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| **Country**: | **Montenegro** | **Date of completion of form by competent authority** | 15/04/2024 |

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| 1. **General information on the competent authority/authorities responsible for residues controls in all commodities included in the national residue control plan** |

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| * 1. **Contact Details:** Provide name and address of the central competent authority (or authorities) and details of the contact point for correspondence on the control plan for residues of pharmacologically active substances, pesticides and contaminants (e-mail addresses, phone details etc.).   [Legal basis: Annex I, Part II, point B(1) in conjunction with Article 2(34) of Regulation (EU) 2022/2292] | Administration for food safety, veterinary and phytosanitary affaires (hereinafter the Administartion)  a: Serdara Jola Piletića 26, 81000 Podgorica, Montenegro  w: www.ubh.gov.me  p: + 382 20 201 945  Jelena Vračar Filipović  Head of Unit  e: jelena.vracar@ubh.gov.me |
| * 1. Describe the **structure of the competent authority** e.g. the levels involved (central, regional, local etc.). If different competent authorities are involved for different commodities, data on their structure should be provided separately.   [Legal basis: Annex I, Part II, point B(2) of Regulation (EU) 2022/2292] | Ministry of Agriculture, Forestry and Water Management adopts the National Residue Monitoring Plan (hereinafter the Plan). The Administration is the competent authority for drawing up the Plan and implementation of the sampling and for the corrective/follow up measures.  Veterinary inspection organised as Unit within the Department for veterinary affairs in the Administration (inspectors are located in different municipalities, but centrally coordinated) carries out sampling and sample dispatch to the laboratory, as well as undertaking the measures in case of non-compliant results. |
| * 1. Describe how **the central competent authority**:   • draws up the control plan for residues of pharmacologically active substances, pesticides and contaminants;  • coordinates and supervises residue control activities at different levels in the competent authority (central, local, regional etc.);  • collects and evaluates the results of residue testing to determine whether sampling has been carried out in accordance with the plan and whether the results demonstrate any trends which would influence the design of future control plans;  • takes corrective measures where required; and  • ensures the submission of annual data to the Commission.  [Legal basis: Annex I, Part II, point B(3) of Regulation (EU) 2022/2292] | Head of the Department for veterinary affairs in the Administration coordinates and supervises residue control activities (in cooperation with the Unit for veterinary profession, veterinary medicines and control of veterinary residues).  Coordination is managed from the central level. Deputy director for veterinary issues is responsible for coordination and supervision of veterinary inspectors. Inspectors involved in sampling receive monthly sampling orders from the Unit responsible for residue monitoring at the central level and send back a copy of each sampling report. Laboratory sends each two weeks report (excel table) to the Unit for residue monitoring on samples received, samples in the process and finalised analysis. Data from laboratory and data from the sampling reports are all recorded and stored in the master excel file, with all information on the sampling and analysis. This file is used to supervise and monitor execution of the sampling.  Unit for veterinary profession, veterinary medicines and control of veterinary residues within the Department for veterinary affairs in the Administration draws up, coordinates, collects and evaluates the results the control plan and ensures the submission of annual data to the Commission (cooperation with the official laboratory).  The plan is based on:  - the data on production and annual distribution,  - availability of validated method in the country,  - medicine authorisations (permits for import) and consumption,  - the data collected through official controls and monitoring,  - data from the EFSA annual reports, neighbouring countries, RASFF reports and EC notifications,  - financial and human resources.  Veterinary inspection organised as Unit within the Department for veterinary affairs in the Administration (inspectors are located in different municipalities but centrally coordinated) carries out sampling and sample dispatch to the laboratory, as well as undertaking the measures in case of non-compliant results. Inspectors involved in sampling are responsible to take corrective measures stipulated in legislation and in accordance with guidelines from the veterinary profession, veterinary medicines and control of veterinary residues. |
| * 1. Please indicate **which services/personnel** are involved in **official sampling.**   Is sampling only carried out by officials or are third parties involved? If third parties are involved, please provide details of what they do and their relationship with the competent authorities.  [Legal basis: Annex I, Part II, point B(3) of Regulation (EU) 2022/2292 and Article 1(1) of Regulation (EU) 2022/1644] | The sampling is only carried out by officials (veterinary inspectors). |

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| 1. **The control plan(s) for residues of pharmacologically active substances, pesticides and contaminants** |

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| * 1. Please indicate the commodities for which your country is currently listed in Annex -I to Regulation (EU) 2021/405, and for which you have submitted residue control plans for **this year**. | |  |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | Bovine | Ovine | Caprine | Porcine | Equine | Poultry | Aquaculture (finfish, including eels, crustaceans and other aquaculture products, such as roes and caviar) [Specify which] | Raw bovine, ovine and caprine milk | Hen eggs and other eggs | Rabbits and farmed game [Specify which] | Honey | Casings | Wild game | |  |  |  |  |  |  |  |  |  |  |  |  |  |   . |
| * 1. Please indicate the commodities for which your country **is currently listed** in Annex -I to Regulation (EU) 2021/405, and for which you have submitted residues testing **results for last year.** | |  |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | Bovine | Ovine | Caprine | Porcine | Equine | Poultry | Aquaculture (finfish, including eels, crustaceans and other aquaculture products, such as roes and caviar) [Specify which] | Raw bovine, ovine and caprine milk | Hen eggs and other eggs | Rabbits and farmed game [Specify which] | Honey | Casings | Wild game | |  |  |  |  |  |  |  |  |  |  |  |  |  | |
| * 1. Please indicate any **new** commodities (1) for which your country is **not currently listed in** Annex -I to Regulation (EU) 2021/405, **but for which you wish to request listing**, and for which you have submitted residue control **plans for this year**. | |  |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | Bovine | Ovine | Caprine | Porcine | Equine | Poultry | Aquaculture (finfish, including eels, crustaceans and other aquaculture products, such as roes and caviar) [Specify which] | Raw bovine, ovine and caprine milk | Hen eggs and other eggs | Rabbits and farmed game [Specify which] | Honey | Casings | Wild game | |  |  |  |  |  |  |  |  |  |  |  |  |  | |
| * 1. Please indicate **any new commodities (**[[1]](#footnote-2)**)** for which your country is **not currently listed in** Annex -I to Regulation (EU) 2021/405, **but for which you wish to request listing**, **and** for which you have (already) submitted **results of residues testing for the last year.** | |  |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | Bovine | Ovine | Caprine | Porcine | Equine | Poultry | Aquaculture (finfish, including eels, crustaceans and other aquaculture products, such as roes and caviar) [Specify which] | Raw bovine, ovine and caprine milk | Hen eggs and other eggs | Rabbits and farmed game [Specify which] | Honey | Casings | Wild game | |  |  |  |  |  |  |  |  |  |  |  |  |  | |

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| * 1. Describe the **legal basis for the control plan** **for residues of pharmacologically active substances, pesticides and contaminants**. Please include details of the legislation giving the competent authority the right to: * enter farms; * take samples; and * take action in the event of a non-compliant result, (such as destruction of animals, imposition of fines etc.).   Please quote the articles in the national legislation that confer these powers.  [Legal basis: Annex I, Part II, point B(4) of Regulation (EU) 2022/2292] | Legal basis for the right to enter the farm, take samples and actions in the event of non-compliant result is laid out in:  - Veterinary Law (OJ MN No. 30/12, 48/15 52/16), Articles 91, 92, 93, 94, 95 and 96;  - Rulebook on residue monitoring in animals and food of animal origin (OJ MN 3/17), harmonised completely with Council Directive 96/23/EC and Commission Decision 97/747/EC. |
| * 1. In relation to the control plan for **pharmacologically active substances (Group A and Group B)**, please state whether the plan is entirely **based on Commission Implementing Regulation (EU) 2022/1646** and **Commission Delegated Regulation (EU) 2022/1644**, *or* on an **equivalent standard** (e.g. Codex Alimentarius guidelines [CAC/GL 71-2009](http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXG%2B71-2009%252FCXG_071e_2014.pdf))   [Legal basis: Article 6(1) of Regulation (EU) 2022/2292]  If the control plan is **not** entirely based on the relevant EU legislation, please describe the **general design principles** (e.g. section 7 of CAC/GL 71-2009), in particular:   1. If the sampling plan is part of a combined system of inspections, provide information on the residue-related control points covered by these inspections (e.g. verification of compliance with applicable rules on authorisation, distribution, use, labelling of veterinary medicinal products – see 5.1 to 6.1) and on how such inspections contribute to the overall verification programme. 2. Identify the population being sampled (i.e. **all national production** *or* a **segregated** EU-eligible population - see questions 2.7 and 2.8). 3. Whenever sampling is **targeted** (i.e. directed) on animals or products from those production sectors in which the use of certain pharmacologically active substances is most likely, please provide the procedures/instructions given to sampling staff to allow them to target samples (e.g. sampling criteria, sources of information); 4. Whenever sampling is **non-biased** (i.e. random), provide a brief description of the statistics used for deciding the number of samples to be taken. | The Plan is entirely based on Commission Implementing Regulation 2022/1644 and Commission Delegated Regulation 2022/1644. |
| * 1. Please provide **national production data** for those animal species (and production classes) and products covered by the control plan for pharmacologically active substances, which are listed (or which you wish to have listed) in Annex -I to Regulation (EU) 2021/405.   *It is recommended that you use the Microsoft Excel templates from Section 4.4. of the following document (available* [*here*](https://food.ec.europa.eu/document/download/a2661e60-c1cc-4b0f-98bc-ee5edcf17c9c_en)*) to record the data referred to above.*  [Legal basis: Annex I, Part II, point A(3) of Regulation (EU) 2022/2292] | National production data used for the Plan preparation are mostly taken are from the Statistical office of Montenegro (MONSTAT), Statistical Yearbook of Montenegro 2022: http://monstat.org/eng/publikacije\_page.php?id=1674&pageid=1 (chapter 12 Agriculture) and in case of Caprine, Poultry and Casings in-house Administration data are used.  Please see the *Microsoft Excel template attached for details.* |
| * 1. In relation to the control plan for **pharmacologically active substances (Group A and Group B)**, please indicate for each commodity **whether** the plan covers either;      1. the **total** national animal population or production. *(This is required if* ***all animals or commodities*** *are eligible for export to the EU) or;*      2. ***only* the production chain for EU export.** (*This is called a* ***segregated production system*** *i.e. the animals or commodities are produced within a segregated system and* ***only these*** *animals /commodities are eligible for export to the EU)*   [Legal basis: Annex I, Part II, point A(4) of Regulation (EU) 2022/2292]  **Whenever your control plan is based on a segregated production system** (Option b) please provide **the EU-eligible production volumes (the number of animals slaughtered or the production volume in tonnes)** for each of those commodities(*i.e. the throughput of all of the EU-approved establishments or the total annual production of all of those farms whose production is eligible for export to the EU, regardless of the final destination of the products (domestic market, export to the EU or to other third countries).*  *When drawing up your control plan it is strongly recommended to use the Microsoft Excel templates from* *Section 4.4. of the following document (available* [*here*](https://food.ec.europa.eu/document/download/a2661e60-c1cc-4b0f-98bc-ee5edcf17c9c_en)*). The numbers of samples to be taken for each of the relevant subgroups of substances are automatically calculated in this Excel file, which facilitates the verification of compliance with the sampling rates laid down in Commission Implementing Regulation (EU) 2022/1646.* | For each commodity the Plan covers the total number of animal/ product production. |
| * 1. **In relation to the control plan for residues of pharmacologically active substances included in Group A:**  1. Please specify whether all of the relevant **Group A** substance groups and subgroups (as listed in Annex I to Regulation (EU) 2022/1644) are included in the plan for each of the relevant commodities (see Annex II to Regulation (EU) 2022/1644).   *Note that a minimum of 5% of the total sample number for Group A substances must be allocated to each substance group required for each of the commodities covered by the plan and the balance must be allocated based on the competent authority’s risk assessment.*   1. Please explain on what basis (e.g. risk profiling) the balance of samples has been allocated to the Group A sub-groups. 2. Please provide a written justification for the selection of the analytes included in each of the Group A sub-groups.   Please note that your approach should be **justified** **with a brief description** of the elements supporting your decisions.  [Legal basis: Annex I, Part II, points C(2)(a), C(3), C(4) and C(5) of Regulation (EU) 2022/2292] | All groups of substances A have been included for commodities for poultry.  Group A3b bovine, ovine/caprine and honey was not included, only amitraz but in B1b. This year we will cover only pesticides and commodities indicated in the Commission Implementing Regulation (EU) 2024/989 of 2 April 2024 concerning a coordinated multiannual control programme of the Union for 2025, 2026 and 2027 to ensure compliance with maximum residue levels of pesticides and to assess the consumer exposure to pesticide residues in and on food of plant and animal origin and repealing Implementing Regulation (EU) 2023/731- commodities included for 2024 bovine fat and eggs.  A2d group was not included for aquaculture, milk, casing and honey (national laboratory does not have validated method, neither subcontracted laboratory and there was no risk-based justification);  A3f groups were not included for honey (national laboratory does not have validated method, neither subcontracted laboratory and there was no risk-based justification).  Porcine, other milk and eggs: due to low production, number of samples is less than five and these commodities will be sampled in the next consecutive year (one per two years).  Allocation of number of samples was made in accordance with previous non compliances found (monitoring, border and other official sampling), information on substances (medicines) imported and sold at national level, status of validation of the laboratory method, cooperation and data exchange with neighbouring countries, RASFF notifications and import data, the balance of non-complainant results in EFSA's reports (2022), scientific studies and studies conducted at national level (e.g. use of antimicrobials in livestock in Montenegro). |
| * 1. In relation to the **control plan for residues of pharmacologically active substances included in Group B:**   (a) Please indicate which **Group B** sub-groups (as listed in Annex I to Regulation (EU) 2022/1644) are included in the plan for each of the relevant commodities.  (b) Please **explain** on what basis (e.g. risk profiling) the balance of samples has been allocated to the Group B sub-groups.  (c) Please provide a written justification for the selection of the analytes included in each of the Group B sub-groups.  Please note that your approach should be **justified with a brief description** of the elements supporting your conclusions (e.g., data on the use and use patterns of veterinary medicinal products in the relevant production sector, the risk to consumers of violative residues in food, results of any surveillance studies performed).  [Legal basis: Annex I, Part II, points C(2)(b) C(3), C(4) and C(5) of Regulation (EU) 2022/2292] | Bovine: groups B1c and B1e were not included.  All substances that are present on the market (imported and sold) and for which laboratory has a method for detection have been included in B groups, and there was no risk-based justification for groups B1c and B1e.  Majority of samples have been allocated to groups B1a, B1b and B1d, as these are the substances mostly sold and used by veterinarians, while group B1a poses additional risk for AMR. Other information used: previous non compliances found (monitoring, border and other official sampling), information on substances (medicines) imported and sold at national level, status of validation of the laboratory method, cooperation and data exchange with neighbouring countries, RASFF notifications and import data, the balance of non-complainant results in EFSA's reports (2022), scientific studies and studies conducted at national level (e.g. use of antimicrobials in livestock in Montenegro).  Ovine and caprine: groups B1c, B1e, B2 were not included.  For B1c and B1e the same justification as for Bovine.  For B2 all relevant substances present on the market (imported and sold) and for which laboratory has a method for detection have been included.  Justification on allocation and selection the same as for Bovine  Poultry: groups B1c and B1e were not included.  The same justification as for Bovine.  Aquaculture: groups B1c, B1d, B1e, B2 were not included.  For B1c and B1e the same justification as for Bovine.  For B1d, and B2 all relevant substances present on the market (imported and sold) and for which laboratory has a method for detection have been included.  Justification on allocation and selection the same as for Bovine  Milk: groups B1c and B1e were not included. All substances that are present on the market (imported and sold) and for which laboratory has a method for detection have been included in B group, and there was no risk-based justification for B1c and B1e.  Majority of planed programme samples have been allocated for bovine milk, due to importance and significance of milk production and milk products for agriculture in Montenegro, and the largest number for antibiotics, due to presence of certain production diseases (mastitis) and risk of AMR.  Honey: all samples have been allocated to the group 1Bd (amitraz and coumafos), as these are the only substances imported and sold for bees.  Porcine, other milk and eggs: due to low production, number of samples is less than five and these commodities will be sampled in the next consecutive year (one per two years). |
| * 1. In relation to the **control plan for residues of pharmacologically active substances (Group A and Group B)**, please provide: * the name of each **analyte tested for**, * the **matrices tested** (i.e. for Group B substances, edible animal tissues such as muscle, liver and kidney, edible products such as milk, eggs or honey, or, for Group A substances, fluids of excretion such as urine, bile or faeces or inedible materials such as hair), * the **screening** and **confirmatory analytical methods** used (e.g. ELISA, HPLC-UV, LC-MS/MS etc), * their **validation** status, * the **limit of detection** (in µg/kg) for the **screening** method (if used), * the **limit of detection** (in µg/kg) for the **confirmatory** method, * the national tolerance or Maximum Residue Limit (MRL) (if established) (in µg/kg) for the edible matrix tested (note that MRLs only apply to edible tissues), * the corresponding EU MRL (in µg/kg) for the edible matrix tested (see the Annex to Regulation (EU) No 37/2010 for the list of EU MRLs for residues of **pharmacologically active substances**, and [Regulation (EC) No 124/2009](https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1585551546057&uri=CELEX:32009R0124) for the MRLs for **coccidiostats in non-target species** due to carry over in feed), * the **level of action** (concentration above which a result is deemed to be non-compliant) in µg/kg, * **The name of the laboratory carrying out the testing.**   *Use of the Microsoft Excel templates from* *Section 4.4. of the following document (available* [*here*](https://food.ec.europa.eu/document/download/a2661e60-c1cc-4b0f-98bc-ee5edcf17c9c_en)*) will facilitate the recording of the data referred to above and the Commission services’ assessment of these data.*  [Legal basis: Annex I, Part II, point C of Regulation (EU) 2022/2292,] | Please see the *Microsoft Excel template attached for details.* |
| * 1. In relation to the control plan for **pesticide residues**, please describe the basis for: * the determination of sample numbers; and * the selection of analytes   [Legal basis: Article 11 of Regulation (EU) 2022/2292, Annex I, Part II, point D thereof, and Regulation 2021/1355] | This year we will cover only pesticides and commodities indicated in the Commission Implementing Regulation (EU) 2024/989 of 2 April 2024 concerning a coordinated multiannual control programme of the Union for 2025, 2026 and 2027 to ensure compliance with maximum residue levels of pesticides and to assess the consumer exposure to pesticide residues in and on food of plant and animal origin and repealing Implementing Regulation (EU) 2023/731- commodities included for 2024 bovine fat and eggs. |
| * 1. In relation to the control plan for **pesticide residues**, please provide * the name of each pesticide tested for, * the edible animal **matrices tested** (i.e. animal tissues such as muscle, liver and kidney, edible products such as milk, eggs or honey), * the **screening** and/or **confirmatory analytical methods** used (e.g. GC-MS etc), * their **validation** status, * the **limit of detection** (in µg/kg) for the **screening** method (if used), * the **limit of detection** (in µg/kg) for the **confirmatory** method, * the national tolerance or Maximum Residue Level (MRL) (if established) (in µg/kg) for the edible matrix tested (note that MRLs only apply to edible tissues), * the corresponding EU MRL (in µg/kg) for the edible matrix tested (see [Regulation (EC) No 396/2005](https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1585556189569&uri=CELEX:32005R0396) (please consult consolidated version) and the [Commission database](http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=homepage&language=EN), * the **level of action** (concentration above which a result is deemed to be non-compliant) in µg/kg. * The name of the laboratory carrying out the testing.   *Use of the Microsoft Excel templates from* *Section 4.4. of the following document (available* [*here*](https://food.ec.europa.eu/document/download/a2661e60-c1cc-4b0f-98bc-ee5edcf17c9c_en)*) will facilitate the recording of the data referred to above and the Commission services’ assessment of these data.*  [Legal basis: Article 11 of Regulation (EU) 2022/2292, Annex I, Part II, point D thereof, and Regulation 2021/1355] | Please see the *Microsoft Excel template attached for details.* |
| * 1. In relation to the control plan for **contaminants**, please describe the basis for: * the determination of sample **numbers**; and * the selection of **analytes**   [Legal basis: Article 12 of Regulation (EU) 2022/2292, Annex I, Part II, point E thereof, and Regulations (EU) 2022/931 and (EU) 2022/932] | Allocation of number of samples was made in accordance with previous non compliances found (monitoring, border and other official sampling), results from the environmental monitoring (air, soil, water), RASFF notifications and import data, the balance of non-complainant results in EFSA's reports (2022).  Porcine, poultry and aquaculture, eggs and honey: due to low production, number of samples is less than five and these commodities will be sampled in the next consecutive year (one per two years).  Bovine milk and other milk, due to previous non compliances will be sampled only for Aflatoxin M1. |
| * 1. In relation to the control plan for **contaminants**, please provide: * the name of each contaminant tested for (e.g. heavy metals, mycotoxins etc), * the edible animal **matrices tested** (i.e. animal tissues such as muscle, liver and kidney, edible products such as milk, eggs or honey), * the **screening** and/or **confirmatory analytical methods** used (e.g. GC-MS, ICP-MS etc), * the **limit of detection** (in mg/kg) for the **screening** method (if used), * the **limit of detection** (in mg/kg) for the **confirmatory** method, * the national tolerance or Maximum Limit (ML) (if established) (in mg/kg) for the edible matrix tested (note that MLs only apply to edible tissues), * the corresponding EU ML (in mg/kg) for the edible matrix tested (see [Regulation (EU) 2023/915](https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1585551701160&uri=CELEX:32006R1881) (please consult consolidated version), * the **level of action** (concentration above which a result is deemed to be non-compliant) in µg/kg, * The name of the laboratory carrying out the testing   *Use of the Microsoft Excel templates from* *Section 4.4. of the following document (available* [*here*](https://food.ec.europa.eu/document/download/a2661e60-c1cc-4b0f-98bc-ee5edcf17c9c_en)*) will facilitate the recording of the data referred to above and the Commission services’ assessment of these data.*  [Legal basis: Article 12 of Regulation (EU) 2022/2292, Annex I, Part II, point E thereof, and Regulations (EU) 2022/931 and (EU) 2022/932] | Please see the *Microsoft Excel template attached for details.* |
| * 1. If the Commission’s excel templates for **each of the above control plans** have not been used, please indicate whether there are any **national residue limits (levels or tolerances)** (for pharmacologically active substances, pesticides and environmental contaminants in edible animal tissues **that differ from EU limits/levels.** Please identify such cases and provide the list of those national residue limits.   [Legal basis: Annex I, Part II, point F(5)(f) of Regulation (EU) 2022/2292]  *Note: The applicable EU limits/levels may be downloaded from the following links to the latest consolidated versions published on the Commission’s EUR-LEX website* [*https://eur-lex.europa.eu/homepage.html*](https://eur-lex.europa.eu/homepage.html)*:*   * **pharmacologically active substances (veterinary medicinal products):** [Regulation (EU) No 37/2010](https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1585551408970&uri=CELEX:32010R0037) (please consult consolidated version) * **coccidiostat residues in non-target species** due to carry over in feed: [Regulation (EC) No 124/2009](https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1585551546057&uri=CELEX:32009R0124) (please consult consolidated version) * **pesticides**: [Regulation (EC) No 396/2005](https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1585556189569&uri=CELEX:32005R0396) (please consult consolidated version) and the [Commission database](http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=homepage&language=EN) * **contaminants**: [Regulation (EU) 2023/915](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L_.2023.119.01.0103.01.ENG&toc=OJ%3AL%3A2023%3A119%3ATOC) (please consult consolidated version) | There are no national residue limits that differ from EU limits/levels. |
| * 1. Whenever there are substances for which the **national tolerance limits** are **greater than the EU MRLs or MLs**, or **where there is no EU MRL established**, please confirm that:      1. **The competent authority has informed those food business operators who are eligible to export food to the EU** about those differences and that any detection of a residue above the EU MRLs/MLs (if applicable) at the EU border would result in rejection of the consignment;      2. In the event that testing carried out under the residue control plan identifies cases where an **EU MRL is exceeded, or there is no EU MRL** (but the result complies with a national MRL), that the competent authority informs the operator and that the operator takes the necessary steps to recall the animal product in question if it is intended for export to, or is in the process of being exported to the EU;      3. Farmers supplying animals (and/or, eggs, milk and honey) to food business operators intending to export food to the EU, have measures in place **to guarantee** that in respect of animal products intended for the EU market only: * Where there is **no EU MRL established** for a given pharmacologically active substance, and where nationally authorised veterinary medicinal products containing that substance have been used in animals, products from which are intended for the EU market, that no detectable residues of the substances in question are present in said product (see Art. 9 (2) of Reg. (EU) 2022/2292); * Where **EU MRLs are lower** than national MRLs for a given pharmacologically active substance, that the drug withholding period (drug withdrawal period) applied following the use of a nationally authorised veterinary medicinal product is extended to ensure that residues in edible tissues will comply with the lower EU MRL.   + 1. The competent authority is in a position to verify that farmers and food business operators satisfy the conditions in point c)   Please provide copies of any documents (e.g. instructions, guidance documents) in relation to the abovementioned. |  |
| * 1. If the Commission’s excel templates for submission of **any of the above control plans** have not been used, please specify, for those pharmacologically active substances which are either *unauthorised* for use in food-producing animals in your country or are *explicitly banned* from use in such animals in your country, what **levels of action** are applied (i.e. the concentration of a residue found which would result in regulatory and enforcement action being taken) and how these are established.   [Legal basis: Annex I, Part II, point F(5)(f) of Regulation (EU) 2022/2292]  *Note that in the EU so-called* ***Reference Points for Action*** *(RPAs) have been established for some 'banned' substances such as chloramphenicol, nitrofurans and malachite green. For other banned substances (e.g. nitroimidazoles), the ALARA principle applies (residue concentrations detected should be "As Low As Reasonably Achievable").* |  |
| * 1. Describe whether sampling is **targeted** **(directed)** or is **random** (see also Q 2.6.).   (Note: Targeted or directed sampling protocols are designed to place a greater intensity of inspection on suppliers or product considered to possibly have a greater potential than the general population of being non-compliant.)  [Legal basis: Article 9(1) of Regulation (EU) 2022/2292 and Annex III, point 3 of Regulation (EU) 2022/1644] | The sampling is targeted according to the criteria laid down in the national control plan, regulation and instructions for sampling.  For Group A substances, sampling is targeted at detection of illegal treatment with prohibited or unauthorised substances  For Group B substances, sampling is targeted on products from those animals, which are most likely to have been treated. |
| * 1. Is all sampling **unforeseen** (by the farmer or food business operator) and **unexpected** (i.e. effected at no fixed time and on no particular day of the week and at no fixed time of the year)?   Is sampling **evenly spread** throughout the year (unless there is seasonality in production)?  If prior notice of farmers and operators is given, please explain the reasons for this, how much time before the visit prior notice is given, if the purpose of this visit is indicated and why it is not possible to carry out sampling without prior notice.  [Legal basis: Article 9(1) of Regulation (EU) 2022/2292 and Annex III, point 1 of Regulation (EU) 2022/1644] | All sampling is unforeseen and unexpected. Sampling is spread throughout the year, respecting seasonality (honey) and patens of production and consumption for allocation of samples number, availability of validated methods. |

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| 1. **The previous year’s residue testing results** |

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| * 1. With regard to the results of the previous year’s residue testing, please explain any discrepancies in the number of samples planned versus the number of samples drawn and analysed.   [Legal basis: Annex I, Part III, point B of Regulation (EU) 2022/2292] | Sampling was implemented as planned: **YES**  **NO**  If **NO**, please explain:  Yes, except for casings.  5 samples of casing (to be analysed on chloramphenicol, nitrofurans and nitroimidazoles) were initially agreed to be sent to Croatian Veterinary Institute (CVI - who was subcontracting AGES - Austrian Agency for Health and Food Safety GmbH for nitrofurans and nitroimidazoles ),  However, beginning of 2024 CVI informed us that they no longer subcontracting AGES, and in order to avoid submission of samples to two different laboratories we decided to subcontract AGES directly for all substances and analyses. The dispatch of samples neither to CVI nor AGES can not be done by post services, as no such service offering submission with cold chain, instead it is transported by CETI.  The process of negotiation took some time and when all was agreed the ASF outbreak occurred in Montenegro and AGES informed us that they are not allowed to accept sample of casing taken from pig. We agreed to remove pig sample from consignment and agreed all procedure with AGES, but at the end, due to Croatian costume procedure, CETI vehicle with casing consignments was rejected to enter to Croatan at the border.  At the end we decided to subcontract and sent samples to the Institute of Meat Hygiene and Technology of Serbia – IMHT. The samples have been sent and we are waiting for analyses to be finished. Once we receive the result, we will communicate it to the Commition (by 26 April the latest).  One ovine sample for A1b Thyrostats was not taken and analysed, as it was not possible to collect urine from one animal (only lambs were slaughtered) in sufficient quantity for analyses. |
| * 1. In respect of the previous year’s non-compliant results, briefly describe: * **the outcome of the follow-up investigations undertaken by the competent authority; and** * **any measures taken to prevent recurrence and bring the operators in question back into compliance.**   [Legal basis: Annex I, Part III, point B of Regulation (EU) 2022/2292] | There were non-compliant results in the implementation of the previous year’s residue control plan: **YES**  **NO**  If **YES**, please complete the separate proforma – available here - <https://food.ec.europa.eu/document/download/2c938e3c-28a8-45aa-87b0-50dfaf417c2d_en> for each of the non-compliant results.  Please see the details attached in separate document. |

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| 1. **The laboratory network** |

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| * 1. Provide the **name(s) and address(es)** of **all laboratories** involved in official residue testing (including laboratories in foreign countries if certain analyses have been outsourced).   [Legal basis: Annex I, Part II, point F(1) of Regulation (EU) 2022/2292].  *The name of each laboratory should be listed in the various control plans for residues alongside each residue they are responsible for analysing. Use of the Microsoft Excel template in Section 4.4. of the following document (available* [*here*](https://food.ec.europa.eu/document/download/a2661e60-c1cc-4b0f-98bc-ee5edcf17c9c_en)*), will facilitate the recording of the data referred to above and the Commission services’ assessment of these data.*  **Please note that, where analyses are sub-contracted to another laboratory, details of the laboratory that actually carries out the analyses should be provided.** | Center for Ecotoxicological Research Podgorica (CETI), Bulevar Šarl de Gola 2, Podgorica Montenegro  CETI is laboratory in charge for screening analysis of samples of animal origin planned according to monitoring program of veterinary drug residues. For methods which are not validated/accredited CETI will contract Institute of Meat Hygiene and Technology of Serbia – IMHT and for confirmatory analysis of some suspicious and positive result.  Croatian Veterinary institute is sub-contracted for confirmatory analysis in case of any suspicious and positive result.  Croatian Veterinary institute, Savska cesta 143, P.O. Box 883, 10000 Zagreb, Croatia.  Institute of Meat Hygiene and Technology of Serbia – IMHT, Kaćanskog 13, 11000, Beograd, Serbia |
| * 1. For **each laboratory** carrying out analyses in the context of the control plans for residues, please indicate whether it is **accredited** to ISO/IEC 17025 and, if so, provide the name the accreditation body and the accreditation number of the laboratory.   For each laboratory carrying out testing in the context of the plan, please provide either a link to the **accreditation certificate** and the **scope** of accreditation, or a copy of these documents. *[Please note that only accredited laboratories may be used for residues testing].*  [Legal basis: Annex I, Part II, point F(2) of Regulation (EU) 2022/2292]. | All laboratories used for the residue control plan are accredited to ISO/IEC 17025: **YES**  **NO**  If this is NOT the case, please indicate which of them are not accredited. |
| * 1. For each laboratory please **confirm** whether or not each of the analytical methods used for the control plans for residues are included in the scope of accreditation to ISO/IEC 17025.   [Legal basis: Annex I, Part II, point F(3) of Regulation (EU) 2022/2292]. | Are the methods used in the residue control plan included in the scope of accreditation of each of the laboratories?   |  |  |  | | --- | --- | --- | | Name of laboratory A: | Center for Ecotoxicological Research Podgorica | YES  NO | | Name of laboratory B: | Croatian Veterinary Institut | YES  NO | | Name of laboratory C: | Institute of Meat Hygiene and Technology of Serbia – IMHT | YES  NO | | Name of laboratory D: |  | YES  NO | | Name of laboratory E: |  | YES  NO |   If the answer is no for one or more laboratories, please specify which methods of analysis are not included in the scope of accreditation.  Center for Ecotoxicological Research Podgorica is accredited under ISO/IEC 17025. Methods that CETI will perform in this monitoring are validated in agreement with EU Regulations 657/2002 and 808/2021, but not all of them are part of the scope of accreditation. |
| * 1. If the analytical methods are not included in the scope of accreditation, please confirm that they have been **validated** (i.e. are fit for purpose).   [Legal basis: Annex I, Part II, point F(4) of Regulation (EU) 2022/2292,].  *Note that validation requirements are described in Commission Implementing Regulation (EU) 2021/808, the Annex to Commission Regulation (EC) No 333/2007 and the Annex II to Commission Regulation (EC) No 401/2006; Commission Regulation (EU) 2017/644.*  *Alternative approaches to method validation are also described in Codex Alimentarius guidelines* [*CAC/GL 71-2009*](http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCAC%2BGL%2B71-2009%252FCXG_071e_2014.pdf) *and in the IUPAC Technical Report "Harmonized guidelines for single laboratory validation of methods of analysis". Pure Appl. Chem., Vol. 74, No. 5, pp. 835–855, 2002.* | All methods not included in the scope of accreditation of the laboratories (listed under point 4.3) are validated in accordance with EU validation requirements or equivalent: YES  NO  If some methods are not validated in some or all relevant matrices, please list them in a separate document, indicating the laboratory involved, the analyte, method, matrix and any deadlines set for the validation.  All methods that CETI will perform in this monitoring are validated. CETI will do only screening methods. In case of the positive or suspicious result CETI will send the samples to laboratory that has accredited/validated methods for confirmation. |

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| 1. **The authorisation and use of pharmacologically active and other substances in food-producing animals** |

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| * 1. Please provide a copy of and indicate the relevant articles of the **national legislation** governing (a) the **authorisation**, (b) **distribution**, (c) **placing on the market** (including specific requirements in place for the production of medicated feedingstuffs) and (d) the **use** of **veterinary medicinal products** in food-producing animals.   [Legal basis: Annex I, Part II, point G(1) of Regulation (EU) 2022/2292] | Legal framework governing the field of veterinary medicines: Law on medicines (OG MN 80/2020), Veterinary Law (OG MN 30/12, 48/15 and 52/16) and Law on Food Safety (OG MN 57/15).  Law on medicines is a framework law in the area of medicines. The law regulates the conditions for the manufacturing, placing on the market, distribution and testing of medicinal products for human use and veterinary use, measures for providing quality, safety and efficacy of medicinal products, competence of bodies in the field of medicinal products, as well as other relevant issues in this area. The law is harmonized with the Directive 2001/82/EC of the European Parliament and of the Council. Chapter IV of the law regulates Marketing Authorization for a medicinal product. Chapter VI regulates manufacturing and Chapter VII regulates marketing of medicinal products (distribution).  In accordance with the article 3 of the Law, only a medicinal product that have been granted marketing authorisation by the Institute for medicines and medical devices may be placed on the market and used in Montenegro. In accordance with article 5 of the Law, by way of exception from the Article 3, Institute for medicines and medical devices may allow procurement, or import of medicinal products without marketing authorisation necessary for the treatment of animals. In accordance with article 56 of the law, marketing authorisation for veterinary medicinal product intended for food-producing species, shall be issued only if the medicinal product contains pharmacologically active substances determined by the list of permitted substances in accordance with the Commission regulation (EU) No 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin.  Institute for medicines and medical devices of Montenegro is in charge of issuing approvals for placing veterinary medicinal products on the market (marketing authorisation - MA), as well as for issuing approvals for imports of veterinary medicinal products without MA.  The Institute issues MA for VMPs on the basis of positive assessment of documentation on chemical, pharmaceutical and biological/microbiological tests, safety and residue tests, pre-clinical and clinical/efficacy tests documenting: quality, safety and efficacy of a medicine.  The Institute issues a national MA valid on the territory of Montenegro. MA issued in other countries, including EU, are not automatically valid in Montenegro, but every medicine has to undergo a registration procedure in the Institute. Nevertheless, in case that a medicine has been granted marketing authorisation in the EU, in accordance with the Law on Medicinal Products, evaluation process may be shortened with acceptance of relevant expert opinions (Assessment Reports). Please see point 4.3 for detail rules for import of veterinary medicines.  In accordance with the Law on medicines (OG MN 80/2020), Article 9, Administration for food safety, veterinary and phytosanitary affaires issue wholesale and retail sale authorisations for veterinary medicinal products and performs inspection supervision of trade and use of veterinary medicines.  There are six wholesales of veterinary medicinal products, entered into the register kept by Administration for food safety, veterinary and phytosanitary affaires.  Veterinary Law defines:  - Chapter VIII. Prohibition of use of certain substances in animals and measures of systematic control of residues and contaminants (articles 91-96) defines:  - Obligations for animal keepers, veterinary staff and food operators engaged in production of food of animal origin while using the veterinary medicinal products and placing of food of animal origin intended for public consumption;  - Adoption of a residue monitoring programme and its financing.  Veterinary Law also defines:  - Measures in case of suspicion that unauthorised substances or products were used for treating animals, or where it is suspected that authorised substances or products were used for purposes other than those authorised or under conditions other than those prescribed;  - Measures in case of unauthorised use of certain substances and medicines.  Administration for food safety, veterinary and phytosanitary affaires carries out inspection control in trade and use of veterinary medicines – pharmaceutical wholesalers, veterinary ambulances and animal keepers. |
| * 1. In relation to the animal commodities which your country is currently eligible to export to the EU (or for which an application to do so has been sent to the Commission), please indicate whether there is a legal requirement for farmers (animal keepers) to provide ‘food chain information’ indicating specifically the **veterinary medicinal products administered to animals and the drug withdrawal periods observed prior to slaughter/harvest.** (Consider also your response to question 2.17, where EU residue limits differ from national limits and the possible need to adjust withdrawal periods accordingly **as regards products destined for the EU market**).   [Legal basis: Annex I, Part II, point G of Regulation (EU) 2022/2292]. | There is a legal requirement in place for farmers (animal keepers) to keep a record of the veterinary medicinal products administered to animals and the drug withdrawal periods observed prior to slaughter/harvest.  YES  NO  If this is not the case, please explain what (if any) arrangements are in place to ensure that appropriate drug withdrawal periods have been observed prior to slaughter/harvest. |
| * 1. Please provide a **list of the veterinary medicinal products** (indicating the pharmacologically active substance(s), the target species and the route of administration) authorised for use in those food-producing animals in your country which are included in the control plan.   *Note – this information may be provided electronically (e.g. in an Excel sheet) or by a hyperlink to a national database or vade mecum. There is no need to provide information on non-food-producing species (i.e. pet or fur animals) or for those food-producing species not intended for the EU market.*  [Legal basis: Annex I, Part II, point G(2) of Regulation (EU) 2022/2292]. | Marketing authorisations for veterinary drugs are available at: https://cinmed.me/registar-veterinarskih-ljekova/#anchor-id.  In accordance with the Law on Medicinal Products (OG MN 80/2020), Article 5, the Institute for medicines and medicine devices issues import authorisations for medicines without MA when it is medically indicated and allowed by the Law. Import authorisations may be granted only to legal persons having wholesale authorisation for veterinary medicines. In order to assess the application for import authorisations, it is necessary to submit appropriate documentation given in the instruction "Required documentation for import of veterinary medicines that do not have marketing authorization and import/export of blood products and immunological products" which is available on CInMED website https://cinmed.me/veterinarski-lijekovi/uvoz-izvoz-ljekova/  The Institute annually publishes a list of veterinary medicinal products that were granted import authorisations into Montenegro during a particular calendar year. The list also contains data on target animal species and withdrawal periods which are an integral part of issued import authorisations. The list for 2022 is available: https://cinmed.me/wp-content/uploads/2023/01/Uvoz\_2022-Spisak-veterinarskih-ljekova.pdf |
| * 1. Indicate whether **stilbenes or thyrostats** are authorised for use in food-producing animals in your country. If such use is expressly prohibited, please provide the national legal basis for the prohibition.   [Legal basis: Annex I, Part II, point G(5) of Regulation (EU) 2022/2292]. | Stilbenes and thyrostats are prohibited for use and treatment of food producing animals in accordance with the Article 1 of the Order prohibiting the use and treatment of animals with certain substances and veterinary medicinal products (OGM No. 17/2024 ), which is harmonised with the point 1d, part of the point 2c and point 3a from Annex I of Regulation 2022/1644, point 2 of article 107 of Regulation 2019/06, Regulation(EU) 2022/1255, Council Directive 96/22, Council’s Decision 99/879 and Table 2 from the Annex of Commission Regulation 37/2010. |
| * 1. Indicate whether the use of **hormones and beta-agonists for growth promotion** in food-producing animals is permitted in your country. If so, describe the measures in place to guarantee that animals receiving these substances for growth promotion purposes are not exported to the EU (there should be a segregated production system in place).   If such use is **prohibited**, please provide the national legal basis for the prohibition.  [Legal basis: Annex I, Part II, point G (6) of Regulation (EU) 2022/2292]. | **Hormones and beta-agonists for growth promotion** are prohibited for use and treatment of food producing animals in accordance with the Article 1 of the Order prohibiting the use and treatment of animals with certain substances and veterinary medicinal products (OGM No. 17/2024 ), which is harmonised with the point 1d, part of the point 2c and point 3a from Annex I of Regulation 2022/1644, point 2 of article 107 of Regulation 2019/06, Regulation(EU) 2022/1255, Council Directive 96/22, Council’s Decision 99/879 and Table 2 from the Annex of Commission Regulation 37/2010. |
| * 1. Indicate whether the use of products containing **oestradiol 17β** are authorised for **zootechnical or therapeutic treatment of food-producing animals** in your country. If so, describe the measures in place to guarantee that animals which have been treated and products derived from such animals and intended for human consumption are not exported to the EU (there should be a segregated production system) in place).   If such use is prohibited, please provide the national legal basis for that prohibition.  [Article 11.2 of Directive 96/22/EC and Annex I, Part II, point G(6) and H(1) of Regulation (EU) 2022/2292]. | Order does not apply to the use for zootechnical purposes:  Substances having estrogenic (other than 17β-estradiol and ester derivatives of 17β-estradiol), androgenic or progestogenic effects for estrous synchronization and embryo implantation can be used for zootechnical purposes by a veterinarian or veterinary technician under the supervision of a veterinarian;  The veterinarian issues a prescription marked "non repetatur", in which he determines the required use and quantity of the required product and keeps records of the prescribed product.  Meat and animal products may not be placed on the market for human consumption unless the prescribed withdrawal period was observed before the slaughter of the animals.  The veterinarian is obliged to keep records, which contain data on:  - type of treatment;  - the type of substance and the name of the veterinary medicinal product used;  - date of treatment of the animal;  - the identification mark of the animal, ie the identity of the animal. |
| * 1. Indicate whether substances which are included in Table 2 of the Annex to [Regulation (EU) No 37/2010](https://eur-lex.europa.eu/search.html?DTA=2010&SUBDOM_INIT=ALL_ALL&DB_TYPE_OF_ACT=regulation&DTS_SUBDOM=ALL_ALL&typeOfActStatus=REGULATION&DTS_DOM=ALL&type=advanced&excConsLeg=true&qid=1670415594921&DTN=0037) are authorised and used in food-producing animals in your country (e.g. **chloramphenicol, nitrofurans and nitroimidazoles**).   If so, describe the measures in place to guarantee that animals which have been administered these substances are not eligible (including products for human consumption derived therefrom) for export to the EU (there should be a segregated production system in place).  If such use is **prohibited**, please provide the national legal basis for the prohibition.  [Legal basis: Annex I, Part II, point G(4) of Regulation (EU) 2022/2292]. | Chloramphenicol, nitrofurans and nitroimidazoles are prohibited for use and treatment of food producing animals in accordance with the Article 1 of the Order prohibiting the use and treatment of animals with certain substances and veterinary medicinal products (OGM No. 17/2024 ), which is harmonised with the point 1d, part of the point 2c and point 3a from Annex I of Regulation 2022/1644, point 2 of article 107 of Regulation 2019/06, Regulation(EU) 2022/1255, Council Directive 96/22, Council’s Decision 99/879 and Table 2 from the Annex of Commission Regulation 37/2010. |
| * 1. Indicate whether substances which are prohibited in the EU from in-feed administration to food-producing animals in the EU because of chemical safety concerns (e.g. **carbadox, olaquindox**, etc) are used in food-producing animals in your country.   If so describe the measures in place to guarantee that residues of these substances are not present in product exported to the EU (see also questions 2.16 and 2.17).  [Legal basis: Annex I, Part II, point G(3) of Regulation (EU) 2022/2292]. | Carbadox, olaquindox and nifursol are not included in the list of authorised feed additives, therefore prohibited to be administered in feed for food producing animals in accordance with the Regulation on feed additives and premixtures authorised for marketing and administration in feed (OJ MN 7/2018, 46/2018, 44/2019, 120/2020 and [9/2023](javascript:void(0)). ), containing also the list of approved feed additives. The Regulation, as well as the list of feed additives are harmonised with the Regulation (EC) No 1831/2003, and the European Union Register of Feed Additives. |
| * 1. In respect of **honey**, (if this is a commodity which is (potentially) being exported to the EU), please indicate whether **antimicrobials** are authorised in your country in apiculture for the treatment of certain diseases in honey bees (e.g. American and European foulbrood).   If so describe the measures in place to guarantee that residues of these substances are not present in product exported to the EU (see also 2.16 and 2.17).  [Legal basis: Annex I, Part II, point I of Regulation (EU) 2022/2292]. | Treatment of European and American foulbrood is prohibited in Montenegro. In case of occurrence eradication measures are applied. |
| * 1. In respect of **aquaculture** (i.e. crustaceans, fin fish and fin fish products such as caviar and roe), if this is a commodity which is (potentially) being exported to the EU, please indicate whether dyes (e.g. **malachite green and crystal violet**) are authorised for the treatment or prevention of disease in aquacultured species in your country.   If so describe the measures in place to guarantee that residues of these substances are not present in product exported to the EU.  [Legal basis: Annex I, Part II, point J of Regulation (EU) 2022/2292]. | Days are prohibited for use and treatment of food producing animals in accordance with the Article 1 of the Order prohibiting the use and treatment of animals with certain substances and veterinary medicinal products (OGM No. 17/2024 ), which is harmonised with the point 1d, part of the point 2c and point 3a from Annex I of Regulation 2022/1644, point 2 of article 107 of Regulation 2019/06, Regulation(EU) 2022/1255, Council Directive 96/22, Council’s Decision 99/879 and Table 2 from the Annex of Commission Regulation 37/2010. |
| * 1. In respect of **horsemeat,** if this is a commodity which is (potentially) being exported to the EU and for which residue control plans for pharmacologically active substances, pesticides and contaminants have been submitted, please **describe the system** in place to ensure that **equine animals** treated with substances which are either prohibited or are not authorised in the EU for use in food-producing animals, and the products derived therefrom, intended for human consumption, are not eligible for export to the EU. The description should include information on identification and traceability of equine animals and record keeping of administration of veterinary medicinal products (pharmacologically active substances).   Where equine animals have been treated with substances considered **essential under EU rules** ([Regulation (EU) No 1950/2006](https://eur-lex.europa.eu/search.html?DTA=2006&SUBDOM_INIT=ALL_ALL&DB_TYPE_OF_ACT=regulation&DTS_SUBDOM=ALL_ALL&typeOfActStatus=REGULATION&DTS_DOM=ALL&type=advanced&excConsLeg=true&qid=1670415808894&DTN=1950)) describe the system in place to ensure that food derived from such animals is not eligible for entry into the EU until six months have elapsed since the last treatment.  [Legal basis: Annex I, Part II, points K(1) & K(2) of Regulation (EU) 2022/2292]. |  |
| * 1. In respect of **casings,** if this is a commodity which is (potentially) being exported to the EU and for which a residue control plan for pharmacologically active substances has been submitted, please **describe the system** in place to ensure that no antimicrobial substances, the use of which in food-producing animals is prohibited in the EU, in accordance with Table 2 the Annex to [Regulation (EU) No 37/2010](https://eur-lex.europa.eu/search.html?DTA=2010&SUBDOM_INIT=ALL_ALL&DB_TYPE_OF_ACT=regulation&DTS_SUBDOM=ALL_ALL&typeOfActStatus=REGULATION&DTS_DOM=ALL&type=advanced&excConsLeg=true&qid=1670415594921&DTN=0037), are used in the treatment of casings.   [Legal basis: Annex I, Part II, point M of Regulation (EU) 2022/2292]. | Official controls are regularly performed at establishments for casings production and sampling for Chloramphenicol, nitrofurans and nitroimidazoles are performed under the monitoring Plan. No such practice ever recorded or detected in Montenegro. |

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| 1. **Additional information** |

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| 1. Please include any supporting information that would provide additional guarantees on the compliance of products eligible for export to the EU with applicable EU MRLs or MLs. Such information could include, but is not limited to, pre-export testing for residues. |  |

1. () Note that in the event of the residue control plan being approved for the new commodity (and listed in Annex -I to Regulation (EU) 2021/405) and assuming that your country is listed for animal health (if such listing is applicable) for the species/commodity in the relevant annex to Regulation (EU) 2021/404, you **must** provide evidence that EU **public health (hygiene)** conditions are satisfied in order for your country to be listed accordingly for public health (hygiene) in Regulation (EU) 2021/405. **The information you must provide is laid down in Article 127 (3) of** [**Regulation (EU) 2017/625**](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0625&qid=1696842781328) **AND Article 4 of** [**Delegated Regulation (EU) 2022/2292**](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022R2292&qid=1696842904218)**. Please contact the desk officer responsible for your country in the DG SANTE unit for Bilateral International Relations -** [**SANTE-Consult-A5@ec.europa.eu**](mailto:SANTE-Consult-A5@ec.europa.eu) **- to request the appropriate commodity-specific template for the provision of these public health (hygiene) guarantees**. [↑](#footnote-ref-2)