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Livestock Production and animal welfare: a critical analysis of legislation and scientific evidence on operator, animal and consumer safety; a case study on ClassyFarm implementation in small-scale dairy farms

Coordinator of the PhD Course: *Prof. Giuseppe Maiorano*

Supervisor: *Prof. Giuseppe Maiorano*

Co-Supervisor: *Prof.ssa Siria Tavaniello*

PhD student: Luigi De Marco

Matr. 169886

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ABSTRACT

This thesis provides a critical analysis of the legislation regarding the safety of operators, consumers, and animals within the meat supply chain, with a particular emphasis on animal welfare. Linked to this introduction is the experimental section, which presents the results of a pilot study on the implementation of the ClassyFarm protocol in small-scale dairy farms, both tie-stall and free-stall housing systems, in the province of Isernia in the Molise region, and the neighbouring towns in the province of L'Aquila in the Abruzzo region.

Specifically, this study represents the first attempt to collect information regarding the *status quo* on biosecurity and animal welfare through the implementation of the ClassyFarm protocol in small-scale dairy farms in the inner areas of South Italy.

In the first part of the thesis the starting point is the farm and the related legislation to ensure workplace safety and regulations aimed at guaranteeing food safety, with consumer protection as the primary goal. These regulations are closely linked to animal welfare, as there is a strong connection between animal welfare, animal health, and foodborne diseases. Animal welfare is increasingly an essential part of an integrated quality system for producing food of animal origin. This system ensures that consumers receive products from farms where animals are raised in accordance with their basic needs. Ensuring animal welfare requires good husbandry practices, as well as proper housing, hygiene, nutrition, and health conditions. Therefore, animal welfare criteria should be integral to supply requirements. Suppliers of meat and animal products must sign agreements to guarantee that their production chains comply with current EU and Italian animal welfare regulations. The safety of operators, animals and consumers in the meat supply chain is also closely linked to the identification of efficient and effective traceability methods. In this broader

context, the adoption in Italy of the ClassyFarm system represent a unique tool to evaluate the performance of farms and highlight best practices in biosecurity, management, and farm structure, suggesting possible interventions to improve animal production, prevent diseases, and combat the spread of antimicrobial resistance. It aims to create a virtuous cycle that encourages the adoption of best practices and promotes healthier animal husbandry. This approach not only provides economic benefits for farmers but also ensures safety and quality for consumers.

The second part of the thesis was focused on the research carried out on 14 dairy cattle farms located in the hilly and mountainous area in the province of Isernia in the Molise region, and the neighbouring towns in the province of L'Aquila in the Abruzzo region. The farms' welfare assessments were performed by a trained veterinarian with the support of one expert livestock technician using the ClassyFarm checklist for dairy cattle, considering different subpopulations (calves, heifers, lactating cows, and dry cows). The checklist was the one considered for the ClassyFarm system which includes 99 questions for tie stall (TS) systems and 105 for free stall (FS) systems split on the five macro-areas: Area A – farm management and staff training; Area B – structures and equipment; Area C – animal-based measures; Biosecurity area; Hazards and Risks area. For the investigated tie-stalls (n. 7) and free-stalls (n.7), the descriptive statistic for the herd size and all the checklist questions belonging to the five areas of ClassyFarm protocol was performed. The results of this pilot study indicated that, overall, all the farms included in the research received adequate ratings. However, several critical issues were identified in each of the five monitored areas. In particular, significant concerns arose in the biosecurity area for free-stall and tie-stall farms, specifically regarding the loading of animal carcasses and live animals: the loading areas did not maintain the required distance of 20 meters from the housing facilities. This issue largely stems from space

constraints that many of the farms face. Furthermore, in tie-stall farms emerged the problem regarding the contact with other animals outside the herd, which significantly increases the risk of spreading common infectious agents. Many farmers in tie-stall farms lack knowledge about health status and consequently do not have prevention or control plans for endo- and ecto-parasitosis. In general, there is a need to raise awareness among farmers about biosecurity practices through effective education and easier access to available European funds, as well as through training courses. This will help address the economic and logistical challenges associated with implementing biosecurity measures, especially in small-scale dairy farms. In the management area, free-stall farms received an adequate or optimal evaluation, even if, one farm had critical issues concerning the cleanliness of the laying area among all observed groups. Differently, tie-stall farms overall received an adequate evaluation, but critical issues were identified in a small percentage of farms, particularly related to feeding management and the cleanliness of the main sections of the housing building. Generally, it can be supposed that the small herd size allows farmers to observe each animal daily and respond quickly to their needs. Regarding the housing area, free-stall farms generally received optimal ratings, while tie-stall farms mostly received adequate ratings. Criticism was noted for laying material in one free-stall farm and for the area destined to calves and for the environmental conditions in one tie-stall farm. The results obtained for the Area C, regarding the animal-based measurements (ABMs), indicate that both the tie- and free-stall farms received an optimal or acceptable evaluation. This suggests that most of the animals are comfortable being approached and touched, or at least show curiosity towards humans and approach them. Again, it can be supposed that the small-scale farms may positively influence animal welfare by providing better individual care and fostering human-animal bonding. However, it should be noted that

one farm faced unfavourable results mainly due to issues with cow cleanliness, udder health, the number of mastitis treatments, and the mortality of heifers and calves. The last area of verification, Hazard risks and alarm systems, was characterized by the highest criticisms, particularly in tie-stall farms, where problems were found related to noise pollution and inadequate alarm systems for ventilation and fire safety. Additionally, there were concerns about the treatment register and stock register.

The results of this study reveal key weaknesses and areas for improvement in the monitored farms. To fully understand the implementation of the innovative ClassyFarm system, further research with a larger number of farms is necessary. In addition, to promote best practices in biosecurity and animal welfare management, targeted interventions and educational initiatives should be prioritized to empower farmers. However, the resulting increase in production costs requires society to be willing to pay more for animal-based food produced under biosecurity conditions, respecting animal welfare and the environment in a contest of sustainability. In most countries this will have to be achieved via education of the public and by legislation.

INTRODUCTION

CHAPTER I

OPERATOR SAFETY

1.1 The farm and the employment relationship

The starting point is the 'farm', with all its implications, including legislation to protect safety at work. An agricultural entrepreneur is defined by Article 2135 of the Civil Code, which states: 'An agricultural entrepreneur is a person who carries out one of the following activities: agriculture, forestry, animal husbandry and related activities'. Agriculture, forestry and animal husbandry are defined as activities aimed at the maintenance and development of a biological cycle, or a necessary stage of a cycle, of a plant or animal nature, using or capable of using land, forest or fresh, brackish or marine water. In any case, related activities are those activities carried out by the farmer for the processing, preservation, transformation, marketing and valorisation of products obtained mainly from the cultivation of the land or woodland or from animal breeding, as well as the supply of goods and services, with the prevalent use of equipment or resources of the holding normally used for the agricultural activity carried out, including those for the valorisation of the territory and the rural and forestry heritage or for the provision of food and drink, as defined by law. In the agricultural sector, the following are considered to be employers: the agricultural entrepreneur (IA), the professional agricultural entrepreneur (IAP) and the direct farmer (CD). The Agricultural Entrepreneur (IA) is a person who carries out an essential and related agricultural activity. The professional agricultural entrepreneur (IAP), on the other hand, is a person who, with adequate professional skills, devotes at least 50% of his working time to agricultural activities (essential and related), either directly or as a

partner in a company, and derives from this activity at least 50% (25% in disadvantaged areas) of his total income; while the direct farmer is a person who is directly and habitually engaged in cultivating the land or rearing livestock and may also be assisted by members of his household. Agricultural activity may employ both permanent and seasonal labour, and any person who, for remuneration, performs manual labour in connection with the cultivation of the land or the rearing of livestock and related activities for the benefit of an agricultural holding or the performance of agricultural activities is considered a worker. Agricultural workers can be: (a) temporary workers, who are hired to do occasional, short-term work to complete a phase of work, and (b) permanent workers. Agriculture is a predominantly seasonal production sector, i.e. farms have to cope with work that only requires staff for certain periods of time. In the agricultural sector, fixed-term contracts are the most common form of employment relationship. In accordance with collective agreements, workers may be hired under a fixed-term contract: to perform short-term, seasonal or occasional work, or per work phase, or to replace absent workers who have the right to remain at work; to perform several seasonal jobs and/or several work phases during the year, with a minimum guaranteed employment of more than 100 days per year within a 12-month period from the date of hiring; and to perform more than 180 days of actual work within a single relationship.

1.2 Safety at work in agriculture

Agricultural work is characterized by a high accident rate, which requires companies and authorities to pay special attention to prevention and protection measures. The Occupational Health and Safety Act sets out the obligations and measures that agricultural enterprises must comply with and take in order to prevent possible risks. Farms are obliged to enforce health and safety rules for all their workers, regardless of their contractual

status. In the Italian legal system, the point of reference for occupational health and safety is Legislative Decree No. 81 of 9 April 2008, known as the 'Testo Unico', because its original purpose was to consolidate and coordinate occupational safety regulations in a single organic text. It is aimed at all types of companies (craft enterprises, commercial activities, snc, srl, sas, cooperatives, etc.), including those in the food sector. In addition to the subjects that make up the company organigram (employer, workers, managers, ...), the safety system also provides for the identification of other figures (head of the prevention and protection service, emergency and first aid officers, competent doctor, ...) necessary to guarantee the correct management of health and safety at work. All have specific legal obligations and must have specific training and, if necessary, appropriate technical skills. The main responsibility lies with the 'employer', but all employees have an active role in preventing, reporting and responding to hazards. In order for safety measures to be effective, the company must establish and implement a 'prevention policy', drawing up programmes for the objective safety of installations and workplaces, promoting the participation, information and training of all company components. The employer is the main point of reference for occupational health and safety, and although he may delegate certain functions, among all the obligations laid down, there are two that cannot be delegated, namely: a) the assessment of all risks with the drafting of the relevant risk assessment document and b) the appointment of the Head of the Risk Prevention and Protection Service (RSPP). In addition to these two obligations, the employer must:

- designate the competent doctor (if provided for in the risk assessment) to carry out health surveillance and periodic medical examinations;
- assigning tasks to workers on the basis of their abilities and health and safety conditions, only allowing access to areas at serious and immediate risk to those who have been adequately instructed and, in any case, requiring compliance with current

legislation and company rules and the use of the collective and individual means of protection made available to them;

- designate employees for the fire-fighting, first aid and emergency teams, take measures (depending on the activity and size of the company) to control risk situations in the event of an emergency and instruct employees to leave the workplace or hazardous area in the event of serious, immediate and unavoidable danger.
- inform, educate and train workers;
- send workers for medical examinations within the time limits laid down in the health surveillance programme and require the competent doctor to fulfil his obligations;
- take measures to control risk situations in the event of an emergency and instruct workers to leave the workplace or hazardous area in the event of serious, immediate and unavoidable danger;
- report accidents at work to the competent authority;
- consult the workers' safety representative;
- provide workers with an identity card (card) for contracted and subcontracted work;
- hold a regular meeting, at least once a year, and
- updating prevention measures in relation to organisational and production changes.

The person in charge is the employee (usually a foreman, forewoman, shift supervisor or simply the most senior or experienced employee) who has been properly trained and assigned by the employer to supervise the application of company policies and established safety rules. On the other hand, the person in charge must supervise compliance with legal obligations, company rules and the use of PPE; ensure that only suitably trained workers access areas where they are exposed to a serious and specific risk; inform workers in the event of serious and immediate risk, indicating the protective measures adopted or to be adopted and the measures to be taken in the event of an emergency, and invite them to

comply with them instruct workers to leave the workplace or hazardous area in the event of serious, immediate and unavoidable danger; do not require workers to return to work if the serious and immediate danger persists, and report to the employer or manager any defects in work equipment and PPE and any other hazardous conditions. The RSPP can be an employee of the company, an external consultant or the employer himself, and must have skills appropriate to the risks present in the workplace, an educational qualification of at least upper secondary level and a certificate of attendance at specific training courses, including periodic updates. The role of the RSPP in a company is to: identify risk factors, assess risks and define health and safety measures for the working environment specific to each company organisation; draw up, within the limits of his or her competence, preventive and protective measures and safety procedures for the various company activities; propose information and training programmes for workers and take part in consultations on health and safety at work, as well as in the annual periodic meeting organised by the employer; provide workers with information on the risks associated with their work activities. In the cases provided for in Annex II of the TU, the employer may directly perform the tasks of RSPP, as well as fire prevention and evacuation, through appropriate training and updating. In addition to the actual worker, i.e. 'any person who, regardless of the nature of the contract, carries out a work activity on behalf of a public or private employer, with or without remuneration, even for the sole purpose of learning a trade, craft or profession, excluding domestic and family service workers', the TU also includes subjects not previously contemplated for the purpose of extending occupational health and safety protection, i.e.:

- a worker who is a member of a cooperative or company, or an associate in participation;
- the beneficiary of apprenticeship initiatives;

- students in educational institutions (university and vocational training courses where laboratories, work equipment, chemical, physical and biological agents and equipment with video terminals are used);
- temporary workers;
- posted workers;
- project workers and coordinated and permanent staff;
- workers who provide occasional services;
- homeworkers and workers covered by the collective agreement for building owners;
- remote workers (teleworkers);
- members of the family business.

They themselves must play an active role in creating a safety culture, which is why specific obligations have been established for workers, based on the assumption that each worker must take care of his or her own health and safety and that of others in the workplace, according to his or her training, instructions and resources. Self-employed workers subject to employment contracts, family businesses, direct cultivators, artisans, small traders and partners of simple companies operating in the agricultural sector also have specific obligations with regard to health and safety at work, such as the use of: work equipment, according to the provisions of the TU; PPE, according to the same provisions; identity cards, in the case of contracted or subcontracted work. They also have the right to benefit from health surveillance and to attend specific health and safety training courses focused on the risks specific to their activities. The Workers' Safety Representative (RLS) is the only one among all the health and safety actors in the company who, as a trustee of the workers (by whom he is elected) and on their behalf, can interact with all the others with regard to occupational health and safety aspects: receives specific training on the risks associated with the specific activities and organisation of the company; verifies the application of health and safety measures on the basis of the risk assessment carried out;

participates in all stages of the occupational risk prevention process (from risk identification to the design and application of prevention and protection measures) and in the designation of those responsible for the safety system (RSPP, first aid officers, competent doctor, etc.); collaborates with the employer in the collection of workers' reports and observations; actively participates in the promotion, design, identification and implementation of preventive measures suitable to protect the health and physical integrity of workers and in the formulation of observations during visits and inspections by the competent authorities; may appeal to the competent authorities if it considers that the risk prevention and protection measures adopted by the employer or managers and the means used to implement them are not adequate to ensure health and safety at work. The training and information of the various actors influence the creation of a safety culture and the reduction of accidents, because they influence everyone's behaviour and human error. Employees are obliged to undergo training, must cooperate if they are appointed to certain functions (emergency teams, safety officers) or must participate in the company's various safety initiatives or activities and in maintaining and updating them (reports, proposals, exercises, compliance). In any case, training and information activities must be simple and easily applicable to the work context (also in the case of foreign workers) and must take place during working hours, without any financial burden on employees. The prevention of occupational accidents and illnesses and the improvement of working conditions depend on knowledge of the risks one is exposed to at work and the preventive and protective measures that can be taken.

We have often dwelt on the critical issues related to the health and safety of agricultural workers, and Inail's accident data for 2023 also show that agriculture is bucking the trend of reducing accidents at work compared to 2022. Moreover, there is no doubt that the barbarity surrounding the accident of Satnam Singh, the farm worker left to die with an amputated arm, and the resurgence of the phenomenon of '*caporalato*' and the exploitation

of immigrant labour, has rightly attention back to the issue of working conditions and health and safety, especially in agriculture. This issue, in recent years, has been the subject of 'an extensive institutional analysis, which has highlighted the close relationship between occupational accidents and low professional qualification of the worker', and the European authorities 'have promoted a new model of sustainable development in agriculture oriented towards environmental protection - aimed at reducing the use of chemical products and greenhouse gas emissions - and social protection, which also concerns the health and safety of agricultural workers'. The mechanism of 'social conditionality', introduced by the EU and transposed into Italian law, 'goes in this direction, foreseeing the curtailment of a part of the subsidies paid by Europe' under the CAP, the Common Agricultural Policy 2023-2027, in favour of economic operators in agriculture 'if they do not respect certain mandatory legal standards, including those concerning workers' health and safety'. It is also worth mentioning the 'New EU policy framework on health and safety at work post-2020' (European Parliament resolution of 10 March 2022), where the relationship between (in)health and (in)safety and agricultural work is addressed 'having regard to: the particular climatic conditions to which workers are exposed when working outdoors, hence the risk of developing particular diseases; the precariousness of the working and living conditions of seasonal workers; and the particular exposure to hazardous chemicals'.

Starting from the EU's 'New Strategic Framework', 'two factors affecting the health and safety of workers are emphasised, the combination of which produces an overload of risks'. The first 'relates to the typicality of the sector'. Indeed, agricultural activity has 'certain peculiarities - work in the open air or in greenhouses, the use of heavy machinery, the presence of animals, isolation in the workplace, the use of chemicals and plant protection products - that increase the risks to which workers are exposed'. The second factor, on the other hand, "concerns the *disempowerment* condition of a (large) segment of agricultural workers, to be understood as "*the inability to control their own lives due to the low position*

they occupy in the social hierarchy" (Rinaldi and Marceca, 2017). The inequality of bargaining power, which is generally already inherent in the subordinate employment relationship, is exacerbated in agriculture, also affecting health. Not infrequently, work in this sector is performed by individuals who are in a condition of exclusion from the labour market or of vulnerability, which still facilitates an attitude of evasion or avoidance of health and safety regulations. In essence, 'in an industry where the health and safety of workers is already endangered by peculiar factors', the power relations often established in it expose workers to further risks to their own health and safety. An attempt to 'strengthen security obligations within the farm organisation' can be found in Article 14 of Regulation (EU) No 2021/2115 of 2 December 2021, laying down rules on support for the strategic plans to be drawn up by the Member States under the Common Agricultural Policy. This regulation introduced so-called 'social cross-compliance' into the CAP 2023-2027, as mentioned above. The mechanism makes *"the full payment of CAP contributions to farmers subject to compliance with 'requirements relating to the applicable working and employment conditions or to the employer's obligations arising from the legal acts referred to in Annex IV*' set out in the Regulation and this Annex 'refers to certain European acts subsequently transposed into domestic law, such as Directive 2019/1152/EU, on transparency of employment relations, and Directives 89/391/EEC and 2009/104/EC, both of which concern the health and safety of workers'. The institute of cross-compliance 'aims to strengthen compliance with the mandatory rules of the law by reducing the amount of those economic resources that have historically foraged the European agricultural production system'. The high rate of ineffectiveness of criminal sanctions pushes both the EU and national legislators towards more effective sanctioning techniques insofar as they affect the employer’s interest in profit, thus bringing the sanctioning apparatus provided for by Legislative Decree No. 81/2008 within the framework of an overall vision of the 'culture of prevention', of which rules and sanctions are the tools. Article 14 of Regulation

2021/2015, as well as the related Annex IV, "were implemented by Legislative Decree No. 42 of 17 March 2023, as amended by Articles 2-3 of Legislative Decree No. 188 of 23 November 2023". The aforementioned D. Lgs. 42/2023 represents the implementation of Parliament Regulation (EU) 2021/2116 of 2 December 2021 on the financing, management and monitoring of the common agricultural policy. In addition, the detailed regulation of the provisions subject to sanctions is contained, in accordance with Legislative Decree No. 42/2023, in the Ministerial Decree of 28 June 2023. The implementation of the social conditionality mechanism in Italy, however, has shown "how the implementation of the social conditionality mechanism in the domestic legal system is not particularly respectful of the regulatory obligations laid down in Article 14 and Annex IV of Regulation 2021/2115 and is incapable of exerting its intimidating vis, having little impact on the strengthening of a safety culture". In particular, the Ministerial Decree of 28 June 2023 "seems to privilege compliance with those obligations proper to the formal-characteristic figure of the employer, deriving from the ownership of the relationship, and less, instead, those of a substantial nature, on which the principle of effectiveness of the prevention system rests more".

CHAPTER II

CONSUMER SAFETY

2.1 Food safety

After having seen who the 'Operator' is and analysed the aspects related to his safety, we move on to the analysis of the safety of the 'Consumer' - the final recipient of the product -, which finds its foundation and starting point in the concept of 'Food Safety', which represents the respect of hygienic requirements at all stages of production, processing and distribution, to ensure the wholesomeness of food and, therefore, the absence of contamination, which could expose consumers to the risk of food poisoning. According to FAO, food security exists when "all people, at all times, have physical, social and economic access to sufficient, safe and nutritious food to meet their dietary needs and food preferences for an active and healthy life". When we talk about 'food security', we are referring to 'quantitative food security', which aims to solve the problem of hunger and forms of food inequality, and 'qualitative food security', which responds to the needs of marketing and health protection. According to this orientation, in more backward societies, the problem is mainly one of food quantity; whereas in more advanced societies, the main concern is food quality, because food poses numerous risks to people's health, due to the globalisation of markets and continuous technological progress, which has led the market to obtain unconventional food at the lowest cost, replacing traditional food. While technological innovation has diversified the food supply, it has also increased the health risks associated with food consumption, as the negative effects of using modern technologies

can take a long time to manifest themselves (Germanò and Basile, 2014; De Marco, 2001, 2005 e 2007).

In recent years, an 'ethical' dimension of food has emerged, which has led to more attention being paid to how food is produced and consumed, in terms of health protection and quality. Consumers have begun to realise the need to buy products that minimise damage to health, while food companies have started to pay more attention to the care of the entire processing cycle according to 'Good Agricultural Practices' and have become aware of the importance of 'Supply Chain Traceability', which has led to a greater commitment to control and risk assessment. However, sectoral interventions by European and national legislators have sometimes made it rather difficult to balance the interests, deserving of protection, of food producers and consumers, due to the existence of a multi-level regulatory system (international, EU, national and regional sources) (Tregidga et al., 2019; De Marco, 2001, 2005 e 2007).

2.2 Food legislation in the European Union and Italy

The application of European legislation in the various Member States often leads to differences in the application of legislation from one Member State to another, making the legal requirements for products complex for operators, who have to deal with different legal provisions applicable to a foodstuff, which may, among other things, vary from one Member State to another. Italian food legislation finds its main source in Articles 32 and 41 of the Constitution. Article 32 of the Constitution has the dual objective of protecting health by providing both individual and collective benefits. In

particular, the second paragraph of Article 32 of the Constitution, according to which 'the law may in no case violate the limits imposed by respect for the human person', allows for balancing situations that benefit the individual with other interests of the community. In this context, Article 41 of the Constitution states that economic freedom must not conflict with the security of the individual and that the law 'shall establish appropriate programmes and controls to direct and coordinate public and private economic activity for social purposes'. According to a doctrinal orientation, from this rule derives '(...) the duty (...) of public control over economic activity in function of the social objectives that must in any case be pursued'. However, the balance between the right to health and other constitutionally protected rights must be made according to the 'principle of proportionality'. In European food law, the free movement of goods, one of the pillars of the internal market, is the starting point. An integrated strategy was therefore developed to ensure a high level of health protection through consistent measures and appropriate controls. However, European action in the field of health is 'subsidiary' to that of the Member States. The European Union therefore plays a coordinating role, unlike the European harmonisation policies implemented in the agricultural sector (Costato and Russo, 2023). European action to protect the right to health has taken the form of direct action through secondary legislation and the adoption of soft law policy documents. With regard to consumer protection, European policy has instead supported and complemented national policies to protect food safety and health. In the Treaty on the Functioning of the European Union, health is protected on an equal footing with business and consumers. Indeed, Art. 3 states that the European Union 'shall work for the sustainable development of Europe based on balanced economic growth and price stability, a highly competitive social market economy, aiming at full employment and social progress, and a high level of protection

and improvement of the quality of the environment (...)' and Art. 6 TFEU states that the European Union shall support, coordinate and complement the activities of the Member States in the field of health and safety at work. Article 168 TFEU (ex-Article 152 TEC) also requires that a high level of human health protection be ensured in the implementation of the Union's policies and activities, through the prevention of diseases and illnesses and the elimination of sources of danger. According to this provision, 'Union action, which shall complement national policies, shall be directed towards improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health. This action includes combating major health scourges, promoting research into their causes, transmission and prevention, as well as health information and education, monitoring, early warning and combating serious cross-border health threats'. With regard to consumer protection, Article 169 TFEU (ex Article 153 TEC) states that 'the Union shall contribute to protecting the health, safety and economic interests of consumers, as well as to promoting their right to information, education and to organise themselves in order to safeguard their interests'. This is the background to the Regulation of the European Parliament and of the Council of 9 November 2011, with which the EU sought to pursue the goal of ensuring citizens' participation in the internal market through greater protection when purchasing goods and services. With the involvement of consumers, a process of education, information and awareness-raising was to be initiated. This brief regulatory reconstruction is completed by Article 191 TFEU (ex Article 174), which provides for the 'precautionary principle', protecting not only the environment but primarily health (Germanò and Basile, 2014).

The precautionary principle is a general principle, codified in European legislation, which obliges the competent authorities of each Member State to take appropriate

measures to prevent potential risks to public health, safety and the environment. The application of this principle, in a situation where the potentially dangerous effects of a product or process have not been identified and where the preliminary scientific assessment has not established the risk with sufficient certainty, has made it possible to prevent the distribution of dangerous foodstuffs or to withdraw them from the market, thus allowing the protection of the right to health or the environment to prevail over economic interests. This principle is based on the principles of free competition, freedom of establishment and freedom to provide services enshrined in the Treaty on European Union. To complete the outlined legal framework, it is necessary to examine the way in which the food trade is controlled within the European Union. Article 36 TFEU (ex-Article 30 TEC) states that 'Articles 34 and 35 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security, the protection of health and life of humans, animals or plants (...)'. However, such prohibitions or restrictions must not constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States. In situations of potential risk to the consumer in the production of a foodstuff, it will be necessary to implement procedures to identify the product placed on the market and withdraw it, even if it has been exported to other countries, and this will be achieved by strengthening and improving monitoring activities. After outlining the principles of European legislation protecting the right to health, it is necessary to review the evolution of food safety legislation. Legislation on the safety of products placed on the market within the European Community (Directive No. 92/59/EEC, replaced by Directive No. 2001/95/EC on industrial products, including foodstuffs) requires operators to place products on the market that are safe for human health. The European legislator has provided for the control of foodstuffs at

all stages of the production process, from production to processing, transport, distribution and supply to the consumer, and in this area European legislation has established preventive and subsequent protection for the consumer. Preventive protection' is based on Directive 2001/95/EC of the European Parliament and of the Council on general product safety, which pursues the dual objective of protecting consumer health and promoting free trade in food. Based on the precautionary principle, the directive lays down safety requirements for any product placed on the market and intended for consumption. In order to ensure a high level of protection of human health, a food is considered safe if it presents no risk or a low, acceptable risk when used. The cornerstone of EU food law is the 'Regulation 178/2002 of the European Parliament and of the Council of 28 January 2002', 'laying down the general principles and requirements of food law and laying down procedures in matters of food safety', aiming to reconcile the free movement of food with the principles of food safety, inspired by the pursuit of a high level of protection of human and animal health and the control of the movement of food and feed along the entire agricultural production chain - 'from farm to fork'.

The analysis of hazards and critical points in the food production and distribution system is specifically regulated by technical standards based on the HACCP system. In this regard, the aforementioned Regulation 178/2022 establishes the obligation for food producers and distributors to place products on the market that comply with pre-established safety requirements, such as risk analysis (Art. 6), the precautionary principle (Art. 7), protection of consumer interests (Art. 8), transparency in the development of food law (Art. 9), consumer information (Art. 10), safety requirements for food business operators (Art. 11-20), the establishment of the European Safety Authority (Art. 22-49) and procedures for food emergencies (Art. 50-57). Before

analysing the safety requirements, however, it is necessary to clarify the definition of 'food'. First, according to Article 2 of Reg. 178/2002, food is defined as any processed, partially processed or unprocessed substance or product intended to be 'ingested' by humans. However, this regulation does not resolve the issue of the different designations in the Member States. The Court of Justice and part of the doctrine have applied the criterion of mutual recognition, which assigns equivalence to national rules on the production and presentation of foodstuffs in intra-Community trade. Secondly, it is necessary to distinguish between foodstuffs for human consumption (foodstuffs) and medicinal products, which, according to Directive 2001/83/EC, are products with a therapeutic effect and products without a therapeutic effect. A further distinction concerns 'feed', which, according to Article 3(4), are processed, partially processed or unprocessed substances or products intended for animal feed. Food legislation imposes specific safety obligations on food operators to protect consumer health. In particular, producers and distributors are obliged to place 'safe products' on the market in compliance with food legislation at the production, processing, transport, storage and final distribution stages. The safety requirements of Articles 14-20 of Regulation 178/2002 apply within the limits of the 'respective activities' and according to the 'control capacity' of the food safety conditions. The content of the conformity obligation is determined according to the requirements of Article 14 et seq. of Regulation 178/2002, the technical annexes of Regulation 852/2004 (on the hygiene of food of animal origin) and sector regulations. With regard to the criteria for identifying unsafe food, there are doubts as to their application to the food business operator. According to some doctrine, the diligence required of the private operator goes beyond the threshold of prevention and includes the adoption of all forms of precaution. However, this approach has been criticised by some scientists, who believe that the

criteria laid down in Article 14 of Regulation 178/2002 provide the framework for public authorities responsible for monitoring and controlling risks, including emerging risks, associated with food consumption. As far as safety requirements are concerned, risk analysis is a general principle of food law to protect consumer health. In particular, Article 6.1 states that 'food law is based on risk analysis' as a decision-making function consisting of three elements assigned to different actors. As far as risk analysis is concerned, the European legislator made a distinction between risk assessment, which is based on scientific evidence and 'must be carried out in an independent, objective and transparent manner' (paragraph 2), and risk management, which must consider the results of risk assessment and the opinions of the Food Safety Authority, as well as the precautionary principle (paragraph 3). It is important to understand when a food poses a health risk to consumers. Regulation 178/2002 defines 'risk' as 'a function of the likelihood and severity of an adverse health effect resulting from the presence of a hazard', defined as 'a chemical or physical biological agent present in a food or feed, or condition of a food or feed, which is capable of causing an adverse health effect' (Art. 3, nos. 9-14). A food is considered to be unsafe if it is injurious to health or unfit for human consumption, considering the "probable immediate and/or short-term and/or long-term effects of the food on the health of a person consuming it and on that of his or her descendants" and the "probable toxic or cumulative effects of a food" (Art. 14 (2) (2) and (4) (a) and (b)). In this context, Article 14(1) of Regulation 178/2002 states that 'unsafe food may not be placed on the market'. The definition of "unsafe food" is also contained in the Regulation, in the part relating to the categories of "food injurious to health" (Art. 14.4) and "food unfit for human consumption" (Art. 14.5). Safety is assessed on the basis of the normal conditions of use of the food itself at each stage of production, processing and distribution, and on the basis of the information on the label

or other information on the harmful effects of the food (Antonacchio, 2007 Romano, 2017; De Marco, 2001, 2005 e 2007).

After these clarifications, it is necessary to examine the risk identification process. Risk is identified by assessing the likelihood and severity of adverse health effects resulting from the presence of a hazard in the food or feed (Article 3(9)). This 'risk assessment' is carried out by means of a scientifically based procedure that evaluates the exposure to the hazard and the risk, as well as the likelihood and severity of the harmful effect on health (Article 3(11)). The review is carried out by EFSA, the European Food Safety Authority (Article 3.13). Following the risk assessment, the European Commission manages the risk (risk management) in accordance with the precautionary principle (Art. 7) and the assessment of available information and possible adverse health effects, analysing alternatives to action and taking restrictive measures and appropriate preventive and control measures to protect health (Art. 3, item 12). The Community Rapid Alert System (RASFF), a kind of network involving the European Commission, the EFSA (Food Safety Authority) and the EU Member States, was set up to provide real-time notification of direct or indirect health risks resulting from the consumption of food or feed. The alert system is based on Council Directive 92/59/EEC, transposed by Legislative Decree 115/1995, on general product safety, and on Regulation 178/2002, which lays down the principles and requirements of food law and establishes the EFSA, setting out the procedures relating to food safety. The flow of 'alerts' must be complete and timely, through notifications communicated and exchanged between Member States through the network and in real time. The alert system works by recalling products that present a risk to human or animal health.

Regulation 178/2002 provides for other safety obligations, such as the 'traceability' obligation introduced for the beef sector following the 'mad cow' crisis (Regulation

1760/2000/EC), which introduced traceability for professional operators in the sector as a food safety tool to carry out 'recalls', informing consumers or control officials (Coltelli et al., 2004). Traceability concerns the flow of raw materials and components within the production process of an individual food company. The traceability system makes it possible to identify the person responsible for the hazard and the damage caused and, with regard to food imported from third countries, provides for the possibility of taking appropriate emergency measures at Union level to protect public health, animal health and the environment in relation to food and feed imported from a third country, if the risk cannot be adequately controlled by measures taken by the Member States. It emerges, therefore, that the legislator's intention was to reconcile the interests of food producers with those of consumers for a healthy and safe food supply, by regulating the various stages of production and the behaviour of the various operators in the sector, providing control mechanisms and an information network capable of involving each Member State in the implementation of this food safety (Marchant, 2002). However, since the early 1990s, food safety issues have been addressed by a series of vertical sectoral directives and a horizontal directive, Directive 93/43, specifically dedicated to the hygiene of food production. The key element introduced by these directives was the 'imposition of self-regulation by companies to ensure the healthiness of the process, with controls and safety systems introduced at the production stage'. Food business operators are required to take direct and primary responsibility for the hygiene of the food they produce through the implementation of two distinct preventive factors: a) the adoption of a scientific system of hazard analysis and critical control points through the mandatory application of the "HACCP" method and b) the adoption of a set of good hygiene practices detailed in Annex I of Directive 93/43. By bringing controls forward to the production phase and introducing a system

to guarantee the wholesomeness of the process, the European legislator wanted to ensure the hygiene of food products undergoing industrial processing, thus overcoming technical obstacles to free movement (Germanò, 2009; De Marco, 2001, 2005 e 2007).

The old Directive 93/43/EEC was superseded and replaced by Regulation 852/2004 on the hygiene of foodstuffs, which eliminated all critical issues that had arisen in individual Member States with the different transposition rules. Regulation 852/2004, being directly applicable in all Member States, constitutes a unique set of rules aimed at ensuring a high level of consumer protection with regard to food safety, from the place of primary production to the place of marketing. The aforementioned Regulation therefore lays down general rules for food business operators on the hygiene of foodstuffs, taking particular account of the following principles: (a) primary responsibility for food safety rests with the food business operator; (b) it is necessary to ensure food safety throughout the food chain, starting with primary production; (c) it is important to maintain the cold chain for foodstuffs that cannot be safely stored at ambient temperature, particularly frozen foodstuffs; (d) it is necessary to ensure that all foodstuffs are produced and marketed in accordance with the requirements of this Regulation; (e) guides to good practice are a valuable tool to assist food business operators to comply with hygiene rules at all levels of the food chain and to apply the principles of HACCP; (f) it is necessary to establish microbiological criteria and temperature control requirements based on a scientific risk assessment; (g) it is necessary to ensure that imported foodstuffs meet at least the same hygiene standards as foodstuffs produced in the Community or equivalent standards. The regulation applies to all stages of food production, processing and distribution, as well as to exports. It does not apply to primary production for private domestic use; to the domestic preparation, handling and storage of food for private domestic use; to the

direct supply of small quantities of primary products from the producer to the final consumer or to local retailers who supply directly to the final consumer; to assembly centres and tanneries that fall under the definition of food business only because they handle raw materials for the production of gelatine or collagen. It is aimed at food business operators, who must in particular ensure that all stages of the production, processing and distribution of food under their control comply with the relevant hygiene requirements laid down in the regulation, by putting in place, implementing and maintaining one or more permanent procedures based on the following HACCP principles:

a. identifies all hazards that must be prevented, eliminated or reduced to acceptable levels;

b. identifies critical control points at the stage(s) where control is essential to prevent, eliminate or reduce a hazard to an acceptable level;

c. establishes critical limits at critical control points that distinguish between acceptability and unacceptability for the prevention, elimination or reduction of identified hazards;

d. establishes and implement effective monitoring procedures at critical control points;

e. defines the corrective actions to be taken when monitoring shows that a particular critical control point is not under control;

f. establishes procedures to be applied regularly to verify the effective functioning of the measures referred to in points (a) to (e);

g. establishes documentation and records, appropriate to the nature and size of the food business, to demonstrate the effective application of the measures set out in points (a) to (f).

Food business operators shall cooperate with the competent authorities in accordance with other applicable Community legislation or, in the absence of such legislation, in accordance with national law and, in particular, each food business operator shall notify the competent authority, in the manner prescribed by that authority, of each establishment under its control that carries out any of the stages of production, processing and distribution of foodstuffs, with a view to the registration of that establishment. The free movement of goods is therefore central to the Union's policies and is one of the fundamental freedoms of the internal market. However, this freedom must guarantee uniform protection of the consumer, the environment and energy resources. Even the Court of Justice, in Case C-269/1997, stated that the pursuit of the objectives of the Union's agricultural policy (ex Article 43 TFEU) cannot disregard the protection of public health and the precautionary principle. This principle, mentioned in Article 191 TFEU, may be invoked when a product or process may have potentially dangerous effects that have been identified through scientific and objective evaluation, even if such evaluation does not allow the risk to be determined with certainty. The aim is to ensure a high level of environmental protection by taking preventive measures in the event of a risk. Today, the scope of the principle also extends to consumer policy, European food law and human, animal and plant health. In the past, this principle has made it possible to prevent the marketing or distribution of potentially harmful foodstuffs, putting the protection of the right to health and the environment before economic interests.

This legal framework also includes EU Regulation 1169/2011 on the provision of food information to consumers, the absence of which could mislead the consumer. Whereas in the past food safety was seen as a problem of the individual company producing a food product, in recent years the approach has been to consider the entire

history of the food product with the ultimate goal of ensuring food safety. The fundamental principles on which the legislation is based include transparency, risk analysis, risk prevention, protection of consumer interests and the free movement of safe products within the EU market and with third countries. The legislation gives primary responsibility for food safety to food business operators (FBO), defined as 'the natural or legal person responsible for ensuring compliance with food law in the business or food sector under their control'. Food safety can only be guaranteed if all those involved in food production implement risk prevention properly. Food business operators have a responsibility to ensure that the food in their businesses complies with the legislation applicable to their activities at all stages of production, processing and distribution; to apply the preventive tools provided by the legislation (HACCP and good hygiene practice standards) and to ensure the effectiveness of these preventive measures through appropriate verification tools, including product analysis; to ensure product traceability, i.e. to be able to quickly identify who has supplied what to whom (Correra and Ottogalli 2007).

However, it should be noted that in Italy, in addition to EU regulations, several national and regional regulations are still in force.

2.3 Traceability

Experience has shown that the lack of traceability of food and feed can jeopardise the functioning of the internal market for these products. It is, therefore, necessary to establish a general product traceability system, covering both the feed and food sectors, in order to be able to carry out targeted and accurate withdrawals or to provide information to

consumers or control officials, thus avoiding serious and unjustified inconveniences in the event of a food safety hazard (Ragionieri and Basile, 2014; Schwagele, 2005).

Hence the need to ensure that food and feed companies, including importers, are able to identify the company that has supplied them with the food, feed, animal or substance that may be part of a particular food or feed, so that traceability can be ensured at all stages in the event of an investigation. Risk reduction means trying to prevent the consumption of a dangerous product, which can be achieved by recalling or withdrawing dangerous products from the market. Withdrawal means any measure aimed at preventing the distribution and display of a dangerous product and its supply to consumers, while recall means measures aimed at obtaining the return of a dangerous product that the producer or distributor has already supplied or made available to consumers. The difference is, therefore, that, in the first case, the hazardous product has left the company where it was manufactured but has not yet reached the retail stage; whereas, in the second case, the product has already passed through the various stages of the distribution chain and is about to be sold or served to the end consumer. In order to enable a recall or withdrawal, food business operators are required to 'trace' the entire history of the product, documenting the flow of information throughout the supply chain 'from field to fork' and from operator to operator, up to the finished product. Traces must be left whenever food passes from one operator to another. In this way, if necessary, it is possible to reconstruct the path that led to the finished product and identify all the raw materials and suppliers that contributed to its creation. Without this information, collected during the various processes in the supply chain, it would be impossible to trace a product that turned out to be unsafe.

Traceability allows dangerous products to be withdrawn or recalled from the market, the causes of problems to be traced and, consequently, the responsibilities of each operator involved in the creation of the product to be identified, from primary production to the last operator who sells or administers the products to the consumer. In all cases where the

potentially hazardous product has already left its premises and is under the control of another operator, the food business operator must immediately trace the hazardous product and inform the competent authorities (so-called 'notification'). The competent authorities activate the RASFF (Rapid Alert System for Food and Feed) and carry out the risk assessment. This alert system makes it possible to disseminate risk information to all potential stakeholders, both inside and outside the Union, thus protecting the consumer. In the event of a recall, operators are obliged to inform consumers by the means they deem most appropriate. The purpose of this obligation is to limit the risk posed by a dangerous product and to try to prevent those still in possession of the product from consuming it. If, on the other hand, the hazardous product is still present on the farm, the operator must handle the 'non-compliance' correctly to prevent the product from being placed on the market, but in this case the traceability mechanism is not activated (Knives, 2004).

Regulation 178/2002 therefore defines 'traceability' as 'the ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed through all stages of production, processing and distribution'. Traceability is the flow of information along the entire supply chain, from field to table, from operator to operator, all the way to the finished product (Evans and Honey 2017; De Marco, 2001, 2005 e 2007). Only by leaving these traces will it be possible, should the need arise, to reconstruct the path that led to the finished product, identifying all the raw materials and suppliers that contributed to forming the food that arrives on our table. To give a very simple example, if an animal intended for human consumption is sold by the breeder to a retailer, and by the latter to a restaurateur, who then feeds it to the final consumer, 'tracing' means that the breeder must know exactly to whom he sold the animal, just as the retailer must know that he resold it to a particular restaurateur. If the restaurateur reveals an immediate health risk to consumers, it will be possible to 'trace' the origin of the product through documentation. The minimum unit to be

considered for traceability is not the individual animal or the individual product package, but the 'production batch'. Since a batch may be destined for several customers and the same customer may purchase several batches of the same product, traceability requires each individual company to make a precise choice on how to organise itself documentally and operationally to ensure that the potentially dangerous batch can be traced quickly to enable consumer protection.

Traceability is therefore the ability to reconstruct and follow the history of a product by identifying and documenting all the activities, materials and specific responsibilities of the operators who contributed to its production (Meuwissen et al., 2003). We can therefore say that traceability and retraceability are two different but closely related processes, so much so that they are often used as synonyms in everyday language.

Regulation 178/2002 makes traceability mandatory for all food, feed, food-producing animals and any substance intended to be part of a food. Every food business operator shall: (a) identify and document the suppliers of raw materials/ingredients; Every food business operator must be able to identify to whom it has supplied a food intended for the production of food or any substance intended or likely to become part of a food; this activity is termed "upstream traceability"; (b) identify the recipients of its products; Every food business operator must be able to identify to whom it has sold a food or any substance intended or likely to be incorporated into a food; this activity is referred to as "downstream traceability"; c) ensure that this information is available to the competent authorities through appropriate systems and procedures; the Regulation stipulates that operators must have "systems and procedures" in place to enable them to make the necessary information available to the competent authorities on request; d) initiate procedures to withdraw or recall the product from the market if the operator considers that a food does not comply with the safety requirements. If a food business operator believes or has reason to believe that a food which it has imported, produced, processed, manufactured or distributed is not

in compliance with food safety requirements, it must immediately initiate procedures to recall the food and inform the competent authorities, customers, suppliers (if they are involved in the problem, e.g. due to a non-compliant raw material supplied by them) and the consumer; e) provide effective and accurate information to the consumer in the event that the unsafe product has already been purchased or made available to the consumer (e.g. in the case of a recall). Upon receipt of the notification, the competent authorities activate the RASFF (Rapid Alert System for Food and Feed) and carry out the risk assessment. This alert system acts as a 'network', allowing risk information to be disseminated to all potential stakeholders, thus protecting the consumer, regardless of the distance 'travelled' by the product. The failure of an operator to notify the competent authorities when he knows that a food produced, distributed or administered by him is dangerous to health is a serious breach of the principle of transparency pursued by the European Union and must be sanctioned. Traceability also represents an opportunity for food companies that want to enhance the value of their product through the so-called 'supply chain traceability', which is an inter-company process resulting from the combination of the internal traceability processes of each operator in the supply chain, united by efficient communication flows. The protagonist of the supply chain guarantee is not a single company, but all the companies involved in the production of the product. The clear and complete knowledge of the identity of the companies that have contributed to the creation of the product is intended to offer the consumer, on a voluntary basis, an 'additional' guarantee of the quality of the traced product and, to this end, it is necessary for the consumer to know the meaning of this system, to perceive it as an 'added value' and to be able to recognise and distinguish the product at the time of purchase (Clark et al., 2017). The supply chain traceability system is generally based on a 'specification' to which all companies involved must adhere and against which a third party carries out checks for compliance. The concept of supply chain is defined as 'the defined set of operators and their material flows that contribute to

the production, distribution and marketing of a product'. Here we also find the idea of a system that allows us to follow the path of a food product through the various stages of the supply chain, 'from the field to the table' (De Marco, 2001). This path is often identified, at the Italian level, with two different terms: traceability and retraceability, which refer to two different processes; by 'traceability' we mean the process that follows a given product 'from upstream to downstream' in the supply chain, and by 'retraceability' the process that goes backwards, 'from downstream to upstream' (Opara and Mazaud 2001).

In other words, traceability means determining what information must be identified for each link in the chain; traceability means finding the most efficient means of reconstructing this information backwards. According to ISO 8402, traceability is defined as 'the ability to establish the origin, history, use and process provenance of a product by reference to written documentation' (ISO, 1994), without defining which parameters are to be measured. A traceability system should be characterised by breadth, depth and accuracy (Golan et al., 2004). The 'breadth' depends on the amount of information recorded (e.g. the feeding regime, genealogical information, veterinary treatment details...); the 'depth' consists of 'how far' the production system has to be traced (e.g. from birth on the farm to the butcher's counter); finally, the 'accuracy' is the degree of certainty with which the system can precisely define the movements of a given product, which must be defined within an acceptable margin of error. The traceability of meat and beef is, in particular, guaranteed at European level by Regulation 1760/2000, which repealed Regulation 820/1997. European legislation has made it mandatory to document all links in the chain. The cornerstones of the system can be summarised as follows (ARSIA, 2003) 1) a computerised information flow management system, in the form of a national zootechnical database (BDN), operational since 31 December 1999, with the obligation to identify all new bovine animals born since January 1998 in a manner that complies with the Regulation itself; and 2) an individual bovine identification system, based on ear tags, two

per animal, to be applied within twenty days of birth. Ear tags must be made of flexible plastic material, designed to remain attached to the animal's ear without damaging it, and must be applied between the two prominent veins on the concave surface of the pinna; they must be tamper-proof and easily readable throughout the animal's life. They must not be reusable. Ear tags must not be used in packs other than those for which they were issued. At the same time as applying the ear tags, the farmer must complete and sign the corresponding identification coupon. Once the ear tags have been correctly applied and the identification coupon filled in, the breeder must update the holding's loading and unloading register, indicating the identification tag, breed, sex, mother's identification code, date of birth, etc. Within seven days, the breeder sends or delivers the animal's identification coupon to the competent territorial veterinary service, which, after checking that the information is complete, registers it in the national database.

If the farmer registers the births of calves directly in the 'National Data Bank', he must do so within seven days of the application of the marks, but does not have to send the identification voucher. The breeder is responsible for the correct traceability of the animal's movement and must check the presence of the tags, passport and model 4 (declaration of origin accompanied by the health certificate issued by the ASL of departure). Also, in this case, the breeder must update the loading and unloading register within three days of handling the animal. Within seven days he must send a copy of model 4 to the veterinary service. At the slaughterhouse, carcasses are systematically registered by means of a reference code corresponding to the individual identification number of each bovine animal. Then there is the labelling stage, which includes compulsory and optional information.

The compulsory information includes: the reference number or code (it highlights the link between the meat and the animal or the batch of animals); the indication of the

bovine ear tag number or any other code that individually identifies the animal is not compulsory, but is foreseen in the specifications of some consortia or certification marks; the approval number of the slaughterhouse; the approval number of the cutting plant; the country of birth; the country of fattening; the country of slaughter. Country of slaughter. Optional information: date of slaughter; net weight in kg; breed; category (calf, bull, steer, cow, heifer); date of birth; age (months); herd of origin; conformation (percentage of lean meat in the carcass: excellent, superior, very good...); fat cover (very low, medium, high...); type of farming (indoor, outdoor...); type of feed (no added animal fat, non-GMO...). This traceability system is based on paper and/or electronic documents that follow the animal 'from birth to the table'. Given the possibility of ear tags being tampered with or lost, scientific research has turned its attention to new identification systems (Mariani et al., 2005). Similar to horses or domestic animals, livestock can be identified by electronic devices. In fact, an automatic data collection and identification system is used, radio frequency identification (RFID), which consists of two elements: the transponder or TAG (chip with antenna). Transponders can be: read-only; write once/multiple read (WORM); read/write multiple (Read/Write). The reader (RFID reader) can be read-only or read/write. TAGs are physically implanted in the animal to be identified at various anatomical locations. Whenever they are in close proximity to an RFID terminal, the signal is picked up and the animals are recognized, allowing all information about the animal to which they are 'paired' to be tracked. The injectable transponder, on the other hand, is an identification system in which the identification device is inserted into the animal's subcutaneous tissue. In general, injectable transponders are passive (Passive Injected Transponder - PIT), i.e. they draw the energy for their operation from an external field (generated by the reader). In cattle, PITs of different sizes (23 and 32 mm) are used, injected at three possible sites: axillary fossa, auricle and upper lip (Connil et al., 2000;

Lambooij et al., 1999). The health status and productivity of the animals are not altered by the application of transponders; complications are rare (less than 4% of implanted cattle) and consist only of local hemorrhages after application (mainly in the ear), perforations during application in the lip and small local abscess infections. In these cases, the animals can be re-injected after a week, even at the same site; rejections and transponder failures are practically anecdotal events. The PIT readability percentage decreases over time in the lip and ear, but not in the axilla. The ruminal bolus is a device consisting of a capsule made of biocompatible, non-porous material (ceramic derivatives and compounds) containing a microchip (Fallon, 2001). The bolus is swallowed by the animal to reach the reticulum, where it remains for life. In cattle, the stress caused by the presence of the bolus is minimal (Stanford et al., 2001), although recent publications (especially in small ruminants) have shown some discomfort in the laryngeal esophagus, mostly due to application errors (Botta et al., 2008). In one-week-old calves, the bolus does not seem to influence growth and lactation (McAllister et al., 1998; Stanford et al., 2001).

The introduction of foreign bodies (magnets, substances released from the bolus) into the rumen of cattle and sheep does not lead to significant changes in animal function (Garin et al. 2003). Traditional and electronic traceability systems, as designed and provided for by current legislation, are potentially prone to errors, resulting in the loss of the link between the animal's identification code and the animal itself. There is therefore a risk of loss of product traceability, both ante-mortem and post-mortem.

The critical points can be summarized as follows:

- breeding and transport: accidental detachment of ear tags (not from bolus or subcutaneous microchip);
- slaughterhouse: loss of connection to the head-carcass registration number or incorrect relationship between the new slaughter identification number and the original registration number due to lack of transponder identification;

- processing phase: incorrect relationship between the new processing ID and the original serial number;
- packaging stage: incorrect relationship between the identification of the new packaging and the original serial number, and
- sale: Incorrect relationship between the identification of the new sale and the original serial number.

Therefore, in addition to traceability systems based on paper registers and/or electronic registers, it is useful for operators in the supply chain to have a tool that allows them to establish the origin of the meat in an absolutely irrefutable manner, in order to have 'absolute control' over the supply chain and quickly identify any anomalies (Colafrancesco, 2003). The traceability system based on DNA analysis is currently the only technology that can guarantee the absolute veracity of the documentation accompanying the meat up to the point of sale (Arana et al., 2002; Dalvit et al., 2006 e 2007; Capoferri et al., 2006). The test is not intended to replace existing traceability systems, but to complement, enhance and verify them, particularly in the context of highly certified products and specific supply chains. The analysis consists of comparing and verifying the genetic identity between the reference sample taken from the live animal (ante-mortem sample), recorded and stored, and the meat sample (post-mortem sample) taken at the point of sale or at any other point in the chain. The scientific principle of genetic traceability thus consists in establishing that the cells of two biological samples under examination contain exactly the same genome. In fact, the genome of two different individuals, even from the same family, shows considerable differences (Mackie et al., 1999; Cunningham and Meghen, 2001; Lombardo). Other important features supporting this type of technology are: 1) DNA is immutable throughout the productive life of an animal; 2) DNA is quite stable to different food treatments; and 3) DNA is present in all cells of an organism. Once the

DNA has been extracted from the chosen matrix, molecular analysis allows to use appropriate markers to obtain a 'fingerprint' or a specific allele frequency to identify the species, race, family group or individual (Marsan el al.; Piatti el al., 2004; Vàzquez et al., 2004; Herraeza et al., 2005). Genetic identification of individual animals is the most obvious application of traceability. Therefore, given an individual, by selecting an appropriate set of microsatellites, it is possible to establish a genetic fingerprint based on the length of the microsatellites. Using specific primers, it is possible to simultaneously amplify the microsatellites of interest by multiple PCR, producing amplifications of different lengths (and thus different molecular weights) for each individual (representing the different allelic variants of certain loci). Once the genetic profile is known, comparisons can be made between two samples (e.g. cartilage and meat).

2.4 Labelling

The labelling, presentation and advertising of food products are regulated by Regulation 1169/2011, which harmonized the rules within the European Union and introduced some important innovations to improve the clarity and transparency of the information provided to the consumer. In the EU, the provision of food information aims to ensure a high level of protection of consumers' health and interests by providing them with the basis for making informed choices and using food safely, considering health, economic, environmental, social and ethical considerations. European legislation on food information aims to create the conditions for the free movement of food, while also considering the need to protect the legitimate interests of producers and to encourage the production of quality products. The legislation 'food information' as all information about a food made available to the final consumer through the label, other accompanying material or any other

means. Article 1 of Regulation 1169/2011 defines 'label' as any mark, trade name, sign, pictorial matter or other graphic representation written, printed, stamped or impressed on the packaging or container of a food or accompanying such packaging or container. There are compulsory and optional claims. The legislation divides the mandatory food information into the following categories 1. information relating to the identity and composition, properties or other characteristics of the food; 2. information relating to consumer health protection and the safe use of the food, in particular characteristics relating to the composition of the product that may have an adverse effect on the health of certain categories of consumers and effects on health; shelf life, storage conditions and safe use; 3. information relating to nutritional characteristics to enable consumers, including those with special dietary needs, to make informed choices. Regulation 1169/2011 addresses some of the shortcomings of previous legislation, such as the highlighting of ingredients that may pose a health risk or the difficulty of reading small print. According to the regulation, the information must be easily visible, clearly legible and, if necessary, indelible. They must not be hidden, obscured, reduced in size or separated from other written or graphic information or other disturbing elements. Regulation 1169/2011 extended the scope of the regulation to all products intended for the final consumer, including products prepared by restaurants, canteens and catering services or sold at a distance. Therefore, the obligation to always provide consumers with comprehensive information on the presence of allergens in food also applies to these products. This information may be provided on menus, by means of special registers or signs, or by any other equivalent system, including technological means, which must be clearly visible and easily and freely accessible to the consumer. The Ministry of Health has specified that where electronic systems (e.g. smartphone applications, barcodes, QR codes) are used, these cannot be the only means of providing the required information, as they are not easily accessible to the entire population and are therefore not suitable for the purpose.

Information on the presence of substances or products causing allergies or intolerances may be obtained in writing, either on the menu, in the register or on a special sign, by contacting the staff on duty or by consulting the relevant documentation that will be made available upon request by the staff on duty; in either case, the information must be contained in appropriate written documentation that is easily accessible to both the competent authority and the final consumer and that has been previously checked and approved in writing by the staff on duty. With regard to non-prepacked food (i.e. loose or prepacked), Regulation 1169/2011 also defines the term 'non-prepacked food' and establishes ingredients or processing aids causing allergies or intolerances as the only mandatory indication, leaving it up to the Member States to decide whether to make other indications mandatory. In Italy, the reference for such guidance is Legislative Decree No. 231 of 15 December 2017. It is also important to note that for microbiologically perishable products, Article 24 of the regulation states that 'after the expiry date, a food shall be deemed to be unsafe within the meaning of Article 14(2) to (5) of Regulation (EC) No 178/2002'. All substances used in production must be listed in descending order by weight. One of the most important innovations concerns the indication of allergens, which must be highlighted in a different font, size, style or color from other ingredients, so that their presence can be quickly identified. It is emphasized that the regulation provides for the compulsory labelling not only of allergenic ingredients, but also of 'any processing aid listed in Annex II or derived from a substance or product listed in that Annex that causes allergies or intolerances, used in the manufacture or preparation of a food and still present in the finished product, even if in an altered form'. 'Place of provenance' means 'any place indicated as the place from which the food came' and differs from 'country of origin' as defined in the Customs Code (EU Reg. 952/2013 as amended). In particular, goods to the production of which two or more countries or territories contribute, shall be deemed to originate in the country or territory where they underwent their last, substantial,

economically justified processing or working in an undertaking equipped for that purpose and resulting in the manufacture of a new product or representing an important stage of manufacture. The indication of origin and provenance is not always compulsory on the label, but it is if its omission is likely to mislead the purchaser as to the origin or provenance of the product, in particular if the information accompanying the food or appearing on the label, taken as a whole, is likely to suggest that the food has a country of origin or place of provenance other than its actual one. The food label, in addition to providing the necessary information on the marketed product, can be used by the producer as a tool to enhance the value of its products and by the consumer to make better choices according to his needs. Regulation 1924/2006 harmonizes so-called 'claims', i.e. nutrition and health claims made on food, in order to guarantee the accuracy and truthfulness of the information to consumers. One of the main objectives of the regulation is to ensure that nutrition claims on food labels are clear and based on scientific evidence. A nutrition claim is "any claim which states, suggests or implies that a food has particular beneficial nutritional properties due to the energy (caloric value) it provides, provides in reduced or increased amounts or does not provide, and/or the nutrients or other substances it contains, contains in reduced or increased amounts or does not contain" (Art. 2 EC Reg. 1924/2006). A health claim (or "claim") is "any claim which states, suggests or implies that a relationship exists between a food or one of its constituents and health" (Art. 2 EC Reg. 1924/2006). The use of nutrition and health claims must not be false, ambiguous or misleading, nor create doubt about the safety or nutritional adequacy of other foods, nor encourage or condone excessive consumption of a food, nor state, suggest or imply that a balanced and varied diet cannot provide adequate amounts of all nutrients (Fugaro et al., 2011).

CHAPTER III

ANIMAL SAFETY: ANIMAL WELFARE

3.1 Animal welfare

Not only the safety of operators and consumers, but also and above all the safety of 'animals', which is summarised in the concept of 'animal welfare', which is used not only by scientists, but also by consumers, politicians and companies, who sometimes attach different meanings to it (Miele et al. 2011).

The first definition of animal welfare is found in the 'Brambell Report' of 1965, which states that 'welfare has a broad meaning, encompassing both the physical and mental well-being of animals. Any attempt to assess welfare must therefore consider the available scientific evidence on the emotions of animals derived from their biology and physiology as well as their behaviour'. Two other definitions that consider the animal's environment have been proposed by Hughes (1976) and Carpenter (1980). For the former, animal welfare is 'a state of complete mental and physical health in which the animal is in harmony with its environment', while for the latter it is 'the ability of animals to live in the environment provided by humans or to adapt to it without suffering'. According to Broom, these definitions were milestones but of little practical value, as they could not be measured scientifically, and he therefore proposed his idea of animal welfare in 1986: 'the welfare of an individual is the state of its attempts to adapt to the environment'. Based on this new definition, Broom proposed indicators to measure welfare, which focus not only on the structure and management of the herd, but also on the behavioural, physiological, immune and emotional characteristics of the individual animal.

Animal welfare is no longer measured in terms of absence or presence, but in terms of 'intensity', ranging from poor to excellent, reflecting the degree of adaptation to the environment of the animal, which may use different mechanisms to cope with environmental difficulties that must be considered if its welfare is to be correctly assessed. Until then, animal welfare had been treated almost exclusively as a scientific issue and it was not until the 1980s that animals were recognized as 'sentient beings', capable of feeling, although the concept was still perceived as relevant in science. A first rapprochement between science and ethics occurred in 2009, when the 'Farm Animal Welfare Council' (an independent UK advisory body) added the notion of 'a life worth living' to the definition of animal welfare and introduced 'animal-based measures' to assess welfare, considering not only animal suffering but also positive aspects such as pleasure levels and expectations.

When one speaks of animal welfare, one inevitably refers to the concept of 'stress', although in the case of farm animals it would be more correct to speak of distress. Stress can be acute or chronic, depending on the persistence or otherwise of the condition causing it, and in animal husbandry can result from a variety of environmental, physiological, pathological or nutritional factors. When the nervous system perceives a threat, four types of biological responses occur: behavioural, nervous, neuroendocrine and immune. The most damaging effects are observed when stressors persist in the environment, where the organism's response is not exhausted in a short time but continues, so that part of the animal's biological activity is constantly engaged in coping with the 'danger'. This phase is called pre-pathological because conditions occur that may predispose the animal to the disease, e.g. a weakened immune system may facilitate infection by an infectious

agent and the onset of the disease. The consequences manifest themselves throughout the body, with reduced growth and milk production, as well as reproductive problems such as reduced fertility and abnormal behaviour.

In order to assess animal welfare correctly, it is necessary to know the representative indicators, which aim to measure and record the reactions of animals in the environment in which they are kept and can be divided into three groups: 1. biological-functional; 2. emotional state; 3. ability to express their natural behaviour.

The first group considers the biological and physiological response of the animal to the stress it may encounter in its environment, including the body's metabolic processes, immune system and behavioural responses (stereotypies, aggression, excessive scratching, etc.). These mechanisms are not always effective in adapting to the environment, so much so that they can affect the growth, reproduction and health of the animal and, in the most extreme cases, lead to its death. For example, in dairy cattle, heat stress leads to a reduction in feed intake, which allows the animal to reduce internal body heat generated by digestive processes, and to an increase in respiratory exchange (an indicator of heat stress is a respiratory rate >60 breaths per minute). Consequently, milk production decreases, which benefits the heat-stressed animal by further reducing metabolic heat production.

Indicators of emotional state refer to the pleasure felt by the animal in a given context, so they can be negative or positive. The interpretation of different behaviours and the attribution of a negative or positive value to them is done by subjecting the animals to different options and observing which of these is preferred or alternatively through 'Qualitative Behavioural Assessment', which is

based on intuitive deductions by experts following observation of animal behaviour.

The last group of 'animal-based' indicators, on the other hand, refers to the animal's ability to express the behavioural repertoire it would have in a natural context. It has not yet been clearly defined what is meant by natural, but in terms of well-being and its improvement, research has considered positive natural behaviours (such as exploration, grazing, offspring care, play and sexual activity) that could be maintained or introduced in captivity. Many of these can be combined with indicators of emotional state, as they produce a positive or negative emotional response. Direct indicators of animal welfare have been classified separately, but in reality, the biological-functional and emotional responses interact to form a whole. For example, hunger produces an unpleasant emotional state, while fear triggers physiological stress-response mechanisms.

Other indicators of animal welfare are the indirect ones, also known as environmental indicators, which include: the assessment of facilities and husbandry systems (type of housing, quality of bedding, ventilation, feeding system, etc.); management (feeding, milking, individual care, maintenance of facilities, etc.); human-animal relations (quantity and quality). Initially, environmental indicators were used to assess animal welfare, but only recently has the importance of ABMs been recognised, which, by focusing directly on the animal, reflect its true state of adaptation to the environment, including indirect indicators.

The animal welfare concept received along the time many interpretations and definition. Ruth Harrison, a British activist and writer, first drew society's attention to the problems associated with the new breeding system in her book Animal Machines (1964), pointing out how animals were reduced to mere production units

and reared in completely unnatural environments (e.g. lack of sunlight, fresh air and space).

Later, the Brambell Report of 1965 defined the concept of 'animal welfare' for the first time, followed by the publication of the 'Five Freedoms' by the Farm Animal Welfare Council in 1979 and updated in 1992:

1. *Freedom from thirst, hunger and malnutrition - through easy access to a diet that maintains full health and physical vigour;*
2. *Freedom from physical and thermal discomfort - providing an appropriate environment, including a shelter and comfortable resting area;*
3. *Freedom from pain, injury and disease - through prevention or timely diagnosis and treatment;*
4. *Freedom from fear and stress - thanks to the availability of adequate space, facilities and company;*
5. *Freedom to express behaviour appropriate to the species - through conditions that prevent psychological distress.*

The European Union has also felt the pressure of public opinion on animal conditions (Bezüglich des Tierschutzes, 2012). Directive 98/58/EC of 1998 laid down, for the first time, standards for the protection of animals kept for farming purposes (including fish, reptiles and amphibians), based on the standards drawn up by the 1992 European Conference on the Protection of Animals kept for Farming Purposes. The five freedoms of the Brambell report were used as a reference for the definition of the first international animal welfare standards, although they are only considered effective in assessing basic animal welfare conditions. The Welfare Quality Project, which involved forty-four institutes and universities from thirteen European countries and four South American countries, developed the four

principles of 'Good Welfare' and, within these, twelve criteria based on Brambell's Five Freedoms: food, housing, health and behaviour.

1. Absence of prolonged starvation: animals must receive sufficient and adequate food;
2. No prolonged thirst: the animals must have sufficient and accessible drinking water available.
3. Behaviour during housing (assessment of welfare rather than injuries);
4. Thermal comfort: the animals must be neither too hot nor too cold;
5. Ease of movement (as opposed to health or sleeping problems: animals must have sufficient space to move freely).
6. Absence of injuries (except those resulting from disease or from therapeutic or preventive procedures; neonatal mortality of piglets is also included);
7. Absence of diseases (including neonatal and transport-related): Farmers must maintain high standards of hygiene and animal care.
8. Absence of pain caused by husbandry practices, handling, slaughter (including stunning) or surgical procedures.
9. Expression of social behaviour (balance between negative aspects, such as prolonged and harmful aggression, and positive aspects, such as grooming): The animals must be able to express normal, non-damaging and presumably positive social behaviour, such as feeding and grooming;
10. Expression of other species-specific behaviour (balance between negative behaviour, such as stereotypies, and positive behaviour, such as exploration);

11. Good human-animal relations (reduction of human fear): animals must be treated well in all situations, i.e. operators must promote good human-animal relations;
12. Positive emotional state: negative emotions such as fear, stress, frustration and apathy should be avoided, while positive emotional states such as security, comfort and satisfaction should be promoted.

The aim is to standardise an effective method for assessing animal welfare. The criteria identified, incorporating Brambell's Five Freedoms, focus on the animal and its ability to adapt to the environment, while data on farm structure and management are of secondary importance (Rizzuto, 2016). In the 20th century, following the emergence of the social movement for animal rights, the Council of Europe (an international organisation to which most European countries belong) adopted a series of conventions for the protection of animals, starting with the Paris Convention for the Protection of Animals during International Transport of 1968, which established basic rules for the transport of all species. This was followed by the adoption of four other conventions:

1- European Convention for the Protection of Animals kept for Farming Purposes (1976)

2 - European Convention for the Protection of Animals at the Time of Slaughter (1979)

3 - European Convention for the Protection of Vertebrate Animals used for Experimental Slaughter and other Scientific Purposes (1986)

4- European Convention for the Protection of Pet Animals (1987)

The European Conventions represent the first international agreement on the protection of animal rights and have been used as a reference for the development

of animal welfare legislation in several European countries and in the European Union itself.

The term 'animal welfare' was first used in an EU legislative context in the Amsterdam Treaty of 1997, replacing the old concept of animals in the 1957 Treaty of Rome, where they were defined as 'goods', i.e. a product of agriculture.

The Treaty of Amsterdam recognised animals as 'sentient beings' and thus acknowledged their right to guaranteed protection and respect for their welfare, which had to be considered when formulating new EU agricultural policies, such as Directive 98/58/EC the following year. It was the first piece of legislation to establish general principles of respect for farmed animals, based on the five freedoms of the Brambell report, and was preceded by two other European directives published in 1991, aimed at improving conditions for calves and pigs, Directives 91/629/EC and 91/630/EC respectively.

The European Commission asked EFSA to analyse animal welfare issues in the context of food safety. An animal under stress is more susceptible to infectious diseases such as those caused by *Salmonella*, *Campylobacter* and *E. coli*, pathogens that are often the cause of food poisoning. Since then, the European Authority has published numerous documents (guidelines, scientific opinions, etc.) on the welfare of animals during transport, slaughter and breeding of the main farmed species, also motivated by the Lisbon Treaty (2004, in force since 2009), which states that the European Union and its Member States have an ethical responsibility to protect animals from suffering, mistreatment and pain. EFSA studies contribute to the development and implementation of European animal welfare legislation as they are directly commissioned by the EU.

While directives published by the European Union must be incorporated into the legislation of member states, regulations are directly applicable.

In the first decade of the 21st century, two important animal welfare regulations were published.

The first is **Regulation 1/2005** on the transport of animals and related activities, which applies to all vertebrate animals involved in an economic activity, and in particular to farmed land animals, although there are also rules for experimental animals, farmed fish, wild animals, dogs and cats. The regulation protects the welfare of animals by requiring that animals are fit to be transported (e.g. an animal unable to walk cannot be transported), that there is a minimum space for each animal in the vehicle and that a certain number of hours of travel per day is not exceeded, depending on the species and age of the animal being transported. In addition, there are mandatory fitness requirements for the person transporting the animals (licence and certificate of fitness) and for the means of transport, particularly if the journey exceeds eight hours.

Secondly, **Regulation 1009/2009** was published on the slaughter of animals, whether in a slaughterhouse or on a farm. The 'stunning of the animal' before slaughter is made compulsory, with the exception of certain religious practices (for halal or kosher meat), provided it takes place in a slaughterhouse. Stunning and killing are carried out in different ways depending on the species: authorised methods are described and, if necessary, minimum technical requirements for specific methods, such as the use of stunning, are established.

EU and non-EU countries must comply with the provisions of the Regulation or, in the case of the latter, at least equivalent conditions.

Other regulations with implications for animal welfare have also been published, including Regulation 73/2009 on cross-compliance (i.e. farmers are encouraged to comply with EU public, plant and animal health and welfare standards); Regulation 1254/1999, which provides subsidies for the export of live cattle; and Regulation 1698/2005 on support for rural development. There are also regulations on organic production, which provide for high animal welfare standards.

In 2012, the European Commission adopted the Strategy for the Protection and Welfare of Animals 2012-2015, a continuation of the 2006-2010 Action Plan for the Protection and Welfare of Animals, which identified five key action areas to achieve the Plan's objectives:

1. Raising the level of minimum standards;
2. Promoting research and alternative methods to animal testing;
3. The introduction of well-being indicators;
4. Improving information to operators and the public, and
5. Supporting international animal welfare initiatives.

The new strategy aims to standardize and strengthen the application of legislation in all EU Member States by adopting animal welfare standards adapted to the different farming systems, climatic conditions and territorial realities of each Member State. The lack of legislation on specific areas of animal welfare and the difficulty of enforcing some of the existing rules have made it necessary to simplify some general rules by adding more specific clauses. Finally, improved on-farm animal welfare standards have increased production costs. This increase does not threaten the economic sustainability of these sectors, but should be considered by

the market as it represents an increase in the value of the product and could therefore increase the competitiveness of EU agriculture (Caporale et al., 2005).

It is also necessary to make better use of the instruments offered by the CAP (Common Agricultural Policy), such as support for voluntary animal welfare commitments and relevant measures, which can achieve higher results than the standards imposed by law.

In December 2019, the European Union presented the 'Green Deal', a plan to achieve zero greenhouse gas emissions by 2050 and, more generally, to address the challenges of climate change and environmental degradation. At the heart of this plan was also the 'From Farm to Fork' strategy, which aimed to address problems related to the food system and its sustainability for human, social and environmental health by addressing the entire food chain through an integrated policy. Animal welfare was an integral part of this strategy, which is why the EU undertook an evaluation of all relevant legislation and asked EFSA to gather all new scientific evidence, focusing in particular on animal transport, slaughter and breeding. Another key element of the 'From Farm to Fork' strategy is the development of a labelling system for food produced according to certain animal welfare standards in order to increase transparency for consumers.

In our country, animal welfare has become increasingly important since the 1980s, when Europe adopted a series of regulations on animal protection. Subsequently, with the recognition of animals as 'sentient beings' in the Treaty of Amsterdam, the introduction of mandatory animal welfare criteria in the CAP in 2007 as 'cross-compliance' criteria under Regulation (EC) 1782/03 and, finally, the change in public opinion on the subject led to the development of the National

Animal Welfare Plan (PNBA) in 2008. The plan is based on a series of regulations drawn up by the European Union and the Italian government, listed below:

1 - Law No 623 of 14 October 1985: Ratification and Execution of the Conventions on the Protection of Animals kept for Farming Purposes and on the Protection of Animals for Slaughter (Strasbourg 10 March 1976 and 10 May 1979)

2 - Legislative Decree No. 533 of 30 December 1992 (transposition of Directive 91/629/EEC) laying down minimum standards for the protection of calves, amended by Legislative Decree No. 331 of 1 September 1998 (transposition of Directive 97/2/EC);

3 - Legislative Decree 534 of 30 December 1992 (transposition of Directive 91/630/EEC) laying down minimum standards for the protection of pigs, as amended by Legislative Decree 53 of 20 February 2004 (transposition of Directives 2001/88/EC and 2001/93/EC);

4 - Legislative Decree no. 146 of 26 March 2001 (transposition of Directive 98/58/EC) on the protection of animals kept for farming purposes, as amended by Law no. 306 of 27.12.2004 and Law no. 17 of 26.02.2007 and the relevant ministerial application and clarification guidelines;

5 - Legislative Decree No 267 of 29 July 2003 (transposition of Directives 1999/74/EC and 2002/4/EC) on the protection of laying hens and the registration of breeding establishments; Article 8(5) was repealed by Article 23 of Law 25/01/06; the annexes were amended by the Decree of the Minister of Health of 20 April 2006;

6 - Council Directive 2007/43/EC of 28 June 2007 laying down minimum rules for the protection of chickens kept for meat production;

7 - Ministry of Health Circular No. 10 of 5 November 2001;

8 - Note of 2 March 2005 prot. DGVA/10/7818 - Procedures for monitoring animal welfare on pig farms - application of Legislative Decree no. 53 of 20 February 2004; - Update note. 53 of 20 February 2004;

9 - Note of 25 July 2006 prot. DGVA/10/27232 - on animal welfare control procedures in calf farms - application of Legislative Decree no. 533, as amended by Legislative Decree no. 331 of 1 September 1998. 331;

10 - Commission Regulation (EC) No 2295/2003 of 23 December 2003 laying down detailed rules for the application of Council Regulation (EEC) No 1907/90;

11 - Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules;

12 - Commission Decision 2006/778/EC of 14 November 2006 concerning minimum requirements for the collection of information during the inspections of production sites on which certain species of animals are kept and repealing Decision 2000/50/EC.

Directive 98/58/EC, transposed in Italy by Legislative Decree No. 146 of 26 March 2001, requires member states to ensure compliance with the rules on the protection of animals kept for farming purposes and to verify their application by means of inspections.

The competent authorities in Italy are the Veterinary Services of the Ministry of Health (Directorate General of Animal Health and Veterinary Drugs), the Regions and Autonomous Provinces of Trento and Bolzano and the Local Health

Authorities. The assessment of the welfare status of animals may only be carried out by competent personnel, i.e. 'veterinarians'.

According to the provisions of Regulation 882/2004, which came into force in 2006, inspection programmes are carried out and annual reports are drawn up on the results of inspections carried out in the various areas of food safety, including animal welfare, which are then sent to the autonomous regions and provinces, which forward the aggregated data to the Ministry. The minimum number of inspections to be carried out by the competent authorities varies according to the species concerned and the number of herds in the area; for cattle, all herds with more than 50 animals are considered, of which at least 25 per cent must be inspected, while for white meat calves, all herds are considered, of which 15 per cent must be inspected.

According to the PNBA, veterinarians have a role to play in educating farmers on animal welfare issues and in educating them on proper husbandry practices and structural requirements to improve animal welfare, while at the same time making them aware that better animal welfare corresponds to higher animal productivity and thus higher profits. A key role is played by the farm veterinarian, who acts as an intermediary between the farmer and the official veterinarian, acting as a real contact person for animal welfare, although the responsibility for enforcing compliance always lies with the farmer. The latter is advised to apply 'good zootechnical practices' and, where possible, to implement self-control plans that include the animal welfare parameters to be respected; self-control documents, if made available to the competent authority, make inspection easier and faster.

According to the PNBA, 'A good husbandry practice/self-control plan must consider various aspects directly or indirectly related to animal welfare, such as: the

formation of homogeneous age groups, microclimate, synanthropic control, wastewater management, maintenance of facilities and equipment'. Official veterinarians should provide guidance on criteria and methods for planning inspections and update checklists for welfare assessment.

Every year, the Ministry of Health evaluates the results of the controls received and, in cooperation with a specific working group and the National Reference Centre for Animal Welfare (CReNBA), carries out a risk categorisation, reschedules control activities and, if necessary, provides new checklists or guidelines. Since 2015, the PNBA has been part of the National Integrated Plan (NIP), which has been tasked with describing the system of official controls carried out throughout the food chain to protect citizens from health risks and unfair production practices.

In view of the high percentage of movements that take place within our country and trade with other EU and non-EU countries, a 'National Official Control Plan for the Protection of Animals during Transport' has been drawn up, with the aim of planning and coordinating activities to verify compliance with EU and national regulations on the protection of animals during transport. This plan is based on Law 222/1973 (ratification of the Council of Europe Convention of 1968 on the protection of animals during international transport), the EC Directive of 1977 on the protection of animals during international transport and Regulation 1/2005 on the protection of animals during transport and related operations. The importance of the topic is also reflected in the publications and legislative updates provided by the Ministry of Health, which are listed below:

- Handbook for the management of fish welfare control during road transport (2019);

- Practical guidelines for assessing the fitness for transport of adult cattle (2012);
- Animal Transport Manual for the handling and welfare of animals during road transport;
- Memorandum of Understanding between the Ministry of the Interior and the Ministry of Health 'on strengthening legality controls in the field of international animal transport' (2011);
- Joint circular of the Ministry of Health and the Ministry of the Interior on strengthening legality controls in the international transport of live animals;
- Note from the Ministry of Health: Regulation (EC) No 1/2005 on the protection of animals during transport - rest periods in assembly centres;
- Ministry of Health note: Animal welfare during transport at high temperatures in the summer months (2019).

Checks on the welfare of animals during transport by the competent authorities are carried out by means of checklists divided into a first part collecting information on the time of the check, the type of transport and the persons responsible, and a second part divided into sections on general requirements to be observed during the transport of live animals and specific requirements for the transport of different species. In addition, a checklist of EU criteria for control posts was drawn up to verify the structural, managerial and functional requirements of Regulation 1255/97. These checklists are also used to certify and document the official controls carried out and to support inspection.

The Ministry of Health has also drawn up a model contingency plan, which is a document to be submitted by transporters and required for the issuance of a type 2 permit for long journeys (more than eight hours), describing the measures to be taken in the event of unforeseen events in order to safeguard animal welfare (in

accordance with Article 13 of Regulation 1/2005). The protection of animal welfare, health and food safety ends at slaughter. In Europe, Regulation 1099/2009 on the protection of animals at the time of killing has come into force:

- increased responsibilities for operators and manufacturers of stunning and killing equipment;
- appropriate training for slaughterhouse workers, with the obligation to obtain a certificate of competence through an examination;
- greater guarantees of compliance with animal welfare conditions during culling operations for the eradication of infectious diseases;
- a list of authorised stunning and killing methods for the different species to be slaughtered.

In order to facilitate and standardise the application of the Regulation on Italian territory, the CReNBA has produced a 'Manual of Good Practices' for veterinarians and operators in the sector, divided into summary sheets for each species, and, in collaboration with the Ministry of Health, checklists for the performance of inspections by the competent authorities, divided into general requirements and specific requirements for the red meat, poultry and rabbit sectors. Official controls are carried out at a frequency determined according to the main risk factors, e.g. in the event of changes in the type or size of animals slaughtered or in the organisation of staff work.

Livestock farming and the production of products of animal origin represent an essential economic and social value and, in order to guarantee health and food safety, it is increasingly necessary to create the conditions for a general improvement in animal welfare. In this sense, the Strategic Plan of the CAP 2023-2027 (SPP) has defined a clear strategy, identifying the National Quality System

for Animal Welfare (SQBNA), approved by Interministerial Decree of 2 August 2022, as one of the fundamental elements to accelerate the process of transition to a more sustainable farming model, improve animal welfare, and increase the quality of agrifood production, combat the phenomenon of antimicrobial resistance (AMR) and make the agri-food market more transparent, given that deficiencies in animal welfare, farm biosecurity and the excessive use of antibiotics are increasingly leading to risks linked not only to zoonoses and food safety, but also to AMR, a phenomenon that affects both human and veterinary health. In Italy, monitoring and surveillance of AMR is considered a national strategic pillar and is part of the Italian integrated plan to fight AMR ('PNCAR'; Italian Ministry of Health 2022) that, among its objectives, includes the reduction of antimicrobial use (AMU) in farmed animals. The current PNCAR (2022–2025) has a broader approach as compared to the previous (first) PNCAR (2017–2020), since it encompasses environmental health besides animal and human health.

3.2 The ClassyFarm system

The Italian Ministry of Health – through the Directorate General of Animal Health and Veterinary Drugs – has developed ClassyFarm (ClassyFarm 2023; https://www.classyfarm.it/index.php/en/), an integrated surveillance system for monitoring and characterising livestock farms according to risk. ClassyFarm is the result of various projects funded by the Italian Ministry of Health. It was developed by the Istituto Zooprofilattico Sperimentale della Lombardia e dell'Emilia Romagna (IZSLER), belonging to the Italian network of public laboratories for veterinary health and epidemiology, in collaboration with the University of Parma

and other public (national and local authorities, universities, etc.) and private subjects (veterinarians, farmers, livestock companies, etc.). This system has been recognised in accordance with the provisions of the Decree of the Minister of Health of 7 December 2017; Article 14 of Legislative Decree No. 136 of 5 August 2022 (transposition of the provisions of EU Regulation 2016/429); and Article 9 of the Interministerial Decree of 2 August 2022 for the 'Discipline of the National Quality System for Animal Welfare'. The ClassyFarm system is an IT platform, integrated into the National Veterinary Portal, which processes a considerable amount of data from different sources (collected in the field or from other information systems) through the following specific business intelligence processes: a) field evaluations of animal welfare and herd biosecurity; b) consumption and sensitivity to antimicrobials; c) herd data (health status, production and feed), and d) slaughterhouse measurements of health and welfare data (ClassyFarm 2023). The information gathered in the field may come from official controls carried out by the competent authorities and from audits by certifiers or veterinarians trained in self-monitoring. Once the data has been processed, the results are made available to registered users through interactive dashboards and reports that can be downloaded from these dashboards. One of the main features of ClassyFarm is its interoperability with other IT systems, such as the animal registry (BDN), the electronic veterinary prescription and the diagnostic laboratories of the IIZZSS (ClassyFarm 2023). Through the ClassyFarm system, a large amount of information from different sources are analysed and compared to classify farms according to risk in terms of:

- Animal welfare
- Farm biosecurity

- Antimicrobial use and resistance

These data are collected by the competent veterinary authorities during official controls, but also resulting from self-control, recorded by the farm veterinarians. Such data are integrated with further information acquired by the databases of other systems in the National Veterinary Information system (VetInfo; https:// www.vetinfo.it/), namely the National Animal Register (BDN), which provides information on farms and animal populations, and the database of the National Electronic Veterinary Prescription system (REV). Regarding the antimicrobial use and resistance, ClassyFarm acquires raw data from other systems databases for further analysis and makes them available to users via its business intelligence dashboards. Currently, ClassyFarm estimates AMU in pig, poultry and ruminants (bovine, buffalo, goat and sheep) farms; other livestock species will be included in the future. The coverage is nationwide and the inclusion of a farm in the system is automatic. The AMU is calculated using a national indicator (DDDAit – defined daily dose animal for Italy), combining information from the REV and the BDN. Benchmarking of a farm is performed by comparing its AMU with the median and weighted (on herd size) mean of the farms of the same production type (e.g. fattening pig farms, dairy cow farms).

For the first time, information about biosecurity, animal welfare, animal nutrition, antimicrobials usage and resistance, health and productions parameters, along to injuries found at the slaughterhouse are collected and elaborated in a unique tool to obtain the risk categorization (Moriconi et al., 2024).

The system evaluates farms' performance and can highlight best practices as regards biosecurity, management, and farm structure (Bertocchi et al., 2018; Ventura et al. 2021; Holighaus et al. 2023), addressing possible interventions for

improving animal production, preventing animal diseases and contrasting AMR spread. ClassyFarm allows livestock farmers to check how they perform compared to the average regarding biosecurity, animal welfare and AMU, to identify areas for improvement and verify the most effective measures to reduce the level of farm risk.

It serves several purposes:

- improve dialogue between the farmer, the veterinarian and the competent authorities to optimise the use of antimicrobials and animal welfare;
- provide aggregated information at different geographical levels (national, regional, local), enabling the monitoring of the territory and comparison between different territorial areas;
- facilitate the collection of data useful for possible voluntary labelling (e.g. SQNBA - National Quality System for Animal Welfare);
- enable the planning of official controls on animal welfare (PNBA), pharmacovigilance (PNFS) and biosecurity, targeting farms with a higher risk index (ClassyFarm 2023).

The ClassyFarm can be accessed by authorised persons who request it (official veterinarians, company veterinarians, operators, delegates, etc.). The system provides public and private *stakeholders* with a tool that can identify any shortcomings at farm or geographical area level (regions, autonomous provinces and ASLs) in order to direct possible improvement actions and strengthen the prevention of animal diseases, the fight against antimicrobial resistance and the efficiency of official controls. In particular, the system offers farmers a tool as close to excellence as possible, with the farm veterinarian as the link between the operator and the competent authorities (ClassyFarm 2023). The ClassyFarm system

thus provides a complete picture of aggregated information by geographic area and farm type, enabling the implementation of a virtuous circle on the emulation of best practices. The categorisation of herd risk according to common standards will also enable the competent authorities to plan more effective and specific controls, since more guarantees are required than the minimum standards laid down in current legislation. At the same time, the application of such a system could provide producers with a useful tool for promoting their product (ClassyFarm 2023).

The development of ClassyFarm is still ongoing, however, the PNCAR already uses it for monitoring AMU in farms and for veterinary pharmaco-surveillance. Recently, the Italian Ministry of Agriculture decided to use the ClassyFarm indicators to evaluate farm compliance with animal welfare and AMU standards required for the direct payments delivered to farms under the 2023–2027 EU's Common Agricultural Policy (CAP).

The participation of famers in Classyfarm is not mandatory in the first place but obligatory for obtaining the animal welfare label *Sistema di Qualità Nazionale per il Benessere Animale – SQNBA*. The aim of *SQNBA* is not only to improve animal welfare and animal health but also to ameliorate processes in production and supply chain in terms of economic, ecological and social sustainability thanks to accreditation of farms and other stakeholders within the production chain (ClassyFarm, 2023).

3.3 The National Quality System for Animal Welfare (SQNBA)

On 8 August 2022, the Interministerial Decree regulating the 'National Quality System for Animal Welfare (SQNBA)', established pursuant to Article 224 bis of

Decree-Law No. 34 of 19 May 2020, introduced by Conversion Law No. 77 of 17 July 2020, was published. The decree establishes the procedure for the definition of animal health and welfare requirements that go beyond the relevant European and national standards, introducing procedures and company data to qualify the management of the breeding process of food-producing animals, differentiated by species, production orientation and method, including the management of emissions in the establishment.

Membership of the National Quality System for Animal Welfare (SQNBA) is voluntary and aims to provide consumers with clear and accurate information on the production and marketing of animals, primary production products and related foodstuffs, through specific instructions on animal welfare, biosecurity on farms and the use of veterinary medicines. All the information necessary to meet the certification requirements under the SQNBA is collected, processed and managed, in accordance with the provisions of the aforementioned Decree, by a Certification Body accredited according to UNI CEI EN ISO IEC 17065 and registered with the Ministry of Agricultural, Food and Forestry Policies. The certification body verifies the requirements of the certification process, including the physical condition of the animals, through documentary checks and subsequent inspections. The production process, from breeding to the marketing of animals, primary products and derived foodstuffs, must be traced and documented all the way through to labelling, which indicates placement in the progressive levels of certification defined by the decree. The entire SQNBA process is based on the ClassyFarm information system, which defines the categorisation of farms according to risk, through the collection and processing of information on self-control and monitoring activities carried out by operators, in accordance with Articles 24 and 25 of Regulation (EU) 429/2016. The

National Quality System for Animal Welfare (SQNBA) reinforces the environmental, economic and social sustainability of livestock production by defining a national production system that establishes the general rules and technical requirements for the management of the livestock breeding process, through the evaluation of parameters established on a scientific basis, thus constituting a unique reference in voluntary certification related to animal welfare and bringing order to the various certification protocols. In defining the general rules for the organisation and functioning of the SQNBA, the regulation states that the requirements for certification in the livestock sector must be established by a Technical and Scientific Committee for Animal Welfare (CTSBA), the composition of which was established by Decree No. 0122818 of 24 February 2023, issued by the Minister of Agriculture, Food Sovereignty and Forestry (MASAF), in agreement with the Minister of Health.

Membership of the SQNBA is, as already mentioned, voluntary and can be accessed by farms (Primary Production Operators) and processing companies (Food Business Operators) from all EU Member States, which apply the requirements described in Interministerial Decree No. 563467 of 23.10.2024 and certify themselves through an accredited certification body from among those on the MASAF website. Once certified, primary sector and supply chain operators will be able to use the information provided by the SQNBA to distinguish and value both animals and products from certified farms. The initiatives envisaged by the SQNBA are therefore fundamental for the valorisation and growth of the livestock supply chain, in line with the new EU guidelines underlying the new CAP for the 2023/2027 period, the NRP and the 'Farm to Fork' strategy, which aims to move all producers towards sustainable food production in the medium term. The SQNBA is

part of a broader strategy to support the transition of the livestock sector to a more sustainable farming model, to improve animal welfare, to enhance the quality and health of agri-food production and to reduce antimicrobial resistance (AMR), recognising that animal welfare and the use of drugs are increasingly linked. Specifically, the SQNBA aims to achieve a single standard that can bring order to the various existing protocols, make animal welfare measures truly effective, ensure fair competition between producers and companies, and provide clearer information to consumers, since food labels are important tools through which a large number of consumers, especially those accustomed to buying food in supermarkets, understand and appreciate the qualities of food (Evans and Honey, 2017).

3.4 Animal welfare labelling: critical analysis

Labels qualify foods with a wealth of information and increasingly communicate the ethical status of animal products with qualifications such as organic, free range, cruelty-free or other descriptions related to the animal compatibility of the production method. Evans and Honey (2017) suggest that ethical food labels act as 'icons', representing specific food types and food production relationships to bridge the gap between producers and consumers. However, farm animal welfare claims are not regulated in the EU and the market for food of animal origin lacks transparency. In this context, there are many doubts about the ability of labels to increase market transparency (Tregidga et al., 2019). Ingenbleek and Krampe (2002) in their article argue that the effectiveness of animal welfare labelling is hindered by a number of problems, including lack of consumer

trust, the proliferation of food labels and the confusion they create, the discrepancy between consumers' understanding of animal welfare, often expressed with the terms natural or organic, and what animal welfare standards actually address (Miele et al, 2011; Miele, 2011; Miele & Pinducciù, 2001), limited innovation in animal welfare labelling, and higher prices of certified animal welfare products. Based on a survey of consumers in four European countries, Ingenbleek and Krampe argue that although attitudes may vary between countries and consumer groups, these problems persist and current labels are not able to significantly influence the market. Stygar et al. (2022) reported that there is a plethora of labelling systems that provide consumers with a range of information on the welfare of farm animals; they quantified and identified 19 certification standards: nine for dairy production and ten for pig production, led by twelve industry-wide quality systems from eight European countries, namely Finland, Sweden, Denmark, Ireland, the Netherlands, Germany, Austria and Spain. These standards use welfare quality protocols (Blokhuis et al., 2013) and monitor the (on-farm) welfare of pigs and dairy cattle by comparing outcome-based, resource-based and management-based measures. Secondly, they described how the data generated were used along the value chain to assess animal welfare. The analysis shows that only five of the 19 standards used predominantly animal-based measures, as stated and defined in the WQ®, while the other schemes used environment-based measures rather than animal-based measures. The results of this study suggest that quality systems could be improved by expanding the use of data generated along the value chain, as only one of the analysed schemes used sensor technology to provide animal welfare information. Furthermore, Collins et al. (2021) examine existing protocols for the assessment of farm animal welfare. The authors argue that outcome-based measures of animal

welfare, including health and behaviour, have proven successful, but are time-consuming and this is the main limitation to their use in current certification schemes. The authors considered the possibility of reducing the number of measures included and compared two approaches: 'pairwise associations' between measures and synthetic measures - the 'iceberg indicators' - of dairy herd welfare that can predict herd welfare status. They analysed the results of these approaches on 51 farms in the UK, where 96 welfare measures were assessed. They found some 'weak' correlations, but not enough to provide adequate information on dairy cow welfare and concluded that many different measures are still needed. Rowe et al. (2021) analysed the rationale for the creation of a recognised network of superior animal welfare schemes from which products can be purchased that are truly derived from animals that have benefited from improved welfare. The results of the analysis of nine schemes and seven food companies confirmed the difficulties faced by food companies in international trade. The study highlights the need for agreement between superior welfare assurance schemes to specify standardisation of recognised measures as a solution to this impasse and proposes practical changes to the current Global Animal Welfare Assurance (GAWA).

The European Commission also published the results of a study on animal welfare labelling commissioned by the Directorate-General for Health and Food Safety - DG SANTE (2022). The objective of the study was to provide the Commission with information to support possible initiatives for the introduction of an animal welfare labelling scheme in the European Union. The study involved the collection and analysis of qualitative and quantitative data on consumers' awareness of animal welfare standards and their need for further information. It also included the collection of data on existing animal welfare labelling schemes in the EU,

assessing their impact on the market, consumers and animals, the impact on competition and the economic return for all stakeholders. It was conducted between April 2021 and February 2022, using a mixed approach, combining different sources and analysing secondary sources, such as articles, EU policy and legislative documents, audit reports and national action plans. According to the results of the study, EU consumers have a low level of awareness of the conditions in which farm animals are kept and treated. However, at least half of the population would like to know more. Two thirds of EU consumers believe that the information available on animal welfare, mainly from traditional media rather than food labels, is insufficient to make informed choices. According to the survey, almost half of EU consumers would like more information on slaughtering conditions (40%; n=9,306), animal feed (40%), access to fresh air (35%) and farming conditions (28%). There is less interest in transport conditions, despite their undoubted impact on welfare. If a label were to be introduced, most consumers would prefer it to be applied to all animal products. However, the study found that current animal welfare labelling schemes create distortions of competition between producers with high welfare standards operating in different EU countries, due to differences in the parameters used in different schemes, associated costs and other factors. However, the existence of multiple animal welfare labelling schemes contributed to confusion among consumers, who found it difficult to correctly interpret visually similar labels or to compare products with different labels. Even when a product carried a single animal welfare label, consumers were confused because of the presence of labels covering other aspects or because the label covered different aspects that they did not fully understand. The data also show that current animal welfare labelling schemes have contributed to the 'renationalisation' of some market

segments, as they often include indications of national origin (symbols and colours), further encouraging consumers to buy domestically produced food. Finally, the existence of multiple labelling schemes has had negative consequences for producers offering the highest welfare standards. According to DG SANTE, it is difficult to accurately assess the extent to which welfare labelling schemes lead to a significant improvement in the lives of animals, due to the absence of a clear baseline, limited monitoring and lack of evaluation.

3.5 Biosafety

Closely related to animal welfare is 'biosecurity', which is one of the main tools to prevent the introduction, development and spread of transmissible animal diseases from and within an animal population (Regulation (EU) 2016/429, recital 43). Regulation (EU) 2016/429 defines 'hazard' as any 'pathogen or condition of an animal or its product, capable of causing an adverse effect on human or animal health (Art. 4(21)); identifying 'risk' as the likelihood of occurrence and the likely magnitude of the biological and economic consequences of an adverse effect on human or animal health, given exposure to a hazard (Art. 4(22)). Biosecurity is defined by the European Regulation 2016/429 ("Animal Health Law") as "the set of managerial and physical measures aimed at reducing the risk of introduction, development and spread of diseases to, from and within an animal population or an establishment, area, compartment, means of transport or any other structure, premises or place". This definition emphasises the importance of preventive tools to keep infectious pressure as low as possible in order to protect animal health and welfare. Biosecurity in animal husbandry is the set of management strategies,

means and procedures aimed at preventing or limiting the introduction and spread of biological and chemical hazards that could cause disease states in animals. The objective of the measures is not only food safety, but also the prevention of all diseases that may affect animals and that may pose a risk to public health, cause economic damage to the farmer or worsen animal welfare.

Attention and discussions on biosecurity actions to be taken on livestock farms have increased significantly in recent years, as the near-absence of specific measures contributes not only to increasing the likelihood of the spread of livestock diseases, but also to increasing the severity of the epidemic itself, with repercussions on animal welfare, the sustainability of livestock farms and the costs of the public health system. The proliferation of infectious diseases forces the use of drugs and, in particular, antibiotics, which, if misused, contribute to the emergence of the dangerous phenomenon of antibiotic resistance. Therefore, the prevention of the entry of diseases, through the application of biosecurity plans, represents a fundamental tool to pursue several objectives: a) protect animals from diseases, safeguarding their health and welfare; b) limit the massive use of antimicrobials, also to the benefit of human public health; c) ensure production efficiency and profitability of livestock farms, reducing production losses and direct intervention costs.

Aware that biosecurity measures cannot totally eliminate the risk of disease entry and spread, but can help reduce its frequency and severity, it is considered essential to identify, for each farm, the different hazards present, establish their importance and set priorities for action.

It is necessary to carry out an assessment of the biosecurity level of the company, to classify it into risk bands and define ad hoc programmes for its

improvement. Regulation (EU) 2016/429 on communicable animal diseases (Animal Health Act), applicable from 21 April 2021, states that "animal health and welfare are interlinked: better animal health promotes better animal welfare and vice versa" (recital 7).

Researchers and industry professionals have developed various methods to estimate biosecurity levels, each with its own strengths and limitations. One commonly used method is questionnaires or surveys, where data is collected directly from farmers about their biosecurity practices. Another approach involves on-farm assessments, during which trained evaluators visit dairy farms to directly observe the physical infrastructure, biosecurity protocols, and animal health management practices in place. In addition to surveys and on-farm assessments, some studies employ quantitative measures, such as disease prevalence or pathogen testing, to evaluate the impact of biosecurity practices on animal health outcomes (reviewed in Zanon et al., 2024).

Italy has implemented the system ClassyFarm, previously described, which includes a dedicated area for evaluating biosecurity. In the "Farm Management and Personnel" section (Area A) of the ClassyFarm checklist, there is an additional evaluation that considers the biosecurity score assigned to the farm. This score, labeled "Biosecurity," is automatically populated by the ClassyFarm system based on the analysis of data collected during the biosecurity assessment.

AIM

The challenges facing the public health and agri-food sectors are becoming increasingly complex and urgent. There are interconnected risks related to deficiencies in animal welfare, livestock biosecurity, and excessive antimicrobial use. These risks concern not only zoonotic diseases and food safety but also antimicrobial resistance, which poses a significant threat to both animal and public health. In response to these issues, the ClassyFarm system aims to enhance disease prevention in animals, slow the spread of antimicrobial resistance, and improve the efficiency of official controls. On the other words, it aims to create a virtuous cycle that encourages the adoption of best practices and promotes healthier animal husbandry. This approach not only provides economic benefits for farmers but also ensures safety and quality for consumers.

In light of these considerations, the present study represents the first attempt to collect information regarding the *status quo* on biosecurity and animal welfare through the implementation of the ClassyFarm protocol in small-scale dairy farms, both tie-stall and free-stall housing systems, in the Molise region and the neighbouring municipalities in the Abruzzo region. Additionally, this study sought to assess the adequacy and effectiveness of the ClassyFarm checklists, which were originally developed and tested in the Po Valley farms. This research is useful also as a starting point for a broader investigation that could provide valuable insights into the current state of welfare and biosecurity in small-scale dairy farming in the inner areas of the Molise region.

MATERIALS AND METHODS

Data collecting

The study was carried out on 14 dairy cattle farms located in the hilly and mountainous area in the province of Isernia in the Molise region, and the neighbouring towns in the province of L'Aquila in the Abruzzo region, as reported in figure 1.

Figure 1. Location of farms

The farms' welfare assessments were performed by a trained veterinarian with the support of one expert livestock technician using the ClassyFarm checklist for dairy cattle, considering different subpopulations (calves, heifers, lactating cows, and dry cows).

The checklist was the one considered for the ClassyFarm system which includes 99 questions for tie stall (TS) systems (ClassyFarm, 2019a) and 105 for free stall (FS) systems (ClassyFarm, 2019b) split on the five macro-areas: Area A – farm management and staff training; Area B – structures and equipment; Area C – animal-based measures; Biosecurity area; Hazards and Risks area. Each observation/question has two or three options for the answer: not acceptable/acceptable; not acceptable/acceptable/excellent. To compare the data regarding the five area of the ClassyFarm checklist a two-point or a three-point scale was considered for each observation: i) score 1 assigned to the worst result (not acceptable); ii) score 2 assigned to acceptable results; iii) score 3 represented the best result for the three-point scale.

Animal-based measures (ABMs)

According to the ClassyFarm manual, the direct evaluation of the animals is carried out on a sample of animals, the number of which is related to the group size as shown in Table 1 (ClassyFarm, 2023).

Table 1. Minimum number of animals to be observed for the assessment of direct ABMs

Group size	*Minimum number of animals to observe*
<30	All
From 31 to 99	From 30 to 39
From 100 to 199	From 40 to 50
From 200 to 299	From 51 to 55
From 300 to 549	From 55 to 59
From 550 to 1000	From 60 to 63
From 1001 to 3000	From 63 to 65

The ClassyFarm protocol described the method that must be used for the assessment of the following animal-based measures: human-animal relationship; body condition score (BCS); cleanliness; lesions; lameness; claws. The average score based on the prevalence of every indicator of the single assessment was calculated and transferred into the three-point scale after the model of the ClassyFarm protocol.

Considering that the investigated farms are mainly small-scale farms, the ABMs assessment for each farm was carried out on all the reared animals for each category (lactating cows; dry cows; young stock or heifers; calves).

Human-animal relationship

Avoidance distance at the feeding rack (ADF) is usually used to measure the human-animal relationship (HAR) for animals indoors (Welfare Quality Consortium, 2009; Waiblinger et al., 2002). According to the protocol, the veterinarian stood 2 m in front of the cow's head, then approached the cow at a speed of one step per second with one arm at 45° in front of the body (palm facing downwards) as shown in Figure 2. The experimenter stopped walking when the cow accepted contact with the hand or when the cow showed a sign of avoidance, as defined in Welfare Quality Consortium (2009).

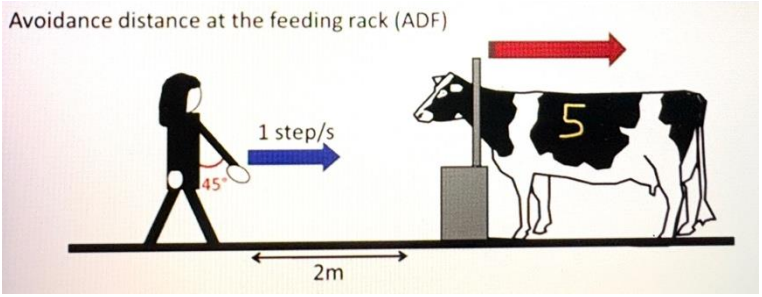

Figure 2. Avoidance test (source: Aubé et al., 2023)

The final evaluation will be defined by quantifying the percentage of animals that do not allow themselves to be approached and move backwards at various predetermined distances and of

animals that can be touched or approached up to a few cm away. Avoidance distance was scored with (1) when the animal tried to avoid the hand with a distance more than 1 m from the muzzle, with (2) when the distance was less than 1 m form the muzzle and (3) when animals that allow themselves to be touched or approached up to a few cm away. At this point, the arithmetic means of the scores given to the observed animals is calculated, rounding off any decimals to the nearest whole number. An average ≤ 1.5 is awarded the insufficient rating; an average between 1.5 and 2.5 is awarded the acceptable rating; an average > 2.5 is awarded the optimum rating.

Body condition score (BCS)

The Body Condition Score (BCS) was assessed from behind the animal, looking at both sides with special attention on protruding bone points and fat accumulation of the tail base, the lumbar spine, the hip bone, and ischial tuberosity. A representative number of subjects in all animal groups and starting with heifers (over 150 kg and/or 6 months of age) was assessed, as per Table 1. For evaluation purposes, animals with BCS are noted:

- equal to or less than 2, i.e. in an obvious state of slenderness: prominence of the bony tuberosities, clearly visible end of the transverse processes of the lumbar vertebrae, sacro-iliac and sacro-ischiatic ligaments without fat cover, absence of fat in the tail groove, etc;

- equal to or greater than 4.25, i.e. in an obvious state of fattening: flat pelvic line, end of the transverse processes of the lumbar vertebrae almost invisible, sacro-iliac and sacro-ischiatic ligaments indistinguishable, tail hollow completely filled with fat.

The number of animals with BCS above the specified limits was related to the total number of subjects observed. The score was assigned as follows: score 1 when more than 10% of animals (according to the 3 categories observed) had a BCS<2 or BCS>4.25; score 2 when the percentage of animals with BCS below or above the limits ranged between 5

and 10%; score 3 the optimal level, is given if less than 5% of subjects have BCS above the limits (2 < BCS < 4.25).

Cleanliness

To evaluate the level of cleanliness, the auditor stayed at a maximum distance of 2 m from the animal and looked out for dirty spots on the udder, upper and lower hindleg. An animal is considered dirty when at least 2 of the anatomical parts evaluated shows "dirty plaques" at least as large as the palm of a hand or more than half of the part considered is covered with liquid dirt. The optimal judgment (score 3) was assigned when subjects with a dirty coat were less than 10%, for acceptable judgment (score 2) between 10% and 20%, while if more than 20% judgment was insufficient (score 1).

Skin lesions

The evaluation of lesions was performed in relation not only to the number but also to the severity and carried out by observing only one side of the animal (chosen at random, before starting the evaluation; otherwise consider the first side seen, approaching the animal). The observation of the cow is carried out at a distance of about 2 m, in a cranio-caudal direction, evaluating the lateral aspect of the entire flank in front of the evaluator and the medial aspect of the contralateral hind limb only. In particular, lesions were assessed by observing in a cranio-caudal direction the animals: head, neck, sternum, shoulder, forelimb, pelvis, thigh, hind limb (lateral face and medial face of the contralateral limb) and udder. Skin lesions were distinguished in: heavy (10 or more small lesions <4cm diameter, 1 big lesion >10cm in diameter, swollen areas, open wounds or big scars); mild (15 small injuries <2cm in diameter, 2–10 lesions <4cm in diameter or 1 medium injurie between 4 - 10cm in diameter); none (up to 14 small lesions <2cm in diameter or 1 lesion

up to 4cm in diameter). It is important to note that one severe skin lesion is equivalent to three mild skin lesions. Score 3 (optimal judgment) was assigned when less than 15% of animals showed mild skin lesions; score 2 (acceptable) was assigned when the percentage of animals with mild skin lesions ranged between 15 and 30%; score 1 (not acceptable) when more than 30% of animals had mild skin lesions.

Lameness

Lameness was evaluated from behind and on both sides of the respective animal. Depending on the husbandry system (TS or FS) the animal was assessed while walking and/or standing. During the examination in the stand (especially for TS) it was looked for whether the investigated animal relieved a leg, showed a malposition of a limb, an abnormal pelvic position, or unilateral muscle atrophy. Additionally, while the investigated animal was moving it was observed if the animal bent its back, showed head nodding, limping, or other irregularities while walking. The rating was differentiated into (1) lame and (2) not lame. The parameter is acceptable if the number of lame animals is between 4 and 8% (score 2); the parameter is not acceptable when lame animals are higher than 8% (score 1); optimal judgment when lame animals are lower than 4% (score 3).

Hoof condition

To evaluate the hoof condition, all four hooves are examined for any changes in length or deformities, as well as for the presence of lesions, infections, or surface irregularities. The condition was categorized into two groups: (1) inadequate and (2) adequate. A score of 3 was assigned if less than 10% of the subjects had deformed claws longer than 10 cm, indicating a positive assessment. If 10% to 40% of the subjects exhibited long and deformed claws, a score of 2 was given, which was considered acceptable. Conversely, a

score of 1 was assigned if more than 40% of the animals had non-compliant and excessively long claws (over 10 cm), indicating a negative assessment.

Statistical analysis

For the statistical analysis of the data, the IBM SPSS Statistic 25 software (Chicago, IL, USA) was used. For the investigated tie-stalls (n. 7) and free-stalls (n.7), the descriptive statistic for the herd size and all the checklist questions belonging to the five areas of ClassyFarm protocol was performed.

RESULTS AND DISCUSSION

Characteristics of the studied dairy farms

The ClassyFarm protocol aims to estimate the risk level of a farm in relation to animal welfare and to detect critical points identifying areas of improvement to prevent animal diseases. Since the welfare level is judged on the whole herd, in dairy cattle breeding, it is necessary to consider the sub-populations of animals that are subject to assessment, namely calves from birth to the first six months of life; young 'unproductive' animals from six months of age to the seven-month pregnant heifer; lactating cows and dry cows.

This study is the first attempt to compare the application of the ClassyFarm protocol as a measurement tool to evaluate the welfare status of small-scale dairy farms, considering both tie-stalls and free-stalls. Currently, free-stall is the most common housing type in Italy; however, tie-stall housing remains prevalent for many small-scale dairy farms, particularly in the mountainous and inland areas of the country. Tie-stall housing accounts for over 98% of all stables in many Alpine regions of Italy (Corazzin et al., 2010) and is also common in several European countries (Robbins et al., 2019). This is why the IZSLER/CReNBA has chosen to include tie-stall housing systems in the ClassyFarm protocol despite concerns regarding animal welfare. The welfare of tied animals can be compromised due to limited exercise, reduced social interaction, and the inability to engage in complete behavioural patterns (EFSA, 2009). Furthermore, in the mountainous regions of Italy, these animals benefit from living outdoors and grazing during the warmer months of the year (Ventura et al., 2021). Developments in recent years have also led to a re-evaluation of the size of the stalls by improving living space, aiming at improving certain management aspects (e.g., proper litter management) and structural aspects (e.g., comfortable laying surface, wider aisles, optimized cubicles etc.). The exact sizing and shape of the various elements are crucial for the health of the animals, which were

previously confined in very small spaces. Free stalls, on the other hand, provide animals with freedom of movement, the possibility of being able to interact with other animals and allow operators to detect oestrus more easily and better manage calves. In addition, this type of housing provides the operator with better working conditions, especially in terms of safety, particularly milking operations, thanks to a room dedicated to this activity.

The herd size of the investigated farms, 7 free stalls and 7 tie stalls, are shown in Tables 1 and 2, respectively. On average, free stalls had a larger herd size than tie stalls (115.9 vs 31.4, respectively). All farms reared more than one breed, among Italian Holstein Friesian, Brown Swiss, Viking Holstein, Viking Red, Montbeliarde, and Fleckvieh. Generally, farms that reared Holstein Friesian and Viking Holstein, as their main breeds, have a larger herd size.

Table 1 Herd size in all investigated free-stall farms

No.	Mean	Std Dev	Min	Max
Lacting cows	78.7	47.1	30	150
Dry cows	19.7	15.8	5	50
Heifers	9.2	3.4	3	12
Calves	8.1	2.9	3	12

Table 2 Herd size in all investigated tie-stall farms

No.	Mean	Std Dev	Min	Max
Lacting cows	43.1	19.4	20	70
Dry cows	13.7	8.4	6	30
Heifers	12.0	9.4	3	30
Calves	4.7	5.1	1	13

The milking performance of the investigated farms, reported in Table 3, showed a huge range of variability from a minimum milk production of 23 Kg/head/day to a maximum of 41 Kg/head/day. The differences in milking efficiency are influenced by several factors, one of which is the milking system used. Many researchers have evaluated the need to enhance the efficiency of the milking process by optimizing

various aspects of the milking routine. Some of these studies have primarily focused on different types of milking parlors, such as parallel, herringbone, and rotary systems, as well as other methods like bucket, trolley, and smaller parlors (Calvo and Airoldi, 2020). In all the investigated tie-stalls milking is carried out with trolley or bucket milking systems. It is known, that in both these systems, the milker's time for each cow is greater than the routine time, because it is necessary to wait for the completion of the milk flow time before moving the machine to the next animal. Furthermore, some critical points were found regarding mainly the use of obsolete milking systems and excessive long milking time. As for the investigated free stalls, only one farm had a milking robot while the other had small parlors mainly tandem parlors and herringbone parlors. All the investigated farms made two milking per day, representing the standard situation in small cow herds, not only in Italy.

Table 3. Average milk production (kg/head/day) in tie-stall and free-stall farms

	Mean	Std Dev	Min	Max
Tie stalls	31.4	5.7	25	38.5
Free stalls	35.0	5.8	23	41

ClassyFarm areas

Biosecurity

Biosecurity, as mentioned, is one of the main preventive tools available to operators and other people working with animals to prevent the introduction, development and spread of transmissible animal diseases from and within an animal population (Regulation (EU) 2016/429). General biosecurity rules should always be applied, as they constitute an overall barrier to the introduction of new diseases and their spread within the herd. They involve a set of guidelines to be applied both during extraordinary operations (e.g. during

disease outbreaks) and during routine activities (e.g. cleaning, sanitization, and maintenance of housing environments) (ClassyFarm, 2023). The results of the monitoring activities for the biosecurity area are shown in Table 4 (free stall) and Table 5 (tie stall).

Table 4. Results of the biosecurity are for free-stall farms

Items	Mean	Std Dev	Min	Max
Pest control (1)	2.71	0.49	1 (0)	3 (71.4%)
Animal contact (2)	2.86	0.38	1 (0)	3 (85.7%)
Entrance of external persons (3)	2.71	0.76	1 (14.3%)	3 (85.7%)
Visitors (4)	2.86	0.38	1 (0)	3 (85.7%)
Disinfection external vehicles (5)	2.71	0.49	1 (0)	3 (71.4%)
Contact animals and vehicles (6)	1.71	0.49	1 (28.6%)	2 (71.4%)
Disposal of animal carcasses (7)	1.57	0.53	1 (42.9%)	2 (57.1%)
Loading/unloading of animals (8)	1.57	0.53	1 (42.9%)	2 (57.1%)
Purchase/movements animals (9)	2.14	1.07	1 (42.9%)	3 (57.1%)
Quarantine (10)	2.57	0.53	1 (0)	3 (57.1%)
Control/Prevention of infectious diseases (11)	2.71	0.49	1 (0)	3 (71.4%)
Submission of pathological material (12)	1.86	0.38	1 (14.3%)	2 (85.7%)
Udder health (13)	2.43	0.79	1 (14.3%)	3 (57.1%)
Control/Prevention of parasites (14)	2.57	0.53	1 (0)	3 (57.1%)
Control/Analyses of supplied water (15)	1.57	0.53	1 (42.9%)	2 (57.1%)

The number indicated in the brackets for each item refers to the corresponding audit item from the ClassyFarm checklist for both free-stall and tie-stall dairy farms. Min represents the worst score, Max the best score. The percentage of farms that achieved each score is provided in brackets.

Table 5. Results of the biosecurity area for tie-stall farms

Items	Mean	Std Dev	Min	Max
Pest control (1)	2.14	0.90	1 (28.6%)	3 (42.9%)
Animal contact (2)	1.86	0.90	1 (42.9%)	3 (28.6%)
Entrance of external persons (3)	2.00	0.82	1 (28.6%)	3 (28.6%)
Visitors (4)	2.00	0.82	1 (28.6%)	3 (28.6%)
Disinfection external vehicles (5)	2.00	0.58	1 (14.3%)	3 (14.3%)
Contact animals and vehicles (6)	1.29	0.49	1 (71.4%)	2 (28.6%)
Disposal of animal carcasses (7)	1.57	0.53	1 (42.9%)	2 (57.1%)
Loading/unloading of animals (8)	1.57	0.53	1 (42.9%)	2 (57.1%)
Purchase/movements animals (9)	2.29	0.76	1 (14.3%)	3 (42.9%)
Quarantine (10)	2.14	0.38	1 (0.0%)	3 (14.3%)
Control/Prevention of infectious diseases (11)	2.14	0.69	1 (14.3%)	3 (28.6%)
Submission of pathological material (12)	1.57	0.53	1 (42.9%)	2 (57.1%)
Udder health (13)	2.14	0.90	1 (28.6%)	3 (42.9%)
Control/Prevention of parasites (14)	2.00	1.00	1 (42.9%)	3 (42.9%)
Control/Analyses of supplied water (15)	1.86	0.69	1 (28.6%)	2 (71.4%)

The number indicated in the brackets for each item refers to the corresponding audit item from the ClassyFarm checklist for both free-stall and tie-stall dairy farms. Min represents the worst score, Max the best score. The percentage of farms that achieved each score is provided in brackets.

The first audit item concerns **pest control** measures. The presence of rodents and insects represents an important source of risk for introducing and spreading pathogenic infectious agents within the farm. Indeed, they can behave as biological and/or mechanical vectors, favouring the spread of infections with an oro-fecal cycle. While rodents are vectors of zoonoses, they can also play a role (either as reservoirs or as mechanical vectors) in the persistence within livestock farms of diseases that can result in clinical forms in domestic animals and/or pose a risk to food safety (ClassyFarm, 2023). Another element of risk is the presence of insects and, in particular, flies, which can act as a mechanical vector in the transmission of diseases among animals and can be a direct cause of severe irritation, often associated with weight loss; in the case of hematophagous flies (e.g., tabanids) can also be the cause of massive blood loss (ClassyFarm, 2023). Concerning the results of the present study, the majority of the free-stall farms (71.4%) showed well-codified procedures in a biosecurity manual, while the remaining 28.60% reported the presence of approximate and non-formalized procedures. On the contrary, among the tie-stall farms there were 2 farms (28.6%) that declared the total absence of procedures.

Regarding the **contact with other animal species**, it is known that many animal species, both domestic and wild, are susceptible to the same pathogens. Contact with other animals outside the herd or flock that are also susceptible to these infectious agents could pose a significant risk factor. The farm should include fencing to prevent uncontrolled access by unwanted animals such as rodents, stray dogs and cats and, if present also for transhumant (e.g. sheep) or wild animals. An exposure factor for infection is also the presence of owned domestic animals (dogs and cats), which are in direct contact with farmed animals and may visit other farms, or synanthropic wild animals (ClassyFarm, 2023). According to the ClassyFarm protocol, when evaluating farms with access to pasture, it is important to assess the situation carefully. Pasture access may lead to

unintended contact with other animals from different herds, grazing areas, or species. Therefore, a rating can only be considered acceptable if the pasture is securely fenced and there is no mingling with other wild or domestic animals. If these conditions are not met, the rating will be deemed insufficient. The results of this study indicate that nearly all of the free-stall farms (85.7%) effectively prevented contact with other animal species, both within the farm perimeter and in adjacent housing areas. In contrast, 42.9% of the tie-stall farms displayed deficiencies in this regard, allowing for obvious and frequent contact with other species.

Another important route of introduction of infectious agents into the farm is the entry of people and vehicles. Therefore, it becomes essential to prevent access by outsiders, especially if they have contact with other farms, by displaying clear prohibition signs and installing physical barriers, such as gates or bars. If entrances are agreed, there should be a register in which all visits to the farm can be documented. All visitors should be obliged to wear disposable clothing provided by the farm itself, while those who have constant access to the farm (e.g., veterinarian, nutritionist, supply chain technician, etc.) should be provided with a special room where they can change and put on their personal clothing and boots. The results of the present activity showed that almost all of the free-stall farms (85.7%) declare the use of defined and organic procedures for the regulation of entry into the farm; while only 28.6% of the tie-stall farms declared the presence of defined and organic procedures and the 42.9% of non-formalized procedures. The total absence of procedures was found in 2 farms, one per housing system. For the management of the entry of **regular visitors** (veterinarians, company consultants, etc.), the majority of free-stall farms (85.7%) have a changing area where visitors are provided with disposable clothing for personal use; they also have specific disinfection devices routinely used for the disinfection of vehicles (audit item n.5). A high proportion of tie-stall farms (42.9%), on the other hand, did not have a designated changing area, although they did provide all

necessary disposable devices for visitors. Additionally, two farms lacked both a changing area and any guidelines regarding the biosecurity measures for the visitors.

As regard the audit item concerning **contact between vehicles and animals**, ideally, the farm should be constructed and organized in such a way as to minimize the entry of vehicles, ensuring that above all operations (e.g., the replenishment of feed, the loading of carcasses, the loading and unloading of live animals, etc.) are carried out outside the farm boundaries or at least 20 meters away from the facilities where the animals are kept. In the case of vehicles transporting milk, the collection area should be easily washable and disinfectable, and it should be ensured that the vehicle does not come into contact with the animals during the loading of the milk. Considering the results obtained from the present study, an opposite trend is evident between the two housing systems: the majority of free-stall farms (71.4%) exclude the possibility of contact between vehicles and animals, while the majority of tie-stall farms (71.4%) do not exclude this possibility of contact (<20 m distance between vehicles and animals).

Regarding the audit items No. 7 and 8, it is desired that vehicles for **animal carcass loading and loading of live animals** should not enter the farm, but carry out loading operations outside the farm. To assign an acceptable judgment, a distance of 20 meters between the housing facilities and the loading vehicle is binding. To guarantee this condition, the farm must either have a pre-loading area, at least 20 meters away from the other housing facilities, where animals can be gathered before boarding the vehicle or have corridors for animal movement (between the building and the vehicle) that are longer than 20 meters. In particular, for the carcass loading, in the majority of farms (57.1%) both free- and tie-stall, the vehicle is stopped at the confines of the farm where the carcasses have previously been collected, although the number of farms (42.9%) that, on the contrary, do not have loading areas distant from the housing facilities is not negligible. The same situation was found for the loading and unloading of live animals.

Audit items No. 9 and 10 refer to the **handling of live and quarantined animals**. In the farming routine, animal handling is normally divided into two major activities:

- introduction of new animals from other herds or re-introduction of own animals after movement outside to fairs, exhibitions, markets or a mountain pasture and transhumance;
- movement of animals within the boundaries of the farm.

The introduction of animals represents the most important risk to the health status of the herd; it is, therefore, necessary to follow a few simple but fundamentally important rules to reduce the risk of infectious and diffusive diseases entering. Firstly, it is essential to know the health status of the animals purchased or re-introduced and to check their arrival conditions (correct identification, presence of symptoms or lesions, sanitary conditions of the animals or of the area of origin). It is, therefore, important to have a quarantine area as a primary biosecurity measure. The dedicated area should be separate from the rest of the farm, with suitable hygienic and microclimatic conditions, its equipment (e.g. milking machine, feeders, etc.) and systems for capturing animals to allow veterinary visits and control sampling. The management of internal movements is certainly less important for the prevention of the entry of new diseases, but it is fundamental in the case of reducing the spread of infections already present on the farm. The possibility of using facilities capable of separating infected or suspected infected animals from healthy animals can be useful in controlling the spread of these infections. On the majority of farms (57.1%), both tie- and free-stall, the loading of animals is carried out away from the housing (> 20m). In addition, most farms (57.1% free-stalls; 42.9% tie-stalls) had not purchased or moved animals for more than 2 years. Concerning the management of quarantine, the majority of tie-stall farms (85.7%) implement partial, empirically performed and non-formalized forms of quarantine; whereas, the majority of free-stall

farms (57.1%) implement correct forms of quarantine, appropriate to time and structure and/or no animal movement for more than 2 years.

Audit items No. 11 and 12 refer to the **control and prevention of major infectious diseases** and health monitoring systems. It is well known that an effective biosecurity plan cannot disregard knowledge of the main pathologies present on the farm and the infectious situation of the one's farm. An essential requisite is the breeder's knowledge of certain pathologies, depending on the species and the production address of the farm. In particular, for cattle, the most frequent pathologies that require a more or less in-depth knowledge are: infectious bovine rhinotracheitis (IBR), bovine viral diarrhoea (BVD), paratuberculosis (ParaTBC); these pathologies, selected by their frequency and importance, can have serious repercussions on the health and welfare of the animals and their productivity. Deficiencies in their knowledge expose the animals to an increased risk of pathogen entry and/or spread. Therefore, if the farmer is found to be totally unaware of these issues and does not apply any prevention or control plan, an insufficient rating should be given (ClassyFarm, 2023). For the same reasons, the total absence of diagnostic examinations aimed at monitoring the health situation of the herd is to be considered insufficient; while the habit of submitting biological and/or pathological material (e.g. feces, nasal mucus, saliva, blood samples, foetuses, carcasses, etc.) to the laboratory of the veterinary service is to be judged acceptable, possibly verifying the presence of documentation of these examinations, carried out at least in the last 12 months (ClassyFarm, 2023). Concerning the results obtained, free-stall farms are confirmed to be more virtuous both in terms of operators' extensive knowledge of diseases, with the consequent application of correct prevention and control plans (71.4%), and in terms of the provision of biological samples for health monitoring of the herd (85.7%). On the contrary, the operators of tie-stall farms showed a partial knowledge and/or presence of undefined control and prevention plans

(57.1%); a slightly higher percentage of farms conferring biological samples for health monitoring compared to those with no conferring at all (57.1 vs. 42.9%, respectively).

Audit element No. 13 relates to the **control and prevention of udder infections**. As is well known, udder infections and diseases are the main health problems on dairy farms, with consequences on animal welfare, on the environmental sustainability of the farm (animals continue to emit but not to produce) with considerable economic losses (lost milk production, related therapeutic expenses, increased labor, etc.). The somatic cell count has become a routinely used tool to monitor the prevalence of infections on the farm, but on its own, it cannot provide the bacteriological diagnosis, based on which therapy and control actions can be based. To pursue these objectives, precise protocols of bacteriological investigation should be applied, such as the analysis of mass milk, to be carried out at least every 6 months, and the analysis of mammary secretion, taken from all quarters, mastitic (except in the case of chronic relapsing mastitis), to be sent periodically, after freezing, to the laboratory for bacteriological diagnosis and antibiogram. This investigation, in addition to highlighting possible problems at an early stage, makes it possible to pay more attention to specific biosecurity regulations and to choose the most suitable active ingredients for antibiotic therapy (ClassyFarm, 2023). The assessment of the level of biosecurity in the monitored farms revealed that the majority of free-stall (57.1%) and tie-stall (42.9%) farms carry out tests on individual animals, to correctly identify the prevalent cause of mastitis and implement the specific eradication and control plans; the remaining share of farms carry out tests on mass milk at least once a year (28.6% for both types of farms); while 14.3% of free-stall and 28.6% of tie stall farms do not carry out any analytical control. For the purpose of assessing the level of biosecurity present on the farm, it is considered acceptable to carry out a check on mass milk, at least once a year, for the main agents of contagious mastitis.

Audit element No. 14 concerns the **control and prevention of endo- and ecto-parasitosis**. In particular, the evaluator must verify the farmer's knowledge of the most widespread endo- and ecto-parasitic diseases (e.g. coccidiosis, strongyloidiasis) and ascertain the presence of any control and eradication plans. Also, in this case, the free-stall farms were more virtuous than the tie stall farms in terms of in-depth knowledge (57.1%) of the main parasitic diseases and planned parasite treatments; on the contrary, in 42.9% of the tie-stall farms an absence of knowledge of the health status and consequent absence of prevention/control plans on the part of the farmers was found.

The last audit item is the **control and analysis of the used water**. Water must always be available for any group of animals on the farm. To ensure good water quality, especially if it comes from the farm well, or from the aqueduct in the presence of intermediate collection tanks, a periodic (at least annual) microbiological analysis must be carried out. Chemical analyses (pH, hardness, presence of nitrites and nitrates, ammonia) are also recommended (ClassyFarm, 2023). In the present study, almost all (71.4%) of the tie- and free-stall farms (57.1%) carry out annual water analyses. A small proportion of farms (42.9%, free-stalls; 28.6% tie-stalls) did not do analyses of the water quality.

Overall, the current results indicate a significant adoption of biosecurity measures among the monitored small-scale dairy farms, with free-stall farms performing better than tie-stall farms, which exhibited different criticisms. This deficiency can be attributed to structural limitations in farm buildings, especially in tie-stall farms, but also to limited financial resources. Additionally, many farmers lack awareness of biosecurity practices, which is often linked to their generally advanced age and the lack of generational turnover in farming. These findings align with the results obtained by Holighaus et al. (2023) and Zanon et al. (2024) in studies carried out in small-scale mountain dairy farms. Holighaus et al. (2023) stated that the ClassyFarm system does not fully consider the peculiarity of the

small-scale mountain dairy farms and might lead to misleading conclusions from risk analysis.

Management and personnel – Area A

Farm management is fundamental to animal welfare and includes all operations involving animal handlers. Overall, the management-based measures consider: the number of stockpersons working on the farm, in relation to the number of animals cared for; their level of technical expertise in performing the activities that most affect animal welfare; and how they work on a daily basis to ensure comfortable living conditions for the animals (ClassyFarm, 2023).

The results of the management-based measures are shown in Table 6 (free-stall farms) and Table 7 (tie-stall farms).

The first audit item of the management area (n.16) considers the number of employees taking care of the animals (stockpersons), a number that varies according to the type of housing and considering whether or not those taking care of the animals on a daily basis are also involved in milking operations. In the present study, the number of stockpersons (ratio: no. stockpersons /no. animals) is acceptable and/or optimal in all tie-stall farms, which have a low average number of animals (average: 74; min: 39; max: 103); while in free-stall farms the number of employees is acceptable (42.9%) and in no. 2 farms (28.6%) it is not sufficient to guarantee optimal health and welfare standards for all animals on the farm. The monitored free-stall farms are bigger than tie-stalls and have an average number of animals of 116, with some farms even reaching 200 animals.

Table 6. Results of the macro-area management for free-stall farms

Items	Mean	Std Dev	Min	Max
Stockpersons (16)	2.00	0.82	1 (28.6%)	3 (28.6%)
Knowledge in handling (17)	2.29	0.76	1 (14.3%)	3 (42.9%)
Division in animal group FS (18)	2.57	0.53	1 (0%)	3 (57.1%)
Number of inspections animals > 6 months (19)	2.43	0.53	1 (0%)	3 (42.9%)
Number of inspections calves < 6 months (20)	2.43	0.53	1 (0%)	3 (42.9%)
Treatment of sick/injured animals (21)	2.57	0.79	1 (14.3%)	3 (71.4%)
Culling of animals (22)	2.71	0.49	1 (0%)	3 (71.4%)
Type of movement (23)	2.00	0.00	1 (0%)	2 (100%)
Feeding of animals >6 months (24)	2.57	0.53	1 (0%)	3 (57.1%)
Feeding times and interval animals >6 months (25)	2.57	0.53	1 (0%)	3 (57.1%)
Amount of concentrate (26)	2.00	0.00	1 (0%)	2 (100%)
Colostrum (27)	2.71	0.49	1 (0%)	3 (71.4%)
Feeding of calves < 6 months (28)	2.71	0.49	1 (0%)	3 (71.4%)
Water and number of drinkers (29)	2.57	0.53	1 (0%)	3 (57.1%)
Cleanliness of the drinkers lactating cows (30)	2.57	0.53	1 (0%)	3 (57.1%)
Cleanliness of the drinkers dry cows (31)	2.57	0.53	1 (0%)	3 (57.1%)
Cleanliness of the drinkers heifers (32)	2.57	0.53	1 (0%)	3 (57.1%)
Cleanliness of the floor/walkways of lactating cows (33)	2.29	0.76	1 (14.3%)	3 (42.9%)
Cleanliness of the floor/walkways of dry cows (34)	2.29	0.76	1 (14.3%)	3 (42.9%)
Cleanliness of the floor/walkways of heifers (35)	2.29	0.76	1 (14.3%)	3 (42.9%)
Cleanliness of laying area of lactating cows (36)	2.57	0.79	1 (14.3%)	3 (71.4%)
Cleanliness of laying area of dry cows (37)	2.71	0.49	1 (0%)	3 (71.4%)
Cleanliness of laying area of pre partum/partum cows (38)	2.71	0.49	1 (0%)	3 (71.4%)
Pre partum/partum area management and cow movement timing (39)	2.86	0.38	1 (0%)	3 (85.7%)
Cleanliness of laying area of heifers (40)	2.71	0.49	1 (0%)	3 (71.4%)
Cleanliness of laying area of calves (41)	2.86	0.38	1 (0%)	3 (85.7%)
Prevention of foot problem (42)	2.86	0.38	1 (0%)	3 (85.7%)
Cleanliness of milking area (43)	2.57	0.53	1 (0%)	3 (57.1%)
Milking management and udder hygiene (44)	2.57	0.53	1 (0%)	3 (57.1%)
Biosecurity (45)	2.43	0.79	1 (14.3%)	3 (57.1%)

The number indicated in the brackets for each item refers to the corresponding audit item from the ClassyFarm checklist for both free-stall and tie-stall dairy farms. Min represents the worst score, Max the best score. The percentage of farms that achieved each score is provided in brackets.

Table 7. Results of the macro-area management for tie-stall farms

Items	Mean	Std Dev	Min	Max
Stockpersons (16)	2.29	0.49	1 (0%)	3 (28.6%)
Knowledge in handling (17)	2.00	0.82	1 (28.6%)	3 (28.6%)
Division in animal group TS (18)	2.00	1.00	1 (42.9%)	3 (42.9%)
Number of inspections animals > 6 months (19)	2.29	0.95	1 (28.6%)	3 (57.1%)
Number of inspections calves < 6 months (20)	2.14	0.69	1 (14.3%)	3 (28.6%)
Treatment of sick/injured animals (21)	2.43	0.79	1 (14.3%)	3 (57.1%)
Culling of animals (22)	2.14	0.38	1 (0%)	3 (14.3%)
Type of movement (23)	1.71	0.49	1 (28.6%)	2 (71.4%)
Feeding of animals >6 months (24)	2.43	0.79	1 (14.3%)	3 (57.1%)
Feeding times and interval animals >6 months (25)	2.29	0.76	1 (14.3%)	3 (42.9%)
Amount of concentrate (26)	1.71	0.49	1 (28.6%)	2 (71.4%)
Colostrum (27)	2.71	0.49	1 (0%)	3 (71.4%)
Feeding of calves < 6 months (28)	2.43	0.53	1 (0%)	3 (42.9%)
Water and number of drinkers (29)	2.57	0.79	1 (14.3%)	3 (71.4%)
Cleanliness of the drinkers lactating cows (30)	2.29	0.76	1 (14.3%)	3 (42.9%)
Cleanliness of the drinkers dry cows (31)	2.14	0.69	1 (14.3%)	3 (28.6%)
Cleanliness of the drinkers heifers (32)	2.29	0.76	1 (14.3%)	3 (42.9%)
Cleanliness of laying area of lactating cows (33)	2.14	0.38	1 (0%)	3 (14.3%)
Cleanliness of laying area of dry cows + pre partum/partum cows (34)	2.14	0.69	1 (14.3%)	3 (28.6%)
Cleanliness of laying area of heifers (35)	2.14	0.38	1 (0%)	3 (14.3%)
Cleanliness of laying area of calves (36)	1.86	0.90	1 (42.9%)	3 (28.6%)
Prevention of foot problem (37)	2.14	0.90	1 (28.6%)	3 (42.9%)
Cleanliness of milking area (38)	2.43	0.79	1 (14.3%)	3 (57.1%)
Milking management and udder hygiene (39)	2.14	0.69	1 (14.3%)	3 (28.6%)
Biosecurity (40)	2.14	0.90	1 (28.6%)	3 (42.9%)

The number indicated in the brackets for each item refers to the corresponding audit item from the ClassyFarm checklist for both free-stall and tie-stall dairy farms. Min represents the worst score, Max the best score. The percentage of farms that achieved each score is provided in brackets.

For the **training of stockpersons** (No.17), the overall skills of the stockpersons are evaluated, which can be either of practical origin (because provided by experience) or of theoretical origin (e.g. training course/education degree). In the present study, the stockpersons of the majority of free- and tie-stall farms (42.9%) demonstrated adequate and/or optimal skills and knowledge.

Another audit item concerns **group management** (No. 18). Generally, in order to meet the different physiological needs of the animals, to bring together subjects that are homogeneous in terms of age and production period and to be able to guarantee them the assistance they require, in a dairy cattle herd (regardless of the type of housing) the presence of at least the following basic groups should be considered: calves up to 6 months of age (according to the provisions of Legislative Decree 126/2011); heifers; lactating cows; dry cows. In view of the management difference between loose-housing and fixed-housing farms, the system provides for different indications for this observation (ClassyFarm, 2023). In the case of free-stall farms, for farms with more than 50 total cows, i.e. more than 20-30 lactating cows, the subdivision of adult cows into more groups (transition cow, primiparous, multiparous, early- to late-lactation, etc.), compared to basic cows, will be judged positively and therefore subject to an optimal evaluation. This consideration is not valid for small herds (indicatively with less than 50 animals in total), because the separation of adult animals, during the production period, may be counterproductive, as the cow is a sociable animal and should only be left alone in exceptional cases. In the case of small herds, therefore, the evaluator should analyse how the farmer handles the transition, milking, and dry phases and if he finds particularly positive attention, he can assign the optimal evaluation. In the case of tie-stalls, the condition of having cows tethered avoids the need to create specific groups to manage animals of the same age, production and reproductive category and with the same metabolic needs. Furthermore, tethered cows are more easily controlled, and individual

care and feeding rations can be provided for them based on their specific metabolic needs. To assign an acceptable judgment it is necessary to recognize the presence of at least two groups/categories of animals: the lactating and dry cows together and undivided. An optimal score is achieved when adult cows are physically separated, such as when dry cows are housed in individual stalls or designated areas. Alternatively, if they are housed adjacent to one another, an automated system should be in place to provide specific feed tailored to their individual needs (ClassyFarm, 2023). In the present study, 57.1% of the free-stall farms displayed optimal group management, while the remaining 42.9% maintained the same number of groups corresponding to the evaluated categories (heifers, drying, and lactation). In contrast, among the tie-stall farms, 42.9% had no separation of groups, while another 42.9% successfully separated the groups into three categories: heifers, dried, and lactation.

Another audit item concerns the **daily inspections** for cattle over 6 months old (No. 19) and calves (No. 20). As stated in the ClassyFarm manual, a correct inspection of animals requires that all reared animals are observed and assessed according to their health and welfare status. The inspections are understood to be supplementary to routine activities such as milking and feed distribution. However, when the number of animals is very small (e.g. less than 40-50 animals in total) or the animals are always recognizable (e.g. adult animals reared at the post), the routine activity such as milking, distribution of food (or milk for calves) or cleaning of bedding can be considered concomitant to the inspection (ClassyFarm, 2023). In the present study, for free-stall farms, a sufficient number of inspections were found in 57.1% of the farms, while, in the remaining 42.9% of farms, the number of visits was higher than expected for both inspection items (No. 19 and 20). A similar situation was found in tie-stall farms, where, however, situations of an inadequate number of inspections were also detected (No. 19: 28.6%; No. 20: 14.3%).

The **treatment of sick or injured animals** is crucial. To ensure effective care, prompt observation, first aid by the farmer, veterinary treatment, and isolation of affected animals when necessary are essential. Best practices should include providing all stockpersons with written procedures for the proper management of these animals. This could involve a management plan for specific cases such as mastitis, lameness, downer cows, dystocia, and other conditions. The results obtained in the present study showed that 71.4 % of free-stall farms and 57.1 % of tie-stall farms showed the optimal level of adequacy of procedures that are also clearly codified. In both housing systems, 14.3% of the farms showed the presence of untrained stockpersons and/or the presence of animals requiring treatment that had not yet been received.

In the case of sick or injured animals with a poor prognosis, **culling** should be considered a humane solution. This process must only be carried out by properly trained individuals, such as veterinarians, certified personnel for slaughter operations, farm staff, or owners who possess the appropriate level of competence. It is essential to use adequate and well-maintained equipment during these operations. Best practices recommend that all stockpersons be provided with written procedures for the proper management of culling and related activities, ensuring that animals are protected from any unnecessary pain, distress, or suffering (Ventura et al., 2021; ClassyFarm, 2023). All monitored farms, both tie- and free-stalls, met the requirement. Additionally, 71.4% of the free-stall farms have written procedures for proper slaughter in line with the suitability criteria.

Stress induced by **animal handling** operations can affect welfare; therefore, specific handling equipment is preferred. Stable personnel must take care in animal handling, avoiding the inappropriate use of restraining equipment and unconventional tools (electric prods, sharp instruments, sticks) that can increase the fear and agitation of the animals. All the farms monitored, except for 2 tie-stall farms, use non-offensive tools for animal handling (audit item No. 23).

An important part of farm management is animal nutrition, a part that is subject to multiple elements of scrutiny (No. 24-28). To meet the nutritional needs of animals, they must be fed according to factors such as their growth stage, parity order, physiological state, and production level. Consequently, it is essential to create a specifically calculated diet for at least each group of animals on the farm. The diet should provide sufficient energy, nutrients and dietary fibre to meet nutritional requirements and respect the animals' digestive and metabolic physiology (ClassyFarm, 2023). Regarding the **feeding management and frequency of feed administration**: the feed should be administered *ad libitum* to ensure that each animal is fed as required during the 24 hours, providing constant access to food during the day. In the case of fractionated feeding, feed should be provided almost constantly over 24 hours, including both the fibrous fraction and the concentrated fraction. In this sense, a total mixed ration (TMR) available 24h/day by using unified mixer wagons is desirable (audit item No. 25). Regarding the results of the present study, all the elements of verification regarding feeding were found to be adequate or optimal, for both tie- and free-stall farms, where, however, a small percentage 14.3-28.6% did not meet the minimum requirements. As far as the type of feeding is concerned, the free-stall farms all adopt the unifeed technique and two farms have the feeding robot; the tie stall farms have unifeed feeding and only one holding has the automatic feeder in post.

The composition of the diet in terms of the **amount of concentrate** is considered as an element of verification. All animals must have an adequate amount of fiber, sufficient to ensure normal rumen fermentation and avoid the risk of ruminal acidosis. For this reason, concentrates should not exceed 60% of ingested dry matter (DM), when the diet is without silomais, and 50% of the DM intake when the diet is composed of at least 15 kg of silomais (corn silage DM is conventionally considered to be completely made up of forage). The totality of the monitored farms showed that they use rations with an adequate percentage of concentrates.

A further audit item (No. 27) concerns the **colostrum management** for new-born calves. Since the calf is born almost without maternal antibody coverage, the transfer of passive immunity must necessarily occur through the intake of colostrum, in adequate quantity and quality, within the first 6 hours after calving. In addition, the capacity of the calf's intestinal mucosa to assimilate maternal immunoglobulins decreases dramatically with each passing hour (Figure 1). This is why it is necessary to respect the 6-hour limit from birth to allow maximum antibody transfer (ClassyFarm, 2023). In fact, the concentration of IgG is highest in the so-called first colostrum (produced in the first few hours post-natal), and tends to decrease thereafter to concentrations below 10 g/L as early as the fourth milking.

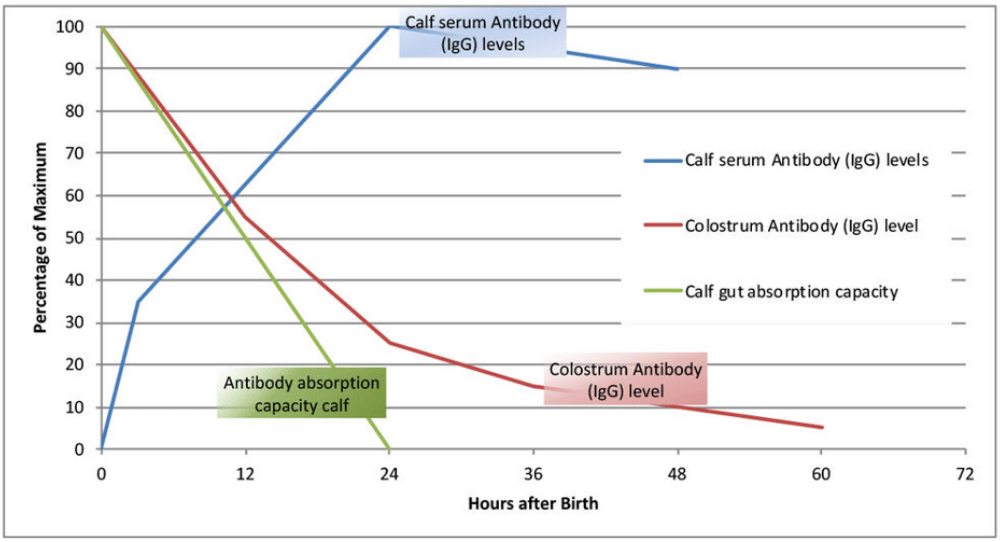

Figure 1. Colostrum and calf immunity

Colostrum can be administered by leaving the calf with the mother, or if the calf is removed from the mother, the farmer must administer the colostrum via bottle or (if necessary) oesophageal tube. Feeding an adequate volume (4 L) of high-quality colostrum with a high immunoglobulin concentration (>50 g/L of IgG or >60 g/L of gamma-globulins) is recommended. In addition, it is important to control bacterial contamination of colostrum by proper udder preparation, collecting it in a clean container and storing it

properly in a refrigerator or freezer. In case of insufficient health status of the mother or insufficient colostrum production, provide a colostrum bank from the healthy cows on the farm (or if necessary, after sanitation treatments) or from colostrum replacement products; the method of feeding the colostrum and maintaining the colostrum bank should be recorded and documented in a good practice manual. The results of the present study showed that all monitored farms, tie- and free-stalls, fully meet the optimal practices for colostrum management.

Feeding management and frequency of food administration in **calves** (milk and fiber): calves should be fed three or more times a day, every day of the week. All the monitored farms satisfy the adequate and optimal requirement for this checkpoint (No. 28).

Other audit items concern the **water availability**, **number and cleanliness of water points** (drinkers or water troughs) for the different groups of animals (audit items 29-32). All animals must always have access to fresh, good quality water, in sufficient quantity to prevent dehydration, free from repulsive odors and tastes, infectious agents, toxic substances and contaminants that could accumulate in body tissues and be detrimental to animal health and welfare (EFSA 2012b - Recommendation 14). Water should be clean and subjected to annual tests for potability or taken directly from the public water supply (without intermediate water storage tanks). All animals should be allowed to satisfy their water requirements by drinking when and as much as they wish (especially during hot weather conditions or when they are ill); provide water troughs or drinkers so that animals do not need to wait too long for drinking, nor compete for water, and allow them to put their mouths into the water (Ventura et al., 2021).

In the present study, the availability of water and the number of drinkers or water troughs (audit item No. 29) met the higher requirements in the majority of the monitored farms, except for one tie-stall farm with inadequate minimum requirements. The cleanliness of the drinkers or water troughs (audit items No. 30-33) for the different animal

groups was also generally acceptable (42.9%) and/or optimal (57.15) for the free-stall farms. Regarding the cleanliness of the drinkers or water troughs, the presence of food or other material on the surface or bottom of the drinkers is acceptable, of course, the water must be clear; the judgment is optimal when neither on the surface nor on the bottom, nor on the walls of the drinkers is there any dirt (mud, food, feces), recent or inveterate (if not in small quantities), and the water is clear. For the monitored farms, all free-stall farms had adequate or optimal judgment; in tie-stall farms, cleanliness was mostly acceptable for the different groups, with only one farm being found to be unacceptable.

With regard to hygiene of the buildings and stabling areas, the following are considered: 1) the **cleanliness of floors in walking areas** (lactating cows - dry cows - heifers) only for free-stall system; 2) the **hygiene, cleanliness and management of the laying areas** (lactating cows - dry cows - pre-parturition/parturition cows - heifers) for both tie- and free-stall systems. According to the ClassyFarm manual, all decubitus and walking surfaces, such as paddocks, floors, corridors and passageways, whether they are used to house young and unproductive animals or adult animals, must be kept clean, dry and hygienically adequate to avoid health problems and/or disturbance in cattle movements and behaviour. In addition, the facilities and surfaces available should provide easy and safe access for personnel to facilitate periodic cleaning and access to bedding. Manure removal (e.g. with scrapers, etc.) should be carried out several times a day to avoid cattle being tempted to decubitate on the floor or remain with their feet immersed in manure for long periods. The latter condition entails a risk to foot health and increased soiling of bedding. Dairy cows remain in decubitus between 9 and 14 hours per day, so poor hygiene conditions and especially high moisture content of bedding material may adversely affect udder and genito-urinary health (ClassyFarm, 2023). The assessment of litter management should consider both the observable level of hygiene and the routine and organization of litter maintenance. With regard to the cleanliness of floors in walking areas (audit items

33-35 for free-stall farms only), the monitored farms showed adequate (42.9%) and optimal (42.9%) levels, while only one farm did not meet the minimum requirements. Hygiene, cleanliness and management of laying areas (audit items 36-41 for free-stall farms; 33-36 for tie-stall farms). Free-stall farms showed full compliance with the optimum hygiene requirements of the various items considered (71.4 - 85.7%). On the contrary, the tie-stall farms were less virtuous, showing average hygiene levels between adequate and optimal, with several farms failing to meet the minimum requirements.

Another audit item concerns the prevention of foot disorders (audit item No. 42 for free-stall farms and No. 37 for tie-stall farms). As stated in the ClassyFarm manual, best practices should prevent foot disorders and, in addition to guaranteeing proper management and housing conditions, include the disinfecting and trimming of the hooves. It is necessary to provide attention to foot hygiene on a weekly basis by using regularly, on all animals, foot sprays or foot bathing for preventive disinfection (e.g., copper sulphate, zinc sulphate, peracetic acid, glutaraldehyde, iodinated and chlorinated disinfectants, etc.). In addition, all cows should have functional hoof trimming at least twice a year and additional therapeutic ones if needed; only properly trained personnel should be involved. To assign the optimum rating, functional hoof trimming must be performed at least every 6 months in conjunction with the routine application on all animals of sprays or foot baths for preventive foot disinfection. According to the monitoring activity carried out, 85.7% of the free-stall farms meet the optimal criteria, whereas in the tie-stall farms there is a non-negligible percentage (28.6%) that does not meet the minimum requirements, while the remaining percentage of farms meet the adequate (28.6%) and optimal (42.9%) criteria.

Other audit items concern the **hygiene of the milking area and the milking routine equipment** (audit item 43 for free-stall and 38 for tie-stall farms) and the **management of milking operations and udder hygiene** (No. 44 for free-stall and 39 for tie-stall farms). The hygiene of milking equipment and operations is of considerable importance, both for

the health and well-being of the animals and for the hygienic aspect of the milk, with obvious repercussions on public health. In this regard, it is recommended that milking equipment be kept clean through the daily removal of feces from the mechanical parts of the milking clusters, the floors and walls of the parlor, to be carried out at the end of milking the animals. From the monitoring activity carried out, 57.1% of the free-stall farms showed an optimal condition, i.e. the presence of a milking parlor that is clean in all its components, in a state of good general hygiene and without visible feces, as well as constructed with materials that are easily washable. In the case of tie-stalls where, for obvious reasons, the milking parlor cannot be observed, the assessment must focus on the equipment used for this purpose (e.g. teat cups, clusters, bucket installations, portable trolley installations, etc.); applying the same concept expressed above, a certain presence of feces can be considered tolerable only on the parts not in direct contact with the cows. Most of the tie-stall farms monitored showed acceptable levels of hygiene, however, one farm showed unsatisfactory requirements.

The last audit item is the general **biosecurity level** of the herd. Since with insufficient or absent biosecurity procedures, the animals may be at greater risk of suffering the discomfort related to new infections or to the greater spread of those present (and therefore of worsening their physical and psychic integrity) it was decided to add, to Area A (Management) of the animal welfare evaluation, a further verification element, deriving from the overall judgement obtained by the farm through the compilation of the evaluation area called Biosecurity (item 1-15) or of the specific dedicated check-list (called Ruminant Biosecurity). This audit item, included in Area A (No. 45 and No. 40, respectively for free- and tie-stall farm) is automatically completed by the ClassyFarm system, following analysis of the data obtained in the biosecurity assessment through a global numerical index (0-100%). Three are the levels assigned: non-adequate from 0 to 33%; adequate from 33.1 to 66%; optimal from 66.1 to 100%. In particular, for the assessed farms we registered

the following situation: for tie-stalls, 3 farms were in the highest ranking, 2 farms in the adequate level and 2 farms were in the lowest ranking; for free-stalls, 4 farms were in the highest ranking, 2 farms in the adequate level and only 1 farm was in the lowest ranking.

In a recent study conducted on small-scale mountain dairy farms, Holighaus et al. (2023) found that South Tyrolean farmers generally possess good skills and knowledge in managing their animals. The authors argued that the small herd size allows farmers to closely observe each animal daily, enabling them to respond promptly to any needs that may arise. Nonetheless, the importance of biosecurity measures appears to be less important on small-scale farms compared to large enterprises. In larger operations, there is a higher number of animals and more frequent movement of equipment, personnel, and animals, which increases the potential for disease spread. Furthermore, farmers often view certain biosecurity measures as impractical due to the economic and logistical challenges involved in implementing them in their daily operations (Holighaus et al. 2023; Zanon et al., 2024).

Farm structures – Area B

Housing and equipment can significantly influence animal welfare. Regardless of the farming system used, animals should have the ability to interact socially, express their own affiliative behaviours and related positive emotions, manifest exploration and play activities, and maintain a stable social hierarchy. From the ClassyFarm point of view, the operator assessing the suitability of facilities must pay particular attention to the risk they pose to animal welfare and less to the zootechnical efficiency or even the architectural appearance of the housing structures. A desirable feature is the presence of suitable supplementary facilities for handling special situations (e.g. infirmary and handling facilities). Also fundamental is the analysis of the equipment necessary to control the main

microclimatic conditions of the barn (temperature, humidity and air quality and exchange), which have the greatest impact on the cattle's living conditions (ClassyFarm, 2023). The results of the monitoring activity concerning farm structures and equipment (AREA B) are shown in Table 8 (free-stall) and Table 9 (tie-stall).

Table 8. Results of the macro-area structures for free-stall farms

Items	Mean	Std Dev	Min	Max
Detrimental facilities (46)	1.86	0.38	1 (14.3%)	2 (85.7%)
Shelter for animals outside (47)	2.86	0.38	1 (0)	3 (85.7%)
Type of husbandry (48)	2.57	0.53	1 (0)	3 (57.1%)
Laying boxes lactating cows (49)	2.71	0.49	1 (0)	3 (71.4%)
Laying boxes dry cows (50)	2.57	0.53	1 (0)	3 (57.1%)
Laying pre-partum/partum area (51)	2.43	0.79	1 (14.3%)	3 (57.1%)
Laying boxes heifers (52)	2.43	0.79	1 (14.3%)	3 (57.1%)
Use of the laying boxes in (53)	2.43	0.79	1 (14.3%)	3 (57.1%)
Characteristics of laying material - lactating cows (54)	2.43	0.79	1 (14.3%)	3 (57.1%)
Characteristics of laying material - dry cows (55)	2.43	0.79	1 (14.3%)	3 (57.1%)
Characteristics of laying material - heifers (56)	2.57	0.53	1 (0.00%)	3 (57.1%)
Surface of the walking area - lactating cows (57)	2.29	0.76	1 (14.3%)	3 (42.9%)
Surface of the walking area - dry cows (58)	2.14	0.69	1 (14.3%)	3 (28.6%)
Surface of the walking area - heifers (59)	2.43	0.53	1 (0)	3 (42.9%)
Access and number of feeding spots - lactating cows (60)	2.29	0.76	1 (14.3%)	3 (42.9%)
Access and number of feeding spots - dry cows (61)	2.29	0.76	1 (14.3%)	3 (42.9%)
Access and number of feeding spots - heifers (62)	2.43	0.53	1 (0)	3 (42.9%)
Dimension of the feeding spots (63)	2.57	0.53	1 (0)	3 (57.1%)
Size and function of the drinkers - lactating cows (64)	2.57	0.53	1 (0)	3 (57.1%)
Size and function of the drinkers - dry cows (65)	2.43	0.53	1 (0)	3 (42.9%)
Size and function of the drinkers - heifers (66)	2.57	0.53	1 (0)	3 (57.1%)
Laying area for calves <2 weeks (67)	2.00	0.58	1 (14.3%)	2 (85.7%)
Individual box space for calves till 8 weeks (68)	2.43	0.53	1 (0)	3 (42.9%)
Visible and tactile contact between calves (69)	2.00	0.00	1 (0)	2 (100%)
Group box calves <6 months (70)	2.86	0.38	1 (0)	3 (85.7%)
Infirmary box (71)	2.71	0.49	1 (0)	3 (71.4%)
Movement to the milking parlor (72)	2.00	0.00	1 (0)	2 (100%)
Waiting room and milking parlor (73)	2.86	0.38	1 (0)	3 (85.7%)
Maintenance of the milking machine (74)	2.67	0.52	1 (0)	3 (57.1%)
Temperature and Humidity (75)	2.57	0.53	1 (0)	3 (57.1%)
Noxious gases (76)	2.43	0.53	1 (0)	3 (42.9%)
Lighting (77)	2.00	0.00	1 (0)	2 (100%)

The number indicated in the brackets for each item refers to the corresponding audit item from the ClassyFarm checklist for both free-stall and tie-stall dairy farms. Min represents the worst score, Max the best score. The percentage of farms that achieved each score is provided in brackets.

Table 9. Results of the macro-area structures for tie-stall farms

Items	Mean	Std Dev	Min	Max
Detrimental Facilities (41)	1.57	0.53	1 (42.9%)	2 (57.1%)
Shelter for animals outside (42)	2.14	0.69	1 (14.3%)	3 (28.6%)
Type of husbandry (43)	2.43	0.53	1 (0)	3 (42.9%)
Laying boxes lactating cows (44)	2.14	0.69	1 (14.3%)	3 (28.6%)
Laying boxes dry cows. pre partum/partum (45)	2.00	0.82	1 (28.6%)	3 (28.6%)
Laying boxes heifers (46)	2.00	0.58	1 (14.3%)	3 (14.3%)
Characteristics of laying material - lactating cows (47)	2.00	0.58	1 (14.3%)	3 (14.3%)
Characteristics of laying material - dry cows (48)	2.00	0.58	1 (14.3%)	3 (14.3%)
Characteristics of laying material - heifers (49)	2.14	0.69	1 (14.3%)	3 (28.6%)
Surface of the walking area - lactating cows (50)	2.14	0.38	1 (0)	3 (14.3%)
Surface of the walking area - dry cows (51)	2.29	0.49	1 (0)	3 (28.6%)
Surface of the walking area - heifers (52)	2.29	0.49	1 (0)	3 (28.6%)
Cow trainers (53)	2.00	0.00	1 (0)	2 (100%)
Access and number of feeding spots-lactating cows (54)	2.00	0.58	1 (14.3%)	3 (14.3%)
Access and number of feeding spots - dry cows (55)	2.29	0.49	1 (0)	3 (16.7%)
Access and number of feeding spots - heifers (56)	2.29	0.49	1 (0)	3 (16.7%)
Size and function of the drinkers - lactating cows (57)	2.43	0.53	1 (0)	3 (42.9%)
Size and function of the drinkers - dry cows (58)	2.71	0.49	1 (0)	3 (71.4%)
Size and function of the drinkers - heifers (59)	2.57	0.53	1 (0)	3 (57.1%)
Laying area for calves <2 weeks (60)	1.71	0.49	1 (28.6%)	2 (71.4%)
Individual box space for calves till 8 weeks (61)	2.00	0.58	1 (14.3%)	3 (14.3%)
Visible and tactile contact between calves (62)	1.86	0.38	1 (14.3%)	2 (85.7%)
Group box calves <6 months (63)	2.14	0.38	1 (0)	3 (14.3%)
Infirmary box (64)	2.29	0.49	1 (0)	3 (28.6%)
Maintenance of the milking machine (65)	2.00	0.58	1 (14.3%)	3 (14.3%)
Temperature and Humidity (66)	2.00	0.58	1 (14.3%)	3 (14.3%)
Noxious gases (67)	2.14	0.69	1 (14.3%)	3 (28.6%)
Lighting (68)	1.83	0.41	1 (16.7%)	3 (83.3%)

The number indicated in the brackets for each item refers to the corresponding audit item from the ClassyFarm checklist for both free-stall and tie-stall dairy farms. Min represents the worst score, Max the best score. The percentage of farms that achieved each score is provided in brackets.

The first audit item for the Area B (No. 46, free-stall; No. 41, tie-stall) consists of verifying the absence of **detrimental facilities** for animals. According to the ClassyFarm Handbook (2023), all materials, bedding and equipment used in the animal housing, as well as the surfaces themselves, with which the animals may come into contact, and the attachment devices, if used, must not be harmful to the animals and must not have sharp edges or protrusions capable of causing trauma or injury. Furthermore, the equipment must be designed, constructed and maintained in such a way that it can be thoroughly cleaned and disinfected. The results of this monitoring showed that 85.7% of the free-stall farms met the requirements for adequacy of facilities. On the contrary, tie-stall farms showed more critical situations with 42.6% of farms not fulfilling the adequacy requirements. The remaining 57.1% of farms satisfied the acceptable requirements.

Another audit item concerns the presence or absence of **shelters in outdoor areas** for animals kept outside the buildings. According to the ClassyFarm manual, shelters are considered to be both natural (trees, ravines, caves, etc.) and artificial (canopies, shelters, etc.) provided that they offer adequate shelter, depending on the season and location. The shelters must be easily accessible to all animals, and suitable to protect them from adverse climatic conditions, predators, and risks to their health; minimum dimensions of the available area should be adequate to allow for comfortable lying down of all the animals and their subpopulations (Ventura et al., 2021). If there are no animals kept on the farm outside the buildings, the rating is intermediate. In the present study, all the tie-stall farms received an intermediate rating the exception of one farm, which was found to be inadequate due to the absence of shelter for even one group of animals. The free-stall farms (87.1%), on the other hand, scored very well for the presence of easily accessible, sufficient and suitable artificial shelters to protect all animals from environmental hazards.

Concerning the **type of housing** of cattle over 6 months of age: "*loose housing systems are to be preferred and the use of tie-stalls should be avoided on newly built and renovated farms*." (EC draft 8/09 article 9, point 6). As known, movement has positive effects on animal welfare and health and, unless there are specific health reasons, animals should not be tethered for all 24 hours of the day. With regard to free-stall housing, the ClassyFarm manual requires that the animals must be able to move freely and manifest their species-specific behaviour. Therefore, if in the herd under evaluation, even one group of animals over 6 months of age, including non-productive animals, is kept permanently tethered, an insufficient rating must be given. If all animals are kept free-range throughout the whole year, the rating is acceptable. The possibility for adult cows to use an exercise area (of at least 4-5 m^2/head) or a grazing area, limited to certain periods of the year and under favourable environmental conditions, is considered optimal. The results obtained in the present study showed that 57.1% of the free-stall farms received an excellent evaluation, while the remaining 42.9% received an acceptable evaluation. Regarding the tie-stall farms most of them received an adequate assessment (57.1%), while the remaining 42.9%, was an optimal assessment. It is important to point out that one of the 7 tie-stall farms monitored is currently in conversion to free-stall housing with the construction of a parlor equipped with a milking robot. As for the investigated free stalls, only one farm had a milking robot while the other had small parlors mainly tandem parlors and herringbone parlors. All the investigated farms made two milking per day, representing the standard situation in small cow herds, not only in Italy.

Another audit item concerns the **space availability for the laying area** inside the barn (No. 49-52 for free-stalls; No.44-46 for tie-stall), which is evaluated for the various categories (lactating cows - dry cows - heifers - pre-parturition/parturition cows), with

specific dimensions and characteristics for each of them and which vary according to the type of housing. The right rest period is fundamental for the daily well-being of the cow, according to the ethology of the species, the cow should rest for 8-12 hours a day, with individual rest periods lasting just over an hour (Grant and Albright, 2001; Jensen, 2009). The size of the laying area should be such as to ensure maximum comfort and hygiene, as well as complete utilization by all animals, without disturbing each other, thus reducing aggression and agonism of dominant animals towards subordinates. Inadequate laying areas can lead to reduced resting times, increase the risk of developing foot disorders, and increase the animal's state of filthiness with the consequent risk of mammary infections. When calculating the free space available for decubitus, the bedding covered and used for this purpose must be considered, excluding from the calculation all obstacles that make this space unusable, such as internal or external exercise areas, passageways and the feeding aisle; in particular, for the latter, it is necessary to exclude from the calculation of the surface area 1 meter in depth. In the case of tie-stall housing, each cow must be provided with a resting area, a feeding trough and a drinking trough (ClassyFarm, 2023). Regarding the results of the monitoring study, the majority of the tie-stall farms (42.9 - 71.4 %) achieved an adequate assessment for the different groups (lactating cows, dry cows, pre partum/partum cows, heifers) and to a lesser extent (14.29 - 28.5 %) an optimal assessment. In two farms the area available for decubitus was found to be inadequate to ensure animal welfare for the different categories considered. In contrast, the free-stall farms were more virtuous with optimal ratings in 57.1 and 71.4 % of cases.

In connection with the previous audit points, audit item No. 53, only for loose housing, considers the adequacy of the laying area for lactating cows by observing the **percentage of occupation of the laying areas** by the animals. Conditions are considered unacceptable when less than 50% of the animals use the cubicles or permanent bedding, acceptable if they are occupied by 50-70% of the animals present, optimal if utilization is complete and

uniform. The observation should be carried out at least 2 hours after feeding, milking or other extraordinary action of potential disturbance (ClassyFarm, 2023). Most of the monitored farms received the optimal evaluation (57.1%), while only 1 farm (14.3%) did not fulfil the adequacy requirements.

Characteristics of bedding material (lactating cows - dry cows – heifers, audit items No. 54-56 for free-stalls, No.47-49 for tie-stalls). As stated in the ClassyFarm manual, the laying area (permanent bedding, bunks or post footprint, depending on the situation) must be constantly covered with plenty of bedding material to prevent injuries or bedsores and to ensure a good state of cleanliness for the animal. This material, usually straw, sawdust, rice husks and other substances of vegetable origin, must be renewed frequently to ensure a dry and clean surface. In addition to hygienic conditions, it is necessary to consider the type of material used in relation to the physical or sanitary damage it may cause. Laying surfaces must provide thermal comfort for the animals, they must be soft and dry, and they must allow the cows to lie down and stand up comfortably without slipping. They should also help to keep the cow clean and healthy (EFSA, 2009). A condition where the presence of bedding material is plentiful, non-abrasive, well maintained, absorbent or in the case of pasture the presence of turf and additional bedding material is considered optimal; while the presence of mats/carpets or sufficient bedding material is considered adequate. Surfaces that tend to be hard (some types of matting or mats) or unhygienic (dry manure) could be considered acceptable if they are kept efficient, clean, and dry through frequent maintenance. On the other hand, the use of a hard, dirty and wet surface, such as grating or concrete, should be considered insufficient. In the present work, most of the tie-stall farms recorded adequate ratings, only in one farm were critical points concerning the condition of the bedding in some places completely absent. The free-stall farms, on the other hand, obtained optimum ratings in 57.1% of cases for both the presence of optimum litter but

also the presence of a grass sward in the case of grazing. Critical points were also found for one farm due to the absence of bedding material for lactating and dry cows.

Concerning the **type of floor in walking areas** (audit items No. 57-59 for free-stalls, No.50-52 for tie-stalls), the EC recommendations declare that "*Floors should be made of suitable, non-harmful materials, should drain and be easy to clean and disinfect. They should create a surface that is hard, smooth and firm, but not slippery. Floors should be suitable for the weight of housed cattle and the size of their hooves, to minimize the likelihood of getting stuck, and not cause discomfort, suffering and injury while standing or walking*." (EC draft 8/09 article 9, point 3). An audit item is the integrity of the flooring, whether solid or cracked, such that it does not cause harm to the animals. An adequate judgement is given when floors meet the integrity characteristics (e.g. for the presence of suitable grooving or rubber lining) on at least the majority of the available surface area (i.e. at least more than 50%) or for the presence of a small amount of litter; while the optimal rating is assigned if the animals are housed freely and the entire surface on which they walk is suitable and rough, whether it is concrete solid grooved or suitable slatted, or covered with permanent bedding with suitable organic material, because it is abundant, non-abrasive, well maintained and absorbent. From the present activity, it emerges that most of the tie-stall farms obtained an adequate assessment and no criticalities were detected; similarly, most of the free-stall farms obtained an adequate assessment with criticalities detected for only one farm.

For tie-stall farms, the presence or absence of **cow trainers** is considered as an element of verification (audit item No. 53). The presence of cow trainers in one or more groups of animals, to prevent soiling of the stalls and bedding is always to be regarded as negative as it limits the manifestation of the cattle's behavioural patterns. The presence of these instruments was not detected on the farms monitored.

Other audit items concern the **dimension and accessibility** of **feeding places** (lactating cows - dry cows – heifers; No. 60-62 for free-stalls, No. 54-56 for tie-stalls) and only in the case of free stalls the size and characteristics of the individual places in the rack (lactating cows) are also taken into consideration (audit item No. 63). The equipment and areas intended for cattle feeding must be suitably sized and constructed with suitable materials to guarantee easy access for the animals and the possibility of ingesting the food necessary for their needs. It is required to check how many animals can access the trough simultaneously, considering that a space of at least 68 linear cm (50 linear cm for heifers) is required for each animal. In the case of a tie-stall farm, it is necessary to check if all animals can access the feed without any negative consequences (ClassyFarm, 2023). The size of the feed bunk must be related to the number of animals and the type of feed. If the ration is not provided *ad libitum*, the feeding area must be accessible to 100 % of the animals simultaneously. If, on the other hand, the ration is provided *ad libitum*, it is acceptable for there to be alternating access of the animals to the trough, as the food is usually available 24 hours a day, remains homogeneous and retains the same nutritional characteristics. For this reason, feeding places are considered sufficient when they reach at least 70% of animals (ClassyFarm, 2023). The monitoring results indicate that all free-stall farms utilized unifeed, with two of these farms employing feeding robots. Among these farms, 42.9% received an optimal assessment, while the remainder were judged to be adequate. However, there was one farm that showed critical issues in the categories of lactating and dry cows. The size and characteristics of the single rack for lactating cows (audit item No. 63) were optimal in 57.1% of the free-stall farms. All tie-stall farms utilized unified, with one of these farms employing an automatic feeder, obtaining a predominantly adequate evaluation with a criticality detected in one farm for the category of lactating cows.

Other audit items for the different categories (lactating cows - dry cows - heifers) concern the **size and function of the drinking troughs**. According to EFSA recommendations (2012), the number and location of drinking troughs must be such that the animal does not need to compete or wait too long to drink, and continuous access to water must be ensured both inside and outside the housing facility. Drinking troughs must operate smoothly, the filling flow should be 20 l/min for level troughs and 10 l/min for cup troughs, periodically checked and cleaned to ensure a constant water flow. According to the ClassyFarm manual (2023), for free-stall farms there must be at least 1 trough for every 10 adult animals (15 heifers) or if tank-based 6-7 cm/head (5 cm/head for heifers). The present monitoring work showed that on most of the free-stall farms, the number and size of drinking troughs were higher than the requirements, with well-diversified locations. Regarding the tie-stall farms, the ClassyFarm protocol reports that all tethered animals must have the possibility to access water and to satisfy their water needs, usually a cup trough for every two animals. The optimal rating (only in the case of clear positive evidence) is given when all animals have easy access to water, taking advantage of the presence of ample drinking troughs, e.g. during periods when they are kept in loose housing (e.g. summer grazing or other area). In the present study, most of the tie-stall farms achieved an optimal rating for the presence of large, easily accessible troughs.

Other verification elements concern the rearing conditions of calves under 6 months of age (n. 67-70 for free stalls; n. 60-63 for tie stalls). The provisions of Legislative Decree No. 126/2011, Art. 3 report that no calf over eight weeks old shall be confined in an individual pen unless the veterinarian has certified that its state of health or behaviour requires isolation from the group for diagnostic and therapeutic treatment. The width of the individual pen must be at least equal to the height at the withers of the calf, measured when the animal is upright (approx. 0.80 - 0.85 m), and the length must be at least equal to the length of the calf, measured from the tip of the nose to the caudal end of the ischial

tuberosity and multiplied by 1.1 (approx. 1.30 - 1.35 m.). Any individual calf pen, except those intended to isolate sick animals, must not have solid walls but perforated walls for visual and tactile contact between calves. Additionally, for calves kept in groups, the free space available for each calf must be: for animals <150 kg live body weight (BW) >1.5 m2/animal; 150–220 kg BW >1.7 m2/animal; >220 kg BW >1.8 m2/animal. All calves should be free to move and never tethered, including when feeding. The provisions do not apply to farms with less than six calves and to calves kept with their mothers for suckling purposes.

The Annex 1 of Legislative Decree No. 126/2011 contains provisions on the characteristics of buildings, stalls and bedding materials with particular attention to *'The area where calves lie down must be comfortable, clean, adequately drained and not harmful to the calves. Adequate bedding must be provided for all calves less than two weeks old'*.

An audit item concerns the assessment of the **laying area for calves less than 2 weeks old** (n. 67 free-stall; n. 60 tie-stall). As stated in the ClassyFarm manual (2023), suitable bedding for new-born calves must be of organic material, usually of plant origin (e.g. straw, rice husks, sawdust, leaves, etc.), abundant, non-abrasive, well preserved, absorbent. The bedding must cover the entire surface on which the calf lies, to guarantee suitable comfort during decubitus and lying down movements and good protection against the winter cold. The finding of a single subject less than two weeks old in an inadequate condition is sufficient to assign an inadequate rating. In the present work, almost all of the tie-stall farms (71.4%) and free-stall farms (85.7%) received an adequate rating, while 2 tie-stall farms and one free-stall farm received an inadequate rating due to the absence of bedding in one or more laying area.

For **calves up to 8 weeks of age**, the **space available in the individual pen** is checked. Generally, during the first 6 to 8 weeks of life, calves are housed in individual boxes to

ensure better monitoring by attendants, to prevent mutual suckling and to control or limit the possibility of pathogen circulation, as this is an extremely delicate phase of calf rearing. After the first 8 weeks of life, calves must be reared in groups and be free to move around the box (Art. 3 Legislative Decree 126/2011). The following dimensions are considered suitable for this element of verification: approximately 130 x 80 cm for a 6-8-week-old calf. These area limits do not apply to herds with fewer than 6 calves (i.e. 5 animals between 0-6 months old) present at the time of the inspection and to calves kept with their mothers for suckling purposes. Furthermore, it is not possible to keep two calves in a single individual pen (single cage); it is only possible to house two calves in the same pen if the width of this space is at least equal to the height at withers of the largest calf multiplied by two and two separate troughs and adequate drinking troughs are present (MINSAN Note No. 0014777 of 19/06/2017). The presence of a single animal in the above-mentioned conditions is sufficient to assign an insufficient rating. However, some cages with measurements smaller than those indicated may still be suitable, if they house smaller animals (a width greater than the height at the withers of the calf and a length greater than 10% of the distance between the tip of the nose and the caudal end of the animal's ischial tuberosity). The results of this monitoring show that free-stall farms have adequate (57.1%) or optimal (42.9%) spaces; while the tie-stall farms have predominantly adequate (71.4%), optimal (14.3%) and, in one case, inadequate spaces below the legal limits.

Another audit item concerns the possibility of **visual and tactile contact between calves**. The walls dividing individual calf pens must not be compact but have perforated partitions; therefore, the contact that could occur through the trough front does not meet the regulatory requirement. All the farms monitored fulfilled this requirement except for one tie-stall farm, which was the same farm that showed criticality due to the absence of bedding in calves less than 2 weeks old.

Giving calves, even very young ones, the opportunity to interact with each other is very important for them to develop better social behaviour, less weaning stress, ease of learning and higher growth rates. This is why it is compulsory that calves over 8 weeks old are kept in groups, except in special cases (for therapeutic purposes or for herds in which there are fewer than 6 calves at the time of inspection). The regulations stipulate that for **group-housed calves (up to 6 months of age),** the free space available for each calf must be at least (the surface area is the total area of the box, excluding any obstacles that make the space unusable for the animals): <150 kg BW = 1.5 m2/head; 150 to 220 kg BW = 1.7 m2/head; > 220 kg BW = 1.8 m2/head. Concerning the requirements of the monitored farms, 85.7 % of the tie-stall farms fulfilled the suitability requirements, while 85.7 % of the free-stall farms achieved an optimum assessment because, in addition to the suitability criteria, the available space per calf was found to be above the legal limits (at least more than 10 %).

Another audit item concerns the presence in the barn of an **infirmary box**. According to the provisions of Legislative Decree 146/2001 "[...] *Where necessary, sick or injured animals are isolated in special rooms equipped, if necessary, with dry or comfortable bedding."*; furthermore, "*A clearly identified, but not necessarily fixed, infirmary room or enclosure must be provided, in which dry bedding and fresh water in sufficient quantity for the sick animals housed therein must be permanently present*. (MINSAN 2006, Explanatory Note Prot. No. 27232 of 25/07/2006, p. 7). For the ClassyFarm checklist the item is considered optimal when there is the presence of an infirmary box with a total capacity of no less than 3% of the average number of animals present daily in the herd and with plenty of space available (e.g. more than 8-10 m2/head), easy to inspect by the operator, with well-managed permanent bedding, drinking troughs and easy access to food. It's important to note that for small herds (e.g., fewer than 50 animals) having a dedicated infirmary is not mandatory. In such cases, only an "identifiable" area is required. However,

the farmer must be able to prove that they can establish an infirmary at any time, if necessary. In the case of tie-stall system, it is acceptable to use specific stalls, if necessary, separate from the other animals for the housing and treatment of injured or sick cows and to avoid unnecessary disturbance and competition. Also, in these contexts, the presence of a permanent litter box in which animals can be free to ensure a more rapid recovery is considered optimal. In all the farms monitored, the presence of an identified and adequately prepared room for housing sick or injured animals with dry bedding or a comfortable mat was found to be adequate (71.4% of the tie-stall farms) and in most of the free-stall farms (71.4%) this parameter was optimal.

Other verification elements concern the milking phase and in particular, the following items are checked: **handling during milking** (audit item No. 72, only for free-stall farms), the **waiting room and milking parlor** (No. 73, only for free-stall farms) and **maintenance of the milking machine** (No. 74 for free-stall and No. 65 for tie-stall farms). Daily movements for access to the milking parlor are of particular interest for the frequency with which they occur. The connections between the housing areas and the milking area, as well as the exit from the milking parlor, should be easy to walk along. They should be linear, free of obstacles, holes, steps, and sharp turns, and the floors must not be slippery. All free-stall farms monitored fully met these requirements. The waiting room must be large and easily accessible. The maximum stay in the waiting area, before milking the last cows, must not exceed 90 minutes or, better still, 60 minutes. The assessment is made considering size, ease of access to the milking parlor and waiting time. If none or only one of the three parameters is satisfactory, an insufficient rating is given, if all parameters are satisfactory with a waiting time of less than 60 minutes, the optimal rating is given (ClassyFarm, 2023). The majority of the fre-stall farms monitored (85.7%) received an optimum rating and no criticalities were found. It should be noted that the presence of the milking robot predisposes to an optimal evaluation, as it allows the animal to be milked

according to its needs, with no or minimal waiting time, despite the continuous occupation of the milking station. In addition, with the use of this system, performing more than 2 milking per day is definitely an improving factor for milk production and animal welfare (ClassyFarm, 2023). As for the investigated free stalls, only one farm had a milking robot while the other had small parlors mainly tandem parlors and herringbone parlors. All the investigated farms made two milking per day, representing the standard situation in small cow herds, not only in Italy. Maintenance of the milking machine is an audit item common to both housing systems. The barn operator needs to know and control the basic parameters (vacuum, claw air inlets, liner change frequency, etc.) related to milking system operation through frequent inspections, as an improperly functioning system increases the risk of injury or incomplete milking, compromising udder health (risk of mastitis). The same considerations are valid for herds with fixed housing, where milking is normally performed at the post, through the use of bucket installations, portable trolley installations, or milk pipeline installations (ClassyFarm, 2023). In the monitored farms, 57.1 % of the free-stall farms achieved an optimal assessment by demonstrating planned maintenance of the milking machine, while the remaining part of the farms achieved an adequate assessment by carrying out rough periodic checks and maintenance interventions only in case of failures. The majority of tie-stall farms (71.3%) obtained an adequate evaluation, while one farm obtained an insufficient evaluation due to lack of knowledge of basic parameters by milkers and absence of planned maintenance.

Lastly, the **environmental conditions** (temperature and humidity, presence of noxious gases and lighting) inside the buildings must be checked. According to Legislative Decree 146/2001, *"Air circulation, dust levels, temperature, relative air humidity and gas concentrations must be kept within limits that are not harmful to the animals*." (Annex 1, point 10). Increases in ambient temperature and relative humidity are two factors that influence the health and welfare of farm animals (and consequently also production). The

bioclimatic THI (temperature humidity index) is a value that associates temperature with ambient relative humidity and is used to analyse the risk of heat load for livestock. Housing and ventilation should be able to provide sufficient air movement for preventing heat stress in summer conditions; in particular, provide adequate temperature and humidity (temperature and humidity index, THI 75) by a cooling plant with a THI automatic control system, especially for lactating cows, dry cows and cows at calving; otherwise, provide summer pasture (at least for 60 days/year) equipped with shelters (Ventura et al., 2021; ClassyFarm, 2023). For the temperature and humidity audit item (No. 75 for free-stall farms, No.66 for tie-stall farms) the type of barn and the cooling equipment are assessed. A barn is considered "open barn" when there are no walls on any of the 4 sides or when there is only one closed side, without this limiting good ventilation of the barn. Microclimatic conditions are considered adequate when they include natural ventilation, such as in open barns, or suitable ventilation systems without automatic controls. For calves, it is essential to provide protection from heat and cold based on weather conditions, utilizing measures like insulated cages, shading, or windproof tarpaulins. To obtain the optimal judgment, in addition to these basic criteria, optimal microclimate conditions for animals should be present in key housing areas for lactating cows, dry cows and cows at calving. These areas should be equipped with microclimate conditioning systems that include automatic control features. For calves, it is important to have appropriate shelter types and implement effective procedures to consistently protect the animals from fluctuations in temperature, humidity, and air quality (ClassyFarm, 2023). Most of the free-stall farms (57.1%) obtained an optimal assessment, while tie-stall farms (71.3%) obtained an adequate assessment, with only one farm being critical due to inadequate microclimatic conditions for the animals.

Another audit item related to the environmental condition inside the barn is the detection of **noxious gases** (No.76 for free-stall farms and No.67 for tie-stall farms). The

gases considered most harmful to the health and welfare of farm animals are ammonia (NH3) and carbon dioxide (CO2). Ammonia results mainly from the catabolism of organic substances, particularly urea contained in slurry. Improper litter and manure management can, therefore, lead to an increase in the level of gas emissions with a worsening of air quality. Manure must be managed properly, i.e. removed frequently and stored in such a way that the gases produced by their fermentation cannot come into contact with animals or remain in the air circulating in farm buildings. The presence of carbon dioxide is, on the other hand, due to the respiration of the animals present. Therefore, a low carbon dioxide content is to be considered normal. In the event of a ventilation deficit (natural or forced) within the shed, the concentration of these two compounds in the air can increase dangerously. Gas levels should be measured on the farm through a portable gas detector to be placed in the middle of the barn at the height of the animals, particularly if it is necessary to confirm the suspicion of an inadequate condition (ClassyFarm, 2023). Most of the monitored farms obtained an adequate assessment, while critical points were found for the same farm with inadequate conditions for temperature and humidity. In particular, this farm with a small number of animals (30 cattle in total) is in the process of transitioning to free-stall housing.

Concerning **lighting**, Legislative Decree 146/2001 states that "*Animals kept in buildings must not be kept constantly in the dark or exposed to artificial lighting without an adequate rest period. If the available natural light is insufficient to meet the behavioural and physiological needs of the animals, adequate artificial lighting must be provided.*" (Annex 1, point 11). Cattle require natural lighting or light programmes that respect the circadian rhythm of the day, to orientate themselves in their living ambient, to have normal behaviour and social contacts, and to satisfy their normal physiological needs (e.g. correct alternation of moments of activity and moments of rest, correct resting times, etc.). In general, for dairy cattle farming, the light-dark cycles throughout the day are

correct, as they are linked to natural lighting. If the conditions of the herd do not guarantee good natural light intake, the presence of a correct artificial lighting system is desirable, with a light schedule that follows a circadian rhythm and includes a light period of no less than 8 hours and a dark period, preferably uninterrupted, also lasting 8 hours (ClassyFarm, 2023). The light intensity must be such that the animals can see each other clearly and explore the environment, thus being able to carry out all the normal activities foreseen by their ethogram (ClassyFarm, 2023). At the time of the farm visit, an acceptable rating can be assigned where adequate natural or artificial lighting (at least 40 lux) is present for at least 8 hours per day. On the other hand, an insufficient rating is assigned where there is no or inadequate natural or artificial lighting. All the farms monitored received an adequate assessment except for one criticality detected in one tie-stall farm.

Animal-based measures (ABMs) – Area C

The ClassyFarm protocol not only evaluates environmental and management practices but also permits the direct observation of animals. The regulations currently in force on the protection of animals on farms (D. L.vo 146/2001; D. L.vo 126/2011) do not provide for direct observation of the animal. However, in recent years, the study of animal welfare has focused mainly on the assessment of the animal and less on the environmental conditions in which it lives. This is because between the living conditions and the animal's welfare lies the animal's ability to adapt to the environment. Therefore, it is important to assess risk factors while also observing the adverse effects they may have on the animals. The analysis of adverse effects is possible through the evaluation of certain welfare indicators (animal-based measures - ABMs) that can be measured directly on the animal or indirectly through the collection of data available on the farm. The animal that is not in a state of well-being manifests, in fact, precise physical signs that can be picked up, interpreted, and evaluated

to understand its state of physical and psychic discomfort. Warnings about unwell conditions are often associated with pathological issues (such as lameness, mastitis, and skin alopecia), abnormal behavioural expressions (like fear and aggression), or changes in physiological conditions (including body condition score - BCS).

The results of the monitoring activity concerning ABMs (AREA C) are shown in Table 10 (free-stall farms) and Table 11 (tie-stall farms).

Table 10. Results of the macro-area ABMs for free-stall farms

Items	Mean	Std Dev	Min	Max
Human avoidance test - lactating cows (78)	2.86	0.38	1 (0)	3 (85.7%)
Human avoidance test - dry cows (79)	2.71	0.49	1 (0)	3 (71.4%)
Human avoidance test - heifers (80)	2.57	0.79	1 (14.3)	3 (71.4%)
BCS lactating cows (81)	2.71	0.49	1 (0)	3 (71.4%)
BCS dry cows (82)	2.86	0.38	1 (0)	3 (85.7%)
BCS heifers (83)	2.71	0.49	1 (0)	3 (71.4%)
Cleanliness lactating cows (84)	2.57	0.79	1 (14.3%)	3 (71.4%)
Cleanliness dry cows (85)	2.71	0.76	1 (14.3%)	3 (85.7%)
Cleanliness heifers (86)	2.43	0.79	1 (14.3%)	3 (57.1%)
Skin lesions lactating cows (87)	2.57	0.53	1 (0)	3 (57.1%)
Skin lesions dry cows (88)	2.71	0.49	1 (0)	3 (71.4%)
Skin lesions heifers (89)	2.71	0.49	1 (0)	3 (71.4%)
Lameness adult cows (90)	2.43	0.53	1 (0)	3 (42.9%)
Udder health (91)	2.29	0.76	1 (14.3%)	3 (42.9%)
Number of Mastitis treatments/year (92)	2.43	0.53	1 (0)	3 (42.9%)
Mortality lactating and dry cows (93)	2.71	0.49	1 (0)	3 (71.4%)
Mortality heifers (94)	2.57	0.79	1 (14.3%)	3 (71.4%)
Mortality calves (95)	2.57	0.79	1 (14.3%)	3 (71.4%)
Mutilations/Castrations (96)	2.43	0.79	1 (14.3%)	3 (57.1%)

The number indicated in the brackets for each item refers to the corresponding audit item from the ClassyFarm checklist for both free-stall and tie-stall dairy farms. Min represents the worst score, Max the best score. The percentage of farms that achieved each score is provided in brackets.

Table 11. Results of the macro-area ABMs for tie-stall farms

Items	Mean	Std Dev	Min	Max
Human avoidance test - lactating cows (69)	3.00	0.00	1 (0)	3 (100.0%)
Human avoidance test - dry cows (70%)	2.86	0.38	1 (0)	3 (85.7%)
Human avoidance test - heifers (71)	2.67	0.52	1 (0)	3 (66.7%)
BCS lactating cows (72)	2.67	0.52	1 (0)	3 (66.7%)
BCS dry cows (73)	2.57	0.53	1 (0)	3 (57.1%)
BCS heifers (74)	2.57	0.53	1 (0)	3 (57.1%)
Cleanliness lactating cows (75)	2.43	0.79	1 (14.3%)	3 (57.1%)
Cleanliness dry cows (76)	2.43	0.79	1 (14.3%)	3 (57.1%)
Cleanliness heifers (77)	2.43	0.53	1 (0)	3 (42.9%)
Skin lesions lactating cows (78)	2.57	0.53	1 (0)	3 (57.1%)
Skin lesions dry cows (79)	2.71	0.49	1 (0)	3 (71.4%)
Skin lesions heifers (80)	2.71	0.49	1 (0)	3 (71.4%)
Lameness adult cows (81)	2.71	0.76	1 (14.3%)	3 (85.7%)
Claw conformation (82)	2.57	0.53	1 (0)	3 (57.1%)
Udder health (83)	2.00	0.58	1 (14.3%)	3 (14.3%)
Number of Mastitis treatments/year (84)	2.14	0.69	1 (14.3%)	3 (28.6%)
Getting up behaviour + grooming lactating cows (85)	2.14	0.38	1 (0)	3 (14.3%)
Getting up behaviour + grooming dry cows (86)	2.14	0.38	1 (0)	3 (14.3%)
Mortality lactating and dry cows (87)	2.57	0.53	1 (0)	3 (57.1%)
Mortality heifers (88)	2.57	0.53	1 (0)	3 (57.1%)
Mortality calves (89)	2.00	0.82	1 (28.6%)	3 (28.6%)
Mutilations/Castrations (90)	2.57	0.79	1 (14.3%)	3 (71.4%)

The number indicated in the brackets for each item refers to the corresponding audit item from the ClassyFarm checklist for both free-stall and tie-stall dairy farms. Min represents the worst score, Max the best score. The percentage of farms that achieved each score is provided in brackets.

The first audit item consists of carrying out the **avoidance test** (No. 78-80 for free-stalls and 69-71 for tie-stalls), which aims to detect the '*quality*' of the human-animal relationship, considering that this relationship is an essential component of farm animal welfare (Welfare Quality® 2009b, chap. 15.2). Cattle have been domesticated for around 10,000 years and do not possess an instinct to flee from humans. On the contrary, when they are in comfortable conditions, they often show curiosity and may approach people, even to the point of making contact. To enhance animal welfare and production, young cattle should have sufficient exposure to human interaction, and all animals must be handled calmly and appropriately, according to EFSA recommendations (2012 - Recommendation 101). The results of the present study indicate that both the tie- and free-stall farms received an optimal or acceptable evaluation. This suggests that most of the animals are comfortable being approached and touched, or at least show curiosity towards humans and approach them. This behaviour demonstrates that animals, as social beings, can express and enjoy their well-being.

Another important audit item is the evaluation of the **state of nutrition** (lactating cows - dry cows – heifers; No. 81-83 for free-stalls and 72-74 for tie-stalls), which is important to verify that the nutritional needs of the animals are met. The animals must be healthy, correctly fed and, consequently, have a suitable body condition. Poor body condition or excessive variations in fat cover could be a consequence of important errors in ration formulation and administration, as well as in group management (overcrowding, promiscuity between primiparous and pluriparous cows, or between cows at the beginning and end of lactation), errors in peri-parturition management. The results of the present study indicate that most of the tie- and free-stall farms achieved an optimal overall score, with less than 5% of animals exceeding the body condition score (BCS) limits, or an acceptable score, with between 5% and 10% of animals exceeding the limits.

The **cleanliness of the animals** is another audit item (No. 84-86 for free-stalls, No. 75-77 for tie-stalls), in particular, the hygienic condition of the coat, which is an indirect but reliable indicator of the management procedures on the farm and the attention paid by the farmer to the hygienic state of facilities and equipment. In addition, this audit item provides a measure of the comfort of resting areas and, when combined with the assessment of skin lesions, may indicate the problems arising with:

- the design characteristics of the barn and cubicles (e.g. The cubicle is either too short, forcing the animal out with its hind end, or too long, causing the animal to defecate in the resting area);
- the lack of bedding material or the use of unsuitable materials;
- the degree of overcrowding and the lack of cubicles for all animals;
- the lack of care in the routine management of the housing areas.

For the farms monitored, the cleanliness of the animals was found to be optimal (subjects with a soiled coat less than 10%) or acceptable (less than 20%). In only two companies, either free- or tie-stall, dirty subjects were more than 20% of the animals observed.

A further audit item for verifying ABMs is the presence or absence of **skin lesions** (lactating cows - dry cows – heifers; No. 87-89 for free-stalls, No. 78-80 for tie-stalls), which makes it possible to investigate whether the barn structures and/or the laying area contain risk factors (acute or chronic) for the cows' safety. The assessment of injuries is carried out on the basis of the indications provided by Welfare Quality® research (6.1.3.1 Absence of injuries - Integument alterations - Welfare Quality®, 2009a; modified). Skin lesions are alterations represented by alopecic areas (including alopecias due to fungal and parasitic causes and hyperkeratosis), swellings and wounds (mammary and teat sores, lesions on bones and joints, ear lesions, etc.) of at least 2 cm in size. The results obtained from the present study show that in most of the farms, both tie- and free-stalls, less than

15% of the animals had mild skin lesions; no critical issues were detected for this verification element.

The inspection of cattle feet is another important element of verification in defining the animal's welfare status. The audit item concerns the occurrence of **lameness** and foot disease (No. 90 for free-stall, No.81 for tie-stall). "*The feet of cattle should be inspected regularly and trimmed if necessary. Where foot problems are identified, an assessment of the causative factors should made and corrective action taken*." (EC draft 8/09 article 6, point 3). Locomotor disorders represent the main problem of poor welfare in dairy cows (EFSA, 2009f, p.40) and are considered the ultimate expression of poor management or structural conditions; they can range from: tendon and muscle injuries, foot and hoof injuries and diseases. Lameness, together with respiratory diseases, is one of the most important pathologies in intensively reared cattle. According to numerous studies, lameness is also the main factor in early culling of dairy cows (Bergsten, 2013). Whatever the cause of lameness, it is characterized by pain that negatively affects all the main activities of the animal: rest, movement, food and water intake, expression of normal behaviour and oestrus in some cases. In general, the main causes of foot disease include: insufficient fiber feeding, difficult access to the feed ration, poor hygiene of the decubitus areas and surfaces where the feet must remain. In the case of tie-stall housing, in addition to the risk of prolonged standing of the feet (especially the hind feet) in the manure, there is a lack of exercise and poor hoof wear resulting in foot lesions and non-compliance of the hooves. The assessment of foot disease is performed by analysing the severity and prevalence of the problem, the indicators to detect them are: irregular foot drop, not putting weight on the affected foot, irregular gait rhythm, head strike and arching of the spine.

The results indicate that in the majority of free-stall farms, the percentage of lame animals was less than 4%. However, one farm reported critical issues, with over 8% of lame animals. Additionally, the condition of the hooves—an important factor for tied

stabling—was found to be satisfactory in most farms, with less than 10% of animals having long or deformed hooves. In fact, 57.1% of the free-stall farms received an adequate evaluation, with the percentage of lame animals falling between 4% and 8%.

The most widely used method for assessing **udder health** (audit item No. 91 for free-stall farms, No. 83 for tie-stall farms) in a group of cows is the Somatic Cell Count (SCC) in bulk milk which is an important measure of milk quality, reflecting the health status of the mammary gland and the risk of nonphysiologically changes to milk composition. As required under EU Regulation 853/2004, the SCC in raw milk must not exceed 400,000 cells/mL (based on a rolling geometric average over a 3-mo period, with at least one sample per month). A mammary quarter is deemed to be healthy when the SCC level is usually lower than 100,000 cells/mL of milk. An increase in SCC indicates the presence of infection. Mastitis is a multi-factorial disease, so the increase in cell count is related, not only to the presence of mastitogenic bacteria in the udder but also to poor farm management conditions and hygiene during milking as well as the hygienic conditions of the barn. According to EFSA recommendations (2012): "In order to reduce udder infections, a full programme of control measures should be implemented. For example, cleaning of milking equipment should be performed adequately by chemical, thermal and physical processes. The environment of the cow should be clean, dry and well ventilated" (Recommendation 83); and again "The prevalence of mastitis should be reduced by the treatment of clinical and subclinical disease, dry cow therapy, identification and elimination of carrier cows, prevention of transmission of infection from cow to cow or through the environment, and improvement of the immune system by minimising stress factors and by a controlled and nutritionally-balanced feed intake" (Recommendation 84).

For the ClassyFarm checklist, the evaluation of udder health considers the **number of treatments for clinical mastitis** in a year (audit item No. 92 for free-stall farms, No. 84 for tie-stall farms). Achieving a low somatic cell count (SCC) in milk is primarily a result

of effective management practices, rather than relying heavily on antibiotic therapy. Herds that administer antibiotic treatments for clinical mastitis in less than 40% of the lactating cows during a visit over the course of a year are evaluated positively. In contrast, herds that exceed antibiotic treatments for 80% of the lactating cows, or for which data is unavailable, are assessed negatively. This information can be obtained from the drug register. The results obtained in the present study showed that in most of the free-stall farms, bulk milk had an average somatic cell count lower than 300,000 cells/ml with a number of annual treatments for clinical mastitis lower than 40%; while in most of the tie-stall farms this value was between 300,000 and 400,000 cells/ml (adequate assessment) with a number of treatments between 40% and 80%. In one tie-stall farm, critical issues were detected with values higher than 400,000 cells/ml indicating critical levels for udder health with a consequent number of treatments higher than 80%.

Another audit item, considered only for tie-stall farms, is the **adequacy of the resting area**: characteristics of stalls and tethers (lactating - dry cows; audit items No. 85-86). To meet the needs of both humans and livestock production, it may be necessary to regularly tether, chain, or restrain some animals, especially in areas where constructing free-stall herds is impractical due to land constraints. Legislative Decree 146/2001 (annex point 7) states that if animals are continuously or regularly tethered, their freedom of movement must not be restricted in a way that causes unnecessary injury or suffering. Additionally, they should be allowed to express their natural behaviours. Considering all existing types of fixed housing and the high variability in the characteristics of the stalls and tethers used, the adequacy and comfort of the decubitus area is assessed by direct observation of the animals, noting how the cows lie down, stand up and remain in decubitus, and whether they show any adverse effects on their health and welfare that indicate poor adaptation to the stall. For example, so-called "straddle" or "seated dog" riser movements (i.e. when a bovine lift first the front train and then the hind train due to the presence of obstacles to the

forward momentum of the body) are to be considered negatively as incompatible with the normal species-specific pattern. In addition, it must be verified that, despite the ligature, the cows can *groom* themselves without difficulty even in the most distant parts of the body (e.g. the udder). During feeding and watering, animals should be able to maintain a proper posture and should not experience skeletal or joint issues, such as the misalignment of the scapular joint (commonly referred to as "open scapulae"), which can occur if the trough wall is too high. A visual assessment can only yield an acceptable judgment if all animals are able to lie down comfortably and correctly at the same time, with very few exhibiting abnormal postures or skeletal deformities. It is tolerable for a maximum of 10-15% of the animals, particularly the older ones in the group, to have "open scapulae." The best scenarios are those where animals have ample opportunities for unrestricted movement and grooming. The present monitoring activities showed that most tie-stall farms had adequate lying areas, allowing the animals to lie down correctly and simultaneously; however, only one farm received an optimal rating.

Another aspect of verification is identifying annual **mortality** (audit items No. 93-95 for free-stall farms, No. 87-89 for tie-stall farms) from natural causes, accidents, euthanasia, or emergency slaughter, viewing this occurrence as a significant indicator of poor welfare conditions and management of health issues (Welfare Quality® protocol, 2009a; 5.1.3.2 and 6.1.3.2 Absence of disease - Mortality; modified). According to the ClassyFarm protocol, the evaluator assesses the number of adult cows (both lactating and dry) and heifers (aged 6 months and older, intended for future production) that have died due to natural causes, been emergency slaughtered, or euthanized in the past 12 months. This evaluation is done in relation to the total number of animals present on the day of the assessment. These data can be deduced from farm registers or from the web platform “BDN-Banca Dati Nazionale dell'anagrafe zootecnica”. A mortality rate of between 2% and 5% for both populations is considered acceptable, while less than 2% is considered

optimal. The assessment of annual calf mortality considers all calves that died on the farm, were emergency slaughtered or euthanized (as per Welfare Quality® protocol, 2009a - 7.1A.3.2 Absence of disease - Mortality), between the 2nd and 180th day of their life. This assessment relates to the total number of calves on the farm (those aged between 0 and 6 months who were present for at least one day in the last 12 months), while excluding stillborn calves or those that died within the first 24 hours of life. The mortality rate is often significantly affected by deficiencies in the calves' immune systems, which can be particularly challenging to address on fattening farms. The immune status of calves is primarily determined by the transfer of passive immunity gained from colostrum on their first day of life, which relies heavily on the management practices of the herd of origin. This calculation is perfectly suited to both meat calf farms, where animals are bought in to be fattened, and farms where calves are born (e.g. dairy farms or cow-calf lines). In the latter, if there is no entry/purchase of calves from other herds, the denominator (otherwise defined by the circulating calves) equals the number of calves born alive and viable in the last 12 months (remembering to exclude stillborn or dead calves in the first 24 hours). A mortality rate between 4% and 10% in dairy cattle herds is considered acceptable. The results obtained in the present monitoring activity indicated that most free-stall farms (71.4%) and tie-stall farms (57.1%) experienced mortality rates of less than 4% for lactating and dry cows, and 2% for calves. However, critical concerns were identified regarding calf mortality, which exceeded 10% in three farms—two with a tie-stall system and one with a free-stall system.

During the examination, it is necessary to check whether there are any animals with **mutilations** (e.g. removal of the corneal sketch, tail docking, castration, cutting off of horns after they have been sprouted) (audit item No. 96 for free-stall farms, No. 90 for tie-stall farms). Mutilation is defined as a practice not carried out for therapeutic or diagnostic purposes, manifested by damage to or loss of a sensitive part of the body or an alteration of

the structure of the bone. According to the regulations in force: 'The [...] cutting [...] of bovine tails is prohibited except for certified therapeutic purposes. Cauterization of the corneal sketch is permitted under three weeks of age. [...] Castration is permitted to maintain product quality and traditional production practices provided that such operations are carried out before the animals reach the sexual maturity by qualified personnel, minimizing any suffering for the animals. [...] The practices referred to in this point shall be carried out under the supervision of the farm veterinarian." (Legislative Decree 146/2001 - Annex, point 19). According to the ClassyFarm Handbook (2023), the competent veterinarian must check whether mutilated animals are present and, if practiced, check that the removal of the corneal bud is carried out under 21 days of age, e.g. by thermal cautery or caustication (application of a caustic paste/pattern) of the corneal bud, and under the supervision of the farm veterinarian. If the removal of the corneal bud takes place after 21 days of age or if other mutilations (e.g. tail docking, castration, antler clipping in adult animals) are found that can be traced back to the time the animal has been on the farm inspected, the treatment logbook (paper or electronic) must be checked to see if an anaesthetic and analgesic treatment was carried out/administered by the veterinarian at the same time. All treatments must be performed with sterile or disposable materials and carried out in such a way as to avoid prolonged or unnecessary pain or suffering to the animal. The absence of any mutilation and/or castration on all animals is considered optimal. The results obtained in the present study showed that in most of the free-stall and tie-stall farms the animals did not show signs of incisions or mutilations/castrations; critical issues were detected in two farms, one free-stall and one tie-stall, where there were animals with incisions or mutilations/castrations performed without respecting the current legislation.

Major risks and alarm systems

The area "major risk and alarm systems" examines various environmental factors that, while not directly impacting animal welfare, could play a crucial role in protecting the health, welfare, and lives of animals during major hazard situations, such as a failure of the water or electrical systems. The results of the monitoring activity for this area are reported in Table 12 (free-stall farms) and Table 13 (fixed-stall farms).

Table 12. Results of the macro-area Hazard and Risks for free-stall farms

Items	Mean	Std Dev	Min	Max
Origin of water (97)	2.43	0.79	1 (14.3%)	3 (57.1%)
Noise pollution (98)	1.71	0.49	1 (28.6%)	2 (71.4%)
Lighting for Inspection (99)	2.00	0.00	1 (0)	2 (100%)
Alarm system ventilation (100)	2.00	0.00	1 (0)	2 (100%)
Fire alarm system (101)	1.83	0.41	1 (16.7%)	2 (83.3%)
Inspections of automatical + mechanical devices (102)	2.57	0.53	1 (0)	3 (57.1%)
Treatment register (103)	1.57	0.53	1 (42.9%)	2 (57.1%)
Stock register (104)	1.71	0.49	1 (28.6%)	2 (71.4%)
Illegal substances (105)	2.00	0.00	1 (0)	2 (100%)

The number indicated in the brackets for each item refers to the corresponding audit item from the ClassyFarm checklist for both free-stall and tie-stall dairy farms. Min represents the worst score, Max the best score. The percentage of farms that achieved each score is provided in brackets.

Table 13. Results of the macro-area Hazard and Risks for tie-stall farms

Items	Mean	Std Dev	Min	Max
Origin of water (91)	2.71	0.49	1 (0)	3 (71.4%)
Noise pollution (92)	1.43	0.53	1 (57.1%)	2 (42.9%)
Lighting for Inspection (93)	1.86	0.38	1 (14.3%)	2 (85.7%)
Alarm system ventilation (94)	1.14	0.38	1 (85.7%)	2 (14.3%)
Fire alarm system (95)	1.14	0.38	1 (85.7%)	2 (14.3%)
Inspections of automatical + mechanical devices (96)	2.29	0.76	1 (14.3%)	3 (42.9%)
Treatment register (97)	1.43	0.53	1 (57.1%)	2 (42.9%)
Stock register (98)	1.57	0.53	1 (42.9%)	2 (57.1%)
Illegal substances (99)	2.00	0.00	1 (0)	2 (100%)

The number indicated in the brackets for each item refers to the corresponding audit item from the ClassyFarm checklist for both free-stall and tie-stall dairy farms. Min represents the worst score, Max the best score. The percentage of farms that achieved each score is provided in brackets.

The first audit item concerns the origin of the **drinking water** (audit item No. 97 for free-stall farms, No. 91 for tie-stall farms), which must always be available to all animals on the farm, "[...] all cattle over two weeks old must always have access to a sufficient supply of water of suitable quality" (EC draft 8/09 article 12, point 1). Water shortages can occur due to issues with the distribution system or the primary water source. A planned control of the system on the farm is necessary to quickly identify and fix any malfunctions or leaks. To prevent the farm from running out of water, it is advisable to have a main water source along with a reserve tank. This reserve tank can help manage and minimize the impacts of an insufficient water supply. Ideally, you should have at least two separate sources of water, such as an aqueduct and a well or natural spring, or two wells. Given the importance of providing animals with an adequate water supply, especially in light of the extreme climatic conditions of recent years, it was found that a majority of tie-stall farms (74.1%) and free-stall farms (57.1%) are equipped with multiple distinct water sources or have reserve tanks (28.6% of free-stall farms). Notably, only one free-stall farm received an inadequate rating due to the absence of a tank.

Another environmental factor that may indirectly affect animal welfare is **environmental noise** (audit item No. 98 for free-stall farms, No. 92 for tie-stall farms). Animals should not be exposed to excessive and, above all, sudden noises, because they could frighten them and trigger escapes or gatherings that could lead to accidents. Noise may also disturb the cattle's lives when it is constant and loud. The results of the present study highlighted that in the majority of tie-stall farms (57.1%), excessive environmental noise was detected. Conversely, free-stall farms showed normal noise levels in 71.4% of the cases.

Regarding the **lighting for inspection** (audit item No. 99 for free-stall, No. 93 for tie-stall) the ClassyFarm protocol refers to the Legislative Decree 146/2001, Annex, point 3: "In order to allow full inspection of the animals at any time, adequate fixed or mobile

lighting must be available." The light intensity and the duration of the light period should allow operators to adequately inspect all animals; in addition, there should be fixed or mobile lighting that allows animals to be inspected at any time, even at night. For the inspection of animals, the presence of fixed artificial lighting is considered adequate; if absent, the evaluator verifies the presence, availability and functionality of a mobile light source. The monitoring carried out in the present study showed that all free-stall farms were equipped with an adequate lighting system; in the case of tie-stall farms only one did not meet this requirement.

The verification of forced **ventilation systems** and the related **alarm system** is another audit item (No. 100 for free-stall farms, No. 94 for tie-stall farms). Forced ventilation systems are those systems that only manage the exchange of air in a room with the outside. This takes place without the opening of windows or doors, using forced ventilation ducts connected to the interior rooms by extractor fans (to remove air) and diffusers (to introduce new air).

If an artificial ventilation system with purely forced ventilation is present and necessary for the health and welfare of the animals, an alarm system must be provided to signal any faults to the farmer. Additionally, there must be a suitable backup system in place to ensure sufficient air exchange for the animals while waiting for the issue to be resolved. Examples of backup solutions include emergency window openings or an electricity generator. The alarm system and the replacement system must be checked regularly, especially if their malfunction would seriously endanger the health and welfare of the animals. If the farm does not require a forced ventilation system (e.g. suitable natural air circulation, grazing, etc.) the requirement is considered not applicable. An inadequate condition includes, in the case of forced ventilation only, the absence of an alarm or replacement system for the artificial ventilation system (e.g. closed rooms without windows, no power generator, etc.) and/or the absence of regular checks of the alarm and replacement system. All free-stall

farms investigated met the suitability requirement, while tie-stall farms showed critical issues in 85.7% of cases.

The presence of a **fire alarm system** must also be checked during the monitoring inspection (audit item No. 101 for free-stall farms, No. 95 for tie-stall farms). There must always be a fire alarm on a farm, such as an audible warning, and associated smoke and flame detection devices.

The results of this monitoring showed that only 2 free-stall farms were not equipped with a fire alarm; while this situation was found in the majority of fixed-stall farms (85.7%).

Automatic systems that may affect animal welfare (automatic milking systems, feeding, ventilation, etc.) should be checked daily and serviced regularly to ensure they are working properly (audit item No. 102 for free-stall farms, No. 96 for tie-stall farms). If defects or malfunctions are found, they must be rectified immediately or appropriate measures must be taken pending resolution of the fault (e.g. power generator). In addition, if such facilities are essential for the welfare of the animals, they should be equipped with alarm systems, which in turn should be checked for their effectiveness, in order to report faults or malfunctions in good time (see relevant item). The evaluator verifies the daily inspections of the facilities and any measures taken in the event of malfunctioning. In this case, since it is impracticable to verify that the inspection takes place on a daily and continuous basis (unless there is evidence of a lack of timely intervention at the time of the visit), the declaration of the farm manager is authoritative. An inadequate condition includes a lack of regular daily inspections and/or a lack of timely intervention. The adequate condition includes at least one inspection per day. The condition for the optimum requirement involves documented procedures or good practice manuals including operating instructions for operators, ensuring daily inspection and record keeping. Most free-stall and

tie-stall farms received adequate or optimal ratings. However, one tie-stall farm lacked proper daily inspections and timely interventions for its automatic equipment.

Another audit item concerns the keeping of the **register of drug treatments** (No. 103 for free-stall farms, No. 97 for tie-stall farms), an element that will be subject to further review. The farm must maintain a register of all therapeutic treatments conducted, in accordance with Articles 4, 5, and 15 of Legislative Decree 193/2006. In this register, the attending veterinarian is required to document the following: the date of treatment, the type of therapeutic treatments prescribed or administered, the identification of the animals treated, and the corresponding waiting periods. Additionally, the breeder must record the date and nature of the treatments performed, ensuring they adhere to the regulations regarding the proper use of medicines. As of January 28, 2022, it is mandatory to maintain treatment records in electronic format only. These records must be entered into the *Vetinfo* - National Pharmacosurveillance Information System by individuals with the appropriate authorizations. Assessors will evaluate the existence and completeness of the register, as well as the regular maintenance of records in *Vetinfo*. They will pay special attention to confirming the proper and timely treatment of sick or injured animals, including the use of analgesics and anaesthetics during any procedures. The following is considered adequate: the presence of the paper register (before 28 January 2022) and adequate storage. After 28 January 2022, the presence of records on *Vetinfo*. For this audit item, critical issues were found both for tie-stall farms (57.1%) and for free-stall farms (42.9%) and these have already been the subject of timely corrective action.

Checking the animal loading and unloading register (**stock register**; audit item No. 104 for free-stall farms, No. 98 for tie-stall farms). The assessor is not required to check the cattle registry, but must verify that the registry is present, filled in and correctly kept to assess whether any cases of abnormal mortality have been correctly reported. Anomalous mortality literally means all cases of new disease or sudden death occurring at a distance of

8 days from a previous case not referable to a common disease already ascertained. The presence of the register is considered adequate and there is no evidence of abnormal mortality not reported under Presidential Decree No. 320 of 8 February 1954. The monitoring activity revealed that the majority of free-stall farms (71.4%) met the adequacy requirements, while major critical issues were detected in 42.9% of fixed-stall farms which obtained an inadequate rating.

A final element of verification concerns the monitoring of the administration of **illegal substances (**audit item No. 105 for free-stall farms, No. 99 for tie-stall farms). According to the legislation in force, 'No other substance, with the exception of those administered for therapeutic or prophylactic purposes or with a view to zootechnical treatment as provided for in Article 1(2)(c) of Directive 96/22/EC, may be administered to an animal unless scientific studies on animal welfare and experience have shown it to be harmless to its health and welfare.' (Legislative Decree 146/2001, Annex, point 18). The assessor ensures that no illegal substances are administered to the animals by checking the treatment register and by inspecting the medicine cabinet or the premises and rooms of the farm. The use of any unauthorised substances can be reported to the competent health authority, which will consider whether to carry out additional tests, e.g. on carcasses at the slaughterhouse or on biological samples, depending on the suspected substance. No evidence of administration or possession of illegal substances was found in the monitored farms.

CONCLUSIONS

Food production systems for human consumption must prioritize sustainability. For today's consumer, product quality often goes beyond its nutritional attributes. People are more thoughtful about what they consume and demand information about the conditions in which animals are raised, transported, and slaughtered. Purchasing decisions are influenced by sensitive aspects such as personal ethics, perceptions, and beliefs. In the light of this, the demand for practices that ensure animal welfare is key to sustainability and creating a new relationship between society and animals. Some actions that improve animal welfare may also have positive environmental effects and each aspect can be measured. Animal welfare is the concern for the quality of life experienced by animals under human control, particularly those raised for agri-food purposes.

This contest raises the question: do citizens and operators in the supply chain know about animal welfare and the systems production? Of course, we must emphasize that, apart from the limited knowledge of farmers, animal welfare is not an issue that everyone is able to understand. Of course, some elements are known, but the complexity and details are completely unknown.

It must also be said that the constant evolution of legislation aimed at harmonizing rules and standards in Europe and simplifying their implementation, as well as the lack of attention paid to the topic by several European countries, does not make it easier for institutions to provide correct information to all stakeholders. However, the Council of the European Union itself highlighted various key issues:

- animal welfare is a strategic issue that must be strengthened and promoted as part of a holistic approach; the legislation of individual Member States must be harmonized and a specific international strategy must be developed that will reduce

unfair competition and raise the level of standards for all products traded in the internal market in the future;

- voluntary quality systems are fundamental to animal welfare policy and farmers should be encouraged to implement them, but procedures and controls should also be simplified, not in the sense of lowering standards, but making them more understandable, transparent and verifiable.

Given what has been said, it is believed that consumers have a key role to play, as it is they who determine the success of the market and the recognition of a price surplus, at least in the first years of implementation. It is widely recognized that a high quality of animal life and protection of their welfare should be ensured not only through repressive actions, such as official inspections, but most importantly by providing and disseminating best farming practices. In this context, the ClassyFarm approach could serve as an effective monitoring tool within a "plan-do-check-act" framework aimed at enhancing the environmental, economic, and social sustainability of livestock operations. The results of this pilot study indicated that, overall, all the farms included in the research received adequate ratings. However, several critical issues were identified in each of the five monitored areas. In particular, significant concerns arose in the biosecurity area for free-stall and tie-stall farms, specifically regarding the loading of animal carcasses and live animals: the loading areas did not maintain the required distance of 20 meters from the housing facilities. This issue largely stems from space constraints that many of the farms face. Furthermore, in tie-stall farms emerged the problem regarding the contact with other animals outside the herd, which significantly increases the risk of spreading common infectious agents. Many farmers in tie-stall farms lack knowledge about health status and consequently do not have prevention or control plans for endo- and ecto-parasitosis. In general, there is a need to raise awareness among farmers about biosecurity practices through effective education and easier access to available European funds, as well as

through training courses. This will help address the economic and logistical challenges associated with implementing biosecurity measures, especially in small-scale dairy farms. In the management area (Area A), free-stall farms received an adequate or optimal evaluation, even if, one farm had critical issues concerning the cleanliness of the laying area among all observed groups. Differently, tie-stall farms overall received an adequate evaluation, but critical issues were identified in a small percentage of farms, particularly related to feeding management and the cleanliness of the main sections of the housing building. Generally, it can be supposed that the small herd size allows farmers to observe each animal daily and respond quickly to their needs. Regarding the housing area (Area B), free-stall farms generally received optimal ratings, while tie-stall farms mostly received adequate ratings. Criticism was noted for laying material in one free-stall farm and for the area destined to calves and for the environmental conditions in one tie-stall farm. The results obtained for the Area C, regarding the animal-based measurements (ABMs), indicate that both the tie- and free-stall farms received an optimal or acceptable evaluation. This suggests that most of the animals are comfortable being approached and touched, or at least show curiosity towards humans and approach them. Again, it can be supposed that the small-scale farms may positively influence animal welfare by providing better individual care and fostering human-animal bonding compared to larger farms. However, it should be noted that one farm faced unfavourable results mainly due to issues with cow cleanliness, udder health, the number of mastitis treatments, and the mortality of heifers and calves. The last area of verification, Hazard risks and alarm systems, was characterized by the highest criticisms, particularly in tie-stall farms, where problems were found related to noise pollution and inadequate alarm systems for ventilation and fire safety. Additionally, there were concerns about the treatment register and stock register.

The results of this study reveal key weaknesses and areas for improvement in the monitored farms. To fully understand the implementation of the innovative ClassyFarm

system, further research with a larger number of farms is necessary. In addition, to promote best practices in biosecurity and animal welfare management, targeted interventions and educational initiatives should be prioritized to empower farmers. However, the resulting increase in production costs requires society to be willing to pay more for animal-based food produced under biosecurity conditions, respecting animal welfare and the environment in a contest of sustainability. In most countries this will have to be achieved via education of the public and by legislation.

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