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Legislation

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II

(Non-legislative acts)

INTERNATIONAL AGREEMENTS

COUNCIL DECISION (EU) 2023/1040

of 15 May 2023

on the signing, on behalf of the Union, and provisional application of the Agreement between the European Union and Montenegro on operational activities carried out by the European Border and Coast Guard Agency in Montenegro

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 77(2), points (b) and (d), and Article 79(2), point (c), in conjunction with Article 218(5) thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) Pursuant to Article 73(3) of Regulation (EU) 2019/1896 of the European Parliament and of the Council ⁽¹⁾, in circumstances requiring the deployment of border management teams from the standing corps of the European Border and Coast Guard to a third country where the members of the teams will exercise executive powers, a status agreement is to be concluded by the Union with the third country concerned on the basis of Article 218 of the Treaty on the Functioning of the European Union.
- (2) On 18 November 2022, the Council authorised the Commission to open negotiations with Montenegro for an agreement on operational activities carried out by the European Border and Coast Guard Agency in Montenegro.
- (3) The negotiations were successfully concluded with the initialling of the Agreement between the European Union and Montenegro on operational activities carried out by the European Border and Coast Guard Agency in Montenegro ('the Agreement').
- (4) This Decision constitutes a development of the provisions of the Schengen *acquis* in which Ireland does not take part, in accordance with Council Decision 2002/192/EC ⁽²⁾; Ireland is therefore not taking part in the adoption of this Decision and is not bound by it or subject to its application.
- (5) In accordance with Articles 1 and 2 of Protocol No 22 on the position of Denmark, annexed to the Treaty on European Union and to the Treaty on the Functioning of the European Union, Denmark is not taking part in the adoption of this Decision and is not bound by it or subject to its application. Given that this Decision builds upon the Schengen *acquis*, Denmark shall, in accordance with Article 4 of that Protocol, decide within a period of six months after the Council has decided on this Decision whether it will implement it in its national law.

⁽¹⁾ Regulation (EU) 2019/1896 of the European Parliament and of the Council of 13 November 2019 on the European Border and Coast Guard and repealing Regulations (EU) No 1052/2013 and (EU) 2016/1624 (OJ L 295, 14.11.2019, p. 1).

⁽²⁾ Council Decision 2002/192/EC of 28 February 2002 concerning Ireland's request to take part in some of the provisions of the Schengen *acquis* (OJ L 64, 7.3.2002, p. 20).

- (6) The Agreement should be signed and the attached declaration with regard to Iceland, Norway, Switzerland and Liechtenstein be approved, on behalf of the Union.
- (7) In order to allow for an urgent deployment of the European Border and Coast Guard standing corps on the territory of Montenegro, the Agreement should be applied on a provisional basis, pending the completion of the procedures necessary for its entry into force,

HAS ADOPTED THIS DECISION:

Article 1

The signing, on behalf of the Union, of the Agreement between the European Union and Montenegro on operational activities carried out by the European Border and Coast Guard Agency in Montenegro ('the Agreement') is hereby authorised, subject to the conclusion of the said Agreement ⁽³⁾.

Article 2

The Declaration attached to this Decision shall be approved on behalf of the Union.

Article 3

The President of the Council is hereby authorised to designate the person(s) empowered to sign the Agreement on behalf of the Union.

Article 4

The Agreement shall be applied on a provisional basis, in accordance with Article 22(2), second subparagraph, thereof, as from the first day of the second month following the date of its signature, pending the completion of the procedures necessary for its entry into force ⁽⁴⁾.

Article 5

This Decision shall enter into force on the date of its adoption.

Done at Brussels, 15 May 2023.

For the Council
The President
J. FORSSMED

⁽³⁾ See page ... of this Official Journal.

⁽⁴⁾ The date of signature of the Agreement will be published in the *Official Journal of the European Union* by the General Secretariat of the Council.

**DECLARATION WITH REGARD TO ICELAND, THE KINGDOM OF NORWAY, THE SWISS
CONFEDERATION AND THE PRINCIPALITY OF LIECHTENSTEIN**

The Parties to the Agreement between the European Union and Montenegro on operational activities carried out by the European Border and Coast Guard Agency in Montenegro take note of the close relationship between the European Union and Iceland, the Kingdom of Norway, the Swiss Confederation and the Principality of Liechtenstein, particularly by virtue of the Agreements of 18 May 1999 and 26 October 2004 concerning the association of those countries with the implementation, application and development of the Schengen *acquis*.

In such circumstances it is desirable that the authorities of Iceland, the Kingdom of Norway, the Swiss Confederation and the Principality of Liechtenstein, on the one hand, and Montenegro, on the other hand, conclude, without delay, bilateral agreements on operational activities carried out by the European Border and Coast Guard Agency in Montenegro in terms similar to those of the Agreement between the European Union and Montenegro on operational activities carried out by the European Border and Coast Guard Agency in Montenegro.

Agreement between the European Union and Montenegro on operational activities carried out by the European Border and Coast Guard Agency in Montenegro

THE EUROPEAN UNION,

and

MONTENEGRO,

hereinafter referred to individually as a "Party" and collectively as the "Parties",

WHEREAS situations may arise where the European Border and Coast Guard Agency ("the Agency") coordinates operational cooperation between the Member States of the European Union and Montenegro, including on the territory of Montenegro,

WHEREAS a legal framework in the form of a status agreement should be established for the situations where the team members deployed by the Agency will have executive powers on the territory of Montenegro,

WHEREAS the status agreement may provide for the establishment by the Agency of antenna offices on the territory of Montenegro to facilitate and improve coordination of operational activities and to ensure the effective management of the human and technical resources of the Agency,

CONSIDERING the high level of protection of personal data in Montenegro and the European Union,

CONSIDERING that Montenegro has ratified the Council of Europe Convention No. 108 of 28 January 1981 for the Protection of Individuals with regard to Automatic Processing of Personal Data and the additional Protocol thereto,

BEARING IN MIND that respect for human rights and democratic principles are fundamental principles governing the cooperation between the Parties,

CONSIDERING that Montenegro has ratified the Council of Europe Convention for the Protection of Human Rights and Fundamental Freedoms of 4 November 1950, the rights enumerated in which correspond to those in the Charter of Fundamental Rights of the European Union,

CONSIDERING that all operational activities of the Agency on the territory of Montenegro should fully respect fundamental rights and the international agreements to which the European Union, its Member States and/or Montenegro are party,

CONSIDERING that all persons participating in an operational activity are obliged to maintain the highest standards of integrity, ethical conduct and professionalism, as well as respect for fundamental rights, and to meet obligations imposed upon them by the provisions of the operational plan and the Agency's code of conduct,

HAVE DECIDED TO CONCLUDE THIS AGREEMENT:

ARTICLE 1

Scope

1. This Agreement governs all matters necessary for the deployment of border management teams from the European Border and Coast Guard standing corps to Montenegro where the team members may exercise executive powers.
2. The deployment referred to in paragraph 1 may take place on the territory of Montenegro.

Subject to the obligations of the Parties under the law of the sea, in particular the 1982 United Nations Convention on the Law of the Sea, operational activities may also take place in the exclusive economic zone of Montenegro. Operational activities implemented under this Agreement shall not affect search and rescue obligations deriving from the law of the sea, in particular the 1982 United Nations Convention on the Law of the Sea, the 1974 International Convention for the Safety of Life at Sea and the 1979 International Convention on Maritime Search and Rescue.

3. The status and delimitation under international law of the respective territories of the Member States and Montenegro is in no way affected either by this Agreement or by any act accomplished in its implementation by the Parties or on their behalf, including the establishment of operational plans or participation in cross-border operations.

ARTICLE 2

Definitions

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

- (1) "Agency" means the European Border and Coast Guard Agency established by Regulation (EU) 2019/1896 of the European Parliament and of the Council ⁽¹⁾ or any amendment thereto;
- (2) "operational activity" means a joint operation or a rapid border intervention;
- (3) "border control" means the activity carried out at a border, in accordance with and for the purposes of this Agreement, in response exclusively to an intention to cross or to the act of crossing that border, regardless of any other consideration, consisting of border checks, border surveillance and assessment of threats to the internal security of the state border;
- (4) "executive powers" means powers necessary to perform the tasks required for border control which are conducted on the territory of Montenegro during an operational activity as provided for in the operational plan;
- (5) "operational plan" means a plan on the basis of which operational activities are carried out as provided for under Articles 38 and 74 of Regulation (EU) 2019/1896;
- (6) "European Border and Coast Guard standing corps" means the European Border and Coast Guard standing corps provided for in Article 54 of Regulation (EU) 2019/1896;
- (7) "border management teams" means teams formed from the European Border and Coast Guard standing corps to be deployed during joint operations and rapid border interventions at the external borders in Member States and in third countries;
- (8) "consultative forum" means the advisory body established by the Agency pursuant to Article 108 of Regulation (EU) 2019/1896;
- (9) "EUROSUR" means the framework for information exchange and cooperation between the Member States and the Agency;
- (10) "fundamental rights monitor" means the fundamental rights monitor as provided for in Article 110 of Regulation (EU) 2019/1896;
- (11) "home Member State" means the Member State from which a staff member is deployed or seconded to the European Border and Coast Guard standing corps;
- (12) "incident" means a situation relating to illegal immigration, cross-border crime or a risk to the lives of migrants at, along, or in proximity to, the external borders of the European Union or Montenegro;
- (13) "joint operation" means an action coordinated or organised by the Agency to support the national authorities of Montenegro responsible for border control aimed at addressing challenges such as irregular migration, present or future threats at the borders of Montenegro or cross-border crime, or aimed at providing increased technical and operational assistance for the control of those borders;

⁽¹⁾ Regulation (EU) 2019/1896 of the European Parliament and of the Council of 13 November 2019 on the European Border and Coast Guard and repealing Regulations (EU) No 1052/2013 and (EU) 2016/1624 (OJ EU L 295, 14.11.2019, p. 1).

- (14) "team member" means a member of the European Border and Coast Guard standing corps deployed through a border management team to participate in an operational activity;
- (15) "Member State" means a Member State of the European Union;
- (16) "operational area" means the geographical area wherein an operational activity is to take place;
- (17) "participating Member State" means a Member State which participates in an operational activity, by providing technical equipment or staff of the European Border and Coast Guard standing corps;
- (18) "personal data" means any information relating to an identified or identifiable natural person ("data subject"); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data or an online identifier, or by reference to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person;
- (19) "rapid border intervention" means an action aimed at responding to a situation of specific and disproportionate challenge at the borders of Montenegro by deploying border management teams in the territory of Montenegro for a limited period of time to conduct border control together with the national authorities of Montenegro responsible for border control;
- (20) "statutory staff" means staff employed by the Agency in accordance with the Staff Regulations of Officials of the European Union and the Conditions of Employment of Other Servants of the Union laid down in Council Regulation (EEC, Euratom, ECSC) No 259/68 ⁽²⁾.

ARTICLE 3

Launching operational activities

1. An operational activity under this Agreement shall be launched by means of a written decision of the executive director of the Agency ("the executive director") upon a written request of the competent authorities of Montenegro. Such a request shall include a description of the situation, possible aims and envisaged needs, and the profiles of staff needed, including those staff having executive powers, as applicable.
2. If the executive director considers that the requested operational activity would likely entail or lead to violations of fundamental rights or international protection obligations that are serious or persistent, then the executive director shall not launch the operational activity.
3. If, following the receipt of a request under paragraph 1, the executive director considers that further information is necessary in order to decide whether to launch an operational activity, he or she may request further information or authorise Agency experts to travel to Montenegro in order to assess the situation there. Montenegro shall facilitate such travel.
4. The executive director shall decide not to launch an operational activity if he or she considers there to be justified cause to suspend or terminate it pursuant to Article 18.

ARTICLE 4

Operational plan

1. An operational plan shall be agreed upon for each operational activity between the Agency and Montenegro in accordance with Articles 38 and 74 of Regulation (EU) 2019/1896. The operational plan shall be binding on the Agency, Montenegro and the participating Member States.

⁽²⁾ OJ EC L 56, 4.3.1968, p. 1.

2. The operational plan shall set out in detail the organisational and procedural aspects of the operational activity, including:

- (a) a description of the situation, with *modus operandi* and objectives of the deployment, including the operational aim;
- (b) the estimated time that the operational activity is expected to last in order to achieve its objectives;
- (c) the operational area;
- (d) a detailed description of the tasks to be performed in the exercise of official function, including those requiring executive powers, responsibilities, including with regard to respect for fundamental rights and data protection requirements, and special instructions for the border management teams, including on permissible consultation of databases and permissible service weapons, ammunition and equipment in Montenegro;
- (e) the composition of the border management team as well as the deployment of other relevant staff and the presence of other members of the statutory staff, including fundamental rights monitors;
- (f) command and control provisions, including the names and ranks of the border police officers or other relevant staff of Montenegro responsible for cooperating with the team members and the Agency, in particular the names and ranks of those border police officers or other relevant staff who are in command during the period of deployment, and the place of the team members in the chain of command;
- (g) the technical equipment to be deployed during the operational activity, including specific requirements such as conditions for use, requested crew, transport and other logistics, and financial provisions;
- (h) detailed provisions on immediate incident reporting by the Agency to the management board and to relevant authorities of the participating Member States and of Montenegro of any incident encountered in the course of an operational activity performed under this Agreement;
- (i) a reporting and evaluation scheme containing benchmarks for the evaluation report, including with regard to the protection of fundamental rights, and final date of submission of the final evaluation report;
- (j) with regard to sea operations, specific information on the application of the relevant jurisdiction and applicable law in the operational area, including references to international, European Union and national law regarding interception, rescue at sea and disembarkation;
- (k) the terms of cooperation with the bodies, offices and agencies of the European Union other than the Agency, other third countries or international organisations;
- (l) general instructions on how to ensure the safeguarding of fundamental rights during the operational activity including personal data protection and obligations deriving from applicable international human rights instruments;
- (m) procedures whereby persons in need of international protection, victims of trafficking in human beings, unaccompanied minors and other persons in vulnerable situations are directed to the competent national authorities for appropriate assistance;
- (n) procedures setting out a mechanism to receive and transmit to the Agency and to Montenegro complaints (including those lodged under Article 8(5)) against any person participating in an operational activity, including border police officers or other relevant staff of Montenegro and team members, alleging breaches of fundamental rights in the context of their participation in an operational activity of the Agency;
- (o) logistical arrangements, including information on working conditions and the environment of the areas in which the operational activity is to take place; and
- (p) provisions concerning an antenna office, as established in accordance with Article 6.

3. The operational plan and any amendments thereto or adaptations thereof shall be subject to the agreement of the Agency, Montenegro and any Member States neighbouring Montenegro or bordering the operational area, after consultation of the participating Member States. The Agency shall coordinate with the relevant Member States in order to confirm their agreement.

4. Exchange of information and operational cooperation for the purposes of EUROSUR shall take place in accordance with the rules for establishing and sharing the specific situational pictures to be set out in the operational plan for the operational activity concerned.
5. The evaluation of the operational activity in accordance with paragraph 2, point (i), shall be conducted jointly by Montenegro and the Agency.
6. The terms of cooperation with the bodies, offices and agencies of the European Union in accordance with paragraph 2, point (k), shall be conducted in line with their respective mandates and within available resources.

ARTICLE 5

Incident reporting

1. The Agency and the Ministry of the Interior – Police Directorate of Montenegro shall each have an incident reporting mechanism to allow timely reporting of any incident encountered in the course of an operational activity performed under this Agreement.
2. The Agency and Montenegro shall assist each other in carrying out all necessary inquiries and investigations into any incident reported via the mechanism referred to in paragraph 1, such as identifying witnesses and collecting and producing evidence, including requests to obtain and, if appropriate, hand over items connected with a reported incident. The handing-over of any such items may be made subject to their return within the terms specified by the competent authority delivering them.

ARTICLE 6

Antenna offices

1. The Agency may establish antenna offices on the territory of Montenegro to facilitate and improve coordination of operational activities and to ensure the effective management of the human and technical resources of the Agency. The location of the antenna office shall be established by the Agency, in consultation with the relevant authorities of Montenegro.
2. The antenna offices shall be established in accordance with operational needs and remain operational for the period of time necessary for the Agency to carry out operational activities in Montenegro and the neighbouring region. Subject to the agreement of Montenegro, that period of time may be prolonged by the Agency.
3. Each antenna office shall be managed by a representative of the Agency, appointed by the executive director as head of the antenna office, who shall oversee the overall work of the office.
4. The antenna offices shall, where applicable:
 - (a) provide operational and logistical support and ensure the coordination of the Agency's activities in the operational areas concerned;
 - (b) provide operational support to Montenegro in the operational areas concerned;
 - (c) monitor the activities of the border management teams and regularly report to the Agency's headquarters;
 - (d) cooperate with Montenegro on all issues related to the practical implementation of the operational activities organised by the Agency in Montenegro, including any additional issues that might have occurred in the course of those activities;
 - (e) support the coordinating officer in his or her cooperation with Montenegro on all issues related to their contribution to operational activities organised by the Agency and, where necessary, liaise with the Agency's headquarters;
 - (f) support the coordinating officer and fundamental rights monitor(s) assigned to monitor an operational activity in facilitating, where necessary, the coordination and communication between the border management teams and the relevant authorities of Montenegro, as well as any relevant tasks;

- (g) organise logistical support relating to the deployment of the team members and the deployment and use of technical equipment;
 - (h) provide all other logistical support regarding the operational area for which a given antenna office is responsible, with a view to facilitating the smooth running of the operational activities organised by the Agency;
 - (i) ensure the effective management of the Agency's own equipment in the areas covered by its activities, including the possible registration and long-term maintenance of that equipment and any logistical support needed; and
 - (j) support other staff and/or activities of the Agency in Montenegro as agreed between the Agency and Montenegro.
5. The Agency and Montenegro shall make the arrangements for the fulfilment of the tasks assigned to the antenna offices.
6. Montenegro shall provide the Agency with assistance to ensure the operational capacity of the antenna offices. Further details shall be set out in a separate arrangement between Montenegro and the Agency.

ARTICLE 7

Coordinating officer

1. Without prejudice to the role of antenna offices as described in Article 6, the executive director shall appoint one or more experts from the statutory staff to be deployed as coordinating officer(s) for each operational activity. The executive director shall notify Montenegro of such appointment.
2. The role of the coordinating officer shall be to:
- (a) act as an interface between the Agency, Montenegro and the team members, providing assistance, on behalf of the Agency, on all issues relating to the conditions of the deployment, to the border management teams;
 - (b) monitor the correct implementation of the operational plan, including, in cooperation with the fundamental rights monitor(s), as regards the protection of fundamental rights, and report to the executive director thereon;
 - (c) act on behalf of the Agency in all aspects of the deployment of the border management teams and report to the Agency on all those aspects; and
 - (d) foster cooperation and coordination among Montenegro and participating Member States.
3. In the context of operational activities, the executive director may authorise the coordinating officer to assist in resolving any disagreement on the execution of the operational plan and deployment of the border management teams.
4. Montenegro shall issue only instructions that are in compliance with the operational plan to the team members. If the coordinating officer considers instructions issued to team members not to be in compliance with the operational plan or with applicable legal obligations, he or she shall immediately communicate this to the Montenegro officers carrying out a coordinating role and to the executive director. The executive director may take appropriate measures, including the suspension or the termination of the operational activity, in accordance with Article 18.

ARTICLE 8

Fundamental rights

1. In performing their obligations under this Agreement, the Parties undertake to act in compliance with all applicable human rights instruments, including the 1950 Council of Europe Convention for the Protection of Human Rights and Fundamental Freedoms, the 1951 United Nations Convention Relating to the Status of Refugees and the 1967 Protocol thereto, the 1965 United Nations International Convention on the Elimination of All Forms of Racial Discrimination, the 1966 United Nations International Covenant on Civil and Political Rights, the 1979 United Nations Convention on the

Elimination of All Forms of Discrimination against Women, the 1984 United Nations Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment, the 1989 United Nations Convention on the Rights of the Child, the 2006 United Nations Convention on the Rights of Persons with Disabilities and the Charter of Fundamental Rights of the European Union.

2. Team members shall, in the performance of their tasks and in the exercise of their powers, fully respect fundamental rights, including access to asylum procedures and human dignity, and shall pay particular attention to vulnerable persons. Any measures taken in the performance of their tasks and in the exercise of their powers shall be proportionate to the objectives pursued by such measures. While performing their tasks and exercising their powers, they shall not discriminate against persons on the basis of any grounds such as sex, race, colour, ethnic or social origin, genetic features, language, religion or belief, political or any other opinion, membership of a national minority, property, birth, disability, age or sexual orientation, in line with Article 21 of the Charter of Fundamental Rights of the European Union.

Measures interfering with fundamental rights and freedoms may be taken by team members in the performance of their tasks or in the exercise of their powers only when necessary and proportionate to the objectives pursued by such measures and must respect the essence of those fundamental rights and freedoms in accordance with applicable international, European Union and national law.

This provision shall apply *mutatis mutandis* to all staff of national authorities of Montenegro participating in an operational activity.

3. The Agency's fundamental rights officer shall monitor each operational activity's compliance with applicable fundamental rights standards. The fundamental rights officer, or his or her deputy, may carry out on-the-spot visits to Montenegro; he or she shall also provide opinions on the operational plans and inform the executive director about possible violations of fundamental rights relating to an operational activity. Montenegro shall support the fundamental rights officer's monitoring efforts, as requested.

4. The Agency and Montenegro agree to provide the consultative forum with timely and effective access to all information concerning respect for fundamental rights in relation to any operational activity performed under this Agreement, including through on-the-spot visits to the operational area.

5. The Agency and Montenegro shall each have a complaints mechanism to process allegations of breaches of fundamental rights committed by their staff in the exercise of their official functions in the course of an operational activity performed under this Agreement. Those mechanisms shall be set out in the operational plan.

ARTICLE 9

Fundamental rights monitors

1. The Agency's fundamental rights officer shall assign at least one fundamental rights monitor to each operational activity to, *inter alia*, assist and advise the coordinating officer.

2. The fundamental rights monitor shall monitor compliance with fundamental rights and provide advice and assistance on fundamental rights in the preparation, conduct and evaluation of the relevant operational activity. This shall include, in particular:

- (a) following the preparation of operational plans and reporting to the fundamental rights officer to enable him or her to fulfil his or her tasks as provided for in Regulation (EU) 2019/1896;
- (b) conducting visits, including long-term visits, where operational activities take place;
- (c) cooperating and liaising with the coordinating officer and providing advice and assistance to him or her;
- (d) informing the coordinating officer of and reporting to the fundamental rights officer on any concerns regarding possible violations of fundamental rights relating to the operational activity; and

(e) contributing to the evaluation of the operational activity as referred to in Article 4(2), point (i).

3. Fundamental rights monitors, independent in the performance of their tasks, shall have access to all areas in which the operational activity takes place and to all documents relevant for the implementation of that activity.

4. While present in the operational area, fundamental rights monitors shall wear insignia that clearly allow for their identification as fundamental rights monitors.

5. The Agency's fundamental rights officer may cooperate with the Institution of the Protector of Human Rights and Freedoms of Montenegro (Ombudsman).

ARTICLE 10

Team members

1. Team members shall have the authority to perform the tasks, including those requiring executive powers, described in the operational plan.

2. While performing their tasks and exercising their powers, team members shall comply with the laws and regulations of Montenegro as well as applicable international and European Union law.

3. Team members may perform tasks and exercise powers in the territory of Montenegro only under instructions from, and in the presence of, border management authorities of Montenegro. Montenegro may authorise team members to perform specific tasks and to exercise specific powers on its territory in the absence of its border management authorities subject to the consent of the Agency or the home Member State, as appropriate.

4. Team members who are statutory staff shall wear the uniform of the European Border and Coast Guard standing corps while performing their tasks and exercising their powers unless specified otherwise in the operational plan.

Team members who are not statutory staff shall wear their national uniform while performing their tasks and exercising their powers unless specified otherwise in the operational plan.

While on duty, all team members shall also wear visible personal identification and a blue brassard with the insignias of the European Union and of the Agency on their uniforms.

5. Montenegro shall authorise relevant team members to perform tasks during an operational activity that require the use of force, including the carrying and use of service weapons, ammunition and other coercive means, in accordance with the relevant provisions of the operational plan, taking into account that:

(a) team members who are statutory staff may carry and use service weapons, ammunition and other coercive means subject to the consent of the Agency;

(b) team members who are not statutory staff may carry and use service weapons, ammunition and other coercive means subject to the consent of the relevant home Member State.

6. The use of force, including the carrying and use of service weapons, ammunition and other coercive means, shall be exercised in accordance with the national law of Montenegro and in the presence of border management authorities of Montenegro. Montenegro may authorise team members to use force in the absence of relevant border management authorities of Montenegro, taking into account that:

(a) for team members who are statutory staff, such authorisation to use force in the absence of border management authorities of Montenegro shall be subject to the consent of the Agency;

(b) for team members who are not statutory staff, such authorisation to use force in the absence of border management authorities of Montenegro shall be subject to the consent of the relevant home Member State.

Without prejudice to the requirements of the national law of Montenegro, any use of force by team members must be necessary and proportionate and comply fully with applicable international, European Union and national law, including, in particular, the requirements laid down in Annex V to Regulation (EU) 2019/1896.

7. The Agency shall, in advance of the deployment of the team members, inform Montenegro of the service weapons, ammunition and other equipment team members may carry under paragraph 5. Montenegro may prohibit the carrying of certain service weapons, ammunition and other equipment, provided that its own law applies the same prohibition to its own border management authorities. Montenegro shall, in advance of the deployment of the team members, inform the Agency of the permissible service weapons, ammunition and equipment and of the conditions for their use. The Agency shall make this information available to Member States.

Montenegro shall make the necessary arrangements for the issuance of any necessary weapon permits and facilitate the import, export, transport and storage of weapons, ammunition and other equipment at the disposal of the team members as requested by the Agency. The procedure to issue the weapon permits shall be set out in the operational plan.

8. Service weapons, ammunition and equipment may be used in legitimate self-defence and in legitimate defence of team members or of other persons in accordance with the national law of Montenegro in line with relevant principles of international and European Union law.

9. Montenegro may authorise team members to consult its national databases if necessary for achieving operational aims specified in the operational plan. Montenegro shall ensure that it provides access to such databases in an efficient and effective manner.

Montenegro shall, in advance of the deployment of the team members, inform the Agency of the national databases which may be consulted.

Team members shall only consult data which are necessary for performing their tasks and exercising their powers. That consultation shall be carried out in accordance with the national data protection law of Montenegro and this Agreement.

10. For the implementation of operational activities, Montenegro shall deploy officers of the Ministry of the Interior – Police Directorate of Montenegro who are able and willing to communicate in English to carry out a coordinating role on behalf of Montenegro in accordance with the operational plan.

ARTICLE 11

Privileges and immunities of the property, funds, assets and operations of the Agency

1. Any premises and buildings of the Agency in Montenegro shall be inviolable. They shall be exempt from search, requisition, confiscation or expropriation.

2. The Agency's property and assets, including means of transport, communications, archives, any correspondence, documents, identity papers and financial assets shall be inviolable.

3. The Agency's assets include assets owned, co-owned, chartered or leased by a Member State and offered to the Agency. Upon the embarkation of representative(s) of competent national authorities, those shall be treated as assets being on government service and authorised to that effect.

4. No measures of execution may be taken in respect of the Agency. The Agency's property and assets shall not be the subject of any administrative or legal measure of constraint. Property of the Agency shall be free from seizure for the satisfaction of a judgment, decision or order.

5. Upon a request by the relevant judicial authorities of Montenegro, the executive director may give consent for relevant national authorities of Montenegro to enter the premises and buildings and/or access to the property and assets of the Agency in cases of serious suspicion of criminal offences.

The consent of the executive director may be assumed in the event of a fire or other disaster requiring prompt protective action.

6. Montenegro shall permit the entry and removal of articles and equipment deployed by the Agency to Montenegro for operational purposes.

7. The Agency shall be exempt from all duties (including customs duties) and taxes as well as any prohibitions and restrictions on imports and exports in respect of articles and equipment intended for its official use, including articles and equipment imported or exported by a third party on behalf of the Agency.

ARTICLE 12

Privileges and immunities of team members

1. The subsequent privileges and immunities granted to team members aim at ensuring the exercise of their official functions in the course of the actions carried out in accordance with the operational plan on the territory of Montenegro.

2. Team members shall not be subject to any form of inquiry or legal proceedings in Montenegro or by authorities of Montenegro, except under the circumstances as referred to in paragraph 3.

3. Team members shall enjoy immunity from the criminal, civil and administrative jurisdiction of Montenegro in respect of all acts performed by them in the exercise of their official functions.

Where the authorities of Montenegro intend to institute criminal, civil or administrative proceedings against a team member, the competent authorities of Montenegro shall immediately notify the executive director thereof. The notification procedure shall be in line with the applicable Agency decision thereon, which shall be set out in the operational plan.

Following receipt of such notification, the executive director shall, without undue delay, inform the relevant authorities of Montenegro whether the act in question was performed by the team member in the exercise of his or her official functions. If the act was stated as having been performed in the exercise of official functions, the proceedings shall not be initiated. If the act was stated as not having been performed in the exercise of official functions, the proceedings may be initiated. The qualification by the executive director shall be binding upon Montenegro, which shall not contest it.

Pending this qualification, the Agency shall refrain from taking any measure intended to jeopardise possible subsequent criminal prosecution of the team member by the competent authorities of Montenegro, including facilitating the departure of the concerned team member from Montenegro.

Privileges granted to team members and immunity from the criminal jurisdiction of Montenegro do not exempt them from the jurisdiction of the home Member State.

4. The initiation of proceedings by team members shall preclude them from invoking immunity from jurisdiction in respect of any counter-claim directly connected with the principal claim.

5. The premises, dwellings, means of transport and communications, and possessions, including any correspondence, documents, identity papers and assets of team members shall be inviolable, except in the case of measures of execution as permitted pursuant to paragraph 10.

6. Montenegro shall be liable for any damage caused by team members to third parties in the exercise of their official functions.

7. In the event of damage caused by gross negligence or wilful misconduct or not in the exercise of official functions by a team member who is a member of the statutory staff, Montenegro may request, via the executive director, that compensation be paid by the Agency.

In the event of damage caused by gross negligence or wilful misconduct or not in the exercise of official functions by a team member who is not a member of the statutory staff, Montenegro may request, via the executive director, that compensation be paid by the home Member State concerned.

8. Neither Party nor any participating Member State nor the Agency shall be liable for damage caused in Montenegro due to a force majeure event beyond its control.

9. Team members shall not be obliged to give evidence as witnesses in legal proceedings in Montenegro. Team members may give evidence through a statement submitted in accordance with the procedural law of Montenegro. Such submission shall not affect the immunity provided for under paragraph 3.

10. No measures of execution may be taken in respect of team members, except in cases where criminal, civil or administrative proceedings not related to their official functions are instituted against them. Property of team members which is certified by the executive director to be necessary for the fulfilment of their official functions shall be free from seizure for the satisfaction of a judgment, decision or order. In criminal, civil or administrative proceedings, team members shall not be subject to any restrictions on their personal liberty or to any other measures of constraint.

11. Team members shall, with respect to services rendered for the Agency, be exempt from social security provisions which may be in force in Montenegro.

12. The salary and emoluments paid to team members by the Agency and/or the home Member States, as well as any income team members receive from outside Montenegro, shall not be taxed in any form in Montenegro.

13. Montenegro shall permit the entry of articles for the personal use of team members and shall grant exemption from all customs duties, taxes, and related charges other than charges for storage, transport and similar services, in respect of such articles. Montenegro shall also allow the export of such articles.

14. Team members' personal baggage shall be exempt from inspection, unless there are serious grounds for suspecting that it contains articles that are not for the personal use of team members, or articles whose import or export is prohibited by the law or subject to quarantine regulations of Montenegro. Inspection of such personal baggage shall be conducted only in the presence of team members concerned or an authorised representative of the Agency.

15. The Agency and Montenegro shall appoint contact points who shall be available at all times and shall be responsible for the exchange of information and immediate actions to be taken where an act performed by a team member may be in violation of criminal law as well as for the exchange of information and the operational activities in relation to any civil or administrative proceedings against a team member.

Until action is taken by the competent authorities of the home Member State, the Agency and Montenegro shall assist each other in carrying out all necessary inquiries and investigations into any alleged criminal offence in respect of which either the Agency or Montenegro, or both, have an interest in the identification of witnesses and in the collection and production of evidence, including the request to obtain and, if appropriate, the handing-over of items connected with a purported criminal offence. The handing-over of any such items may be made subject to their return within the terms specified by the competent authority delivering them.

ARTICLE 13

Injured or deceased team members

1. Without prejudice to Article 12, the executive director shall have the right to take charge of, and make suitable arrangements for, the repatriation of any injured or deceased team members, as well as of their personal property.

2. An autopsy shall be performed on a deceased team member only with the express consent of the home Member State concerned and in the presence of a representative of the Agency or of the home Member State concerned.

3. Montenegro and the Agency shall cooperate to the fullest extent possible to enable the prompt repatriation of injured or deceased team members.

ARTICLE 14

Accreditation document

1. The Agency shall issue a document in Montenegrin and in English to each team member for the purposes of identification vis-à-vis the national authorities of Montenegro and as proof of the holder's rights to perform the tasks and exercise the powers referred to in Article 10 of this Agreement and in the operational plan ("the accreditation document").
2. The accreditation document shall include the following information on the staff member: name and nationality, rank or job title, a recent digitised photograph, and tasks authorised to be performed during the deployment. The accreditation document shall include an expiry date.
3. For the purposes of identification vis-à-vis the national authorities of Montenegro, team members shall be obliged to carry the accreditation document on their person at all times.
4. Montenegro shall recognise the accreditation document, in combination with a valid travel document, as granting the relevant team member entry and stay in Montenegro without the need for a visa, residence permit, prior authorisation or any other document up to the day of its expiration.
5. The accreditation document shall be returned to the Agency at the end of the deployment. The competent authorities of Montenegro shall be informed thereof.

ARTICLE 15

Application to staff not deployed as team members

Articles 12, 13 and 14 shall apply *mutatis mutandis* to all staff deployed to Montenegro under this Agreement or an operational plan thereunder who are not team members, including fundamental rights monitors and the statutory staff deployed to antenna offices.

ARTICLE 16

Protection of personal data

1. The communication of personal data shall take place only if such communication is necessary for the implementation of this Agreement by the competent authorities of Montenegro or the Agency. The processing of personal data by an authority in a particular case, including the transfer of such personal data to the other Party, shall be subject to the data protection rules applicable to that authority. The Parties shall ensure the following minimum safeguards as a precondition for any data transfer:
 - (a) personal data must be processed lawfully, fairly, and in a transparent manner in relation to the data subject;
 - (b) personal data must be collected for the specified, explicit and legitimate purpose of implementing this Agreement and not further processed by the communicating authority nor receiving authority in a way incompatible with that purpose;
 - (c) personal data must be adequate, relevant and limited to what is necessary in relation to the purpose for which they are collected or further processed; in particular, personal data communicated in accordance with the law applicable to the communicating authority may concern only one or more of the following:
 - first name,
 - last name,
 - date of birth,

- nationality,
- rank,
- travel document bio page,
- accreditation document,
- ID/passport/accreditation document picture,
- e-mail address,
- mobile phone number,
- weapon details,
- duration of the deployment,
- location of the deployment,
- aircraft or vessel identification numbers,
- arrival date,
- arrival airport/border crossing point,
- arrival flight number,
- departure date,
- departure airport / border crossing point,
- departure flight number,
- home Member State / third country,
- deploying authority,
- tasks/operational profile,
- means of transportation,
- route

of team members, Agency staff, relevant observers, or members of staff exchange programmes;

- (d) personal data must be accurate and, where necessary, kept up to date;
- (e) personal data must be kept in a form which permits identification of data subjects for no longer than is necessary for the purpose for which the data were collected or for which they are further processed;
- (f) personal data must be processed in a manner that ensures appropriate security of the personal data, taking into account the specific risks of processing, including protection against unauthorised or unlawful processing and against accidental loss, destruction or damage, using appropriate technical or organisational measures ("data breach"); the receiving Party shall take appropriate measures to address any data breach, and shall notify the communicating Party of such breach without undue delay and within 72 hours;
- (g) both the communicating authority and the receiving authority shall take every reasonable step to ensure without delay the rectification or erasure, as appropriate, of personal data where the processing does not comply with this Article, in particular because those data are not adequate, relevant or accurate, or because they are excessive in relation to the purpose of processing; this includes the notification of any rectification or erasure to the other Party;
- (h) upon request, the receiving authority shall inform the communicating authority of the use of the communicated data;
- (i) personal data may be communicated only to the following competent authorities:
 - the Agency; and
 - the Ministry of the Interior – Police Directorate of Montenegro,

further communication to other bodies requires the prior authorisation of the communicating authority;

- (j) the communicating and the receiving authorities are under an obligation to make a written record of the communication and receipt of personal data;
- (k) independent oversight shall be in place to oversee data protection compliance, including to inspect such records; data subjects shall have the right to bring complaints to the oversight body, and to receive a response without undue delay;
- (l) data subjects shall have the right to receive information on the processing of their personal data, access such data and the rectification or erasure of inaccurate or unlawfully processed data, subject to necessary and proportionate limitations on important grounds of public interest; and
- (m) data subjects shall have the right to effective administrative and judicial redress for violation of the aforementioned safeguards.

2. Each Party shall conduct periodic reviews of its own policies and procedures that implement this Article. Upon request by the other Party, the Party that received the request shall review its personal data processing policies and procedures to ascertain and confirm that the safeguards in this Article are implemented effectively. The results of the review shall be communicated to the Party that requested the review within a reasonable time.

3. The data protection safeguards under this Agreement shall be subject to oversight by the European Data Protection Supervisor and the Agency for Personal Data Protection and Free Access to Information of Montenegro.

4. The Parties shall cooperate with the European Data Protection Supervisor, as the supervisory authority of the Agency.

5. The Agency and Montenegro shall draw up a common report on the application of this Article at the end of each operational activity. That report shall be sent to the Agency's fundamental rights officer and data protection officer as well as to the Agency for Personal Data Protection and Free Access to Information of Montenegro.

6. The Agency and Montenegro shall set out detailed rules on the communication and processing of personal data for the purposes of operational activities under this Agreement in specific provisions of the relevant operational plans. Those provisions shall comply with the relevant requirements of European Union law and the law of Montenegro. They shall describe, *inter alia*, the intended purpose of the communication, the controller(s) and all roles and responsibilities, the categories of data communicated, the specific data retention periods, and all minimum safeguards. In the interest of transparency and foreseeability, those provisions shall be made publicly available in accordance with the relevant guidance of the European Data Protection Board.

ARTICLE 17

Exchange of classified and sensitive non-classified information

1. Any exchange, sharing or dissemination of classified information in the framework of this Agreement shall be covered by a separate administrative arrangement concluded between the Agency and the relevant authorities of Montenegro that shall be subject to the prior approval of the European Commission.

2. Any exchange of sensitive non-classified information in the framework of this Agreement:

- (a) shall be handled by the Agency in accordance with Article 9(5) of Commission Decision (EU, Euratom) 2015/443 ⁽¹⁾ and by Montenegro in accordance with its national law;
- (b) shall receive a level of protection by the receiving Party that is equivalent to the level of protection offered by the measures applied to that information by the communicating Party in terms of confidentiality, integrity and availability; and

⁽¹⁾ Commission Decision (EU, Euratom) 2015/443 of 13 March 2015 on Security in the Commission (OJ EU L 72, 17.3.2015, p. 41).

(c) shall be conducted via an information exchange system that fulfils the criteria of availability, confidentiality and integrity for sensitive non-classified information, such as the communication network referred to in Article 14 of Regulation (EU) 2019/1896.

3. The Parties shall comply with intellectual property rights related to any data processed in the framework of this Agreement.

ARTICLE 18

Decision to suspend, terminate and/or withdraw financing for an operational activity

1. If the conditions to conduct an operational activity are no longer fulfilled, including as notified by Montenegro, the executive director shall terminate that operational activity after informing Montenegro. Such information shall be made in writing and shall include the reasons therefor.

2. If this Agreement or an operational plan has not been respected by Montenegro, the executive director may withdraw financing of the relevant operational activity, and/or suspend or terminate it, after informing Montenegro in writing.

3. If the security of any participant of an operational activity deployed in Montenegro cannot be guaranteed, the executive director may suspend or terminate the relevant operational activity or aspects thereof.

4. If the executive director considers that violations of fundamental rights or international protection obligations that are of a serious nature or are likely to persist have taken place or are likely to take place in relation to an operational activity performed under this Agreement, he or she shall withdraw the financing of the relevant operational activity, and/or suspend or terminate it, after informing Montenegro.

5. Montenegro may request the executive director to suspend or terminate an operational activity. Such request shall be made in writing and shall include the reasons therefor.

6. A suspension, termination or withdrawal of financing under this Article shall take effect from the date of notification to Montenegro. It shall not affect any rights or obligations arising out of the application of this Agreement or the operational plan before such suspension, termination or withdrawal of financing.

7. Montenegro may request the termination of deployment of any team member, or other relevant staff member, who does not respect this Agreement or an operational plan thereunder or who commits serious violations of Montenegrin legislation. The decision to terminate the deployment shall be made by the executive director or the respective home Member State, as appropriate, and notified to the relevant authorities of Montenegro.

ARTICLE 19

Combating fraud

1. Montenegro shall notify the Agency, the European Public Prosecutor's Office and/or the European Anti-Fraud Office forthwith if it becomes aware of the existence of credible allegations of fraud, corruption or any other illegal activities connected to the implementation of this Agreement that may affect the interests of the European Union.

2. Where such allegations relate to European Union funds disbursed in relation to this Agreement, Montenegro shall provide all necessary assistance to the European Public Prosecutor's Office and/or the European Anti-Fraud Office in relation to investigative activities on its territory, including facilitating interviews, on-the-spot checks and inspections (including access to information systems and databases in Montenegro) and facilitating access to any relevant information concerning the technical and financial management of matters financed partly or wholly by the European Union.

ARTICLE 20

Implementation of this Agreement

1. For Montenegro, this Agreement shall be implemented by the Ministry of the Interior – Police Directorate of Montenegro.
2. For the European Union, this Agreement shall be implemented by the Agency.

ARTICLE 21

Dispute settlement

1. Any disputes arising in connection with the application of this Agreement shall be examined jointly by representatives of the Agency and the competent authorities Montenegro.
2. Failing any prior settlement, disputes concerning the interpretation or application of this Agreement shall be settled exclusively by negotiation between the Parties.

ARTICLE 22

Entry into force, provisional application, amendment, duration, suspension and termination of the Agreement and termination of predecessor Agreement

1. This Agreement shall be subject to ratification, acceptance or approval by the Parties in accordance with their own internal legal procedures. The Parties shall notify one another of the completion of the procedures necessary for that purpose.
2. This Agreement shall enter into force on the first day of the second month following the date on which the Parties have notified each other of the completion of the internal legal procedures in accordance with paragraph 1.

Pending the completion of the procedures necessary for its entry into force, this Agreement shall be applied on a provisional basis as from the first day of the second month following the date of its signature by the Parties.

3. This Agreement may be amended only in writing by mutual consent of the Parties.
4. This Agreement is concluded for an indefinite period. It may be suspended or terminated by written agreement between the Parties or unilaterally by either Party.

In the event of a unilateral suspension or termination, the Party wishing to suspend or terminate shall notify the other Party thereof in writing. A unilateral termination or suspension of this Agreement shall take effect on the first day of the second month following the month during which the notification was given.

5. The Status Agreement between the European Union and Montenegro on actions carried out by the European Border and Coast Guard Agency in Montenegro, signed in Luxembourg on 7 October 2019, is hereby repealed and replaced by this Agreement.

During the period when this Agreement is applied on a provisional basis, the application of the Status Agreement between the European Union and Montenegro on actions carried out by the European Border and Coast Guard Agency in Montenegro, signed in Luxembourg on 7 October 2019, shall be suspended.

Any operational activity launched on the basis of the Status Agreement between the European Union and Montenegro on actions carried out by the European Border and Coast Guard Agency in Montenegro, signed in Luxembourg on 7 October 2019, that are ongoing at the time of the provisional application or entry into force of this Agreement may continue, subject to the amendment or adaptation of the respective operational plan in line with this Agreement.

6. Notifications made in accordance with this Article shall be sent, in the case of the European Union, to the Secretary-General of the Council of the European Union and, in the case of Montenegro, to the Ministry of Foreign Affairs of Montenegro.

Done in duplicate in the Bulgarian, Croatian, Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Hungarian, Irish, Italian, Latvian, Lithuanian, Maltese, Polish, Portuguese, Romanian, Slovak, Slovenian, Spanish, Swedish and Montenegrin languages, each of those texts being equally authentic.

IN WITNESS WHEREOF, the undersigned Plenipotentiaries, duly authorised to this effect, have signed this Agreement.

Za Европейския съюз
Por la Unión Europea
Za Evropskou unii
For Den Europæiske Union
Für die Europäische Union
Euroopa Liidu nimel
Για την Ευρωπαϊκή Ένωση
For the European Union
Pour l'Union européenne
Thar ceann an Aontais Eorpaigh
Za Europejską uniję
Per l'Unione europea
Eiropas Savienības vārdā –
Europos Sąjungos vardu
Az Európa Unió részéről
Għall-Unjoni Ewropea
Voor de Europese Unie
W imieniu Unii Europejskiej
Pela União Europeia
Pentru Uniunea Europeană
Za Európsku úniu
Za Evropsko unijo
Euroopan unionin puolesta
För Europeiska unionen
Za Evropsku uniju

Za Черна гора
Por Montenegro
Za Černou Horu
For Montenegro
Für Montenegro
Montenegro nimel
Για το Μαυροβούνιο
For Montenegro
Pour le Monténégro
Thar ceann Mhontainéagró
Za Crnu Goru
Per il Montenegro
Melnkalnes vārdā –
Juodkalnijos vardu
Montenegró részéről
Għall-Montenegro
Voor Montenegro
W imieniu Czarnogóry
Pelo Montenegro
Pentru Muntenegru
Za Čiernu Horu
Za Črno goro
Montenegron puolesta
För Montenegro
Za Crnu Goru

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1041

of 24 May 2023

granting a Union authorisation for the biocidal product ‘TWP 094’ 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 12 November 2018, TROY CHEMICAL COMPANY BV submitted to the European Chemicals Agency (‘the Agency’) an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 for a Union authorisation of a biocidal product named TWP 094 of product-type 8, as described in Annex V to that Regulation, providing written confirmation that the competent authority of Denmark had agreed to evaluate the application. The application was recorded under case number BC-QN044827-14 in the Register for Biocidal Products.
- (2) TWP 094 contains 3-Iodo-2-propynyl butylcarbamate (IPBC) as the active substance, included in the Union list of approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012 for product-type 8.
- (3) On 7 January 2022, the evaluating competent authority submitted, in accordance with Article 44(1) of Regulation (EU) No 528/2012, an assessment report and the conclusions of its evaluation to the Agency.
- (4) On 5 July 2022, the Agency submitted to the Commission its opinion ⁽²⁾, the draft summary of the biocidal product characteristics (‘SPC’) of TWP 094 and the final assessment report on the biocidal product, in accordance with Article 44(3) of Regulation (EU) No 528/2012.
- (5) The opinion concludes that TWP 094 is a biocidal product within the meaning of Article 3(1), point (a), of Regulation (EU) No 528/2012, that it is eligible for Union authorisation in accordance with Article 42(1) of that Regulation and that, subject to compliance with the draft SPC, it meets the conditions laid down in Article 19(1) of that Regulation.
- (6) On 18 August 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.
- (7) The Commission concurs with the opinion of the Agency and considers it therefore appropriate to grant a Union authorisation for TWP 094.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ ECHA opinion of 16 June 2022 on the Union authorisation of TWP 094 (ECHA/BPC/348/2022), <https://echa.europa.eu/opinions-on-union-authorisation>

- (8) In its opinion, the Agency states that the authorisation holder is to complete a long-term storage test at ambient temperature for TWP 094 and provide a test on persistent foaming and a test on the degree of dissolution and dilution stability for the soluble concentrate formulation type of the product as a condition in the authorisation. The results of the long-term storage test should confirm the shelf life of the biocidal product of one year granted based on an accelerated storage stability test and the submitted interim results of a long-term storage stability test at ambient temperature. The information to be provided on persistent foaming and degree of dissolution and dilution stability should confirm the technical properties of the product for the formulation type soluble concentrate of the product.
- (9) The Commission agrees with the opinion of the Agency and considers that the submission of the results of the test and the information for the soluble concentrate formulation type should be a condition relating to the making available on the market and use of the biocidal product TWP 094 pursuant to Article 22(1) of Regulation (EU) No 528/2012. The Commission also considers that the fact that data is to be provided after the authorisation is granted does not affect the conclusion on the fulfilment of the condition under Article 19(1), point (d), of that Regulation based on existing data.
- (10) 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-0028968-0000 is hereby granted to TROY CHEMICAL COMPANY BV for the making available on the market and use of the biocidal product TWP 094 subject to compliance with the terms and conditions set out in Annex I and in accordance with the summary of the biocidal product characteristics set out in Annex II.

The Union authorisation is valid from 19 June 2023 to 31 May 2033.

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, 24 May 2023.

For the Commission
The President
Ursula VON DER LEYEN

*ANNEX I***TERMS AND CONDITIONS (EU-0028968-0000)**

The authorisation holder shall conduct a long-term storage test at ambient temperature for the product TWP 094 to confirm the shelf life of the biocidal product of 12 months. The study must include a test of degree of dissolution and dilution stability after storage for 12 months at ambient temperature. If the degradation exceeds 10%, efficacy data and information on the degradation products and their impact on risk assessment is required and shall be included.

The authorisation holder shall provide a test of persistent foaming and a test on degree of dissolution and dilution stability to confirm the soluble concentrate formulation type of the product TWP 094.

By 19 June 2024 the authorisation holder shall submit the results of the test and the information to the Agency.

ANNEX II

Summary of product characteristics for a biocidal product

TWP 094

Product type 8 - Wood preservatives (Preservatives)

Authorisation number: EU-0028968-0000

R4BP asset number: EU-0028968-0000

1. ADMINISTRATIVE INFORMATION**1.1. Trade name(s) of the product**

Trade name(s)	TWP 094 StoPrim Protect W 22 Aqua Holz-Imprägnier-Grund Gjøco Impregnering Aqua Omnia Preservative Voima Aqua Base Aqua IG-16 Aqua Holz-Imprägnierung Induline SW-906 Sadolin QD Wood Preserver WB Holz-Öl Imprägniergrund WX Imprägniergrund W21000 Imprägniergrund W219 Protox Woodprotect B3 Grundingsolie WP GVK-Pohjuste Plus Pinja Base Grundolja Villa Protect Primex Olja plus Primex Olja Valtti Plus Primer Gori Professional Træimprægnering Vandig Sigmalife WB Primer GORI Transparent grunder træværk 11 IM151A profilan-prevent pro impralan-Grund I100 pro impralan-Grund G300 pro impralan-Grund G400 pro Rhenocryl pro-TL 30 EU Rhenocryl pro-TL 45 EU Holzschutzgrund / sous-couche de protection du bois Impregnační základ Impregnačný základ Houtimpregneer Grund pentru protecția lemnului Holzschutzgrundierung Osmo Træimprægnering WR Aqua 4019 Osmo Träimpregnering WR Aqua 4019 Osmo Treimpregnering WR Aqua 4019 Osmo Puunsuojapohjuste WR Aqua 4019 Osmo Color Träimpregnering WR Aqua 4019 Osmo Imprégnation pour le bois WR aqua 4019 Osmo Holz-Imprägnierung WR Aqua 4019 Osmo Impregnace dřeva WR Aqua 4019
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Osmo Impregnácia dreva WR Aqua 4019
 Osmo Impregnazione per legno WR Aqua 4019
 Osmo Impregnálás WR Aqua 4019
 Osmo Impregnat do drewna WR Aqua 4019
 Osmo Houtimpregneer WR Aqua 4019
 Osmo Imprégnation pour le bois WR Aqua 4019
 Osmo Holz-Imprägnierung WR Aqua 4019
 Osmo Houtimpregneer WR Aqua 4019
 Osmo Impregnarea lemnului WR Aqua 4019
 Osmo WR Base Coat Aqua 4019
 Osmo Color Puiduimmutus WR Aqua 4019
 Osmo Impregněšana kokam WR Aqua 4019
 Osmo Impregnavimas WR Aqua 4019
 Osmo WR Base Coat Aqua 4019
 Osmo Impregnación para madera WR Aqua 4019
 Osmo Impregnação para madeira WR Aqua 4019
 Osmo Impregnacija lesa WR Aqua 4019
 Osmo Impregnacija drva WR Aqua 4019
 Flügger 01 Wood Tex Grund-olie
 Flügger 01 Wood Tex Grund-olja
 Flügger 01 Wood Tex Grunn-olje
 Flügger 01 Wood Tex Grundieröl
 Flügger 01 Wood Tex Primaire Bois Hydrofuge
 Flügger 01 Wood Tex Olej-gruntujacy
 Flügger 01 Wood Tex
 Flügger 01 Wood Tex Grundolie
 Holzschutzgrund
 WOODEX AQUA BASE +
 AM0572/00 Hydroplus protettivo per legno
 458-0004/2 Idro Ceopren protettivo per legno
 HI2550 Linea Blu protettivo per Legno
 AM0572/00 Hydroplus Wood protection
 458-0004/2 IDRO CEOPREN Wood protection
 HI2550 Linea Blu Wood Protection
 AA1960 Laqvin Seal
 37647 Ronseal Multi-Purpose Wood Treatment
 37648 Ronseal Multi-Purpose Wood Treatment
 MasqueWoodPro 10
 CETOL WP 5000-02
 BAUFIX Holz-Imprägnierung
 YM--M103/———
 674840 HF PROTECTIVE PRIMER W
 Grundolja V
 Ronseal Wood Preserver
 Ronseal Trade Wood Preserver
 Screwfix Wood Preserver
 B&Q Wood Preserver
 Good Home Wood Preserver
 Sherwin Williams Wood Preserver
 Ronseal Fence Life Wood Preserver
 Ronseal Shed & Fence Preserver
 Castorama Traitement Bois Extérieur
 Brico Depot Traitement Bois Extérieur
 Good Home Traitement Bois Extérieur
 Altax Traitement Bois Extérieur
 Ronseal Traitement Bois Extérieur
 Valspar Traitement Bois Extérieur
 Valspar Pro Traitement Bois Extérieur
 Sherwin Williams Traitement Bois Extérieur
 Luxens Traitement Bois Extérieur
 Castorama Impregnat do drewna
 Good Home Impregnat do drewna
 Altax Impregnat do drewna

	Valspar Impregnat do drewna Valspar Pro Impregnat do drewna Sherwin Williams Impregnat do drewna Luxens Impregnat do drewna Castorama Conservant pentru lemn Good Home Conservant pentru lemn Altax pentru lemn Valspar pentru lemn Valspar Pro pentru lemn Sherwin Williams pentru lemn
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1.2. Authorisation holder

Name and address of the authorisation holder	Name	TROY CHEMICAL COMPANY BV
	Address	Poortweg 4C, 2612PA Delft Netherlands
Authorisation number	EU-0028968-0000	
R4BP asset number	EU-0028968-0000	
Date of the authorisation	19 June 2023	
Expiry date of the authorisation	31 May 2033	

1.3. Manufacturer(s) of the product

Name of manufacturer	Troy Chemical Company BV
Address of manufacturer	Poortweg 4C, 2612 PA Delft Netherlands
Location of manufacturing sites	Westelijke Randweg 9, 4791 RT Klundert Netherlands Industriepark 23, 56593 Horhausen Germany Geschwister-Scholl-Straße 127, 39218 Schönebeck/Elbe Germany Mecklenburger Str. 229, 23568 Lübeck Germany Halchtersche Str. 33, 38304 Wolfenbüttel Germany Am Nordturm 5, 46562 Voerde Germany Am Alten Galgen 14, 56410 Montabaur Germany

Name of manufacturer	Tikkurila Oyj
Address of manufacturer	Kuninkaalantie 1, FI-01301 Vantaa Finland
Location of manufacturing sites	Kuninkaalantie 1, FI-01301 Vantaa Finland uL.Mościckiego 23, 39-200 DĘBICA Poland

Name of manufacturer	Akzo Nobel Industrial Coatings AB
Address of manufacturer	Staffanstorpsvägen 50, 20517 Malmö Sweden
Location of manufacturing sites	Staffanstorpsvägen 50, 20517 Malmö Sweden

Name of manufacturer	Schulz Farben- und Lackfabrik GmbH
Address of manufacturer	An der Altnah 10, 55450 Langenlonsheim Germany
Location of manufacturing sites	An der Altnah 10, 55450 Langenlonsheim Germany

Name of manufacturer	Remmers GmbH
Address of manufacturer	Bernhard-Remmers-Straße 13, 49624 Lönigen Germany
Location of manufacturing sites	Bernhard-Remmers-Straße 13, 49624 Lönigen Germany Füllenbruchstr. 13, 32120 Hiddenhausen Germany

Name of manufacturer	Remmers Industrielacke GmbH
Address of manufacturer	Füllenbruchstr. 13, 32120 Hiddenhausen Germany
Location of manufacturing sites	Füllenbruchstr. 13, 32120 Hiddenhausen Germany

Name of manufacturer	Teknos A/S
Address of manufacturer	Industrivej 16, DK-6580 Vamdrup Denmark
Location of manufacturing sites	Industrivej 16, DK-6580 Vamdrup Denmark

Name of manufacturer	Sherwin Williams
Address of manufacturer	Thorncliffe Park Estate, Thorncliffe Rd, Chapeltown, S35 2YP Sheffield United Kingdom
Location of manufacturing sites	Thorncliffe Park Estate, Thorncliffe Rd, Chapeltown,, S35 2YP Sheffield United Kingdom Kopanińska 7, 60-119 Brodziszewo Poland

Name of manufacturer	Sherwin-Williams Italy S.r.l.
Address of manufacturer	Via Del Fiffio 12, 40065 Pianoro (BO) Italy
Location of manufacturing sites	Via Del Fiffio 12, 40065 Pianoro (BO) Italy

Name of manufacturer	Sherwin-Williams Sweden AB
Address of manufacturer	Bellö, 570 32 Hjärtevad Sweden
Location of manufacturing sites	Bellö, 570 32 Hjärtevad Sweden

Name of manufacturer	PPG Industries (Dyrup A/S)
Address of manufacturer	Gladsaxevej 300, 2860 Gladsaxe Denmark
Location of manufacturing sites	Gladsaxevej 300, 2860 Gladsaxe Denmark

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

Active substance	3-iodo-2-propynylbutylcarbamate (IPBC)
Name of manufacturer	Troy Corporation
Address of manufacturer	8 Vreeland Road, Florham Park, NJ 07105 New Jersey United States
Location of manufacturing sites	One Avenue L, NJ 07105 Newark United States

Active substance	3-iodo-2-propynylbutylcarbamate (IPBC)
Name of manufacturer	Troy Chemical Company BV
Address of manufacturer	Poortweg 4C, 2612 PA Delft Netherlands
Location of manufacturing sites	Industriepark 23, 56593 Horhausen 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 (%)
3-iodo-2-propynylbutylcarbamate (IPBC)		Active Substance	55406-53-6	259-627-5	0,75

2.2. Type of formulation

Any other liquid (AL) and Soluble concentrate (SL)

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	Harmful to aquatic life with long lasting effects. Contains 3-iodo-2-propynyl butylcarbamate (IPBC). May produce an allergic reaction.
Precautionary statements	Avoid release to the environment. Dispose of contents in accordance with local / national regulations. Dispose of container in accordance with local / national regulations.

4. AUTHORISED USE(S)

4.1. Use description

Table 1. Use # 1 – Brushing and rolling (general public, professional)

Product type	PT08 - Wood preservatives (Preservatives)
Where relevant, an exact description of the authorised use	Fungicide.

Target organism(s) (including development stage)	Common name: Blue stain fungi Development stage: Scientific name: Basidiomycetes: Common name: Brown rot fungi Development stage:
Field(s) of use	Indoor Outdoor Softwood Preventative treatment Use class 2 as described in EN standard 335:2013 (situation in which the wood or wood-based product is under cover and not exposed to the weather (particularly rain and wind-driven rain) but where occasional, but not persistent, wetting can occur. Use class 3 as described in EN standard 335:2013 (situation in which the wood or wood-based product is above ground and exposed to the weather (particularly rain) See section 6 for the full titles of the EN standards.
Application method(s)	Method: brushing and rolling Detailed description: Superficial treatment
Application rate(s) and frequency	Application Rate: 100 ml/m ² (against blue stain fungi); 150 - 160 ml/m ² (against wood-rotting fungi) Dilution (%): - Ready-to-use product Number and timing of application: 1 application
Category(ies) of users	Professional General public (non-professional)
Pack sizes and packaging material	Can (high-density polyethylene) HDPE: 0,375 l, 0,75 l, 1,0 l, 2,5 l, 5,0 l For professional use only: Can HDPE: 10 l, 20 l, 25 l

4.1.1. Use-specific instructions for use

Do not dilute (ready-to-use).

Apply the product to the wood with a brush or roller and let dry for approximately 24 hours. Cleaning of the tools can be performed using mild soap and water.

Use of a topcoat is required. The topcoat cannot contain a film- or wood preservative. The topcoat should be maintained.

The product protects the wood surface against blue stain fungi on wood that is minimum 'moderately to slightly durable to fungi' according to EN 350:2016: Durability Class (DC) 3-4. See section 6 for the full title of the EN standards.

4.1.2. Use-specific risk mitigation measures

Do not use/apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock/pets.

Do not apply near bodies of surface water.

During product application (to timbers) and whilst surfaces are drying, do not contaminate the environment. All losses of the product have to be contained by covering the ground (e.g. by tarpaulin) and disposed of in a safe way.

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 direction for use.

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

See general direction 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 direction for use.

4.2. Use description

Table 2. Use # 2 – Manual dipping (professional)

Product type	PT08 - Wood preservatives (Preservatives)
Where relevant, an exact description of the authorised use	Fungicide.
Target organism(s) (including development stage)	Common name: Blue stain fungi Development stage: Scientific name: Basidiomycetes: Common name: Brown rot fungi Development stage:
Field(s) of use	Indoor Softwood Preventative treatment Use class 2 Use class 3
Application method(s)	Method: manual dipping Detailed description: Superficial treatment
Application rate(s) and frequency	Application Rate: 100 ml/m ² (against blue stain fungi); 150 - 160 ml/m ² (against wood-rotting fungi) Dilution (%): - Ready-to-use product Number and timing of application: 1 application
Category(ies) of users	Professional
Pack sizes and packaging material	Can HDPE: 0,375 l, 0,75 l, 1,0 l, 2,5 l, 5,0 l, 10 l, 20 l, 25 l

4.2.1. Use-specific instructions for use

Do not dilute (ready-to-use).

Drying time: Dry to handle and ready for topcoat: approximately 24 hours.

Cleaning of tools: Use water and mild soap.

Use of a topcoat is required. The topcoat cannot contain a film- or wood preservative. The topcoat should be maintained.

The product protects the wood surface against blue stain fungi on wood that is minimum 'moderately to slightly durable to fungi' according to EN 350:2016: Durability Class (DC) 3-4. See section 6 for the full title of the EN standards.

4.2.2. Use-specific risk mitigation measures

Wear protective chemical resistant gloves during product handling phase classified under the European Standard EN 374 or equivalent. Glove material to be specified by the authorisation holder within product information.

Wear a protective coverall (type 6, EN 13034 or equivalent).

This is without prejudice to the application of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work.

See section 6 for the full titles of the EN standards and legislation.

Application by manual dipping shall be performed for a maximum of 30 minutes per day.

Do not use/apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock/pets.

During product application (to timbers) and whilst surfaces are drying, do not contaminate the environment. All losses of the product have to be contained by covering the ground (e.g. by tarpaulin) and disposed of in a safe way.

Freshly treated timber must be stored after treatment under shelter or on a hard, impermeable surface to prevent direct losses to soil and water.

Any losses should be collected for reuse or disposal.

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 direction for use.

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

See general direction 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 direction for use.

4.3. Use description

Table 3. Use # 3 – Automated dipping, automated spraying, flow coating/deluging (industrial)

Product type	PT08 - Wood preservatives (Preservatives)
Where relevant, an exact description of the authorised use	Fungicide.
Target organism(s) (including development stage)	Common name: Blue stain fungi Development stage: Scientific name: Basidiomycetes: Common name: Brown rot fungi Development stage:
Field(s) of use	Indoor Softwood Preventative treatment Use class 2 Use class 3
Application method(s)	Method: automated dipping, automated spraying, flow coating/deluging Detailed description: Superficial treatment. Similar to flow coating/deluging, automated spraying is assumed to be an essentially fully enclosed process, whereby operator exposure occurs mainly by handling wet treated wood.
Application rate(s) and frequency	Application Rate: 100 ml/m ² (against blue stain fungi); 150 - 160 ml/m ² (against wood-rotting fungi) Dilution (%): - Ready-to-use product Number and timing of application: 1 application

Category(ies) of users	Industrial
Pack sizes and packaging material	Can/ intermediate bulk container (IBC) HDPE: 1 20 l, 220 l, 1 000 l

4.3.1. *Use-specific instructions for use*

Do not dilute (ready-to-use).

Drying time: until dry to touch.

Use of a topcoat is required. The topcoat cannot contain a film- or wood preservative. The topcoat shall be maintained.

The product protects the wood surface against blue stain fungi on wood that is minimum 'moderately to slightly durable to fungi' according to EN 350:2016: Durability Class (DC) 3-4. See section 6 for the full title of the EN standards.

4.3.2. *Use-specific risk mitigation measures*

The product must only be loaded into industrial application equipment via a fully-automated pumping/transfer system.

Wear protective chemical resistant gloves during product handling phase classified under the European Standard EN 374 or equivalent. Glove material to be specified by the authorisation holder within product information.

Wear a protective coverall (type 6, EN 13034 or equivalent).

This is without prejudice to the application of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work.

See section 6 for the full titles of EN standards and legislation.

The product must only be used in fully automated dipping processes where all steps in the treatment and drying process are mechanised and no manual handling takes place, including when the treated articles are transported through the dip tank to draining/drying and storage (if not already surface dry before moving to storage). Where appropriate, the wooden articles to be treated must be fully secured (e.g. via tension belts or clamping devices) prior to treatment and during the dipping process, and must not be manually handled until after the treated articles are surface dry.

Freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer and water.

Any losses of the product shall be collected for reuse or disposal.

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

See general direction for use.

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

See general direction for use.

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

See general direction for use.

4.4. Use description

Table 4. Use # 4 – Double vacuum/low pressure process (industrial)

Product type	PT08 - Wood preservatives (Preservatives)
Where relevant, an exact description of the authorised use	Fungicide.
Target organism(s) (including development stage)	Scientific name: Basidiomycetes: Common name: Brown rot fungi Development stage:
Field(s) of use	Indoor Softwood Preventative treatment Use class 2 Use class 3
Application method(s)	Method: Double vacuum/low pressure process Detailed description: Penetrative treatment.
Application rate(s) and frequency	Application Rate: 74.6 - 79.5 kg/m ³ Dilution (%): 10% in-use solution (1 part product: 9 parts water) Number and timing of application: 1 application
Category(ies) of users	Industrial
Pack sizes and packaging material	Can/IBC HDPE: 120 l, 220 l, 1 000 l

4.4.1. Use-specific instructions for use

Drying time: until dry to touch.

4.4.2. Use-specific risk mitigation measures

The product must only be loaded into industrial application equipment via a fully-automated pumping/transfer system.

Wear protective chemical resistant gloves during product handling phase classified under the European Standard EN 374 or equivalent. Glove material to be specified by the authorisation holder within product information.

Wear a protective coverall (type 6, EN 13034 or equivalent).

This is without prejudice to the application of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work.

See section 6 for full titles of the EN standards and legislation.

Freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer or water.

Any losses of the product shall be collected for reuse or disposal.

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

See general direction for use.

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

See general direction for use.

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

See general direction for use.

5. **GENERAL DIRECTIONS FOR USE** ⁽¹⁾

5.1. **Instructions for use**

Comply with the instructions for use.

Do not use product on wood or wooden structures intended for use indoors, except for internal surfaces of external window frames and of external doors/door frames.

The temperature must be above 5°C and relative humidity below 80% during application and drying.

Stir product before use.

Avoid contact with skin and eyes.

Wash hands and face after application and use of the product, and before eating, drinking or smoking.

5.2. **Risk mitigation measures**

Do not use on wood which may come in direct contact with food, feed and livestock.

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

IF SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor.

IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor.

IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.

IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.

When seeking medical advice, have the product container or label at hand.

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

This product and its container must be disposed of safely as hazardous waste.

Any product collected during application that is not reused must be disposed of safely as hazardous waste.

Dispose of packaging and of unused product in accordance with local regulations. If required, consult a professional waste operator or local authority.

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

Keep out of reach of children and non-target animals/pets.

Do not store near food, drink and animal feeding stuff.

Shelf life: 12 months.

Store below 35°C.

Store in a cool, dry, well-ventilated place.

Protect from frost.

Protect from light.

Opened containers must be carefully resealed and kept upright to prevent leakage.

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

6. OTHER INFORMATION

Regarding Use 1 and Use 2: Professionals and/or trained professionals if required by national legislation.

Full titles of EN standards and legislation mentioned in section 4.1.1, 4.2.1, 4.3.1, 4.2.2, 4.3.2 and 4.4.2:

EN 335:2013 - Durability of wood and wood-based products - Use classes: definitions, application to solid wood and wood-based products

EN 350:2016, Durability of wood and wood-based products - Testing and classification of the durability to biological agents of wood and wood-based materials

EN 374 – Protective gloves against dangerous chemicals and micro-organisms. Part 1: terminology and performance requirements for chemical risks.

EN 13034 - Protective clothing against liquid chemicals. Performance requirements for chemical protective clothing offering limited protective performance against liquid chemicals (Type 6 and Type PB [6] equipment).

Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11).

COMMISSION REGULATION (EU) 2023/1042**of 26 May 2023****amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for folpet in or on certain products****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC ⁽¹⁾, and in particular Article 14(1), point (a), thereof,

Whereas:

- (1) Maximum residue levels ('MRLs') for folpet were set in Annex II to Regulation (EC) No 396/2005.
- (2) An application pursuant to Article 6(1) of Regulation (EC) No 396/2005 was submitted requesting a modification of the existing MRL for folpet in lettuces.
- (3) In accordance with Article 8 of Regulation (EC) No 396/2005, this application was evaluated by the Member State concerned and the evaluation report was forwarded to the Commission.
- (4) The European Food Safety Authority ('the Authority') assessed the application and the evaluation report, examining in particular the risks to consumers and, where relevant, to animals, and gave a reasoned opinion on the proposed MRL ⁽²⁾. It forwarded the opinion to the applicant, the Commission and the Member States and made it available to the public.
- (5) As regards the modification to the MRL requested by the applicant, the Authority concluded that all requirements with respect to completeness of data submission were met and that the modification to the MRL requested by the applicant was acceptable with regard to consumer safety, on the basis of a consumer exposure assessment for 27 specific European consumer groups. In so concluding, the Authority took into account the most recent data on the toxicological properties of the substance. Neither the long-term exposure to this substance via consumption of all food products that may contain it, nor the short-term exposure due to high consumption of the relevant products showed a risk that the acceptable daily intake or the acute reference dose is exceeded.
- (6) Based on the reasoned opinion of the Authority and taking into account the relevant factors listed in Article 14(2) of Regulation (EC) No 396/2005, the proposed modification to the MRL fulfils the requirements of Article 14(2) of that Regulation.
- (7) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁽¹⁾ OJ L 70, 16.3.2005, p. 1.

⁽²⁾ Reasoned opinion on the modification of the existing maximum residue level for folpet in lettuces. EFSA Journal 2022;20(4):7309.

HAS ADOPTED THIS REGULATION:

Article 1

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

Article 2

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

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

Done at Brussels, 26 May 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

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

Pesticide residues and maximum residue levels (mg/kg)

Code number	Groups and examples of individual products to which the MRLs apply (*)	Folpet (sum of folpet and phthalimide, expressed as folpet) (R)
(1)	(2)	(3)
0100000	FRUITS, FRESH or FROZEN; TREE NUTS	
0110000	Citrus fruits	0,03 (*)
0110010	Grapefruits	
0110020	Oranges	
0110030	Lemons	
0110040	Limes	
0110050	Mandarins	
0110990	Others (2)	
0120000	Tree nuts	0,07 (*)
0120010	Almonds	
0120020	Brazil nuts	
0120030	Cashew nuts	
0120040	Chestnuts	
0120050	Coconuts	
0120060	Hazelnuts/cobnuts	
0120070	Macadamias	
0120080	Pecans	
0120090	Pine nut kernels	
0120100	Pistachios	
0120110	Walnuts	
0120990	Others (2)	
0130000	Pome fruits	
0130010	Apples	0,3
0130020	Pears	0,3
0130030	Quinces	0,03 (*)
0130040	Medlars	0,03 (*)

(1)	(2)	(3)
0130050	Loquats/Japanese medlars	0,03 (*)
0130990	Others (2)	0,03 (*)
0140000	Stone fruits	0,03 (*)
0140010	Apricots	
0140020	Cherries (sweet)	
0140030	Peaches	
0140040	Plums	
0140990	Others (2)	
0150000	Berries and small fruits	
0151000	(a) grapes	
0151010	Table grapes	6
0151020	Wine grapes	20
0152000	(b) strawberries	5(+)
0153000	(c) cane fruits	0,03 (*)
0153010	Blackberries	
0153020	Dewberries	
0153030	Raspberries (red and yellow)	
0153990	Others (2)	
0154000	(d) other small fruits and berries	0,03 (*)
0154010	Blueberries	
0154020	Cranberries	
0154030	Currants (black, red and white)	
0154040	Gooseberries (green, red and yellow)	
0154050	Rose hips	
0154060	Mulberries (black and white)	
0154070	Azaroles/Mediterranean medlars	
0154080	Elderberries	
0154990	Others (2)	
0160000	Miscellaneous fruits with	
0161000	(a) edible peel	
0161010	Dates	0,03 (*)
0161020	Figs	0,03 (*)
0161030	Table olives	0,15 (*) (+)
0161040	Kumquats	0,03 (*)
0161050	Carambolas	0,03 (*)
0161060	Kaki/Japanese persimmons	0,03 (*)

(1)	(2)	(3)
0161070	Jambuls/jambolans	0,03 (*)
0161990	Others (2)	0,03 (*)
0162000	(b) inedible peel, small	0,03 (*)
0162010	Kiwi fruits (green, red, yellow)	
0162020	Litchis/lychees	
0162030	Passionfruits/maracujas	
0162040	Prickly pears/cactus fruits	
0162050	Star apples/cainitos	
0162060	American persimmons/Virginia kaki	
0162990	Others (2)	
0163000	(c) inedible peel, large	0,03 (*)
0163010	Avocados	
0163020	Bananas	
0163030	Mangoes	
0163040	Papayas	
0163050	Granate apples/pomegranates	
0163060	Cherimoyas	
0163070	Guavas	
0163080	Pineapples	
0163090	Breadfruits	
0163100	Durians	
0163110	Soursops/guanabanas	
0163990	Others (2)	
0200000	VEGETABLES, FRESH or FROZEN	
0210000	Root and tuber vegetables	
0211000	(a) potatoes	0,06 (*) (+)
0212000	(b) tropical root and tuber vegetables	0,03 (*)
0212010	Cassava roots/manioc	
0212020	Sweet potatoes	
0212030	Yams	
0212040	Arrowroots	
0212990	Others (2)	
0213000	(c) other root and tuber vegetables except sugar beets	
0213010	Beetroots	0,03 (*)
0213020	Carrots	0,03 (*)
0213030	Celeriacs/turnip rooted celeries	0,03 (*)
0213040	Horseradishes	0,03 (*)

(1)	(2)	(3)
0213050	Jerusalem artichokes	0,03 (*)
0213060	Parsnips	0,03 (*)
0213070	Parsley roots/Hamburg roots parsley	0,03 (*)
0213080	Radishes	0,04 (*) (+)
0213090	Salsifies	0,04 (*) (+)
0213100	Swedes/rutabagas	0,03 (*)
0213110	Turnips	0,03 (*)
0213990	Others (2)	0,03 (*)
0220000	Bulb vegetables	0,03 (*)
0220010	Garlic	
0220020	Onions	
0220030	Shallots	
0220040	Spring onions/green onions and Welsh onions	
0220990	Others (2)	
0230000	Fruiting vegetables	
0231000	(a) Solanaceae and Malvaceae	
0231010	Tomatoes	5(+)
0231020	Sweet peppers/bell peppers	0,03 (*)
0231030	Aubergines/eggplants	0,03 (*)
0231040	Okra/lady's fingers	0,03 (*)
0231990	Others (2)	0,03 (*)
0232000	(b) cucurbits with edible peel	0,03 (*)
0232010	Cucumbers	
0232020	Gherkins	
0232030	Courgettes	
0232990	Others (2)	
0233000	(c) cucurbits with inedible peel	
0233010	Melons	0,4(+)
0233020	Pumpkins	0,03 (*)
0233030	Watermelons	0,03 (*)
0233990	Others (2)	0,03 (*)
0234000	(d) sweet corn	0,03 (*)
0239000	(e) other fruiting vegetables	0,03 (*)
0240000	Brassica vegetables(excluding brassica roots and brassica baby leaf crops)	0,03 (*)
0241000	(a) flowering brassica	
0241010	Broccoli	
0241020	Cauliflowers	

(1)	(2)	(3)
0241990	Others (2)	
0242000	(b) head brassica	
0242010	Brussels sprouts	
0242020	Head cabbages	
0242990	Others (2)	
0243000	(c) leafy brassica	
0243010	Chinese cabbages/pe-tsai	
0243020	Kales	
0243990	Others (2)	
0244000	(d) kohlrabies	
0250000	Leaf vegetables, herbs and edible flowers	
0251000	(a) lettuces and salad plants	
0251010	Lamb's lettuces/corn salads	0,03 (*)
0251020	Lettuces	1,5
0251030	Escaroles/broad-leaved endives	0,03 (*)
0251040	Cresses and other sprouts and shoots	0,03 (*)
0251050	Land cresses	0,03 (*)
0251060	Roman rocket/rucola	0,03 (*)
0251070	Red mustards	0,03 (*)
0251080	Baby leaf crops (including brassica species)	0,03 (*)
0251990	Others (2)	0,03 (*)
0252000	(b) spinaches and similar leaves	0,03 (*)
0252010	Spinaches	
0252020	Purslanes	
0252030	Chards/beet leaves	
0252990	Others (2)	
0253000	(c) grape leaves and similar species	0,03 (*)
0254000	(d) watercresses	0,03 (*)
0255000	(e) witloofs/Belgian endives	0,03 (*)
0256000	(f) herbs and edible flowers	0,06 (*)
0256010	Chervil	
0256020	Chives	
0256030	Celery leaves	
0256040	Parsley	
0256050	Sage	
0256060	Rosemary	
0256070	Thyme	

(1)	(2)	(3)
0256080	Basil and edible flowers	
0256090	Laurel/bay leaves	
0256100	Tarragon	
0256990	Others (2)	
0260000	Legume vegetables	0,03 (*)
0260010	Beans (with pods)	
0260020	Beans (without pods)	
0260030	Peas (with pods)	
0260040	Peas (without pods)	
0260050	Lentils	
0260990	Others (2)	
0270000	Stem vegetables	0,03 (*)
0270010	Asparagus	
0270020	Cardoons	
0270030	Celeries	
0270040	Florence fennels	
0270050	Globe artichokes	
0270060	Leeks	
0270070	Rhubarbs	
0270080	Bamboo shoots	
0270090	Palm hearts	
0270990	Others (2)	
0280000	Fungi, mosses and lichens	0,03 (*)
0280010	Cultivated fungi	
0280020	Wild fungi	
0280990	Mosses and lichens	
0290000	Algae and prokaryotes organisms	0,03 (*)
0300000	PULSES	0,07 (*)
0300010	Beans	
0300020	Lentils	
0300030	Peas	
0300040	Lupins/lupini beans	
0300990	Others (2)	
0400000	OILSEEDS AND OIL FRUITS	
0401000	Oilseeds	0,07 (*)
0401010	Linseeds	
0401020	Peanuts/groundnuts	
0401030	Poppy seeds	

(1)	(2)	(3)
0401040	Sesame seeds	
0401050	Sunflower seeds	
0401060	Rapeseeds/canola seeds	
0401070	Soyabeans	
0401080	Mustard seeds	
0401090	Cotton seeds	
0401100	Pumpkin seeds	
0401110	Safflower seeds	
0401120	Borage seeds	
0401130	Gold of pleasure seeds	
0401140	Hemp seeds	
0401150	Castor beans	
0401990	Others (2)	
0402000	Oil fruits	
0402010	Olives for oil production	0,15 (*) (+)
0402020	Oil palms kernels	0,07 (*)
0402030	Oil palms fruits	0,07 (*)
0402040	Kapok	0,07 (*)
0402990	Others (2)	0,07 (*)
0500000	CEREALS	
0500010	Barley	2
0500020	Buckwheat and other pseudocereals	0,07 (*)
0500030	Maize/corn	0,07 (*)
0500040	Common millet/proso millet	0,07 (*)
0500050	Oat	2
0500060	Rice	0,07 (*)
0500070	Rye	0,3
0500080	Sorghum	0,07 (*)
0500090	Wheat	0,4 (+)
0500990	Others (2)	0,07 (*)
0600000	TEAS, COFFEE, HERBAL INFUSIONS, COCOA AND CAROBS	0,1 (*)
0610000	Teas	
0620000	Coffee beans	
0630000	Herbal infusions from	
0631000	(a) flowers	
0631010	Chamomile	
0631020	Hibiscus/roselle	

(1)	(2)	(3)
0631030	Rose	
0631040	Jasmine	
0631050	Lime/linden	
0631990	Others (2)	
0632000	(b) leaves and herbs	
0632010	Strawberry	
0632020	Rooibos	
0632030	Mate/maté	
0632990	Others (2)	
0633000	(c) roots	
0633010	Valerian	
0633020	Ginseng	
0633990	Others (2)	
0639000	(d) any other parts of the plant	
0640000	Cocoa beans	
0650000	Carobs/Saint John's breads	
0700000	HOPS	400(+)
0800000	SPICES	
0810000	Seed spices	0,1 (*)
0810010	Anise/aniseed	
0810020	Black caraway/black cumin	
0810030	Celery	
0810040	Coriander	
0810050	Cumin	
0810060	Dill	
0810070	Fennel	
0810080	Fenugreek	
0810090	Nutmeg	
0810990	Others (2)	
0820000	Fruit spices	0,1 (*)
0820010	Allspice/pimento	
0820020	Sichuan pepper	
0820030	Caraway	
0820040	Cardamom	
0820050	Juniper berry	
0820060	Peppercorn (black, green and white)	
0820070	Vanilla	

(1)	(2)	(3)
0820080	Tamarind	
0820990	Others (2)	
0830000	Bark spices	0,1 (*)
0830010	Cinnamon	
0830990	Others (2)	
0840000	Root and rhizome spices	
0840010	Liquorice	0,1 (*)
0840020	Ginger (10)	
0840030	Turmeric/curcuma	0,1 (*)
0840040	Horseradish (11)	
0840990	Others (2)	0,1 (*)
0850000	Bud spices	0,1 (*)
0850010	Cloves	
0850020	Capers	
0850990	Others (2)	
0860000	Flower pistil spices	0,1 (*)
0860010	Saffron	
0860990	Others (2)	
0870000	Aril spices	0,1 (*)
0870010	Mace	
0870990	Others (2)	
0900000	SUGAR PLANTS	0,03 (*)
0900010	Sugar beet roots	
0900020	Sugar canes	
0900030	Chicory roots	
0900990	Others (2)	
1000000	PRODUCTS OF ANIMAL ORIGIN - TERRESTRIAL ANIMALS	0,05 (*)
1010000	Commodities from	
1011000	(a) swine	
1011010	Muscle	
1011020	Fat	
1011030	Liver	
1011040	Kidney	
1011050	Edible offals (other than liver and kidney)	
1011990	Others (2)	
1012000	(b) bovine	
1012010	Muscle	
1012020	Fat	

(1)	(2)	(3)
1012030	Liver	
1012040	Kidney	
1012050	Edible offals (other than liver and kidney)	
1012990	Others (2)	
1013000	(c) sheep	
1013010	Muscle	
1013020	Fat	
1013030	Liver	
1013040	Kidney	
1013050	Edible offals (other than liver and kidney)	
1013990	Others (2)	
1014000	d) goat	
1014010	Muscle	
1014020	Fat	
1014030	Liver	
1014040	Kidney	
1014050	Edible offals (other than liver and kidney)	
1014990	Others (2)	
1015000	(e) equine	
1015010	Muscle	
1015020	Fat	
1015030	Liver	
1015040	Kidney	
1015050	Edible offals (other than liver and kidney)	
1015990	Others (2)	
1016000	(f) poultry	
1016010	Muscle	(+)
1016020	Fat	(+)
1016030	Liver	(+)
1016040	Kidney	
1016050	Edible offals (other than liver and kidney)	
1016990	Others (2)	
1017000	(g) other farmed terrestrial animals	
1017010	Muscle	
1017020	Fat	
1017030	Liver	
1017040	Kidney	

(1)	(2)	(3)
1017050	Edible offals (other than liver and kidney)	
1017990	Others (2)	
1020000	Milk	
1020010	Cattle	
1020020	Sheep	
1020030	Goat	
1020040	Horse	
1020990	Others (2)	
1030000	Birds eggs	(+)
1030010	Chicken	(+)
1030020	Duck	(+)
1030030	Geese	(+)
1030040	Quail	(+)
1030990	Others (2)	(+)
1040000	Honey and other apiculture products (7)	
1050000	Amphibians and Reptiles	
1060000	Terrestrial invertebrate animals	
1070000	Wild terrestrial vertebrate animals	
1100000	PRODUCTS OF ANIMAL ORIGIN - FISH, FISHPRODUCTS AND ANY OTHER MARINE AND FRESHWATER FOOD PRODUCTS (8)	
1200000	PRODUCTS OR PART OF PRODUCTS EXCLUSIVELY USED FOR ANIMAL FEED PRODUCTION (8)	
1300000	PROCESSED FOOD PRODUCTS (9)	

(*) Indicates lower limit of analytical determination

(^e) For the complete list of products of plant and animal origin to which MRL's apply, reference should be made to Annex I

Folpet (sum of folpet and phtalimide, expressed as folpet) (R)

The European Food Safety Authority identified some information on residue trials as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 6 February 2018, or, if that information is not submitted by that date, the lack of it.

0152000 (b) strawberries

The European Food Safety Authority identified some information on analytical methods and storage stability as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 6 February 2018, or, if that information is not submitted by that date, the lack of it.

0161030 Table olives

0402010 Olives for oil production

The European Food Safety Authority identified some information on residue trials and analytical methods as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 6 February 2018, or, if that information is not submitted by that date, the lack of it.

0211000 (a) potatoes

0231010 Tomatoes

0233010 Melons

0500090 Wheat

The European Food Safety Authority identified some information on analytical methods as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 6 February 2018, or, if that information is not submitted by that date, the lack of it.

0213080 Radishes

0213090 Salsifies

0700000 HOPS

The European Food Safety Authority identified some information on the nature and magnitude of residues as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 6 February 2018, or, if that information is not submitted by that date, the lack of it.

1016010 Muscle

1016020 Fat

1016030 Liver

1030000 Birds eggs

1030010 Chicken

1030020 Duck

1030030 Geese

1030040 Quail

1030990 Others (2)

DECISIONS

COUNCIL DECISION (EU) 2023/1043

of 22 May 2023

establishing the position to be adopted on behalf of the European Union within the Committee on Trade in Civil Aircraft on the accession of Brazil to the Agreement on Trade in Civil Aircraft

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 207(4), first subparagraph, in conjunction with Article 218(9) thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) The Agreement on Trade in Civil Aircraft ⁽¹⁾ (the 'Agreement') was concluded by the Union by Council Decision 80/271/EEC ⁽²⁾ and entered into force on 1 January 1980.
- (2) Brazil submitted its application to the Committee on Trade in Civil Aircraft (the 'Committee') for accession to the Agreement, together with its proposed tariff commitments, on 14 June 2022.
- (3) In view of those commitments, Brazil's application for accession to the Agreement meets the requirements set out therein.
- (4) Brazil's accession to the Agreement is expected to make a positive contribution to free and undistorted trade in the civil aircraft sector.
- (5) Pursuant to Article 9.1.3 of the Agreement and point 5 of the Guidance Note on the Implementation of Article 9.1.3 of the Agreement, the Committee has the power to take a decision agreeing to the terms of accession and to give its consent to the applicant government to deposit with the Director-General of the WTO an instrument of accession, which states the terms so agreed.
- (6) It is therefore appropriate to establish the position to be adopted on the Union's behalf within the Committee in relation to the accession of Brazil to the Agreement,

HAS ADOPTED THIS DECISION:

Article 1

The position to be adopted on the Union's behalf within the Committee on Trade in Civil Aircraft shall be to approve the accession of Brazil to the Agreement on Trade in Civil Aircraft.

Article 2

This Decision shall enter into force on the date of its adoption.

⁽¹⁾ OJ L 71, 17.3.1980, p. 58.

⁽²⁾ Council Decision 80/271/EEC of 10 December 1979 concerning the conclusion of the Multilateral Agreements resulting from the 1973 to 1979 trade negotiations (OJ L 71, 17.3.1980, p. 1).

Done at Brussels, 22 May 2023.

For the Council
The President
E. BUSCH

ACTS ADOPTED BY BODIES CREATED BY INTERNATIONAL AGREEMENTS

**Decision No 2536/2023 of the Joint Sectoral Committee established under Article 14 of the United States – European Union amended Sectoral Annex for pharmaceutical good manufacturing practices (GMPs) (the ‘Annex’) on including veterinary products within the product coverage of the Annex
of 11 May 2023 [2023/1044]**

THE JOINT SECTORAL COMMITTEE,

Whereas Article 20 of the Annex requires the Joint Sectoral Committee to consider whether to include veterinary products within the product coverage of the Annex,

Whereas the Joint Sectoral Committee has duly considered to include veterinary products, as defined in Appendix 3, paragraph 6, within the product coverage of the Annex,

Taking into account that Article 4(2) of the Annex expressly excludes veterinary immunologicals from the product coverage of the Annex,

Recognizing that any decision to include veterinary products within the product coverage of the Annex can be implemented only after successful mutual assessments of each Party's authorities in accordance with Article 5 and Appendix 4 of the Annex,

Recognizing that to this end the Parties have agreed that each Party will complete the assessment of the other party regulatory authorities as set out in Attachment A to this Decision,

Recognizing that the Food and Drug Administration ('FDA') has completed the assessment of 14 authorities of the Member States of the European Union ('EU') competent for veterinary products (of which five are competent for veterinary products only, and considering that at least one capability assessment of those five authorities of the EU Member States, is favorable) in accordance with paragraph II.A of Appendix 4,

Recognizing that the EU has completed the assessment of the FDA in accordance with paragraph II.B of Appendix 4,

Recognizing that the FDA addressed the outstanding observations resulting from the audit in accordance with paragraph II.B (i) of Appendix 4,

Recognizing that FDA has already satisfied paragraph II.B (ii) of Appendix 4 as part of the EU's assessment of the FDA for human pharmaceuticals.

Confirming that Article 9 of the Annex does not apply to veterinary products, *mutatis mutandis*, until the date on which all authorities of the Member States of the EU competent for veterinary products listed in Appendix 2 have been recognized by the FDA,

Considering that the List of Authorities in Appendix 2 of the Annex need to be updated,

HAS DECIDED AS FOLLOWS:

1. Veterinary products, as defined in Appendix 3, paragraph 6, are included within the product coverage of the Annex.

FDA shall complete the capability assessment of the authorities of all the Member States of the EU according to Attachment A to this Decision,

FDA has addressed the outstanding observations resulting from the audit in accordance with paragraph II.B (i) of Appendix 4.

Article 9 of the Annex will apply to veterinary products on the date on which all EU Member State authorities competent for veterinary products listed in Appendix 2, have been recognized by the FDA.

2. The text of Appendix 2 of the Annex is replaced with the text of the Appendix 2 in Attachment B to this Decision.

Attachment A: Schedule for Assessment of Member State Authorities for Veterinary Products

Attachment B: Appendix 2 List of Authorities

This Decision, done in duplicate, shall be signed by the co-chairs of the Joint Sectoral Committee as referred to in Article 14(2) of the Annex. This Decision shall be effective from the date of the later of these signatures.

On behalf of the United States of America

Mark ABDON

Signed in Silver Spring, MD, on 5 May 2023

On behalf of the European Union

Sylvain GIRAUD

Signed in Brussels, on 11 May 2023

ATTACHMENT A

Schedule for Assessment of Member State Authorities for Veterinary Products

1. Member States authorities for veterinary products listed in Appendix 2 of the Annex shall submit complete capability assessment packages containing the information specified in Appendix 4 of the Annex according to the following schedule:
 - No later than 1 December 2022: capability assessment packages from nineteen Member States authorities;
 - No later than 1 June 2023: capability assessment packages from four additional Member States authorities;
 - No later than 1 December 2023: capability assessment packages from four additional Member State authorities;
 - No later than 1 February 2024: any remaining capability assessment packages (due to FDA's determination that a full capability assessment is needed for a dual human and veterinary competence authority of a Member State)
 2. The FDA shall complete the capability assessments of Member States authorities for veterinary products listed in Appendix 2 of the Annex and as set out in Appendix 4 of the Annex, according to the following schedule, provided that the FDA receives complete capability assessment packages for such authorities containing the information specified in Appendix 4 of the Annex according to the schedule set out in paragraph 1:
 - 31 December 2022: seventeen capability assessments
 - 31 December 2023: five additional capability assessments
 - 31 July 2024: five additional capability assessments
 3. For each Member State authority:
 - (a) The EU shall submit a final audit report to the FDA no later than 60 days before the due date of the capability assessment package for the Member State authority.
 - (b) The FDA shall provide a finalized capability assessment package checklist to the Member State authority no later than 20 days after the FDA receives the audit report.
 - (c) The Member State authority shall submit the capability assessment package to FDA no later than 40 days after that Member State authority receives the capability assessment package checklist.
 4. The deadline for delivering capability assessment packages will be automatically extended by 3 months, if these cannot be completed in time due to repercussions of measures related to the COVID-19 pandemic or similar disruptive event, such as travel restrictions, quarantine measures, sick leaves and resource shortages arising thereof. The EU shall inform the FDA in a timely manner of relevant delays and shall propose an updated timeline for agreement in the Joint Sectoral Committee.
 5. The communication of the recognition of Member States authorities assessed shall be done promptly following the conclusion of the capability assessment (on a rolling basis) and in line with Article 7 of the Annex.
-

ATTACHMENT B

Appendix 2 List of Authorities

United States:

The Food and Drug Administration

European Union:

Country	For medicinal products for human use	For veterinary medicinal products
Austria	Austrian Agency for Health and Food Safety / <i>Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH</i>	See responsible authority for medicinal products for human use
Belgium	Federal Agency for Medicines and Health Products – FAMHP / <i>Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten – FAGG / Agence fédérale des médicaments et des produits de santé – AFMPS</i>	See responsible authority for medicinal products for human use
Bulgaria	Bulgarian Drug Agency / <i>Изпълнителна агенция по лекарствата</i>	Bulgarian Food Safety Agency / <i>Българска агенция по безопасност на храните</i>
Croatia	Agency for Medicinal Products and Medical Devices / <i>Agencija za lijekove i medicinske proizvode (HALMED)</i>	Agency for Medicinal Products and Medical Devices / <i>Agencija za lijekove i medicinske proizvode (HALMED)</i> Ministry of Agriculture, Veterinary and Food Safety Directorate / <i>Ministarstvo poljoprivrede, Uprava za veterinarstvo i sigurnost hrane</i>
Cyprus	Ministry of Health – Pharmaceutical Services / <i>Φαρμακευτικές Υπηρεσίες, Υπουργείο Υγείας</i>	Ministry of Agriculture, Rural Development and Environment – Veterinary Services / <i>Υπουργείο Γεωργίας, Αγροτικής Ανάπτυξης και Περιβάλλοντος – Κτηνιατρικές Υπηρεσίες</i>
Czechia	State Institute for Drug Control / <i>Státní ústav pro kontrolu léčiv (SÚKL)</i>	Institute for State Control of Veterinary Biologicals and Medicines / <i>Ústav pro státní kontrolu veterinárních biopreparátů a léčiv (ÚSKVBL)</i>
Denmark	Danish Medicines Agency / <i>Lægemiddelstyrelsen</i>	See responsible authority for medicinal products for human use
Estonia	State Agency of Medicines / <i>Ravimiamet</i>	See responsible authority for medicinal products for human use
Finland	Finnish Medicines Agency / <i>Lääkealan turvallisuus- ja kehittämiskeskus (FIMEA)</i>	See responsible authority for medicinal products for human use
France	French National Agency for Medicines and Health Products Safety / <i>Agence nationale de sécurité du médicament et des produits de santé (ANSM)</i>	French agency for food, environmental and occupational health safety – French Agency for Veterinary Medicinal Products / <i>Agence Nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail – Agence Nationale du Médicament Vétérinaire (Anses-ANMV)</i>

Country	For medicinal products for human use	For veterinary medicinal products
Germany	Federal Institute for Drugs and Medical Devices / <i>Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)</i> Paul-Ehrlich-Institute (PEI), Federal Institute for Vaccines and Biomedicines / <i>Paul-Ehrlich-Institut (PEI)</i> <i>Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel</i> Federal Ministry of Health / <i>Bundesministerium für Gesundheit (BMG)</i> Central Authority of the Länder for Health Protection with regard to Medicinal Products and Medical Devices / <i>Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG ⁽¹⁾)</i>	Federal Office for Consumer Protection and Food Safety / <i>Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)</i> Federal Ministry of Food and Agriculture / <i>Bundesministerium für Ernährung und Landwirtschaft</i>
Greece	National Organisation for Medicines / <i>Ethnikos Organismos Farmakon (EOF) – (Εθνικός Οργανισμός Φαρμάκων)</i>	See responsible authority for medicinal products for human use
Hungary	National Institute of Pharmacy and Nutrition / <i>Országos Gyógyszerészeti és Élelmezés-egészségügyi Intézet</i>	National Food Chain Safety Office, Directorate of Veterinary Medicinal Products / <i>Nemzeti Élelmiszerlánc-biztonsági Hivatal, Állatgyógyászati Termékek Igazgatósága (ÁTI)</i>
Ireland	Health Products Regulatory Authority (HPRA)	See responsible authority for medicinal products for human use
Italy	Italian Medicines Agency / <i>Agenzia Italiana del Farmaco</i>	Ministry of Health, Direction General for Animal Health and Veterinary Medicinal Products / <i>Ministero della Salute, Direzione Generale della Sanità Animale e dei Farmaci Veterinari</i>
Latvia	State Agency of Medicines / <i>Zāļu valsts aģentūra</i>	Food and Veterinary Service / <i>Pārtikas un veterinārais dienests</i>
Lithuania	State Medicines Control Agency / <i>Valstybinė vaistų kontrolės tarnyba</i>	State Food and Veterinary Service / <i>Valstybinė maisto ir veterinarijos tarnyba</i>
Luxembourg	Ministry of Health, Division of Pharmacy and Medicines / <i>Ministère de la Santé, Division de la Pharmacie et des Médicaments</i>	See responsible authority for medicinal products for human use
Malta	Malta Medicines Authority (MMA)	The Animal Health and Welfare Department (AHWD)
Netherlands	Healthcare and Youth Care Inspectorate, Ministry of Health, Welfare and Sport / <i>Inspectie Gezondheidszorg en Jeugd (IGJ), Ministerie van Volksgezondheid, Welzijn en Sport</i>	Medicines Evaluation Board (MEB) / <i>College ter Beoordeling van Geneesmiddelen (CBG)</i> Veterinary Medicinal Products Unit / <i>Bureau Diergeneesmiddelen</i>
Poland	Chief Pharmaceutical Inspectorate / <i>Główny Inspektorat Farmaceutyczny (GIF)</i>	See responsible authority for medicinal products for human use

Country	For medicinal products for human use	For veterinary medicinal products
Portugal	National Authority of Medicines and Health Products / <i>INFARMED, I.P. Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.</i>	General Directorate of Food and Veterinary / <i>Direção-Geral de Alimentação e Veterinária (DGAV)</i>
Romania	National Agency for Medicines and Medical Devices of Romania / <i>Agenția Națională a Medicamentului și a Dispozitivelor Medicale din România</i>	National Sanitary Veterinary and Food Safety Authority / <i>Autoritatea Națională Sanitară Veterinară și pentru Siguranța Alimentelor</i>
Slovakia	State Institute for Drug Control / <i>Štátny ústav pre kontrolu liečiv (ŠÚKL)</i>	Institute for State Control of Veterinary Biologicals and Medicaments / <i>Ústav štátnej kontroly veterinárnych biopreparátov a liečiv (USKVBL)</i>
Slovenia	Agency for Medicinal Products and Medical Devices of the Republic of Slovenia / <i>Javna agencija Republike Slovenije za zdravila in medicinske pripomočke (JAZMP)</i>	See responsible authority for medicinal products for human use
Spain	Spanish Agency of Medicines and Medical Devices / <i>Agencia Española de Medicamentos y Productos Sanitarios</i> ⁽²⁾	See responsible authority for medicinal products for human use
Sweden	Swedish Medical Product Agency / <i>Läkemedelsverket</i>	See responsible authority for medicinal products for human use

⁽¹⁾ For the purpose of this Annex, and without prejudice to the internal division of competence in Germany on matters falling within the scope of this Annex, ZLG shall be understood as coordinating authority for all competent Länder authorities issuing GMP documents and conducting pharmaceutical inspections.

⁽²⁾ For the purpose of this Annex, and without prejudice to the internal division of competence in Spain on matters falling within the scope of this Annex, Agencia Española de Medicamentos y Productos Sanitarios shall be understood as covering all the competent regional authorities issuing GMP documents and conducting pharmaceutical inspections.

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