Competent Authority response to recommendations in report, received 18 December 2023

N°	Recommendation	Action Proposed by the competent authority
	To ensure that official controls on biosecurity on pig establishments are carried out with appropriate frequency, in particular to ensure that requirements for derogations of movements of porcine animals kept in restricted zones I, II and III as laid down in Article 16 (1), point b) are complied with, taking into account biosecurity requirements as laid down in Annex III of Regulation (EU) 2023/594. Article 9 of Regulation (EU) 2017/625; Articles 16 (1) point b) of Regulation (EU) 2023/594. Recommendation based on conclusion No. 3 and associated findings Nos. 9, 10, 11 and 12.	As regards controls in the infected area and in the restriction zones II and III, article 3, letter b), point iv of the Ordinance no. 5/2023 of the Special Commissioner for ASF, provides that any continuation or resumption of the check performed by the official veterinarian of the local competent veterinary service. In addition, the enhanced biosecurity measures referred to in Annex 3 to the Implementing Regulation (EU) 2023/594 as amended must be adopted and the biosecurity levels referred to in the Ministerial Decree of 28 June 2022 must be ensured. In order to be considered valid, the results of the official control must be uploaded in the Classyfarm.it information system by specific checklists. Also for restriction zone I, article 4 of the Ordinance provides for the official control of all commercial farms to check the presence of enhanced biosecurity measures, again by the checklists of the Classyfarm.it system. The system is currently fully operating and where some mandatory requirements set by national or community legislation are not met by the operator, the system records an unfavorable outcome of the official control and the farm cannot be authorized to carry out commercial activities in the restriction zone. For 2024, for the free territories of the Regions without any restriction zone, it is deemed useful to maintain the minimum control objective of 1% of the total number of farms and 1/3 of the semi-wild farms (also including family farms). In the Regions with restriction zones will be subject to official controls, while in the free areas, these Regions will consider an increase in the percentage of commercial farms to be checked, together with the

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		National Reference Center and the Ministry of Health, also based
		on a risk assessment and the epidemiological surveillance data
		available.
		As an example, Lombardy Region, which has approximately 80%
		of the total number of pigs raised in the national territory, last year
		planned to raise the minimum objective of farms to be checked for
		biosecurity to 50% of the regional commercial farms, also
		providing for the control of all open farms with animals located in
		the restriction zone.
		The frequency of checks by the official veterinarian on the farms
		located in the restriction zone is based on the risk assessment
		conducted by the competent authority, and must in any case
		comply with the minimum frequencies laid down by article 16,
		paragraph 1, letter a) of Implementing Regulation (EU) 2023/594
		as amended (at least twice a year, with an interval of at least four
		months between the checks in restriction zones I and II and at least
		once every three months in restriction zone III). As a result of the
		ASF emergency in Lombardy Region, starting from September
		2023 until late November 2023, the Ministry of Health ordered
		checks to be carried out by the official veterinarian in the 24 hours
		before the first load and then every 72 hours for all movements
		from the farms located in Regions with restriction zones.
		The Ministry of Health is considering computerizing the data on
		the clinical examination so that this information is automatically
		included in the electronic form accompanying the animals and is
		available to the competent authority of the farm of destination.
		Pending this procedure, the Ministry informed the Regions that, if
		the farm is located in the restriction zone, the official veterinarian
		must insert the date and result of the inspection in the notes of the
		electronic model accompanying the animals.
		In Piedmont Region, in 2023, the competent authorities (local
		health units - ASL) carried out a widespread activity to check the

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2	To ensure that the targets for taking samples for ASF testing in the frame of passive surveillance in backyard/family farms are implemented as stated in the approved 2023 "programme for the control and	implementation of the biosecurity measures set out by the Ministerial Decree of 28 June 2022, with a coverage that will reach 100% of the farms at the end of the year, through the compilation of the Classyfarm checklists. The central authority monitors the progress of passive surveillance in domestic animals through the level of power and implementation of SINVSA, simultaneously recommending to the
	eradic ation of classical swine fever and African swine fever in Italy" as submitted under number 1670858138674-19287. Articles 26 and 27 of Regulation (EU) 2016/429. Recommendation based on conclusion No. 6 and associated finding Nos. 32 and 33.	Regions and Public Administrations to meet the surveillance objectives set out in the National Plan. In addition, in accordance with the current Ordinance of the Special Commissioner for ASF, in the areas subject to restrictions both as part of the control measures in the infected area and in areas II and III, the local competent authority provides for immediate slaughter of the pigs kept on family farms, on semi-wild farms with commercial purposes and on mixed farms that keep pigs, wild boars or their crossbreeds intended for food production, and provides for a ban on repopulation. From the beginning of application of the Plan, it was clear that the passive surveillance activities envisaged for domestic pigs were difficult to carry out, both for operators and for veterinary services. For this reason, the Ministry of Health provided some tools to fill the gap, including risk analysis, in order to identify high-risk farms (based on different parameters) and to ensure an optimal allocation of resources. At the same time, training courses and communication activities were carried out by the veterinary services throughout their territories, as well as by the National Reference Center for Pests in different Regions, and were addressed to different stakeholders, including breeders, breeders' associations, pig producers and their associates, public veterinarians and independent veterinarians. In addition, while managing domestic outbreaks in the Province of Pavia, a special protocol was prepared for exceptional movements from the restriction zones. Control and surveillance

activities were intensified throughout the national territory and biosecurity checks and surveillance activities were further recalled and promoted. Moreover, the timely sampling of every single pig dead on the farms located in the restriction zones and the recording of pig deaths in the national database were ordered. In this respect, pending the implementation of the technical functions provided for by the Ministerial Decree of 7 March 2023 (Identification and Registration Operating Manual), the operators are required to record in the national database the death of the pigs kept, identified both individually and in groups, within seven days from the event. Limited to the territories subject to ASF restrictions, these data must be inserted as soon as possible and in any case no later than 48 hours from the event. It should also be pointed out that the emergency occurred in Lombardy Region inevitably raised awareness, even in the family farming sector, despite the culling obligation in case of inclusion in the restriction zone. When in August 2023 in Lombardy Region a farmer notified the disease with a certain delay, there were serious repercussions throughout the national territory. On the one hand, this event highlighted the lack of collaboration, but on the other hand, it encouraged farmers to improve their knowledge and sensitivity towards a correct approach. Furthermore, after the consequent outbreaks, various measures were implemented to contain the infection in the restriction zones (enhanced passive surveillance, biosecurity controls, tracing activity, preventive culling, etc.). Preliminary tests on live pigs were requested for
farms in Regions with ASF restriction zones, as well as in the cases when traceability confirmed a link between animal movements and the outbreaks in Lombardy Region. For some months (September to November 2023), the movements of live

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		- clinical examination carried out in the 24 hours before the first load and repeated every 72 hours; - check of the mortality trend in the 24 hours before the first load and repeated within 72 hours. In addition to the clinical examination for the identification of clinical signs, an EDTA blood sample was requested for PCR testing on unresponsive animals or animals affected by pathologies of non-traumatic origin. Furthermore, as part of the check of mortality trends, it was provided for a testing to be executed on the spleens of the last three dead animals. Starting from the early stages of the epidemic, Piedmont Region ordered the closure of the family farms located in restriction zones I and II and the local health units were required not to authorize their repopulation.
3	To ensure that the targets of the regional programmes for the eradication of ASF, in addition to the National action plan for wild porcine animals according to Article 56 of Regulation (EU) 2023/594, are achieved, in particular as regards reduction of wild porcine animal population and confinement of infected of wild porcine animal meta population. Article 70 of Regulation (EU) 2016/429; Articles 56 of Regulation (EU) 2023/594 Recommendation based on conclusion No. 5 and associated findings Nos. 16, 17, 19, 20, 21 and 22	In September 2023, the "Extraordinary Plan for the Capture, Culling and Disposal of Wild Boars (Sus Scrofa) and Strategic Actions for the Development of Eradication Plans in ASF Restriction Zones" was officially launched for the five-year period 2023-2028. The Plan applies throughout the national territory, with the exception of Sardinia Region. The regional plans for urgent actions enforce the afore-mentioned extraordinary capture and culling plan throughout the national territory free from ASF, with the exception of Sardinia Region. The provisions of the Eradication Plans and the Ordinances of the Extraordinary Commissioner for ASF apply in the restriction zones. Regions were divided into criticality classes, based on: • number of pigs kept; • number of pig farms; • average annual economic extent of damage to agriculture declared between 2019 and 2021;

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		ASF epidemiological situation.
		For each Region, the values of the different criticality classes were
		added to obtain a summary value of their level of criticality.
		With a view to achieving the general objective of significantly
		reducing the disease in the short/medium term, also by effectively
		applying the "Regional Plans for urgent actions for the
		management, control and eradication of ASF in farmed pigs and
		wild boars (Sus scrofa)", and based on the assessment of the actual
		feasibility of high sampling levels and the time required, led to the
		preparation of a Plan providing for the culling of approximately
		600,000 wild boars in the first year of activity. It involved a 96%
		increase compared to the average of culling activities carried out
		in 2019-2021. The Plan is valid for five years and the amount of
		sampling is to be remodulated annually to ensure a high level even
		at a later stage.
		The Regions were asked to adapt their Plans, to plan hunting and
		control activities in order to achieve the objectives set out in the
		National Plan, to intensify controls, also in agricultural funds, and
		to establish the Territorial Operating Groups (Gruppi Operativi
		Territoriali - GOT).
		The territorial hunting areas, with the alpine districts and private
		institutes, must intensify selective hunting throughout the
		territory, even during sensitive seasons.
		All actors are asked to carry out specific training and
		specialization courses for hunters, operators and dogs involved in
		hunting and capture activities with a reduced number of dogs.
		The Territorial Operating Groups are responsible for checking the
		achievement of the results expected, as well as for developing the
		distribution plan of captures.
		Finally, the Regions are required to activate regional supply chains
		for the marketing of meat, providing for dedicated

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		collection/staging centers and processing plants, as well as to donate the animals collected to charitable and non-profit bodies. As regards the so-called restriction zones, the National Plan provides for 6 Strategic Actions with a view to developing the ASF Eradication Plan: • assignment of active search tasks to the local competent authorities, with particular reference to carcasses; • wild boar depopulation through capture and culling, in complete biosecurity, in order to create a sanitary vacuum; • application of biosecurity measures on pig farms, including the building of bio-barriers, the opening of designated slaughter points, as well as training and information activities; • installation of physical barriers limiting the infected area and the movement of potentially infected animals; • correct waste management; • development of alternative methods of containment of the species.
		The afore-mentioned Plan is attached for further details. Furthermore, Ordinance no. 4/2023 established the role of bioregulators. Bio-regulators are authorized under current legislation to carry out hunting activities with specific training in biosecurity. For the period of application of the ASF Eradication Plan and the Extraordinary Capture Plan at national and regional level, they act as bio-regulators and may register in the national list of bioregulators available in the Vetinfo veterinary information system. The local competent authorities can refer to such list for wild boar containment activities throughout the national territory. In general, in recent years, the Italian Ministry of Agriculture, which is responsible for the management of wild animals,

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		prepared and issued guidelines to support the Regions in applying
		the wild fauna control plans and in estimating the size of wild boar
		populations. However, the Regions had difficulties in updating the
		size of wild boar populations. Both the regional plans for urgent
		actions and the eradication plans of the infected Regions
		considered this aspect. Particular attention was paid to
		depopulation, also through awareness-raising activities to promote
		hunters' awareness and collaboration. Despite a more effective
		contribution of the hunting sector in the early stages of the
		emergency, the continuation of the emergency, with the related
		limitations and bans, decreased the hunting sector's willingness to
		contribute. The construction of fences was delayed due to a series
		of bureaucratic and management issues and difficulties in
		allocating resources. There was also opposition by citizens and
		municipal leaders that led to a further slowdown in the
		construction of fences. Even the infection dynamics had a negative
		impact on the works, contributing to increasing operational and
		management issues.
		As for the findings in the wild sector, Piedmont Region submitted the comments below.
		From late 2023, Piedmont Region will start a collaboration with
		the Department of Biology and Biological Sciences of the University of Turin to develop a study model to estimate the size
		and distribution of wild boar populations.
		Piedmont Region also implemented the guidelines deriving from
		the application of national regulations, as well as the regional plan
		for urgent actions in free areas and the eradication plan in the
		infected areas. It also issued measures aimed at facilitating and
		increasing culling also thanks to auxiliary staff to carry out safe
		and more effective interventions. Selective hunting with the use of
		dogs was also permitted for all hunting institutes.

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		Piedmont Region also implemented an IT procedure to timely
		collect data on the culling of wild boars in order to monitor
		progresses and maximize the effectiveness of depopulation. The
		real time acquisition of data made it possible to implement a
		virtuous system involving periodic meetings with the Provinces,
		the Municipality of Turin, the territorial hunting areas, the alpine
		districts and private hunting institutes, which allows to intervene
		where depopulation actions are not effective in achieving the
		objectives. Furthermore, the regional Agriculture Department
		envisaged a regional contribution for the Provinces and the
		Municipality of Turin to carry out actions in wildlife hunting, in
		particular to be used for expense reimbursements which would
		encourage an active involvement in wild boar control activities.
		With Directorial Decree no. 958 of 3 May 2023 and Decree of the Regional Council no. 26-7087 of 20 June 2023, the Health
		Department of Piedmont Region provided the local health units
		with resources destined for the culling of females in restriction
		zone I. With a similar provision, the Agriculture Department
		financed the culling (both males and females) throughout the
		remaining territory at risk. On a periodic basis, the Vice
		Presidency convenes the Provinces to collect information on
		containment actions and to monitor the progress expected.
		The current regulatory system does not allow to bind hunters to
		carried out depopulation operations. However, it should be noted
		that compared to 2022 a significant increase is being observed in
		wild boar culling conducted under the supervision of the Public
		Administration.
		However, with a view to encouraging the support of the hunting
		sector in the management of wild boars, Piedmont Region deemed
		it essential to promote a widespread knowledge of the ASF issue
		and of the virus impact on hunting and other activities in the
		hunting areas.

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		The Region therefore promoted the activation of training courses for both technicians and hunters, aimed at increasing awareness and acceptance of the objectives to be pursued for eradication. As regards biosecurity controls during hunting, they take place at the time of carcass delivery to the facilities where sampling is later carried out. Also in the Liguria Region, wild depopulation activities have been strengthened by increasing the collaboration with the agricultural world for the management and operation with traps with excellent results also if only used sporadically. For this purpose, a training program has been launched for those who voluntarily join this program, implemented under the coordination and supervision of the Region, which also financed it (DGR 1132/2023) As for the active search for carcasses, after the initial phase involving some volunteers, with a view to optimizing resources, the efforts were concentrated in the sectors at risk of spreading the virus t owards Piedmont's pig area@dentified based on the epidemiological assessment by the IZS), entrusting the operations to the staff employed at the local health units (multi-area centers) and at Piedmont Region (forestry workers).
4	To ensure that requirements on specific prohibitions of movements of consignments of porcine animals kept in restricted zones I, II and III within and outside those restricted zones according to Art. 9 are adhered to, and derogations are only granted fully in line with Articles 14, 15, 16, 17, 23 and 24 of Regulation (EU) 2023/594. Article 9 of Commission Implementing Regulation (EU) 2023/594. Recommendation based on conclusion No. 8 and associated findings Nos. 62, 63, 64, 65, 66 and 67.	In October 2023, the two competent Directorates General for Animal Health and Food Safety developed guidelines and decision-making schemes for the issue of special authorizations pursuant to Regulation (EU) 2023/594. This allowed to support the competent authorities in issuing derogations to the movement of pigs, products and by-products of animal origin from the ASF restriction zones, as well as to ensure clearer and more uniform procedures for designating plants, marking, certification and destination of the products above in accordance with the general and specific requirements set out in Regulation (EU) 2023/594.

N^{o}	Recommendation	Action Proposed by the competent authority
		Furthermore, following the outbreaks occurred in Lombardy
		Region, extraordinary control and surveillance measures were
		adopted throughout the national territory. In particular, for the
		movement of animals destined for breeding and for slaughter,
		without prejudice to the specific prohibitions in force in the
		protection and surveillance zones pursuant to Regulation (EU)
		2020/687, and in the restriction zones pursuant to Regulation (EU)
		2023/594, the movements of pigs destined for both breeding and
		slaughter from farms in the Regions with ASF restriction zones as
		well as in those where tracing confirmed a direct/indirect link
		between movements and outbreaks, were only permitted based on
		the favorable result of an official control by the local competent
		authority. This control included:
		• clinical examination of all animals in the batch carried out in the
		24 hours before the first load and repeated every 72 hours in the
		case of multiple shipments;
		• check, in the 24 hours before loading, of the trend in mortality
		observed on the farm in the previous month or at least in the last
		10 days, where an abnormal increase in mortality has not already
		been reported. In the case of multiple shipments, checks must be
		carried out in the two days after the first check.
		Besides the mandatory report of any increase in mortality by the
		operator and the farm/supply chain veterinarian, the Regions and
		Autonomous Provinces, without prejudice to the provision of the
		2023 National Eradication and Surveillance Plan and based on the
		epidemiological situation and risk assessment, had the right to
		arrange tests for ASF to be performed on the spleens of two pigs dead recently, possibly no later than 5 days, in the 72 hours before
		the first load and every 72 hours for subsequent loads. In the
		absence of recently dead animals, sampling had to be carried out
		on the animals dead more recently, just like the EDTA blood
		sampling in the presence of unresponsive animals.
		sampling in the presence of unresponsive animals.

No	Recommendation	Action Proposed by the competent authority
		For all pig farms throughout the national territory, the national
		database provided for a "conditional" block on all outbound
		movements of live animals, with the obligation for the veterinary
		services of origin to validate the documents accompanying the
		animals. In the Regions and Autonomous Provinces affected by
		clusters of ASF infection in wild and domestic animals and in
		those where tracing confirmed a direct/indirect link between
		movements and outbreaks, the afore-mentioned validation was
		subject to the favorable outcome of the clinical and possibly
		laboratory checks as described above.
		Furthermore, in the case of movements by vehicles with a license
		plate not correctly mentioned on the accompanying document
		issued by the national database, the movement was not permitted. Similarly, it was recommended to check traceability of the
		equipment or products other than animals (feed, carcasses and by-
		products of animal origin, and any other equipment for farm
		management) through the timely and accurate vehicle registration
		in the farm registry, as well as to check the procedures for
		accessing the farm, including external disinfection of the vehicle
		and management of loading and unloading operations.
		As regards animal by-products, in certain cases defined by the
		local competent veterinary service, the official veterinarian is
		allowed to seal the vehicle. In any case, it is understood that for
		the movement of category 1, 2 and 3 materials of pigs kept in
		restriction zones II and III towards areas not included in the
		restriction zones, but still within national borders, the vehicle must
		be equipped with a satellite navigation system.
		With reference to the findings on the failure to designate plants for
		the slaughter of pigs coming from zone II and on the risk linked to
		untreated meat products that could have left zone II, the competent
		authorities of Piedmont Region informed of the following. The
		current regulatory system does not provide for specific obligations

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5	To ensure that requirements on specific prohibitions of movements of consignments of fresh meat and meat products, including casings, from porcine animals kept in restricted zones II and III outside those restricted zones according to Art. 12 are adhered to, and derogations are only granted only fully in line with Article 41 of Regulation (EU) 2023/594. Article 12 of Commission Implementing Regulation (EU) 2023/594. Recommendation based on conclusion No. 8 and associated finding Nos. 62, 63, 64, 65, 66 and 67.	for the operators in the slaughter sector. Furthermore, unlike Regulation 2021/605 in force in the audit reference period, Regulation 2023/594 covers the movements of pigs within the restriction zones. In Piedmont Region, the slaughterhouses located in zone II were attached to retail stores and sold the products directly to the final consumer. The checks carried out by the local veterinary service revealed that no meat products were sold to other plants either inside or outside zone II. Since the entry into force of Regulation 2023/594, the competent authorities of the local health units have verified and will promptly verify that the exemptions are only granted in compliance with Regulation 2023/594, also on the basis of ministerial indications and guidelines. In order to standardize compliance and adoption throughout the national territory of the conditions referred to in Regulation 2023/594, all official veterinarians in charge of the supervision and control of slaughterhouses and plants for subsequent cutting and processing received the documents and decision-making schemes referred to in recommendation no. 3. These also include all the conditions that the animals must meet to access the slaughterhouse of destination and that must be documented by the accompanying document and the other information systems available to the official veterinarians. These documents also specify the cases when the common mark can be used on meat and products and those when the special mark must be applied, as well as the cases requiring health certification and those where the exemptions provided for by article 18 of
6	To ensure that regional laboratories (IZS) which perform confirmatory tests for ASF are accredited for the test method used.	Regulation 2023/594 can be applied. Accreditation ensures that testing laboratories, including the public labs, fulfill all the requirements of the standards to undertake conformity assessment activities. Istituti Zooprofilattici

N°	Recommendation	Action Proposed by the competent authority
	Article 40 (2) in conjunction with Article 37 (4) point e) of Regulation (EU) 2017/625 Recommendation based on conclusion No. 9 and associated findings Nos. 45, 47 and 48.	Sperimentali (IIZZSS) labs, in charge for one/two or three regions, are public labs, operating under an accreditation scheme (UNI CEI EN ISO/IEC 17025), whereas the diagnostic tests to be accredited are established by each IZS, based on the strategic directions of the IZS Directorates. In Italy the sole Accreditation Body appointed by the Government is Accredia. ACCREDIA: the steps of the accreditation path for diagnostic tests The process of accreditation for a diagnostic test runs from the application to the granting of accreditation, as follows: 1. Application The application must be made in the original form, clearly and fully, according to the specific activities required by the lab. It must include also all the documents requested and be signed by an authorised representative of the IZS. It is examined by the Technical Officer of the relevant Accredia department for compliance with all the above requirements. If the outcome of this phase is positive Accredia informs the CAB and sends a cost estimate. 2. Document review The analysis of the documents presented together with the application is carried out by a team tasked by the Department Director of Accredia. The aim is to assess the conformity of the lab activities with the applicable requirements, as well as those prescribed by the contract drawn up by Accredia. If any further documents are needed or if the application is incorrectly completed, this shall be done by the applicant lab. When the process has been successfully completed, an on-site assessment is performed at the lab location. 3. On-site assessments These are conducted by a team consisting of selected qualified assessors and experts from Accredia. The aim is to ascertain that

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		for ASF eradication. In November 2023 (29 November), a meeting was held at the NRL on the topic of biosafety, and all Italian IIZZSS took part on it. During this meeting NRL informed all laboratories about the need of accreditation for ASF Real Time PCR test used for confirmation of secondary cases in territories subject to eradication; at the same time, the NRL invited all noncompliant laboratories to fulfill this requirement, including those that are currently competent for territories subject to surveillance, with a view to a possible transition to ASF affected territory status. NRL will support all IIZZSS labs in case, including supply of reference material for procedure validation testing. In order to verify the adherence of the IIZZSS network laboratories to the guidance provided, the NRL will request periodic updates about the progress of the accreditation process, e.g., at the time of the next national ring test.
7	To use control verification procedures, including audits, to effectively identify and correct shortcomings, e.g. in granting of movement derogations within ASF restricted zones or in delay in sampling and testing of wild porcine carcasses. Article 12 (2 and 3) of Regulation (EU) 2017/625. Recommendation based on conclusion No. 10 and associated findings Nos. 26, 42 and 71.	The audit activity by the central authority was carried out as a result of the audit referred to in these recommendations to check compliance and effectiveness of the measures and procedures implemented by the Regions subject to ASF restrictions. Moreover, as specified above, the two competent Directorates General of the Ministry of Health developed specific guidelines and decision-making schemes for the issue of special authorizations pursuant to Regulation (EU) 2023/594. This allowed to support the competent authorities in issuing derogations to the movement of pigs, products and by-products of animal origin from the ASF restriction zones, as well as to ensure clearer and more uniform procedures for designating plants, marking, certification and destination of the products above in accordance with the general and specific requirements set out in Regulation (EU) 2023/594.