December 2021, the Agency submitted to the Commission an opinion (3) and the draft summary of the biocidal product characteristics ('SPC') of 'APESIN Spray' in accordance with Article 6 of Implementing Regulation (EU) No 414/2013.
- (4) The opinion concludes that the proposed differences between the same single biocidal product and the related reference biocidal product are limited to information which can be the subject of an administrative change in accordance with Commission Implementing Regulation (EU) No 354/2013 (4), and that based on the assessment of the related reference biocidal product family 'Knieler & Team Propanol Family' and subject to compliance with the draft SPC, the same single biocidal product meets the conditions laid down in Article 19(1) of Regulation (EU) No 528/2012.
- (5) On 20 October 2022, 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 single biocidal product 'APESIN Spray'.

⁽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 for 'APESIN Spray', 8 December 2021, https://echa.europa.eu/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 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-0027671-0000 is granted to Tana-Chemie GmbH for the making available on the market and use of the same single biocidal product 'APESIN Spray' in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 27 June 2023 until 31 July 2032.

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, 6 June 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Summary of product characteristics for a biocidal product

APESIN Spray

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-0027671-0000

R4BP asset number: EU-0027671-0000

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	APESIN Spray APESIN spray F APESIN flex F APESIN flex APESIN express F APESIN express
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1.2. Authorisation holder

Name and address of the authorisation holder	Name tana-Chemie GmbH	
	Address	Rheinallee 96, 55120 Mainz Germany
Authorisation number	EU-0027671-0000	
R4BP asset number	EU-0027671	-0000
Date of the authorisation	27 June 2023	
Expiry date of the authorisation	31 July 2032	

1.3. Manufacturer(s) of the product

Name of manufacturer	tana-Chemie GmbH	
Address of manufacturer	Rheinallee 96, 55120 Mainz Germany	
Location of manufacturing sites	Werner & Mertz GmbH & Co KG, Neualmerstr. 13, 5400 Hallein Austria Werner & Mertz GmbH, Rheinallee 96, 55120 Mainz Germany	

1.4. Manufacturer(s) of the active substance(s)

Active substance	Propan-1-ol
Name of manufacturer	OQ Chemicals GmbH (formerly Oxea GmbH)
Address of manufacturer	Rheinpromenade 4a, 40789 Monheim am Rhein Germany

Location of manufacturing sites	OQ Chemicals Corperation (formerly Oxea Coperation), 2001 FM 3057 TX, 77414 Bay City United States	
Active substance	Propan-1-ol	
Name of manufacturer	BASF SE	
Address of manufacturer	Carl-Bosch-Str. 38, 67056 Ludwigshafen Germany	
Location of manufacturing sites	BASF SE, Carl-Bosch-Str. 38, 67056 Ludwigshafen Germany	
Active substance	Propan-1-ol	
Name of manufacturer	SASOL Chemie GmbH & Co. KG	
Address of manufacturer	Secunda Chemical Operations, Sasol Place, 50 Katherine Street, 2090 Sandton South Africa	
Location of manufacturing sites	Secunda Chemical Operations, PDP Kruger Street, 2302 Secunda South Africa	
Active substance	Propan-2-ol	
Name of manufacturer	INEOS Solvent Germany GmbH	
Address of manufacturer	Römerstrasse 733, 47443 Moers Germany	
Location of manufacturing sites	INEOS Solvent Germany GmbH, Römerstrasse 733, 47443 Moers Germany INEOS Solvent Germany GmbH, Shamrockstrasse 88, 44623 Herne Germany	

2. PRODUCT COMPOSITION AND FORMULATION

2.1. Qualitative and quantitative information on the composition of the product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active Substance	71-23-8	200-746-9	25,0
Propan-2-ol		Active Substance	67-63-0	200-661-7	40,0

2.2. Type of formulation

AL - Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	Flammable liquid and vapour. Causes serious eye damage. May cause drowsiness or dizziness. Repeated exposure may cause skin dryness or cracking.

Keep away from heat, hot surfaces, sparks, open flames and other ignition
sources No smoking.
Keep container tightly closed.
Avoid breathing vapours.
Use only outdoors or in a well-ventilated area.
Wear eye protection
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.
Immediately call a POISON CENTER/doctor.
Store in a well-ventilated place.Keep cool.
Store locked up.
Dispose of container to an authorised waste collection point.

4. AUTHORISED USE(S)

4.1. Use description

Table 1

Use # 1 – hard non-porous small surface disinfection RTU liquid

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	Not relevant
Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data Scientific name: no data Common name: Yeasts Development stage: no data Scientific name: no data Common name: viruses (limited spectrum virucidal activity) Development stage: no data
Field(s) of use	Indoor Health care facilities and pharmaceutical and cosmetic industry, for example patient-near surrounding, working areas/desks, general equipment (excluding food contact surfaces): disinfection of small hard/non-porous surfaces. For professional use only.
Application method(s)	Method: Manual application Detailed description: Ready-to-use surface disinfectant at room temperature (20±2 °C). The entire surface to be disinfected is wetted by pouring or spraying from a short distance and subsequently thoroughly wiped with a cloth. The amount of product should be sufficient (max. 50 ml/m²) to keep the surface wet during the contact time.



Application rate(s) and frequency	Application Rate: Minimum exposure time: • for the control of bacteria, yeasts and enveloped viruses: 60 sec • for the control of viruses (limited spectrum virucidal activity): 5 min Dilution (%): Ready-to-use product Number and timing of application: A reasonable frequency of disinfection in a patient's room is 1-2 per day. Maximum number of applications is 6 per day. No safety intervals need to be considered between the application phases.		
Category(ies) of users	Industrial Professional		
Pack sizes and packaging material	100, 500, 750 and 1 000 ml transparent/white high-density polyethylene (HDPE) bottle with polypropylene (PP) flip top caps (accessory: PP screw closure with spray head); 5 000 ml transparent/white HDPE canister with HDPE screwed cap.		

4.1.1. Use-specific instructions for use

Surfaces should always be visibly clean prior to disinfection. Maximum number of applications is 6 per day.

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 See general directions for use
- 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 – hard non-porous small surface disinfection RTU liquid

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data Scientific name: no data Common name: Yeasts Development stage: no data

Field(s) of use	Indoor Health care facilities and in food industry, for example food preparation and handling in kitchens/restaurants: disinfection of small hard/non-porous surfaces. For professional use only.
Application method(s)	Method: Manual application Detailed description: Ready-to-use surface disinfectant at room temperature (20±2 °C). The entire surface to be disinfected is wetted by pouring or spraying from a short distance and subsequently thoroughly wiped with a cloth. The amount of product should be sufficient (max. 50 ml/m²) to keep the surface wet during the contact time.
Application rate(s) and frequency	Application Rate: Minimum exposure time: for the control of bacteria and yeasts at 20°C: 60 sec Dilution (%): Ready-to-use product Number and timing of application: The products can be used as often as necessary. A reasonable frequency in kitchens is 1-2 per day. No safety intervals need to be considered between the application phases.
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	100, 500, 750 and 1 000 ml transparent/white high-density polyethylene (HDPE) bottle with polypropylene (PP) flip top caps (accessory: PP screw closure with spray head); 5 000 ml transparent/white HDPE canister with HDPE screwed cap.

4.2.1. Use-specific instructions for use

Surfaces should always be visibly clean prior to disinfection.

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

See general directions for use

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** (1)

5.1. **Instructions for use**

For professional use only.

5.2. Risk mitigation measures

The use of eye protection during handling of the product is mandatory.

Keep out of reach of children

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

First-aid measures general: Move the affected person away from the contaminated area. Get medical advice/attention if you feel unwell. If possible, show this sheet.

IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTRE or a doctor.

IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor.

IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance.

Information to Healthcare personnel/doctor:

The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid.

IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.

Accidental release measures: Stop leak if safe to do so. Remove ignition sources. Use special care to avoid static electric charges. No open flames. No smoking. Prevent entry to sewers and public waters. Wipe up with absorbent material (for example cloth). Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Take up mechanically (sweeping, shovelling). Dispose of in accordance with relevant local regulations.

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

Disposal must be done according to official regulations. Do not empty into drains. Do not dispose of with domestic waste. Dispose of contents/container to an authorised waste collection point. Empty the packaging completely prior to disposal. When totally empty, containers are recyclable like any other packing.

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

Shelf-life: 24 months

Store in dry, cool, well-ventilated area. Keep container tightly closed. Keep out of direct sunlight.

Recommended storage temperature: 0-30°C

Do not store at temperatures below 0°C

Do not store near food, drink and animal feedingstuff. Keep away from combustible material.

6. **OTHER INFORMATION**

⁽¹⁾ Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses.

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1110

of 6 June 2023

amending Implementing Regulation (EU) 2019/1793 on the temporary increase of official controls and emergency measures governing the entry into the Union of certain goods from certain third countries implementing Regulations (EU) 2017/625 and (EC) No 178/2002 of the European Parliament and of the Council

(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 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (1), and in particular Article 53(1), point (b)(ii), thereof,

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, 96/93/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (²), and in particular Article 47(2), first subparagraph, point (b), and Article 54(4), first subparagraph, points (a) and (b), thereof,

Whereas:

- (1) Commission Implementing Regulation (EU) 2019/1793 (³) lays down rules on the temporary increase of official controls at the entry into the Union on certain consignments of food and feed of non-animal origin from certain third countries listed in Annex I to that Implementing Regulation, and on the imposition of special conditions governing the entry into the Union of certain consignments of food and feed from certain third countries due to the risk of contamination by mycotoxins, including aflatoxins, pesticide residues, pentachlorophenol and dioxins, microbiological contamination, Sudan dyes, Rhodamine B and plant toxins listed in Annex II to that Implementing Regulation.
- (2) Article 12 of Implementing Regulation (EU) 2019/1793 lays down the obligation of the Commission to review at regular intervals not exceeding six months the lists set out in the Annexes to that Implementing Regulation, in order to take into account new information related to risks to human health and non-compliance with Union legislation. Such new information includes the data resulting from notifications received through the Rapid Alert System for Food and Feed ('RASFF') established by Regulation (EC) No 178/2002, as well as data and information concerning consignments and the results of the documentary, identity and physical checks carried out by Member States and communicated to the Commission.

⁽¹⁾ OJ L 31, 1.2.2002, p. 1.

⁽²⁾ OJ L 95, 7.4.2017, p. 1.

^(*) Commission Implementing Regulation (EU) 2019/1793 of 22 October 2019 on the temporary increase of official controls and emergency measures governing the entry into the Union of certain goods from certain third countries implementing Regulations (EU) 2017/625 and (EC) No 178/2002 of the European Parliament and of the Council and repealing Commission Regulations (EC) No 669/2009, (EU) No 884/2014, (EU) 2015/175, (EU) 2017/186 and (EU) 2018/1660 (OJ L 277, 29.10.2019, p. 89).

- (3) Recent notifications received through the RASFF indicate the existence of serious direct or indirect risk to human health deriving from some food or feed. Additionally, official controls performed by the Member States on some food and feed of non-animal origin in the second semester of 2022 indicate that the lists set out in Annexes I and II to Implementing Regulation (EU) 2019/1793 should be amended in order to protect human health in the Union.
- (4) Sweet peppers (*Capsicum annuum*) and peppers of the genus *Capsicum* (other than sweet) from the Dominican Republic have been subject to an increased level of official controls and to special conditions at their entry into the Union, due to the risk of contamination by pesticide residues since January 2010. The official controls carried out by the Member States show improvement in compliance with the relevant requirements provided for in Union legislation. The results of those controls provide evidence that the entry of those foodstuffs into the Union no longer constitutes a serious risk for human health. Consequently, it is not necessary to continue to provide that each consignment be accompanied by an official certificate stating that all results of sampling and analysis show compliance with Regulation (EC) No 396/2005 of the European Parliament and of the Council (*). At the same time, Member States should continue to carry out official controls to ensure that the current level of compliance will be maintained. Therefore, the entry of sweet peppers (*Capsicum annuum*) and peppers of the genus *Capsicum* (other than sweet) from Dominican Republic in point 1 of Annex II to Implementing Regulation (EU) 2019/1793 should be deleted and transferred to Annex I to that Implementing Regulation, maintaining the level of frequency of identity and physical checks at 50 % of consignments entering the Union.
- (5) In relation to consignments of sweet peppers (*Capsicum annuum*), peppers of the genus *Capsicum* (other than sweet) and oranges from Egypt, a high rate of non-compliance with the relevant requirements provided for in Union legislation with respect to contamination by pesticide residues was detected during official controls performed by the Member States in accordance with Articles 5 and 6 of Implementing Regulation (EU) 2019/1793. It is therefore appropriate to increase the frequency of identity and physical checks to be performed on those consignments entering the Union to 30 %.
- (6) In relation to consignments of sugar apple (Annona squamosa) from Egypt, data from RASFF notifications and information regarding official controls performed by the Member States indicate the emergence of new risks to human health, due to a possible contamination by pesticide residues. It is therefore necessary to require an increased level of official controls on entries of that commodity from Egypt. That commodity should therefore be included in Annex I to Implementing Regulation (EU) 2019/1793, with a frequency of identity and physical checks set at 20 % of consignments entering the Union.
- (7) Groundnuts and products produced from groundnuts from The Gambia have been subjected to an increased level of official controls and to special conditions at their entry into the Union due to the risk of contamination by aflatoxins since January 2019. Those commodities have not been imported into the Union for more than three years. Therefore, the entry on groundnuts and products produced from groundnuts from The Gambia in point 1 of Annex II to Implementing Regulation (EU) 2019/1793 should be deleted and transferred to Annex I to that Implementing Regulation, with a frequency of identity and physical checks set at 50 % of consignments entering the Union. Member States should continue to carry out official controls to ensure that after the lifting of the special conditions, when trade potentially restarts, those commodities introduced into the Union comply with the relevant requirements provided for in Union legislation with respect to contamination by aflatoxins.
- (8) In relation to consignments of drumsticks (Moringa oleifera) from India, a high rate of non-compliance with the relevant requirements provided for in Union legislation with respect to contamination by pesticide residues was detected during official controls performed by the Member States in accordance with Articles 5 and 6 of Implementing Regulation (EU) 2019/1793. It is therefore appropriate to increase the frequency of identity and physical checks to be performed on those consignments entering the Union to 20 %.

^(*) 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 (OJ L 70, 16.3.2005, p. 1).

- (9) In relation to consignments of rice from India, a high rate of non-compliance with the relevant requirements provided for in Union legislation with respect to contamination by pesticide residues was detected during official controls performed by the Member States in accordance with Articles 5 and 6 of Implementing Regulation (EU) 2019/1793. It is therefore appropriate to increase the frequency of identity and physical checks to be performed on those consignments entering the Union to 10 %.
- (10) In relation to consignments of guava (*Psidium guajava*) from India, a high rate of non-compliance with the relevant requirements provided for in Union legislation with respect to contamination by pesticide residues was detected during official controls performed by the Member States in accordance with Articles 5 and 6 of Implementing Regulation (EU) 2019/1793. It is therefore appropriate to increase the frequency of identity and physical checks to be performed on those consignments entering the Union to 30 %.
- (11) Peppers of the genus *Capsicum* (sweet or other than sweet) from India have been subjected to an increased level of official controls and to special conditions at their entry into the Union due to the risk of contamination by aflatoxins since January 2016. The official controls carried out by the Member States show improvements in compliance with the relevant requirements provided for in Union legislation. The results of those controls provide evidence that the entry of those foodstuffs into the Union does not constitute a serious risk for human health. Consequently, it is not necessary to continue to provide that each consignment is to be accompanied by an official certificate stating that all results of sampling and analysis show compliance with Commission Regulation (EC) No 1881/2006 (3). At the same time, Member States should continue to carry out official controls to ensure that the current level of compliance will be maintained. Therefore, the entry on peppers of the genus *Capsicum* (sweet or other than sweet) from India in point 1 of Annex II to Implementing Regulation (EU) 2019/1793 should be deleted and transferred to Annex I to that Implementing Regulation, with a frequency of identity and physical checks set at 10 % of consignments entering the Union.
- (12) Locust beans (carob), locust beans seeds, not decorticated, crushed or ground, and mucilages and thickeners, whether or not modified, derived from locust beans or locust beans seeds, from India and guar gum from India have been subjected to an increased level of official controls and to special conditions at their entry into the Union due to the risk of contamination by ethylene oxide since January 2022. The official controls carried out by the Member States show improvements in compliance with the relevant requirements provided for in Union legislation. The results of those controls provide evidence that the entry of those foodstuffs into the Union does not constitute a serious risk for human health. Consequently, it is not necessary to continue to provide that each consignment is to be accompanied by an official certificate stating that all results of sampling and analysis show compliance with Regulation (EC) No 396/2005. At the same time, Member States should continue to carry out official controls to ensure that the current level of compliance will be maintained. Therefore, the entries on locust beans (carob), locust beans seeds, not decorticated, crushed or ground, and mucilages and thickeners, whether or not modified, derived from locust beans or locust beans seeds, from India and guar gum from India in point 1 of Annex II to Implementing Regulation (EU) 2019/1793 should be deleted and transferred to Annex I to that Implementing Regulation, with a frequency of identity and physical checks set at 20 % of consignments entering the Union.
- (13) Guar gum from India has been subjected to an increased level of official controls and to special conditions at its entry into the Union due to the risk of contamination by pentachlorophenol and dioxins since February 2015. The official controls carried out by the Member States show improvements in compliance with the relevant requirements provided for in Union legislation. The results of those controls provide evidence that the entry of those foodstuffs into the Union does not constitute a serious risk for human health. Consequently, it is not necessary to continue to provide that each consignment is to be accompanied by an official certificate stating that all results of sampling and analysis show compliance with Union requirements. At the same time, Member States should continue to carry out official controls to ensure that the current level of compliance will be maintained. Therefore, the entry on guar gum from India in point 1 of Annex II to Implementing Regulation (EU) 2019/1793 should be deleted and transferred to Annex I to that Implementing Regulation, with a frequency of identity and physical checks set at 50 % of consignments entering the Union.

⁽⁵⁾ Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs (OJ L 364, 20.12.2006, p. 5).

- (14) In relation to consignments of cumin seeds from India, data from RASFF notifications and information regarding official controls performed by the Member States indicate the emergence of new risks to human health, due to possible contamination by pesticide residues. It is therefore necessary to require an increased level of official controls on entries of that commodity from India. That commodity should therefore be included in Annex I to Implementing Regulation (EU) 2019/1793, with a frequency of identity and physical checks set at 20 % of consignments entering the Union.
- (15) Instant noodles containing spices/seasonings or sauces from South Korea have been subjected to an increased level of official controls and to special conditions at their entry into the Union due to the risk of contamination by ethylene oxide since December 2021. The official controls carried out by the Member States show improvements in compliance with the relevant requirements provided for in Union legislation. The results of those controls provide evidence that the entry of those foodstuffs into the Union does not constitute a serious risk for human health. Consequently, it is not necessary to continue to provide that each consignment is to be accompanied by an official certificate stating that all results of sampling and analysis show compliance with Regulation (EC) No 396/2005. At the same time, Member States should continue to carry out official controls to ensure that the current level of compliance will be maintained. Therefore, the entry on instant noodles containing spices/seasonings or sauces from South Korea in point 1 of Annex II to Implementing Regulation (EU) 2019/1793 should be deleted and transferred to Annex I to that Implementing Regulation, with a frequency of identity and physical checks set at 20 % of consignments entering the Union.
- (16) In relation to consignments of gotukola (*Centella asiatica*) and mukunuwenna (*Alternanthera sessilis*) from Sri Lanka, a high rate of non-compliance with the relevant requirements provided for in Union legislation with respect to contamination by pesticide residues was detected during official controls performed by the Member States in accordance with Articles 5 and 6 of Implementing Regulation (EU) 2019/1793. It is therefore appropriate to increase the frequency of identity and physical checks to be performed on those consignments entering the Union to 50 %.
- (17) Locust beans (carob), locust beans seeds, not decorticated, crushed or ground, and mucilages and thickeners, whether or not modified, derived from locust beans or locust beans seeds, from Malaysia have been subjected to an increased level of official controls due to the risk of contamination by ethylene oxide since December 2021. Those commodities have not been imported into the Union for more than one year. Therefore, their entry in Annex I to Implementing Regulation (EU) 2019/1793 should be deleted.
- (18) In relation to consignments of green papaya (*Carica papaya*) from Mexico, data from RASFF notifications and information regarding official controls performed by the Member States indicate the emergence of new risks to human health, due to a possible contamination by pesticide residues. It is therefore necessary to require an increased level of official controls on entries of that commodity from Mexico. That commodity should therefore be included in Annex I to Implementing Regulation (EU) 2019/1793, with a frequency of identity and physical checks set at 20 % of consignments entering the Union.
- (19) Watermelon (Egusi, *Citrullus* spp.) seeds and derived products from Nigeria have been subjected to an increased level of official controls due to the risk of contamination by aflatoxins since January 2019. Those commodities have not been imported into the Union for more than three years. Therefore, their entry in Annex I to Implementing Regulation (EU) 2019/1793 should be deleted.
- (20) Peppers of the genus *Capsicum* (other than sweet) from Pakistan have been subjected to an increased level of official controls and to special conditions at their entry into the Union due to the risk of contamination by pesticide residues since January 2019. Those commodities have not been imported into the Union for more than three years. Therefore, the entry on peppers of the genus *Capsicum* (other than sweet) from Pakistan in point 1 of Annex II to Implementing Regulation (EU) 2019/1793 should be deleted and transferred to Annex I to that Implementing Regulation, with a frequency of identity and physical checks set at 20 % of consignments entering the Union. Member States should continue to carry out official controls to ensure that after the lifting of the special conditions, when trade potentially restarts, those commodities introduced into the Union comply with the relevant requirements provided for in Union legislation with respect to contamination by pesticide residues.

- (21) Groundnuts and products produced from groundnuts from Senegal have been subjected to an increased level of official controls due to the risk of contamination by aflatoxins since July 2017. Those commodities have not been imported into the Union for more than three years. Therefore, their entry in Annex I to Implementing Regulation (EU) 2019/1793 should be deleted.
- (22) Groundnuts and products produced from groundnuts from Sudan have been subjected to an increased level of official controls and to special conditions at their entry into the Union due to the risk of contamination by aflatoxins since January 2019. Those commodities have not been imported into the Union for more than three years. Therefore, the entry on groundnuts and products produced from groundnuts from Sudan in point 1 of Annex II to Implementing Regulation (EU) 2019/1793 should be deleted and transferred to Annex I to that Implementing Regulation, with a frequency of identity and physical checks set at 50 % of consignments entering the Union. Member States should continue to carry out official controls to ensure that after the lifting of the special conditions, when trade potentially restarts, those commodities introduced into the Union comply with the relevant requirements provided for in Union legislation with respect to contamination by aflatoxins.
- (23) In relation to consignments of tahini and halva from Syria, data from RASFF notifications and information regarding official controls performed by the Member States indicate the emergence of new risks to human health, due to a possible contamination by *Salmonella*. It is therefore necessary to require an increased level of official controls on entries of those commodities from Syria. Those commodities should therefore be included in Annex I to Implementing Regulation (EU) 2019/1793, with a frequency of identity and physical checks set at 20 % of consignments entering the Union.
- (24) In relation to consignments of pomegranates from Türkiye, a high rate of non-compliance with the relevant requirements provided for in Union legislation with respect to contamination by pesticide residues was detected during official controls performed by the Member States in accordance with Articles 5 and 6 of Implementing Regulation (EU) 2019/1793. It is therefore appropriate to increase the frequency of identity and physical checks to be performed on those consignments entering the Union to 30 %.
- (25) Locust beans (carob), locust beans seeds, not decorticated, crushed or ground, and mucilages and thickeners, whether or not modified, derived from locust beans or locust beans seeds, from Türkiye have been subjected to an increased level of official controls and to special conditions at their entry into the Union due to the risk of contamination by ethylene oxide since December 2021. The official controls carried out by the Member States show improvements in compliance with the relevant requirements provided for in Union legislation. The results of those controls provide evidence that the entry of those foodstuffs into the Union does not constitute a serious risk for human health. Consequently, it is not necessary to continue to provide that each consignment is to be accompanied by an official certificate stating that all results of sampling and analysis show compliance with Regulation (EC) No 396/2005. At the same time, Member States should continue to carry out official controls to ensure that the current level of compliance will be maintained. Therefore, the entry on locust beans (carob), locust beans seeds, not decorticated, crushed or ground, and mucilages and thickeners, whether or not modified, derived from locust beans or locust beans seeds, from Türkiye in point 1 of Annex II to Implementing Regulation (EU) 2019/1793 should be deleted and transferred to Annex I to that Implementing Regulation, with a frequency of identity and physical checks set at 20 % of consignments entering the Union.
- (26) Dried apricots and apricots, otherwise prepared or preserved, from Uzbekistan have been subjected to an increased level of official controls due to the risk of contamination by sulphites since April 2015. The official controls carried out on those commodities by the Member States indicate an overall satisfactory degree of compliance with the relevant requirements provided for in Union legislation. Therefore, an increased level of official controls is no longer justified for these commodities and their entry in Annex I to Implementing Regulation (EU) 2019/1793 should be deleted.
- (27) Instant noodles containing spices/seasonings or sauces from Vietnam have been subjected to an increased level of official controls and to special conditions at their entry into the Union due to the risk of contamination by ethylene oxide since December 2021. The official controls carried out by the Member States show improvements in compliance with the relevant requirements provided for in Union legislation. The results of those controls provide evidence that the entry of those foodstuffs into the Union does not constitute a serious risk for human health.

Consequently, it is not necessary to continue to provide that each consignment is to be accompanied by an official certificate stating that all results of sampling and analysis show compliance with Regulation (EC) No 396/2005. At the same time, Member States should continue to carry out official controls to ensure that the current level of compliance will be maintained. Therefore, the entry on instant noodles containing spices/seasonings or sauces from Vietnam in point 1 of Annex II to Implementing Regulation (EU) 2019/1793 should be deleted and transferred to Annex I to that Implementing Regulation, with a frequency of identity and physical checks set at 20 % of consignments entering the Union.

- (28) In order to ensure efficient protection against potential health risks arising from a possible contamination of groundnuts by aflatoxins, in the entry for Bolivia, in the column referring to 'food and feed (intended use)', in the table in point 1 of Annex II to Implementing Regulation (EU) 2019/1793, the wording 'including mixtures' should be added in the row referring to 'groundnuts (peanuts), otherwise prepared or preserved'. Equally, in the column referring to 'CN code', the CN codes for mixtures should be added.
- (29) In relation to consignments of groundnuts and products produced from groundnuts from Egypt, a high rate of non-compliance with the relevant requirements provided for in Union legislation with respect to contamination by aflatoxins was detected during official controls performed by the Member States in accordance with Articles 7 and 8 of Implementing Regulation (EU) 2019/1793. It is therefore appropriate to increase the frequency of identity and physical checks to be performed on those consignments entering the Union to 30 %.
- (30) In relation to the entry relating to *Sesamum* seeds from India, subjected to an increased level of official controls and to special conditions at their entry into the Union due to the risk of contamination by *Salmonella* and ethylene oxide, the intended use was extended to 'feed' since October 2021. Since then, that commodity has not been imported into the Union for the intended use as 'feed'. Therefore, an increased level of official controls and special conditions due to the risk of contamination by *Salmonella* in *Sesamum* seeds from India intended to be used as 'feed' are no longer justified and in the entry for India, in the column referring to 'food and feed (intended use)', in the table in point 1 of Annex II to Implementing Regulation (EU) 2019/1793, the wording should be adapted accordingly in the row referring to 'food and feed'.
- (31) In relation to consignments of oranges from Türkiye, a high rate of non-compliance with the relevant requirements provided for in Union legislation with respect to contamination by pesticide residues was detected during official controls performed by the Member States in accordance with Articles 7 and 8 of Implementing Regulation (EU) 2019/1793. It is therefore appropriate to increase the frequency of identity and physical checks to be performed on those consignments entering the Union to 30 %.
- (32) Unprocessed apricot kernels from Türkiye intended to be placed on the market for the final consumer have been subjected to an increased level of official controls and to special conditions at their entry into the Union due to the risk of contamination by cyanide since July 2019. The official controls carried out on that commodity by the Member States show a persistent high rate of non-compliance since the establishment of the increased level of official controls. Those controls provide evidence that the entry of that commodity into the Union constitutes a serious risk for human health. It is therefore necessary, in addition to the increased level of official controls, to provide for special conditions in relation to the importation of unprocessed apricot kernels from Türkiye intended to be placed on the market for the final consumer. In particular, all consignments of unprocessed apricot kernels from Türkiye intended to be placed on the market for the final consumer should be accompanied by an official certificate stating that all the results of sampling and analyses show compliance with Regulation (EC) No 1881/2006. The results of sampling and analyses should be attached to that certificate. Therefore, the entry of unprocessed apricot kernels from Türkiye intended to be placed on the market for the final consumer in Annex I to Implementing Regulation (EU) 2019/1793 should be deleted and transferred to point 1 of Annex II to that Implementing Regulation, with a frequency of identity and physical checks set at 50 % of consignments entering the Union.
- (33) Pistachios and derived products from Türkiye are listed in point 1 of Annex II to Implementing Regulation (EU) 2019/1793 because of a possible contamination by aflatoxins with a frequency of identity and physical checks set at 50 % of consignments entering the Union. Pistachios and derived products from the United States were delisted from Implementing Regulation (EU) 2019/1793 by Commission Implementing Regulation (EU) 2021/1900 (6) as

^(°) Commission Implementing Regulation (EU) 2021/1900 of 27 October 2021 amending Implementing Regulation (EU) 2019/1793 on the temporary increase of official controls and emergency measures governing the entry into the Union of certain goods from certain third countries implementing Regulation (EU) 2017/625 and (EC) No 178/2002 of the European Parliament and of the Council (OJ L 387, 3.11.2021, p. 78).

the results of official controls performed by the Member States indicated an overall satisfactory degree of compliance with the relevant requirements provided for in Union legislation as regards contamination by aflatoxins and no longer required an increased level of official controls. Nonetheless, data from RASFF notifications and information regarding official controls performed by the Member States in the second semester of 2022 indicate the emergence of new risks to human health requiring special import conditions, due to a possible contamination by aflatoxins of pistachios and derived products originating in the United States and dispatched to the Union from Türkiye.

- (34) In order to ensure protection against potential health risks arising from a possible contamination by the hazards referred to in Annex II to Implementing Regulation (EU) 2019/1793, a point 3 listing food and feed of non-animal origin dispatched to the Union from a third country other than the country of origin should be added in that Annex.
- (35) In light of the new information related to consignments of pistachios and derived products originating in the United States and dispatched to the Union from Türkiye, it is necessary to establish special conditions governing their entry into the Union. Therefore, pistachios and derived products originating in the United States and dispatched to the Union from Türkiye should be included in point 3 of Annex II to Implementing Regulation (EU) 2019/1793, with a frequency of identity and physical checks set at 50 % of consignments entering the Union, and should be accompanied by an official certificate issued by the competent authorities of Türkiye stating that all the results of sampling show compliance with Regulation (EC) No 1881/2006.
- (36) In order to ensure legal certainty for the entry into the Union of consignments that have already been dispatched from the country of origin or from another third country if that country is different from the country of origin, when this Regulation enters into force, it is appropriate to provide for a transitional period for consignments of unprocessed apricot kernels from Türkiye intended to be placed on the market for the final consumer and for consignments of pistachios and derived products originating in the United States and dispatched to the Union from Türkiye, which are not accompanied by the results of sampling and analyses and an official certificate. At the same time, public health protection is ensured for consignments of unprocessed apricot kernels from Türkiye intended to be placed on the market for the final consumer and for consignments of pistachios and derived products originating in the United States and dispatched to the Union from Türkiye, since those commodities are subject to identity and physical checks at a frequency of 50 % of consignments entering the Union.
- (37) Implementing Regulation (EU) 2019/1793 should therefore be amended accordingly. In order to ensure consistency and clarity, it is appropriate to replace Annexes I and II to Implementing Regulation (EU) 2019/1793 in their entirety by the text set out in the Annex to this Regulation.
- (38) 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

Implementing Regulation (EU) 2019/1793 is amended as follows:

- 1. in Article 1(1), point (b) is replaced by the following:
 - '(b) special conditions governing the entry into the Union of the following categories of consignments of food and feed due to the risk of contamination by mycotoxins, including aflatoxins, pesticide residues, pentachlorophenol and dioxins, microbiological contamination, Sudan dyes, Rhodamine B and plant toxins, in accordance with Article 53(1), point (b), of Regulation (EC) No 178/2002:
 - (i) consignments of food and feed of non-animal origin from third countries or parts of those third countries containing any of the food and feed listed in the table in point 1 of Annex II and falling within the CN codes and TARIC classifications laid down in that Annex;

- (ii) consignments of food consisting of two or more ingredients, containing any of the food listed in the table in point 1 of Annex II due to the risk of contamination by aflatoxins in a quantity above 20 % of either a single product or as the sum of those products and falling within the CN codes laid down in the table in point 2 of that Annex:
- (iii) consignments of food and feed of non-animal origin dispatched to the Union from a third country other than the country of origin and containing any of the food and feed listed in the table in point 3 of Annex II;';
- 2. Article 14 is replaced by the following:

'Article 14

Transitional periods

- 1. Consignments of unprocessed apricot kernels from Türkiye intended to be placed on the market for the final consumer, which have been dispatched to the Union from Türkiye, or from another third country if that country is different from the country of origin, before the date of entry into force of Commission Implementing Regulation (EU) 2023/1110 (*), may enter the Union until 27 August 2023 without being accompanied by the results of sampling and analyses and the official certificate provided for in Articles 10 and 11.
- 2. Consignments of pistachios and derived products originating in the United States, which have been dispatched to the Union from Türkiye before the date of entry into force of Implementing Regulation (EU) 2023/1110, may enter the Union until 27 August 2023 without being accompanied by the results of sampling and analyses and the official certificate provided for in Articles 10 and 11.
- (*) Commission Implementing Regulation (EU) 2023/1110 of 6 June 2023 amending Implementing Regulation (EU) 2019/1793 on the temporary increase of official controls and emergency measures governing the entry into the Union of certain goods from certain third countries implementing Regulations (EU) 2017/625 and (EC) No 178/2002 of the European Parliament and of the Council (OJ L 147, 7.6.2023, p. 111).'
- 3. Annexes I and II are replaced by the text set out in 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, 6 June 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

'ANNEX I

Food and feed of non-animal origin from certain third countries subject to a temporary increase of official controls at border control posts and control points

Row	Country of origin	Food and feed (intended use)	CN code (¹)	TARIC sub- division	Hazard	Frequency of identity and physical checks (%)
		— Hazelnuts (Corylus sp.), in shell	0802 21 00			
		— Hazelnuts (Corylus sp.), shelled	0802 22 00			
		— Mixtures of nuts or dried	ex 0813 50 39;	70		
		fruits containing hazelnuts	ex 0813 50 91;	70		
			ex 0813 50 99	70		
		— Hazelnut paste	ex 2007 10 10;	70		
			ex 2007 10 99;	40		
			ex 2007 99 39;	05; 06		
			ex 2007 99 50;	33		
			ex 2007 99 97	23		
		Hazelnuts, otherwise pre- pared or preserved, includ- ing mixtures	ex 2008 19 12;	30		
		ing materies	ex 2008 19 19;	30		
			ex 2008 19 92;	30		
			ex 2008 19 95;	20		
			ex 2008 19 99;	30		
			ex 2008 97 12;	15		
1	Azerbaijan		ex 2008 97 14;	15	Aflatoxins	20
	(AZ)		ex 2008 97 16;	15		
			ex 2008 97 18;	15		
			ex 2008 97 32;	15		
			ex 2008 97 34;	15		
			ex 2008 97 36;	15		
			ex 2008 97 38;	15		
			ex 2008 97 51;	15		
			ex 2008 97 59;	15		
			ex 2008 97 72;	15		

			ex 2008 97 74;	15		
			ex 2008 97 76;	15		
			ex 2008 97 78;	15		
			ex 2008 97 92;	15		
			ex 2008 97 93;	15		
			ex 2008 97 94;	15		
			ex 2008 97 96;	15		
			ex 2008 97 97;	15		
			ex 2008 97 98;	15		
		Flours, meals and powder of hazelnuts	ex 1106 30 90	40		
		— Hazelnut oil	ex 1515 90 99	20		
		(Food)				
		— Brazil nuts in shell	0801 21 00;			_
		— Mixtures of nuts or dried	ex 0813 50 31;	20		
		fruits containing Brazil nuts in shell	ex 0813 50 39;	20	Aflatoxins	50
		(Food)	ex 0813 50 91;	20		
			ex 0813 50 99	20		
		— Groundnuts (peanuts), in shell	1202 41 00			
		— Groundnuts (peanuts), shelled	1202 42 00			
		— Peanut butter	2008 11 10			
2	Brazil (BR)	Groundnuts (peanuts), otherwise prepared or pre- served	2008 11 91;		Pesticide residues (³)	30
			2008 11 96;			
			2008 11 98			
		Oilcake and other solid residues, whether or not ground or in the form of pellets, resulting from the extraction of groundnut oil	2305 00 00			
		— Groundnut flours and meals	ex 1208 90 00	20		
		— Groundnuts paste	ex 2007 10 10	80		
		(Food and feed)	ex 2007 10 99	50		
			ex 2007 99 39	07; 08		
		· · · · · · · · · · · · · · · · · · ·				

		Palm oil	1511 10 90			
	GA.				g 1	20
3	Côte d'Ivoire	(Food)	1511 90 11		Sudan dyes (14)	20
	(CI)		ex 1511 90 19	90		
			1511 90 99			
		— Groundnuts (peanuts), in shell	1202 41 00			
		— Groundnuts (peanuts), shelled	1202 42 00			
		— Peanut butter	2008 11 10			
		Groundnuts (peanuts), otherwise prepared or pre- served	2008 11 91;			
			2008 11 96;			
			2008 11 98		Aflatoxins	
4	China (CN)	Oilcake and other solid residues, whether or not ground or in the form of pellets, resulting from the extraction of groundnut oil	2305 00 00		Aflatoxins	10
		— Groundnut flours and meals	ex 1208 90 00	20		
		— Groundnuts paste	ex 2007 10 10	80		
		(Food and feed)	ex 2007 10 99	50		
			ex 2007 99 39	07; 08		
		Sweet peppers (Capsicum annuum) (Food – crushed or ground)	ex 0904 22 00	11	Salmonella(*)	10
		Tea, whether or not flavoured (Food)	0902		Pesticide residues(3)(5)	20
5	Colombia (CO)	Granadilla and passion fruit (Passiflora ligularis and Passiflora edulis) (Food)	ex 0810 90 20	30	Pesticide residues (3)	10
		— Sweet peppers (Capsicum	0709 60 10		Pesticide	50
	Dominican	annuum)	0710 80 51		resi- dues (3) (17)	
6	Republic (DO)	— Peppers of the genus <i>Capsi</i> -	ex 0709 60 99	20	uucs () ()	
	(DO)	cum (other than sweet) (Food – fresh, chilled or frozen)	ex 0710 80 59	20		

		Sweet peppers (Capsicum annuum)	0709 60 10 0710 80 51		Pesticide residues(3)(6)	30
7	Egypt (EG)	— Peppers of the genus Capsi-	ex 0709 60 99	20		
		cum (other than sweet) (Food – fresh, chilled or frozen)	ex 0710 80 59	20		
		Oranges (Food – fresh or dried)	0805 10		Pesticide residues (3)	30
		Sugar apple (Annona squamosa) (Food – fresh or chilled)	ex 0810 90 75	20	Pesticide residues (3)	20
		— Hazelnuts (Corylus sp.), in shell	0802 21 00			
		— Hazelnuts (Corylus sp.), shelled	0802 22 00			
		— Mixtures of nuts or dried	ex 0813 50 39;	70		
		fruits containing hazelnuts	ex 0813 50 91;	70		
			ex 0813 50 99	70		
		— Hazelnut paste	ex 2007 10 10;	70		
			ex 2007 10 99;	40		
			ex 2007 99 39;	05; 06		
			ex 2007 99 50;	33		
			ex 2007 99 97	23		
		Hazelnuts, otherwise pre- pared or preserved, includ- ing mixtures	ex 2008 19 12;	30		
			ex 2008 19 19;	30		
			ex 2008 19 92;	30		
			ex 2008 19 95;	20		
			ex 2008 19 99;	30		
			ex 2008 97 12;	15		
8	Georgia (GE)		ex 2008 97 14;	15	Aflatoxins	30
			ex 2008 97 16;	15		
			ex 2008 97 18;	15		
			ex 2008 97 32;	15		
			ex 2008 97 34;	15		
			ex 2008 97 36;	15		
			ex 2008 97 38;	15		
			ex 2008 97 51;	15		
			ex 2008 97 59;	15		

			ex 2008 97 72;	15		_
			ex 2008 97 74;	15		
			ex 2008 97 76;	15		
			ex 2008 97 78;	15		
			ex 2008 97 92;	15		
			ex 2008 97 93;	15		
			ex 2008 97 94;	15		
			ex 2008 97 96;	15		
			ex 2008 97 97;	15		
			ex 2008 97 98;	15		
		Flours, meals and powder of hazelnuts	ex 1106 30 90	40		
		— Hazelnut oil	ex 1515 90 99	20		
		(Food)				
		— Groundnuts (peanuts), in shell	1202 41 00			
		— Groundnuts (peanuts), shelled	1202 42 00			
		— Peanut butter	2008 11 10			
		 Groundnuts (peanuts), otherwise prepared or pre- served, including mixtures 	2008 11 91;			
			2008 11 96;			
			2008 11 98;			
			ex 2008 19 12;	40		
	The		ex 2008 19 19;	50	Aflatoxins	50
9	Gambia		ex 2008 19 92;	40		
	(GM)		ex 2008 19 95;	40		
			ex 2008 19 99	50		
		Oilcake and other solid residues, whether or not ground or in the form of pellets, resulting from the extraction of groundnut oil	2305 00 00			
		— Groundnut flours and meals	ex 1208 90 00	20		
		— Groundnuts paste	ex 2007 10 10	80		
		(Food and feed)	ex 2007 10 99	50		
			ex 2007 99 39	07; 08		

10	Israel (IL)	Basil (Ocimum basilicum) (Food)	ex 1211 90 86	20	Pesticide residues (3)	10
10		Mint (Mentha) (Food)	ex 1211 90 86	30	Pesticide residues (3)	10
		Betel leaves (Piper betle L.) (Food)	ex 1404 90 00 (10)	10	Salmonella(4)	30
		Okra (Food – fresh, chilled or frozen)	ex 0709 99 90; ex 0710 80 95	20 30	Pesticide residues(3)(7)	20
		Drumsticks (Moringa oleifera) (Food fresh, chilled or frozen)	ex 0709 99 90 ex 0710 80 95	10 75	Pesticide residues (3)	20
		Rice (Food)	1006		Aflatoxins and Ochratoxin A	5
					Pesticide residues (3)	10
		Yardlong beans (Vigna unguiculata ssp. sesquipedalis, Vigna unguiculata ssp. unguiculata) (Food – fresh, chilled or frozen vegetables)	ex 0708 20 00; ex 0710 22 00	10	Pesticide residues (³)	20
		Guava (Psidium guajava) (Food)	ex 0804 50 00	30	Pesticide residues (3)	30
		Nutmeg (Myristica fragrans) (Food – dried spices)	0908 11 00; 0908 12 00		Aflatoxins	30
11	India (IN)	Peppers of the genus Capsicum (sweet or other than sweet) (Food – dried, roasted, crushed or ground)	0904 21 10 ex 0904 22 00 ex 0904 21 90 ex 2005 99 10 ex 2005 99 80	11; 19 20 10; 90 94	Aflatoxins	10

		— Locust beans (carob)	1212 92 00			
		Locust beans seeds, not decorticated, crushed or ground	1212 99 41		Pesticide	
		Mucilages and thickeners, whether or not modified, derived from locust beans or locust bean seeds (Food and feed)	1302 32 10		residues (13)	20
		Guar gum (Food and feed)	ex 1302 32 90		Pesticide residues (13)	20
					Pentachlor- ophenoland dioxins	50
		— Cumin seeds	0909 31 00			
		Cumin seeds crushed or ground (Food)	0909 32 00		Pesticide residues (³)	20
	Kenya (KE)	Beans (Vigna spp., Phaseolus spp.)	0708 20		Pesticide residues (3)	10
12		(Food – fresh or chilled)			()	
		Peppers of the genus Capsicum (other than sweet) (Food – fresh, chilled or frozen)	ex 0709 60 99; ex 0710 80 59	20 20	Pesticide residues (3)	20
		Food supplements containing botanicals (15) (Food)	ex 1302 ex 2106		Pesticide residues (13)	30
13	South Korea (KR)	Instant noodles containing spices/seasonings or sauces (Food)	ex 1902 30 10	30	Pesticide residues (13)	20
	Sri Lanka	Gotukola (Centella asiatica) (Food)	ex 1211 90 86	60	Pesticide residues (3)	50
14	(LK)	Mukunuwenna (Alternanthera sessilis) (Food)	ex 0709 99 90	35	Pesticide residues (3)	50
15	Madagas- car (MG)	Black eyed beans (Vigna unguiculata) (Food)	0713 35 00		Pesticide residues (3)	10
16	Mexico (MX)	Green papaya (Carica papaya) (Food – fresh and chilled)	0807 20 00		Pesticide residues (3)	20

17	Malaysia (MY)	Jackfruit (Artocarpus heterophyllus) (Food – fresh)	ex 0810 90 20	20	Pesticide residues (3)	50
		Spice mixes (Food)	0910 91 10; 0910 91 90		Aflatoxins	50
18	Pakistan (PK)	Rice (Food)	1006		Aflatoxins and Ochratoxin A	10
					Pesticide residues (3)	5
		Peppers of the genus Capsicum (other than sweet) (Food – fresh, chilled or frozen)	ex 0709 60 99; ex 0710 80 59	20 20	Pesticide residues (3)	20
	n 1	Peppers of the genus Capsicum	ex 0709 60 99;	20	D1	
19	Rwanda (RW)	(other than sweet) (Food – fresh, chilled or frozen)	ex 0710 80 59	20	Pesticide residues (3)	20
		— Groundnuts (peanuts), in shell	1202 41 00			
		— Groundnuts (peanuts), shelled	1202 42 00			
		— Peanut butter	2008 11 10			
		— Groundnuts (peanuts),	2008 11 91;			
		otherwise prepared or pre- served, including mixtures	2008 11 96;			
20	Sudan (SD)		2008 11 98;		Aflatoxins	50
			ex 2008 19 12;	40		
			ex 2008 19 19;	50		
			ex 2008 19 92;	40		
			ex 2008 19 95;	40		
			ex 2008 19 99	50	-	
		Oilcake and other solid residues, whether or not ground or in the form of pellets, resulting from the extraction of groundnut oil	2305 00 00			
		— Groundnut flours and meals	ex 1208 90 00	20		
		— Groundnuts paste	ex 2007 10 10	80		

			ex 2007 10 99	50		
		(Food and feed)	ex 2007 99 39	07; 08		
21	Syria (SY)	Tahini and halva from Sesamum seeds (Food)	ex 1704 90 99 ex 1806 20 95 ex 1806 90 50 ex 1806 90 60 ex 2008 19 19 ex 2008 19 99	12; 92 13; 93 10 11; 91 40 40	Salmonella(²)	20
22	Thailand (TH)	Peppers of the genus Capsicum (other than sweet) (Food – fresh, chilled or frozen)	ex 0709 60 99; ex 0710 80 59	20 20	Pesticide residues(3)(8)	30
		Lemons (Citrus limon, Citrus limonum) (Food – fresh, chilled or dried)	0805 50 10		Pesticide residues (3)	30
		Grapefruits (Food)	0805 40 00		Pesticide residues (3)	30
		Pomegranates (Food – fresh or chilled)	ex 0810 90 75	30	Pesticide residues(3)(9)	30
23	Türkiye (TR)	 — Sweet peppers (Capsicum annuum) — Peppers of the genus Capsicum (other than sweet) (Food – fresh, chilled or frozen) 	0709 60 10 0710 80 51 ex 0709 60 99 ex 0710 80 59	20 20	Pesticide resi- dues (³) (¹0)	20
		Cumin seeds Cumin seeds crushed or ground (Food)	0909 31 00 0909 32 00		Pyrrolizi- dine alkaloids	20
		Dried oregano (Food)	ex 1211 90 86	40	Pyrrolizi- dine alkaloids	20
		Sesamum seeds (Food)	1207 40 90 ex 2008 19 19 ex 2008 19 99	40 40	Salmonella(²)	20
		— Locust beans (carob)	1212 92 00			
		 Locust beans seeds, not decorticated, crushed or ground Mucilages and thickeners, whether or not modified, derived from locust beans or locust beans seeds (Food and feed) 	1212 99 41 1302 32 10		Pesticide residues (¹³)	20

		Peppers of the genus Capsicum (other than sweet)	ex 0709 60 99;	20	Pesticide residues (3)	50
24	Uganda (UG)	(Food – fresh, chilled or frozen)	ex 0710 80 59	20	Pesticide residues (13)	10
		— Groundnuts (peanuts), in shell	1202 41 00			
		— Groundnuts (peanuts), shelled	1202 42 00			
		— Peanut butter	2008 11 10			
	United States (US)	Groundnuts (peanuts), otherwise prepared or pre- served	2008 11 91; 2008 11 96; 2008 11 98			
25		Oilcake and other solid residues, whether or not ground or in the form of pellets, resulting from the extraction of groundnut oil	2305 00 00		Aflatoxins	20
		— Groundnut flours and meals	ex 1208 90 00	20		
		— Groundnuts paste	ex 2007 10 10	80		
		(Food and feed)	ex 2007 10 99	50		
			ex 2007 99 39	07; 08		
		Peppers of the genus Capsicum	ex 0709 60 99;	20	Pesticide	F.O.
	Y	(other than sweet) (Food – fresh, chilled or frozen)	ex 0710 80 59	20	resi- dues (³) (¹²)	50
26	Vietnam (VN)	Instant noodles containing spices/seasonings or sauces (Food)	ex 1902 30 10	30	Pesticide residues (13)	20

- (1) Where only certain products under any CN code are required to be examined, the CN code is marked 'ex'.
- (2) The sampling and the analyses shall be performed in accordance with the sampling procedures and the analytical reference methods set out in point 1(a) of Annex III.
- (3) Residues of at least those pesticides listed in the control programme adopted in accordance with Article 29(2) of 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 (OJ L 70, 16.3.2005, p. 1) that can be analysed with multi-residue methods based on GC-MS and LC-MS (pesticides to be monitored in/on products of plant origin only).
- (4) The sampling and the analyses shall be performed in accordance with the sampling procedures and the analytical reference methods set out in point 1(b) of Annex III.
- (5) Residues of Tolfenpyrad.
- (6) Residues of Dicofol (sum of p, p' and o,p' isomers), Dinotefuran, Folpet, Prochloraz (sum of prochloraz and its metabolites containing the 2,4,6-trichlorophenol moiety expressed as prochloraz), Thiophanate-methyl and Triforine.
- (7) Residues of Diafenthiuron.
- (8) Residues of Formetanate (sum of formetanate and its salts expressed as formetanate (hydrochloride)), Prothiofos and Triforine.
- (9) Residues of Prochloraz.
- (10) Residues of Diafenthiuron, Formetanate (sum of formetanate and its salts expressed as formetanate (hydrochloride)) and Thiophanatemethyl.
- (11) Reference methods: EN 1988-1:1998, EN 1988-2:1998 or ISO 5522:1981.

- (12) Residues of Dithiocarbamates (dithiocarbamates expressed as CS2, including maneb, mancozeb, metiram, propineb, thiram and ziram), Phenthoate and Quinalphos.
- (13) Residues of Ethylene Oxide (sum of ethylene oxide and 2-chloro-ethanol, expressed as ethylene oxide). In case of food additives, the applicable maximum residue level (MRL) is 0,1 mg/kg (limit of quantification (LOQ)). Prohibition of use of Ethylene Oxide provided for in Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).
- (14) For the purposes of this Annex, 'Sudan dyes' refers to the following chemical substances: (i) Sudan I (CAS Number 842-07-9); (ii) Sudan II (CAS Number 3118-97-6); (iii) Sudan III (CAS Number 85-86-9); (iv) Scarlet Red or Sudan IV (CAS Number 85-83-6). Residues of Sudan dyes, using a method of analysis with an LOQ, shall be lower than 0,5 mg/kg).
- (15) Both finished products and raw materials containing any botanicals intended for the production of food supplements declared under CN codes mentioned in column 'CN code'.
- (16) Hereinafter understood as the State of Israel, excluding the territories under the administration of the State of Israel after 5 June 1967, namely the Golan Heights, the Gaza Strip, East Jerusalem and the rest of the West Bank.
- (17) Residues of Acephate.

ANNEX II

Food and feed from certain third countries subject to special conditions for the entry into the Union due to contamination risk by mycotoxins, including aflatoxins, pesticide residues, pentachlorophenol and dioxins, microbiological contamination, Sudan dyes, Rhodamine B and plant toxins

1. Food and feed of non-animal origin referred to in Article 1(1), point (b)(i)

Row	Country of origin	Food and feed (intended use)	CN code (¹)	TARIC sub- division	Hazard	Frequency of identity and physical checks (%)
1	Bangladesh (BD)	Foodstuffs containing or consisting of betel leaves (<i>Piper betle</i>) (<i>Food</i>)	ex 1404 90 00 (s)	10	Salmonella(5)	50
		— Groundnuts (peanuts), in shell	1202 41 00			
		— Groundnuts (peanuts), shelled	1202 42 00			
	Bolivia (BO)	— Peanut butter	2008 11 10			
		— Groundnuts (peanuts),	2008 11 91;			
		otherwise prepared or pre- served, including mixtures	2008 11 96;			
		0	2008 11 98;			
			ex 2008 19 12;	40		
			ex 2008 19 19;	50		
2			ex 2008 19 92;	40	Aflatoxins	50
			ex 2008 19 95;	40		
			ex 2008 19 99	50		
		Oilcake and other solid residues, whether or not ground or in the form of pellets, resulting from the extraction of groundnut oil	2305 00 00			
		— Groundnut flours and meals	ex 1208 90 00	20		
		— Groundnuts paste	ex 2007 10 10	80		
		(Food and feed)	ex 2007 10 99	50		
			ex 2007 99 39	07; 08		
3	Brazil (BR)	Black pepper (Piper nigrum) (Food – neither crushed nor ground)	ex 0904 11 00	10	Salmonella(²)	50

4	China (CN)	Xanthan gum (Food and feed)	ex 3913 90 00	40	Pesticide residues (9)	20
		Aubergines (Solanum melongena) (Food – fresh or chilled)	0709 30 00		Pesticide residues (3)	50
		Yardlong beans (Vigna	ex 0708 20 00	10	Pesticide	30
5	Dominican Republic (DO)	unguiculata ssp. sesquipedalis, Vigna unguiculata ssp. unguiculata) (Food – fresh, chilled or frozen)	ex 0710 22 00	10	resi- dues (³) (¹¹)	
		(1000 Jiesii, eiiiieu oi jiozeii)				
		— Groundnuts (peanuts), in shell	1202 41 00			
		— Groundnuts (peanuts), shelled	1202 42 00			
		— Peanut butter	2008 11 10			
		— Groundnuts (peanuts),	2008 11 91;			
		otherwise prepared or pre- served, including mixtures	2008 11 96;			
			2008 11 98;			
			ex 2008 19 12;	40		
			ex 2008 19 19;	50		
6	Egypt (EG)		ex 2008 19 92;	40	Aflatoxins	30
			ex 2008 19 95;	40		
			ex 2008 19 99	50		
	dues, whether or ground or in the for pellets, resulting from extraction of ground	Oilcake and other solid residues, whether or not ground or in the form of pellets, resulting from the extraction of groundnut oil	2305 00 00			
			ex 1208 90 00	20		
		— Groundnuts paste	ex 2007 10 10	80		
		(Food and feed)	ex 2007 10 99	50		
			ex 2007 99 39	07; 08		

	Т	T	T		T	
7	Ethiopia (ET)	 Pepper of the genus Piper; dried or crushed or ground fruit of the genus Capsicum or of the genus Pimenta Ginger, saffron, turmeric (curcuma), thyme, bay leaves, curry and other spices (Food – dried spices) 	0904		Aflatoxins	50
		Sesamum seeds	1207 40 90		Salmonella(5)	50
		(Food)	ex 2008 19 19	40		
			ex 2008 19 99	40		
		— Groundnuts (peanuts), in shell	1202 41 00			
		— Groundnuts (peanuts), shelled	1202 42 00			
		— Peanut butter	2008 11 10			
		— Groundnuts (peanuts),	2008 11 91;			
		otherwise prepared or pre- served, including mixtures	2008 11 96;			
			2008 11 98;			
	Ghana (GH)		ex 2008 19 12;	40		
			ex 2008 19 19;	50	Aflatoxins	50
			ex 2008 19 92;	40		
8			ex 2008 19 95;	40		
			ex 2008 19 99	50		
		Oilcake and other solid residues, whether or not ground or in the form of pellets, resulting from the extraction of groundnut oil	2305 00 00			
		— Groundnut flours and meals	ex 1208 90 00	20		
		— Groundnuts paste	ex 2007 10 10	80		
		(Food and feed)	ex 2007 10 99	50		
			ex 2007 99 39	07; 08		
		Palm oil	1511 10 90			
		(Food)	1511 90 11		Sudan	50
			ex 1511 90 19	90	dyes (10)	, , ,
			1511 90 99			

9	Indonesia (ID)	Nutmeg (Myristica fragrans) (Food – dried spices)	0908 11 00; 0908 12 00		Aflatoxins	30
		Curry leaves (Bergera/Murraya koenigii) (Food – fresh, chilled, frozen or dried)	ex 1211 90 86	10	Pesticide resi- dues (3) (12)	50
		— Groundnuts (peanuts), in shell	1202 41 00			
		— Groundnuts (peanuts), shelled	1202 42 00			
		— Peanut butter	2008 11 10			
		— Groundnuts (peanuts),	2008 11 91;			
	India (IN)	otherwise prepared or pre- served, including mixtures	2008 11 96;			
		, 8	2008 11 98;			
			ex 2008 19 12;	40		
			ex 2008 19 19;	50	A Cl - 4 :	50
			ex 2008 19 92;	40	Aflatoxins	50
			ex 2008 19 95;	40		
			ex 2008 19 99	50		
10		Oilcake and other solid residues, whether or not ground or in the form of pellets, resulting from the extraction of groundnut oil	2305 00 00			
		— Groundnut flours and meals	ex 1208 90 00	20		
		— Groundnuts paste	ex 2007 10 10	80		
		(Food and feed)	ex 2007 10 99	50		
			ex 2007 99 39	07; 08		
		Peppers of the genus Capsicum	ex 0709 60 99;	20	Pesticide	
		(other than sweet) (Food – fresh, chilled or frozen)	ex 0710 80 59	20	residues(3)(4)	20
		Sesamum seeds	1207 40 90		Salmonella(5)	20
		(Food)	ex 2008 19 19	40		
			ex 2008 19 99	40		
		Sesamum seeds	1207 40 90		Pesticide	50
		(Food and feed)	ex 2008 19 19	40	residues (9)	
			ex 2008 19 99	40		

Mixtures of food additives containing locust bean gum or guar gum (Food)	ex 2106 90 92 ex 2106 90 98 ex 3824 99 93 ex 3824 99 96		Pesticide residues (°)	20
Pepper of the genus <i>Piper</i> ; dried or crushed or ground fruit of the genus <i>Capsicum</i> or of the genus <i>Pimenta</i> (Food – dried spices)	0904		Pesticide residues (9)	20
Vanilla (Food – dried spices)	0905		Pesticide residues (°)	20
Cinnamon and cinnamon-tree flowers (Food – dried spices)	0906		Pesticide residues (9)	20
Cloves (whole fruit, cloves and stems) (Food – dried spices)	0907		Pesticide residues (9)	20
Nutmeg, mace and cardamoms (Food – dried spices)	0908		Pesticide residues (°)	20
Seeds of anise, badian, fennel, coriander, cumin or caraway, juniper berries (Food – dried spices)	0909		Pesticide residues (°)	20
Ginger, saffron, turmeric (curcuma), thyme, bay leaves, curry and other spices (Food – dried spices)	0910		Pesticide residues (°)	20
Sauces and preparations thereof; mixed condiments and mixed seasonings; mustard flours and meals and prepared mustard (Food)	2103		Pesticide residues (º)	20
Calcium carbonate (Food and feed)	ex 2106 90 92 ex 2106 90 98 ex 2530 90 70 2836 50 00	55 60 10	Pesticide residues (°)	30
Food supplements containing botanicals (13) (Food)	ex 1302 ex 2106		Pesticide residues (9)	20

		— Pistachios, in shell	0802 51 00			
		— Pistachios, shelled	0802 52 00			
		— Mixtures of nuts or dried	ex 0813 50 39;	60		
		fruits containing pistachios	ex 0813 50 91;	60		
			ex 0813 50 99	60		
		— Pistachio paste	ex 2007 10 10;	60		
			ex 2007 10 99;	30		
			ex 2007 99 39;	03; 04		
			ex 2007 99 50;	32		
			ex 2007 99 97	22		
11	Iran (IR)	— Pistachios, prepared or pre-	ex 2008 19 13;	20	Aflatoxins	50
		served, including mixtures	ex 2008 19 93;	20		
			ex 2008 97 12;	19		
			ex 2008 97 14;	19		
			ex 2008 97 16;	19		
			ex 2008 97 18;	19		
			ex 2008 97 32;	19		
			ex 2008 97 34;	19		
			ex 2008 97 36;	19		
			ex 2008 97 38;	19		
			ex 2008 97 51;	19		
			ex 2008 97 59;	19		
			ex 2008 97 72;	19		
			ex 2008 97 74;	19		
			ex 2008 97 76;	19		
			ex 2008 97 78;	19		
			ex 2008 97 92;	19		
			ex 2008 97 93;	19		
			ex 2008 97 94;	19		
			ex 2008 97 96;	19		
			ex 2008 97 97;	19		
			ex 2008 97 98	19		
		Flours, meals and powder of pistachios	ex 1106 30 90	50		
		(Food)				
	1	l .	l	l	1	L

	Lebanon	Turnips (Brassica rapa ssp. rapa) (Food – prepared or preserved by vinegar or acetic acid)	ex 2001 90 97	11; 19	Rhodamine B (14)	50
12	(LB)	Turnips (Brassica rapa ssp. rapa) (Food – prepared or preserved by brine or citric acid, not frozen)	ex 2005 99 80	93	Rhodamine B (14)	50
		Peppers of the genus Capsicum	0904 21 10		Aflatoxins	
	3 Sri Lanka (LK)	(sweet or other than sweet) (Food – dried, roasted, crushed)	ex 0904 21 90	20		
13		or ground)	ex 0904 22 00	11; 19		50
			ex 2005 99 10	10; 90		
			ex 2005 99 80	94		
		Mixtures of food additives	ex 2106 90 92		Pesticide	
1.4	Malaysia (MY)	containing locust bean gum (Food)	ex 2106 90 98		residues (9)	20
14			ex 3824 99 93			20
			ex 3824 99 96			
	Nigeria (NG)	Sesamum seeds	1207 40 90		Salmonella(5)	
15		(Food)	ex 2008 19 19	40		50
	(1.0)		ex 2008 19 99	40		
		Sesamum seeds	1207 40 90		Salmonella(5)	
16	Sudan (SD)	(Food)	ex 2008 19 19	40		50
			ex 2008 19 99	40		
		— Dried figs	0804 20 90			
		Mixtures of nuts or dried fruits containing figs	ex 0813 50 99	50		
		— Dried fig paste	ex 2007 10 10;	50		
			ex 2007 10 99;	20		
			ex 2007 99 39;	01; 02		
			ex 2007 99 50;	31		
			ex 2007 99 97	21		
		— Dried figs, prepared or pre-	ex 2008 97 12;	11		
		served, including mixtures	ex 2008 97 14;	11		
			ex 2008 97 16;	11		
			ex 2008 97 18;	11		
			ex 2008 97 32;	11		
			ex 2008 97 34;	11		
			ex 2008 97 36;	11		
			ex 2008 97 38;	11		



₇ Türkiye		ex 2008 97 51;	11	Aflatoxins	30
7 (TR)		ex 2008 97 59;	11		
		ex 2008 97 72;	11		
		ex 2008 97 74;	11		
		ex 2008 97 76;	11		
		ex 2008 97 78;	11		
		ex 2008 97 92;	11		
		ex 2008 97 93;	11		
		ex 2008 97 94;	11		
		ex 2008 97 96;	11		
		ex 2008 97 97;	11		
		ex 2008 97 98;	11		
		ex 2008 99 28;	10		
		ex 2008 99 34;	10		
		ex 2008 99 37;	10		
		ex 2008 99 40;	10		
		ex 2008 99 49;	60		
		ex 2008 99 67;	95		
		ex 2008 99 99	60		
	 Flours, meals and powder of dried figs 	ex 1106 30 90	60		
	(Food)				
	— Pistachios, in shell	0802 51 00			
	— Pistachios, shelled	0802 52 00			
	— Mixtures of nuts or dried	ex 0813 50 39;	60		
	fruits containing pistachios	ex 0813 50 91;	60		
		ex 0813 50 99	60		
	— Pistachio paste	ex 2007 10 10;	60		
		ex 2007 10 99;	30		
		ex 2007 99 39;	03; 04		
		ex 2007 99 50;	32		
		ex 2007 99 97	22		
	- Pistachios, otherwise pre-	ex 2008 19 13;	20	Aflatoxins	50
	pared or preserved, including mixtures	ex 2008 19 93;	20		
		ex 2008 97 12;	19		
		ex 2008 97 14;	19		

		ex 2008 97 16;	19		
		ex 2008 97 18;	19		
		ex 2008 97 32;	19		
		ex 2008 97 34;	19		
		ex 2008 97 36;	19		
		ex 2008 97 38;	19		
		ex 2008 97 51;	19		
		ex 2008 97 59;	19		
		ex 2008 97 72;	19		
		ex 2008 97 74;	19		
		ex 2008 97 76;	19		
		ex 2008 97 78;	19		
		ex 2008 97 92;	19		
		ex 2008 97 93;	19		
		ex 2008 97 94;	19		
		ex 2008 97 96;	19		
		ex 2008 97 97;	19		
		ex 2008 97 98	19		
	— Flours, meals and powder of	ex 1106 30 90	50		
	pistachios				
	(Food)				
	Vine leaves (Food)	ex 2008 99 99	11; 19	Pesticide residues(3)(6)	50
	Mandarins (including tangerines and satsumas); clementines, wilkings and similar citrus hybrids (Food – fresh or dried)	0805 21; 0805 22 00; 0805 29 00		Pesticide residues (3)	20
	Oranges (Food – fresh or dried)	0805 10		Pesticide residues (3)	30
	Mixtures of food additives containing locust bean gum (Food)	ex 2106 90 92 ex 2106 90 98 ex 3824 99 93 ex 3824 99 96		Pesticide residues (°)	20
	Unprocessed whole, ground, milled, cracked, chopped apricot kernels intended to be placed on the market for the final consumer (15) (16) (Food)	ex 1212 99 95	20	Cyanide	50

18	Uganda (UG)	Sesamum seeds (Food)	1207 40 90		Salmonella(5)	20
			ex 2008 19 19	40		
			ex 2008 19 99	40		
20	United States (US)	Vanilla extract (Food)	1302 19 05		Pesticide residues (9)	20
21	Vietnam (VN)	Okra (Food – fresh, chilled or frozen)	ex 0709 99 90; ex 0710 80 95	20 30	Pesticide residues(3)(7)	50
		Pitahaya (dragon fruit) (Food – fresh or chilled)	ex 0810 90 20	10	Pesticide residues(3)(7)	20

- (1) Where only certain products under any CN code are required to be examined, the CN code is marked 'ex'.
- (2) The sampling and the analyses shall be performed in accordance with the sampling procedures and the analytical reference methods set out in point 1(b) of Annex III.
- (3) Residues of at least those pesticides listed in the control programme adopted in accordance with Article 29(2) of 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 (OJ L 70, 16.3.2005, p. 1) that can be analysed with multi-residue methods based on GC-MS and LC-MS (pesticides to be monitored in/on products of plant origin only).
- (4) Residues of Carbofuran.
- (3) The sampling and the analyses shall be performed in accordance with the sampling procedures and the analytical reference methods set out in point 1(a) of Annex III.
- (6) Residues of Dithiocarbamates (dithiocarbamates expressed as CS2, including maneb, mancozeb, metiram, propineb, thiram and ziram) and Metrafenone.
- (7) Residues of Dithiocarbamates (dithiocarbamates expressed as CS2, including maneb, mancozeb, metiram, propineb, thiram and ziram), Phenthoate and Quinalphos.
- (8) Foodstuffs containing or consisting of betel leaves (Piper betle) including, but not limited to, those declared under CN code 1404 90 00.
- (9) Residues of Ethylene Oxide (sum of ethylene oxide and 2-chloro-ethanol, expressed as ethylene oxide). In case of food additives, the applicable MRL is 0,1 mg/kg (LOQ). Prohibition of use of Ethylene Oxide provided for in Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).
- (10) For the purposes of this Annex, 'Sudan dyes' refers to the following chemical substances: (i) Sudan I (CAS Number 842-07-9); (ii) Sudan II (CAS Number 3118-97-6); (iii) Sudan III (CAS Number 85-86-9); (iv) Scarlet Red or Sudan IV (CAS Number 85-83-6). Residues of Sudan dyes, using a method of analysis with an LOQ, shall be lower than 0,5 mg/kg.
- (11) Residues of Amitraz (amitraz including the metabolites containing the 2,4-dimethylaniline moiety expressed as amitraz), Diafenthiuron, Dicofol (sum of p, p' and o,p' isomers) and Dithiocarbamates (dithiocarbamates expressed as CS2, including maneb, mancozeb, metiram, propineb, thiram and ziram).
- (12) Residues of Acephate.
- (13) Both finished products and raw materials containing any botanicals intended for the production of food supplements declared under CN codes mentioned in column 'CN code'.
- (14) For purpose of this Annex, residues of Rhodamine B, using a method of analysis with an LOQ, shall be lower than 0,1 mg/kg.
- (15) 'Unprocessed products' as defined in Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1).
- (16) 'Placing on the market' and 'final consumer' as defined in Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

2. Food referred to in Article 1(1), point (b)(ii)

Row	Food consisting of two or more ingredients, containing any of the individual products listed in the table in point 1 due to risk of contamination by aflatoxins in a quantity above 20 % of either a single product or as the sum of products listed			
	CN code (1) Description (2)			
1	ex 1704 90	Sugar confectionery (including white chocolate), not containing cocoa, other than chewing gum, whether or not sugar-coated		
2	ex 1806	Chocolate and other food preparations containing cocoa		
3	ex 1905	Bread, pastry, cakes, biscuits and other bakers' wares, whether or not containing cocoa, communion wafers, empty cachets of a kind suitable for pharmaceutical use, sealing wafers, rice paper and similar products		

⁽¹) Where only certain products under any CN code are required to be examined, the CN code is marked 'ex'.

3. Food and feed of non-animal origin referred to in Article 1(1), point (b)(iii)

Row	Country of origin	Country from where consign- ments are dispatched to the Union	Food and feed (intended use)	CN code (¹)	TARIC sub- division	Hazard	Frequency of identity and physical checks (%)
	United States (US)	Türkiye (TR) (²)	— Pistachios, in shell— Pistachios, shelled	0802 51 00 0802 52 00			
			Mixtures of nuts or dried fruits containing pistachios	ex 0813 50 39;	60		
				ex 0813 50 91;	60		
				ex 0813 50 99	60		
			— Pistachio paste	ex 2007 10 10;	60		
				ex 2007 10 99;	30		
1			Pistachios, otherwise prepared or preserved, including mixtures	ex 2007 99 39;	03; 04	Aflatox- ins	50
				ex 2007 99 50;	32		
				ex 2007 99 97	22		
				ex 2008 19 13;	20		
				ex 2008 19 93;	20		
				ex 2008 97 12;	19		
				ex 2008 97 14;	19		
				ex 2008 97 16;	19		
				ex 2008 97 18;	19		

⁽²⁾ The description of the goods is as laid down in the description column of the CN in Annex I to Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff (OJ L 256, 7.9.1987, p. 1).

			ex 2008 97 32;	19		
			ex 2008 97 34;	19		
			ex 2008 97 36;	19		
			ex 2008 97 38;	19		
			ex 2008 97 51;	19		
			ex 2008 97 59;	19		
			ex 2008 97 72;	19		
			ex 2008 97 74;	19		
			ex 2008 97 76;	19		
			ex 2008 97 78;	19		
			ex 2008 97 92;	19		
			ex 2008 97 93;	19		
			ex 2008 97 94;	19		
			ex 2008 97 96;	19		
			ex 2008 97 97;	19		
			ex 2008 97 98	19		
				17		
		 Flours, meals and powder of pista- 	ex 1106 30 90	50		
		chios				
		(Food)				
i e	1				1	

 ⁽¹) Where only certain products under any CN code are required to be examined, the CN code is marked 'ex'.
 (²) In accordance with Articles 10 and 11, consignments shall be accompanied by the results of sampling and analyses performed on those consignments and by the official certificate issued by the country from where consignments are dispatched to the Union.'

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1111

of 6 June 2023

amending Regulation (EC) No 474/2006 as regards the list of air carriers banned from operating or subject to operational restrictions within the Union

(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 2111/2005 of the European Parliament and of the Council of 14 December 2005 on the establishment of a Community list of air carriers subject to an operating ban within the Community and on informing air transport passengers of the identity of the operating carrier, and repealing Article 9 of Directive 2004/36/EC (1), and in particular Article 4(2) thereof,

Whereas:

- (1) Commission Regulation (EC) No 474/2006 (2) establishes the list of air carriers, which are subject to an operating ban within the Union.
- (2) Certain Member States and the European Union Aviation Safety Agency ('the Agency') communicated to the Commission, pursuant to Article 4(3) of Regulation (EC) No 2111/2005, information that is relevant for updating that list. Third countries and international organisations also provided relevant information. On the basis of the information provided, that list should be updated.
- (3) The Commission informed all air carriers concerned, either directly or through the authorities responsible for their regulatory oversight, about the essential facts and considerations, which would form the basis of a decision to impose an operating ban on them within the Union or to modify the conditions of an operating ban imposed on an air carrier, which is included in the list set out in Annex A or B to Regulation (EC) No 474/2006.
- (4) The Commission gave the air carriers concerned the opportunity to consult all relevant documentation, to submit written comments and to make an oral presentation to the Commission and to the Committee established by Article 15 of Regulation (EC) No 2111/2005 (the 'EU Air Safety Committee').
- (5) The Commission has informed the EU Air Safety Committee about the ongoing consultations, within the framework of Regulation (EC) No 2111/2005 and Commission Delegated Regulation (EU) 2023/660 (³), with the competent authorities and air carriers of Armenia, Democratic Republic of the Congo, Iraq, and Kyrgyzstan. The Commission also informed the EU Air Safety Committee about the aviation safety situation in Argentina, Congo (Brazzaville), Egypt, Kazakhstan, Kenya, Madagascar, Moldova, Nepal, Pakistan, and South Sudan.

⁽¹⁾ OJ L 344, 27.12.2005, p. 15.

⁽²⁾ Commission Regulation (EC) No 474/2006 of 22 March 2006 establishing the Community list of air carriers which are subject to an operating ban within the Community referred to in Chapter II of Regulation (EC) No 2111/2005 of the European Parliament and of the Council (OJ L 84, 23.3.2006, p. 14).

⁽³⁾ Commission Delegated Regulation (EU) 2023/660 of 2 December 2022 laying down detailed rules for the list of air carriers banned from operating or subject to operational restrictions within the Union referred to in Chapter II of Regulation (EC) No 2111/2005 of the European Parliament and of the Council and repealing Regulation (EC) No 473/2006 laying down implementing rules for the Community list of air carriers which are subject to an operating ban within the Community referred to in Chapter II of Regulation (EC) No 2111/2005 of the European Parliament and of the Council (OJ L 83 22.3.2023, p. 47).

- (6) The Agency informed the Commission and the EU Air Safety Committee about the technical assessments conducted for the initial evaluation and the continuous monitoring of third country operator ('TCO') authorisations, issued pursuant to Commission Regulation (EU) No 452/2014 (4).
- (7) The Agency also informed the Commission and the EU Air Safety Committee about the results of the analysis of ramp inspections carried out under the Safety Assessment of Foreign Aircraft programme ('SAFA'), in accordance with Commission Regulation (EU) No 965/2012 (5).
- (8) In addition, the Agency informed the Commission and the EU Air Safety Committee about the technical assistance projects carried out in third countries affected by an operating ban under Regulation (EC) No 474/2006. Furthermore, the Agency provided information on the plans and requests for further technical assistance and cooperation to improve the administrative and technical capability of civil aviation authorities in third countries with a view to helping them assure compliance with applicable international civil aviation safety standards. Member States were invited to respond to such requests on a bilateral basis in coordination with the Commission and the Agency. In that regard, the Commission reiterated the usefulness of providing information to the international aviation community, particularly through the International Civil Aviation Organisation's (TCAO') Aviation Safety Implementation Assistance Partnership tool, on technical assistance to third countries provided by the Union and Member States to improve aviation safety around the world.
- (9) Eurocontrol provided the Commission and the EU Air Safety Committee with an update on the status of the SAFA and TCO alarming functions, including statistics about alert messages for banned air carriers.

Union air carriers

- (10) Following the Agency's analysis of information resulting from ramp inspections carried out on the aircraft of Union air carriers, as well as standardisation inspections carried out by the Agency, and complemented with information stemming from specific inspections and audits carried out by national aviation authorities, Member States and the Agency, acting as competent authorities, have taken certain corrective and enforcement measures, and informed the Commission and the EU Air Safety Committee about those measures.
- (11) Member States and the Agency, acting as competent authorities, reiterated their readiness to act, as necessary, in the event that pertinent safety information indicates imminent safety risks resulting from non-compliance by Union air carriers with relevant safety standards.

Air carriers from Armenia

- (12) In June 2020, air carriers certified in Armenia were included in Annex A to Regulation (EC) No 474/2006, by Commission Implementing Regulation (EU) 2020/736 (6).
- (13) As part of the continuous monitoring activities the Commission identified that the new air carrier Armenian Airlines has been certified by the Civil Aviation Committee of Armenia ('CAC') in December 2022. Since CAC has not provided the Commission with evidence to demonstrate a sufficient ability to implement and enforce the relevant international safety standards, the issuance of an air operator certificate ('AOC') to this new air carrier does not guarantee sufficient compliance with the relevant international safety standards.

⁽⁴⁾ Commission Regulation (EU) No 452/2014 of 29 April 2014 laying down technical requirements and administrative procedures related to air operations of third country operators pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council (OJ L 133, 6.5.2014, p. 12).

⁽⁵⁾ Commission Regulation (EU) No 965/2012 of 5 October 2012 laying down technical requirements and administrative procedures related to air operations pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council (OJ L 296, 25.10.2012, p. 1).

^(°) Commission Implementing Regulation (EU) 2020/736 of 2 June 2020 amending Regulation (EC) No 474/2006 as regards the list of air carriers banned from operating or subject to operational restrictions within the Union (OJ L 172, 3.6.2020, p. 7).

- (14) In accordance with the common criteria set out in the Annex to Regulation (EC) No 2111/2005, the Commission considers that with respect to air carriers from Armenia, the list of air carriers, which are subject to an operating ban within the Union should be amended to include Armenian Airlines in Annex A to Regulation (EC) No 474/2006.
- (15) Member States should continue verifying the effective compliance of air carriers certified in Armenia with the relevant international safety standards through prioritisation of ramp inspections of those air carriers, pursuant to Regulation (EU) No 965/2012.

Air carriers from the Democratic Republic of the Congo

- (16) In March 2006, air carriers certified in the Democratic Republic of the Congo were included in Regulation (EC) No 474/2006.
- (17) Upon request from the Autorité de l'Aviation Civile of the Democratic Republic of the Congo ('AAC/RDC') a technical meeting took place on 19 April 2023. During that technical meeting AAC/RDC provided a comprehensive presentation of its organisation and functions, and the measures taken to improve the safety oversight in the Democratic Republic of the Congo. AAC/RDC also informed the Commission about the preliminary results of the ICAO's Universal Safety Oversight Audit Programme ('USOAP') visit which was conducted in September 2022 and in February 2023.
- (18) The meeting showed that AAC/RDC still needs to provide the Commission with further clarifications and evidence regarding certain actions and measures taken, in particular as regards the certification of air carriers engaged in commercial air transport and the renewal of the validity of AOCs.
- (19) During that technical meeting, AAC/RDC informed the Commission that the air carriers AB BUSINESS, AIR KASAI, GOMA EXPRESS, and TRACEP CONGO AVIATION have been certified since the last update it provided to the Commission on 6 and 13 May 2020.
- (20) The ICAO, by means of its Electronic Bulletin 2023/18 of 1 May 2023, notified its contracting States of the identification of two Significant Safety Concerns ('SSC') during its audit of February 2023, pertaining to the area of air navigation services in relation to instrument flight procedures and flight inspections for navigational aids.
- (21) On the basis of the information provided by AAC/RDC and the notification of two SSC by ICAO, the Commission has justified reservations about AAC/RDC's capacity to ensure that operations by air carriers certified in the Democratic Republic of the Congo are conducted in accordance with the relevant international safety standards. As a consequence, further technical meetings will take place to monitor the progress of AAC/RDC in ensuring that its aviation safety oversight system complies with the relevant international safety standards.
- (22) Since AAC/RDC has not demonstrated a sufficient ability to implement and enforce the relevant international safety standards, the issuance of an AOC to the air carriers AB BUSINESS, AIR KASAI, GOMA EXPRESS, and TRACEP CONGO AVIATION does not guarantee sufficient compliance with such standards, and therefore these air carriers should be added in Annex A to Regulation (EC) No 474/2006.
- (23) On 8 May 2023, AAC/RDC provided the Commission with evidence that the air carrier MWANT JET no longer holds a valid AOC. Therefore this air carrier should be removed from Annex A to Regulation (EC) No 474/2006.
- (24) In accordance with the common criteria set out in the Annex to Regulation (EC) No 2111/2005, the Commission considers that the list of air carriers which are subject to an operating ban within the Union should be amended to remove the air carrier MWANT JET from Annex A to Regulation (EC) No 474/2006 and to add the air carriers AB BUSINESS, AIR KASAI, GOMA EXPRESS, AND TRACEP CONGO AVIATION in Annex A to Regulation (EC) No 474/2006.
- (25) Member States should continue verifying the effective compliance of air carriers certified in the Democratic Republic of the Congo with the relevant international safety standards through prioritisation of ramp inspections of those air carriers, pursuant to Regulation (EU) No 965/2012.

Air carriers from Iraq

- (26) In December 2015, the air carrier Iraqi Airways was included in Annex A to Regulation (EC) No 474/2006, by Commission Implementing Regulation (EU) 2015/2322 (7).
- (27) As part of its ongoing EU Air Safety List ('ASL') consultations the Commission, in cooperation with the Agency and Member States, has organised a number of technical meetings with the Iraq Civil Aviation Authority ('ICAA') and Iraqi Airways. Those discussions focused on efforts made by the ICAA in dealing with the safety concerns previously identified by the Commission and the Agency experts, as well as regards the oversight of Iraqi certified air carriers.
- (28) On 20 April 2023, as part of the continuous monitoring activities of the Commission, a technical meeting was held between the Commission, the Agency, Member States and the ICAA. During that meeting, ICAA has provided information on several key elements related to their safety oversight activities, highlighting the Iraqi government decision to allocate substantial resources to support ICAA efforts to ensure effective safety oversight in the country, notably for inspector training, and suitable facilities.
- (29) In relation to the safety oversight, ICAA disclosed that there are six AOC holders, four Approved Maintenance Organisations, and one Air Traffic Organisation based in Iraq for which ICAA is responsible.
- (30) ICAA reported that a new Aviation Law had been drafted and is undergoing consultation, and when passed it would result in significant changes to ICAA's internal regulations and procedures. Furthermore, ICAA is currently working on updating the ICAO On-Line Framework, pending ICAO's review of the ICAA proposed Corrective Action Plan ('CAP').
- (31) During that technical meeting, ICAA also informed the Commission that the Flight Operations Inspectors ('FOI') were partially managed through the designation of air operators' pilots on a part-time basis. Furthermore, they presented their plans to recruit full-time dedicated FOIs. A recent decision by the General Secretariat for the Council of Ministers has allowed ICAA to contract and recruit experts in the fields of aircraft operations, licensing, medical assessment, airworthiness, air navigation services, and aerodrome certification.
- (32) Additionally, the technical meeting included a brief exchange about *Fly Baghdad*'s recent negative TCO decision taken on safety grounds.
- (33) The Commission acknowledges the efforts being made by the ICAA and the fact that the ICAA is committed to carrying out its international obligations in relation to aviation safety. Notwithstanding these developments, the information provided so far requires further verification through additional technical meetings.
- (34) In accordance with the common criteria set out in the Annex to Regulation (EC) No 2111/2005, the Commission considers that at this time there are no grounds for amending the list of air carriers, which are subject to an operating ban within the Union with respect to air carriers certified in Iraq.
- (35) Member States should continue verifying the effective compliance of air carriers certified in Iraq with the relevant international safety standards through prioritisation of ramp inspections of those air carriers, pursuant to Regulation (EU) No 965/2012.
- (36) Where any pertinent safety information reveals imminent safety risks resulting from non-compliance with the relevant international safety standards, further action by the Commission may become necessary, in accordance with Regulation (EC) No 2111/2005.

⁽⁷⁾ Commission Implementing Regulation (EU) 2015/2322 of 10 December 2015 amending Regulation (EC) No 474/2006 establishing the Community list of air carriers which are subject to an operating ban within the Community (OJ L 328, 12.12.2015, p. 67).

Air carriers from Kyrgyzstan

- (37) In October 2006, air carriers certified in Kyrgyzstan were included in Annex A to Regulation (EC) No 474/2006, by Commission Regulation (EC) No 1543/2006 (8).
- (38) On 12 May 2023, as part of the continuous monitoring activities of the Commission, a technical meeting was held between the Commission and the representatives from the State Civil Aviation Agency under the Cabinet of Ministers of the Kyrgyz Republic ('CAA KG').
- (39) During that meeting, CAA KG expressed its commitment to engage in a safety dialogue with the Commission for the purpose of an eventual removal from Annex A to Regulation (EC) No 474/2006, and emphasized its willingness to hold additional meetings as deemed necessary by the Commission. Furthermore, CAA KG pledged to share any pertinent safety information with the Commission as part of the official consultations involving the regulatory authorities responsible for safety oversight of the air carriers certified in Kyrgyzstan, including results from the USOAP visit planned for September 2023.
- (40) Moreover, CAA KG provided a comprehensive overview of its organizational structure and outlined its plans for the establishment of the new entity that will be responsible for the safety oversight process, reporting directly to the CAA KG.
- (41) CAA KG mentioned the State Safety Program implementation status and highlighted the amendments made to the Kyrgyz Air Code. Furthermore, CAA KG explained that they were actively striving to become a self-financing institution, which would enable them to augment their resources and allocate additional funds towards the training of their inspectors.
- (42) Notwithstanding these positive developments, there is currently not enough substantiated evidence that CAA KG has effectively addressed all the safety concerns that led to the imposition of an operating ban by Commission Regulation (EC) No 1543/2006.
- (43) Furthermore, on 16 May 2023, CAA KG informed the Commission that the AOCs of the air carriers Air Manas and Valor Air had been revoked. Therefore these air carriers should be removed from Annex A to Regulation (EC) No 474/2006.
- (44) At the same time, the CAA KG also informed the Commission that the new air carriers Aero Nomad Airlines, CENTRAL ASIAN AVIATION SERVICES, Global 8 Airlines, Mac.KG Airlines, Aircompany Moalem Aviation, SAPSAN Airline, Sky Jet, and TRANS CARAVAN KG had been certified. Since the CAA KG has not demonstrated a sufficient ability to implement and enforce the relevant international safety standards, the issuance of an AOC to these new air carriers does not guarantee sufficient compliance with such standards, and therefore these air carriers should be added in Annex A to Regulation (EC) No 474/2006.
- (45) In accordance with the common criteria set out in the Annex to Regulation (EC) No 2111/2005, the Commission considers that with respect to air carriers from Kyrgyzstan, the list of air carriers, which are subject to an operating ban within the Union should be amended to include Aero Nomad Airlines, CENTRAL ASIAN AVIATION SERVICES, Global 8 Airlines, Mac.KG Airlines, Aircompany Moalem Aviation, SAPSAN Airline, Sky Jet, and TRANS CARAVAN KG in Annex A to Regulation (EC) No 474/2006, and to remove Air Manas and Valor Air from that Annex.
- (46) Member States should continue verifying the effective compliance of air carriers certified in Kyrgyzstan with the relevant international safety standards through prioritisation of ramp inspections of those air carriers, pursuant to Regulation (EU) No 965/2012.
- (47) Regulation (EC) No 474/2006 should therefore be amended accordingly.

⁽⁸⁾ Commission Regulation (EC) No 1543/2006 of 12 October 2006 amending Regulation (EC) No 474/2006 establishing the Community list of air carriers which are subject to an operating ban within the Community referred to in Chapter II of Regulation (EC) No 2111/2005 of the European Parliament and of the Council and as amended by Regulation (EC) No 910/2006 (OJ L 283, 14.10.2006, p. 27).

- (48) Articles 5 and 6 of Regulation (EC) No 2111/2005 recognise the need for decisions to be taken swiftly and, where appropriate, urgently, given the safety implications. It is therefore essential, for the protection of sensitive information and the traveling public, that any decisions in the context of updating the list of air carriers, which are subject to an operating ban or restriction within the Union, are published and enter into force immediately after their adoption.
- (49) The measures provided for in this Regulation are in accordance with the opinion of the EU Air Safety Committee established pursuant to Article 15 of Regulation (EC) No 2111/2005,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 474/2006 is amended as follows:

- (1) Annex A is replaced by the text in Annex I to this Regulation;
- (2) Annex B is replaced by the text in Annex II to this Regulation.

Article 2

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

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

Done at Brussels, 6 June 2023.

For the Commission,
On behalf of the President,
Adina VĂLEAN
Member of the Commission

ANNEX I

'ANNEX A

LIST OF AIR CARRIERS WHICH ARE BANNED FROM OPERATING WITHIN THE UNION, WITH EXCEPTIONS $(^{\mbox{\tiny 1}})$

Name of the legal entity of the air carrier as indicated on its AOC (and its trading name, if different)	Air Operator Certificate ('AOC') Number or Operating Licence Number	ICAO three letter designator	State of the Operator	
AVIOR AIRLINES	ROI-RNR-011	ROI	Venezuela	
BLUE WING AIRLINES	SRBWA-01/2002	BWI	Suriname	
IRAN ASEMAN AIRLINES	FS-102	IRC	Iran	
IRAQI AIRWAYS	001	IAW	Iraq	
AIR ZIMBABWE (PVT)	177/04	AZW	Zimbabwe	
All air carriers certified by the authorities with responsibility for regulatory oversight of Afghanistan, including			Afghanistan	
ARIANA AFGHAN AIRLINES	AOC 009	AFG	Afghanistan	
KAM AIR	AOC 001	KMF	Afghanistan	
All air carriers certified by the authorities with responsibility for regulatory oversight of Angola, with the exception of TAAG Angola Airlines and Heli Malongo, including			Angola	
AEROJET	AO-008/11-07/17 TEJ	TEJ	Angola	
GUICANGO	AO-009/11-06/17 YYY	Unknown	Angola	
AIR JET	AO-006/11-08/18 MBC	MBC	Angola	
BESTFLYA AIRCRAFT MANAGEMENT	AO-015/15-06/17YYY	Unknown	Angola	
HELIANG	AO 007/11-08/18 YYY	Unknown	Angola	
SJL	AO-014/13-08/18YYY	Unknown	Angola	
SONAIR	AO-002/11-08/17 SOR	SOR	Angola	

⁽¹) Air carriers listed in Annex A could be permitted to exercise traffic rights by using wet-leased aircraft of an air carrier which is not subject to an operating ban, provided that the relevant safety standards are complied with.

Name of the legal entity of the air carrier as indicated on its AOC (and its trading name, if different)	Air Operator Certificate ('AOC') Number or Operating Licence Number	ICAO three letter designator	State of the Operator	
All air carriers certified by the authorities with responsibility for regulatory oversight of Armenia, including			Armenia	
AIRCOMPANY ARMENIA	AM AOC 065	NGT	Armenia	
ARMENIAN AIRLINES	AM AOC 076	AAG	Armenia	
ARMENIA AIRWAYS	AM AOC 063	AMW	Armenia	
ARMENIAN HELICOPTERS	AM AOC 067	KAV	Armenia	
FLY ARNA	AM AOC 075	ACY	Armenia	
FLYONE ARMENIA	AM AOC 074	FIE	Armenia	
NOVAIR	AM AOC 071	NAI	Armenia	
SHIRAK AVIA	AM AOC 072	SHS	Armenia	
SKYBALL	AM AOC 073	N/A	Armenia	
All air carriers certified by the authorities with responsibility for regulatory oversight of Congo (Brazzaville), including			Congo (Brazzaville)	
CANADIAN AIRWAYS CONGO	CG-CTA 006	TWC	Congo (Brazzaville)	
EQUAFLIGHT SERVICES	CG-CTA 002	EKA	Congo (Brazzaville)	
EQUAJET	RAC06-007	ЕКЈ	Congo (Brazzaville)	
TRANS AIR CONGO	CG-CTA 001	TSG	Congo (Brazzaville)	
SOCIETE NOUVELLE AIR CONGO	CG-CTA 004	Unknown	Congo (Brazzaville)	
All air carriers certified by the authorities with responsibility for regulatory oversight of Democratic Republic of the Congo (DRC), including			Democratic Republic of the Congo (DRC)	
AB BUSINESS	AAC/DG/OPS-09/14	Unknown	Democratic Republic of the Congo (DRC)	
AIR FAST CONGO	AAC/DG/OPS-09/03	Unknown	Democratic Republic of the Congo (DRC)	
AIR KASAI	AAC/DG/OPS-09/11	Unknown	Democratic Republic of the Congo (DRC)	

Name of the legal entity of the air carrier as indicated on its AOC (and its trading name, if different)	Air Operator Certificate ('AOC') Number or Operating Licence Number	ICAO three letter designator	State of the Operator	
AIR KATANGA	AAC/DG/OPS-09/08	Unknown	Democratic Republic of the Congo (DRC)	
BUSY BEE CONGO	AAC/DG/OPS-09/04	Unknown	Democratic Republic of the Congo (DRC)	
COMPAGNIE AFRICAINE D'AVIATION (CAA)	AAC/DG/OPS-09/02	DBP	Democratic Republic of the Congo (DRC)	
CONGO AIRWAYS	AAC/DG/OPS-09/01	COG	Democratic Republic of the Congo (DRC)	
GOMA EXPRESS	AAC/DG/OPS-09/13	Unknown	Democratic Republic of the Congo (DRC)	
KIN AVIA	AAC/DG/OPS-09/10	Unknown	Democratic Republic of the Congo (DRC)	
MALU AVIATION	AAC/DG/OPS-09/05	Unknown	Democratic Republic of the Congo (DRC)	
SERVE AIR CARGO	AAC/DG/OPS-09/07	Unknown	Democratic Republic of the Congo (DRC)	
SWALA AVIATION	AAC/DG/OPS-09/06	Unknown	Democratic Republic of the Congo (DRC)	
TRACEP CONGO AVIATION	AAC/DG/OPS-09/15	Unknown	Democratic Republic of the Congo (DRC)	
All air carriers certified by the authorities with responsibility for regulatory oversight of Djibouti, including			Djibouti	
DAALLO AIRLINES	Unknown	DAO	Djibouti	
All air carriers certified by the authorities with responsibility for regulatory oversight of Equatorial Guinea, including			Equatorial Guinea	
CEIBA INTERCONTINENTAL	2011/0001/MTTCT/ DGAC/SOPS	CEL	Equatorial Guinea	
CRONOS AIRLINES	2011/0004/MTTCT/ DGAC/SOPS	Unknown	Equatorial Guinea	
All air carriers certified by the authorities with responsibility for regulatory oversight of Eritrea, including			Eritrea	

Name of the legal entity of the air carrier as indicated on its AOC (and its trading name, if different)	Air Operator Certificate ('AOC') Number or Operating Licence Number	ICAO three letter designator	State of the Operator
ERITREAN AIRLINES	AOC No 004	ERT	Eritrea
NASAIR ERITREA	AOC No 005	NAS	Eritrea
All air carriers certified by the authorities with responsibility for regulatory oversight of Kyrgyzstan, including			Kyrgyzstan
AERO NOMAD AIRLINES	57	ANK	Kyrgyzstan
AEROSTAN	08	BSC	Kyrgyzstan
AIR COMPANY AIR KG	50	KGC	Kyrgyzstan
AIRCOMPANY MOALEM AVIATION	56	AMA	Kyrgyzstan
AVIA TRAFFIC COMPANY	23	AVJ	Kyrgyzstan
CENTRAL ASIAN AVIATION SERVICES	58	KAS	Kyrgyzstan
FLYSKY AIRLINES	53	FSQ	Kyrgyzstan
GLOBAL 8 AIRLINES	59	Unknown	Kyrgyzstan
HELI SKY	47	HAC	Kyrgyzstan
KAP.KG AIRCOMPANY	52	KGS	Kyrgyzstan
MAC.KG AIRLINES	61	MSK	Kyrgyzstan
SAPSAN AIRLINE	54	KGB	Kyrgyzstan
SKY JET	60	SJL	Kyrgyzstan
SKY KG AIRLINES	41	KGK	Kyrgyzstan
TRANS CARAVAN KG	55	TCK	Kyrgyzstan
TEZ JET	46	TEZ	Kyrgyzstan
All air carriers certified by the authorities with responsibility for regulatory oversight of Liberia.			Liberia
All air carriers certified by the authorities with responsibility for regulatory oversight of Libya, including			Libya
AFRIQIYAH AIRWAYS	007/01	AAW	Libya
AIR LIBYA	004/01	TLR	Libya
AL MAHA AVIATION	030/18	Unknown	Libya
BERNIQ AIRWAYS	032/21	BNL	Libya
BURAQ AIR	002/01	BRQ	Libya
GLOBAL AIR TRANSPORT	008/05	GAK	Libya
HALA AIRLINES	033/21	НТР	Libya

Name of the legal entity of the air carrier as indicated on its AOC (and its trading name, if different)	Air Operator Certificate ('AOC') Number or Operating Licence Number	ICAO three letter designator	State of the Operator	
LIBYAN AIRLINES	001/01	LAA	Libya	
LIBYAN WINGS AIRLINES	029/15	LWA	Libya	
PETRO AIR	025/08	PEO	Libya	
All air carriers certified by the authorities with responsibility for regulatory oversight of Nepal, including			Nepal	
AIR DYNASTY HELI. S.	035/2001	Unknown	Nepal	
ALTITUDE AIR	085/2016	Unknown	Nepal	
BUDDHA AIR	014/1996	вна	Nepal	
FISHTAIL AIR	017/2001	Unknown	Nepal	
SUMMIT AIR	064/2010	Unknown	Nepal	
HELI EVEREST	086/2016	Unknown	Nepal	
HIMALAYA AIRLINES	084/2015	HIM	Nepal	
KAILASH HELICOPTER SERVICES	087/2018	Unknown	Nepal	
MAKALU AIR	057A/2009	Unknown	Nepal	
MANANG AIR PVT	082/2014	Unknown	Nepal	
MOUNTAIN HELICOPTERS	055/2009	Unknown	Nepal	
PRABHU HELICOPTERS	081/2013	Unknown	Nepal	
NEPAL AIRLINES CORPORATION	003/2000	RNA	Nepal	
SAURYA AIRLINES	083/2014	Unknown	Nepal	
SHREE AIRLINES	030/2002	SHA	Nepal	
SIMRIK AIR	034/2000	Unknown	Nepal	
SIMRIK AIRLINES	052/2009	RMK	Nepal	
SITA AIR	033/2000	Unknown	Nepal	
TARA AIR	053/2009	Unknown	Nepal	
YETI AIRLINES	037/2004	NYT	Nepal	
The following air carriers certified by the authorities with responsibility for regulatory oversight of Russia			Russia	
AURORA AIRLINES	486	SHU	Russia	
AVIACOMPANY "AVIASTAR-TU" CO. LTD	458	TUP	Russia	
IZHAVIA	479	IZA	Russia	
JOINT STOCK COMPANY "AIR COMPANY "YAKUTIA"	464	SYL	Russia	

Name of the legal entity of the air carrier as indicated on its AOC (and its trading name, if different)	Air Operator Certificate ('AOC') Number or Operating Licence Number	ICAO three letter designator	State of the Operator
JOINT STOCK COMPANY "RUSJET"	498	RSJ	Russia
JOINT STOCK COMPANY "UVT AERO"	567	UVT	Russia
JOINT STOCK COMPANY SIBERIA AIRLINES	31	SBI	Russia
JOINT STOCK COMPANY SMARTAVIA AIRLINES	466	AUL	Russia
JOINT-STOCK COMPANY "IRAERO" AIRLINES	480	IAE	Russia
JOINT-STOCK COMPANY "URAL AIRLINES"	18	SVR	Russia
JOINT-STOCK COMPANY ALROSA AIR COMPANY	230	DRU	Russia
JOINT-STOCK COMPANY NORDSTAR AIRLINES	452	TYA	Russia
JS AVIATION COMPANY "RUSLINE"	225	RLU	Russia
JSC YAMAL AIRLINES	142	LLM	Russia
LLC "NORD WIND"	516	NWS	Russia
LLC "AIRCOMPANY IKAR"	36	KAR	Russia
LTD. I FLY	533	RSY	Russia
POBEDA AIRLINES LIMITED LIABILITY COMPANY	562	PBD	Russia
PUBLIC JOINT STOCK COMPANY "AEROFLOT - RUSSIAN AIRLINES"	1	AFL	Russia
ROSSIYA AIRLINES, JOINT STOCK COMPANY	2	SDM	Russia
SKOL AIRLINE LLC	228	CDV	Russia
UTAIR AVIATION, JOINT-STOCK COMPANY	6	UTA	Russia
All air carriers certified by the authorities with responsibility for regulatory oversight of São Tomé and Príncipe, including			São Tomé and Príncipe
AFRICA'S CONNECTION	10/AOC/2008	ACH	São Tomé and Príncipe
STP AIRWAYS	03/AOC/2006	STP	São Tomé and Príncipe
All air carriers certified by the authorities with responsibility for regulatory oversight of Sierra Leone			Sierra Leone

Name of the legal entity of the air carrier as indicated on its AOC (and its trading name, if different)	Air Operator Certificate ('AOC') Number or Operating Licence Number	ICAO three letter designator	State of the Operator
All air carriers certified by the authorities with responsibility for regulatory oversight of Sudan, including			Sudan
ALFA AIRLINES SD	54	AAJ	Sudan
BADR AIRLINES	35	BDR	Sudan
BLUE BIRD AVIATION	11	BLB	Sudan
ELDINDER AVIATION	8	DND	Sudan
GREEN FLAG AVIATION	17	GNF	Sudan
HELEJETIC AIR	57	нјт	Sudan
KATA AIR TRANSPORT	9	KTV	Sudan
KUSH AVIATION CO.	60	KUH	Sudan
NOVA AIRWAYS	46	NOV	Sudan
SUDAN AIRWAYS CO.	1	SUD	Sudan
SUN AIR	51	SNR	Sudan
TARCO AIR	56	TRQ	Sudan'

ANNEX II

'ANNEX B

LIST OF AIR CARRIERS WHICH ARE SUBJECT TO OPERATIONAL RESTRICTIONS WITHIN THE UNION $(^{\rm i})$

Name of the legal entity of the air carrier as indicated on its AOC (and its trading name, if different)	Air Operator Certificate ('AOC') Number	ICAO three letter designator	State of the Operator	Aircraft type restricted	Registration mark(s) and, when available, construction serial number(s) of restricted aircraft	State of registry
IRAN AIR	IR.AOC.100	IRA	Iran	All aircraft of type Fokker F100 and of type Boeing B747	Aircraft of type Fokker F100 as mentioned on the AOC; aircraft of type Boeing B747 as mentioned on the AOC	Iran
AIR KORYO	GAC- AOC/KOR-01	KOR	North Korea	All fleet with the exception of: 2 aircraft of type TU-204.	All fleet with the exception of: P-632, P-633.	North Korea'

⁽¹) Air carriers listed in Annex B could be permitted to exercise traffic rights by using wet-leased aircraft of an air carrier which is not subject to an operating ban, provided that the relevant safety standards are complied with.

DECISIONS

COMMISSION DECISION (Euratom) 2023/1112

of 17 July 2020

on the notification of changes to the Euratom delineated peaceful nuclear programme in Annex A to the Agreement for cooperation in the peaceful uses of nuclear energy between the European Atomic Energy Community and the United States of America

THE EUROPEAN COMMISSION,

Having regard to the Treaty establishing the European Atomic Energy Community, and in particular Article 77(b) thereof,

Having regard to the Agreement for cooperation in the peaceful uses of nuclear energy between the European Atomic Energy Community and the United States of America (¹), and in particular the second paragraph of Article 8(2) thereof, as well as paragraph 6 and paragraph 7(A) and (C) of the Agreed Minute thereto (²),

Whereas:

- (1) The Agreement for cooperation in the peaceful uses of nuclear energy between the European Atomic Energy Community and the United States of America was signed at Brussels on 7 November 1995 and entered into force on 12 April 1996 (the Agreement).
- (2) The Studiecentrum voor Kernenergie Centre d'Étude de l'Énergie Nucléaire (SCK.CEN) and the Institut National des Radioéléments (IRE) jointly plan to set up an installation for recycling of the highly radioactive residues resulting from the production of radioactive isotopes for medical purposes in order to ensure sustainable, long-term management of these residues and to support the continuing secure supply of radioactive isotopes for medical purposes. The output of the installation will be a high purity substance suitable for reuse. The construction of this installation, which will be named RECUMO, is scheduled to start in 2020, with operation commencing in 2023. It will be operated by SCK.CEN, at its site in Mol, Belgium.
- (3) By its decision of 21 February 2020 (*), the Commission granted its approval for the techniques to be used in the RECUMO facility for the chemical processing described in the basic technical characteristics submitted by SCK.CEN at the project's conceptual design phase.
- (4) The irradiated materials which are going to be processed in the RECUMO facility are of US origin, thus subject to the Agreement. In particular, Article 8(2) of the Agreement requires that those irradiated materials may only be processed in the facilities forming part of the Euratom delineated peaceful nuclear programme described in Annex A thereto. In this respect, the RECUMO facility should be added to the list of facilities in Annex A.
- (5) The procedure for changing Annex A is set out in paragraph 6 and paragraph 7(A) of the Agreed Minute to the Agreement. In particular, a written notification and a written acknowledgment made by the appropriate authorities are required for making changes to the peaceful nuclear programmes defined in Annex A.
- (6) Therefore, a notification for adding a new facility in accordance with paragraph 7(A) of the Agreed Minute to the Agreement should be approved for transmission to the US Department of State.

⁽¹⁾ OJ L 120, 20.5.1996, p. 1.

⁽²⁾ OJ L 120, 20.5.1996, p. 12.

^(*) Commission Decision C(2020) 940 final of 21 February 2020 on approval of the techniques to be used for the chemical processing of irradiated materials in the SCK.CEN RECUMO installation, located in Mol, Belgium.

(7) In addition, two decommissioned nuclear facilities should be deleted from the Euratom delineated peaceful nuclear programme and notified in accordance with paragraph 7(C) of the Agreed Minute to the Agreement,

HAS DECIDED AS FOLLOWS:

Article 1

The notification of changes to the Euratom delineated peaceful nuclear programme in Annex A to the Agreement for Cooperation in the Peaceful Uses of Nuclear Energy between the European Atomic Energy Community and the United States of America is hereby approved. The text of the notification is attached to this Decision.

Article 2

The Commissioner responsible for Energy or the Director-General of the Directorate-General for Energy, or their designated representative, are hereby authorised to transmit the notification to the US Department of State.

Done at Brussels, 17 July 2020.

For the Commission Kadri SIMSON Member of the Commission

ISSN 1977-0677 (electronic edition) ISSN 1725-2555 (paper edition)



