

ORGANIZATION, MANAGEMENT AND CONTROL MODEL

GENERAL PART

**REGULATORY REFERENCES: LEGISLATIVE DECREE NO. 231/01 AND
LEGISLATIVE DECREE NO. 24/2023**

APTUIT (Verona) s.r.l.

Headquarters in Via Alessandro Fleming, 4 – Verona -

Reg. Imprese VR - 379303

Tax code and VAT number 03954300236

Share capital Euro 8.010.000 i.v.

Rev. No. 05 - 28/03/2025

Index

Summary

INDEX 2

1.	ADMINISTRATIVE LIABILITY PURSUANT TO LEGISLATIVE DECREE 231/01 ..	4
1.1.	The Regulatory Framework	4
1.2.	The objective profile: the relevant crimes	6
1.3.	The Subjective Profile of Administrative Liability and the Exemption Hypotheses.....	26
1.4.	Scope of application of the Organisational Model: the natural persons required to comply with it	27
1.5.	The Organizational Model as an essential part of the compliance and prevention system	29
1.6.	The definition of " <i>Acceptable Risk</i> "	31
1.7.	Confindustria and Fise – Assoambiente Guidelines and the UNI ISO 11961/2024 and 37301/2021 Guidelines	32
1.8.	The Approach of the Company Aptuit (Verona) S.r.l. to the "231" regulation ...	33
2.	THE METHODS OF DRAFTING THE ORGANIZATIONAL MODEL	37
2.1.	The Principles for defining the procedure for drafting the Model.....	37
2.2.	The essential phases of implementation of the Organizational Model.....	38
2.3.	Control Principles at the basis of Aptuit's Organizational Model	41
2.4.	The main phases of implementation of the Model.....	42
3.	COMPANY PROFILE.....	42
3.1.	The History and Activities of the Company	42
3.2.	The Organization	44
4.	THE SURVEILLANCE BODY	46
4.1.	Identification, Composition and Appointment.....	46
4.2.	Requirements.....	47
4.3.	Functions and Powers	49
4.4.	Information Flow Directed to the Surveillance Body	52
4.5.	Periodic checks by the Surveillance Body	54
4.6.	Reporting methods and periodicity	54
4.7.	Management Review	55
4.8.	Criminal profiles of the liability of the Surveillance Body	55
5.	VIOLATIONS AND WHISTLEBLOWING REPORTING SYSTEM PURSUANT TO LEGISLATIVE DECREE NO. 24 OF 10 MARCH 2023 AND INTERNAL REPORTING CHANNEL	55
5.1.	Prohibition of retaliatory behaviour	57
5.2.	Whistleblowing and protection of personal data	58
5.3.	Whistleblowing and protection of confidentiality	59
6.	DISCIPLINARY SANCTIONS AND SANCTIONING SYSTEM	60
6.1.	Disciplinary sanctions and protection of confidentiality	61

6.2.	Disciplinary sanctions for employees	61
6.3.	Disciplinary sanctions for management staff.....	63
6.4.	Measures against directors.....	64
6.5.	Subjects having contractual/commercial relationships and "para-subordinated" subjects.....	65
6.6.	Penalties for whistleblowing violations	66
6.7.	Application of penalties	66

1. ADMINISTRATIVE LIABILITY PURSUANT TO LEGISLATIVE DECREE 231/01

1.1. The Regulatory Framework

Legislative Decree no. 231 of 8 June 2001 on "*Discipline of the administrative liability of legal persons, companies and associations, including those without legal personality, pursuant to art. 11 of Law no. 300 of 29 September 2000*" introduced for the first time in our legal system the criminal liability of entities, which is added to that of the natural person who materially committed the unlawful act¹.

The extension of liability aims to involve in the punishment of certain criminal offences the assets of the entities and, ultimately, the economic interests of the shareholders, who, until the entry into force of the law in question, did not suffer consequences from the commission of crimes committed, to the advantage of the company, by directors and/or employees.

The principle of personality of criminal liability left them, in fact, free from sanctioning consequences other than any compensation for damages, if and to the extent that they existed. In terms of criminal consequences, in fact, only art. 196 and 197 of the Criminal Code provided (and still provide) for a civil obligation for the payment of fines or fines imposed, but only in the event of the insolvency of the material author of the act. The regulatory innovation, therefore, is of no small moment as neither the entity nor the members of the companies or associations can be said to be extraneous to the criminal proceedings for crimes committed to the advantage or in the interest of the entity.

This, of course, determines an interest of those subjects (partners, associates, etc.) who participate in the financial affairs of the entity, in the control of the regularity and legality of the company's operations.

The liability outlined by the rule, although it is defined as "*administrative*", has several peculiarities typical of criminal liability; the procedural system adopted, in fact, is the one provided for criminally relevant conduct.

¹ The provision of an administrative (but in fact criminal) liability of entities for certain types of crime was contained in art. 2 of the OECD Convention of 17 December 1997 on bribery of foreign public officials in international business transactions. This type of liability was subsequently introduced into our legal system by art. 11 of Law no. 300 of 29 September 2000, ratifying and implementing the OECD and European Union conventions against corruption in international trade and against fraud against the European Community. Art. 11, in particular, delegated the Government to regulate the articulation of this type of responsibility. In implementation of this delegation, the Government adopted Legislative Decree no. 231/2001.

In the explanatory memorandum accompanying the decree it is reported: *"This liability, since it is consequent from a crime and linked (by the express will of the enabling law) to the guarantees of the criminal process, diverges in many points from the paradigm of the administrative offence now classically deduced from Law 689/1981, with the consequence of giving rise to a tertium genus that combines the essential features of the criminal and administrative systems in an attempt to reconcile the reasons of preventive effectiveness with those, even more inescapable, of the maximum guarantee"*. Administrative liability is autonomous, but it is the consequence of the conduct of a natural person, in cases where such conduct constitutes a crime provided for by the decree.

This *tertium genus* of liability has been qualified by the most recent jurisprudence as *"organizational"*, characterized by the psychological element of the fault of the Entity that has not adequately organized itself internally to prevent the commission of the crimes referred to in Legislative Decree 231/2001.

With Legislative **Decree no. 24 of 10 March 2023**, published in the Official Gazette of 15 March 2023, EU Directive 2019/1937 on "the protection of persons who report breaches of Union law" (so-called "protection of persons who report breaches of Union law") was transposed into Italian law. "whistleblowing regulations"). The aim of the European directive is to establish common minimum standards to ensure a high level of protection for individuals who report breaches of EU law, by creating secure channels of communication, both within an organisation and externally. The Decree provides that the new discipline will apply, in general, as of 15 July 2023 (art. 24). On the other hand, for private sector entities which, in the last year, have employed an average of up to 249 employees, the obligation to establish an internal reporting channel takes effect as of 17 December 2023; until that day, the previous regulations continue to apply (Article 6, paragraph 2-bis of Legislative Decree No. 231 of 8 June 2001, hereinafter also referred to as "Decree 231"). As a result of the provisions of the Decree, the following are repealed: art. 54 bis of D. Legislative Decree no. 165 of 30 March 2001 TUPI for public bodies; art. 6, paragraphs 2 ter and 2 quarter, of Decree 231; art. 3 of Legislative Decree 179/2017. Art. 6 paragraph 2 bis of Decree 231.

ANAC has issued Whistleblowing Guidelines that have provided more detailed indications - and implemented in this document - regarding the contents of the Organisational Management and Control Model pursuant to Legislative Decree 231/01 (also "Model 231" or "Model") relating to the whistleblowing channel pursuant to Legislative Decree 24/2023.

The UNI 11961 Guidelines - published in December 2024 - UNI 11961 for the integration of the UNI ISO 37301:2021 compliance management system in support of the Organizational Management and Control Models and the Supervisory Bodies in accordance with Legislative Decree 231/2001 are **also included in the reference regulatory framework** . They have been adopted in order to facilitate the Authorities in the development of effective models based on the

principles and requirements expressed by the national and international UNI ISO technical standards. These guidelines - together with those of Confindustria - have been taken into account in the method adopted for the preparation of the Model 231.

1.2. The objective profile: the relevant crimes

The crimes for which the formation of administrative liability is provided are listed in section III of Chapter I of Legislative Decree 231/01, which has been amended several times with the inclusion of new criminal hypotheses not initially envisaged.

In relation to the type of offences to which the legislation in question applies, the delegated legislator initially made a minimalist choice with respect to the indications contained in the enabling law (Law no. 300/2000). In fact, of the four categories of offences indicated in Law no. 300/2000, the Government has taken into consideration only those relating to offences against the Public Administration, indicated by Articles 24 - Undue receipt of public funds, Fraud to the detriment of the State or other public body or to obtain public funds and Computer fraud to the detriment of the State or other public body and 25 - Bribery and Corruption, highlighting, in the report accompanying Legislative Decree no. 231/2001, the foreseeable extension of the discipline in question to other categories of crimes as well. This relationship was prophetic, since subsequent regulatory interventions have extended the catalogue of crimes to which the discipline of Legislative Decree no. 231/2001 applies.

All the families of offences provided for by Legislative Decree 231/01, updated at the date of drafting of this document, are listed below.

Art. 24 - UNDUE RECEIPT OF DISBURSEMENTS, FRAUD TO THE DETRIMENT OF THE STATE, A PUBLIC BODY OR THE EUROPEAN UNION OR TO OBTAIN PUBLIC DISBURSEMENTS, COMPUTER FRAUD TO THE DETRIMENT OF THE STATE OR A PUBLIC BODY AND FRAUD IN PUBLIC PROCUREMENT

The predicate offences referred to are supplemented by conduct carried out maliciously to the detriment of the Public Administration or the European Union and by fraud that harms the financial interests of the European Union. Among the predicate offences are also those of "*Disturbed freedom of enchantments*" and "*Disturbed freedom of the procedure for choosing the contractor*", both detrimental to the principle of good performance of the public administration and its right to better bargaining. It provides for financial penalties for a maximum of 600 shares in addition to some disqualification sanctions.

Art. 24-bis - COMPUTER CRIMES AND UNLAWFUL DATA PROCESSING

Law no. 48 of 18 March 2008 on "Ratification and execution of the Council of Europe Convention on Computer Crime, made in Budapest on 23 November 2001, and rules for the adaptation of the domestic legal system" has expanded the types of offences that can generate the liability of the entity, introducing, in the body of Legislative Decree no. 231/2001, art. 24-bis "Computer crimes and unlawful data processing". The new Article 24bis of Legislative Decree No. 231/2001 has extended the administrative liability of legal persons and entities to almost all computer crimes. As specified in the explanatory memorandum accompanying the original bill, in fact, the introduction of this article responds to the need to introduce forms of criminal liability for legal persons also with reference to the most serious computer crimes.

In light of the application conditions of the decree, entities will be held liable for computer crimes committed in their interest or to their advantage by persons who hold representation, administration, management functions of the entity or one of its organizational units, but also by persons subject to their direction or supervision.

The types of computer crime, therefore, concern those unlawful behaviors carried out by persons in a top or subordinate position (employees and/or collaborators), who use company IT/telematic tools and technologies to carry out normal work activities.

The legislator with Legislative Decree 21/09/2019 no. 105 converted by Law 18/11/2019 no. 13 included among the predicate crimes of the administrative liability of entities those integrated by commissive or omissive conduct supported by the specific intent of hindering or conditioning the procedures and requirements to ensure a high level of security of networks, information systems and IT services of collective interest through the establishment of the so-called "security perimeter national cybernetics".

The maximum penalties provided for amount to up to 800 quotas in addition to all the disqualification sanctions.

Art. 24-ter - CRIMES OF ORGANIZED CRIME

Law no. 94 of 15 July 2009 containing provisions on public security introduces article 24-ter "Organised crime crimes" into Legislative Decree no. 231/01 definitively approved by the Senate. Thus, the offences referred to in Articles 416, sixth paragraph, 416-bis, 416-ter and 630 of the Criminal Code, and the offences referred to in Article 416 of the Criminal Code, with the exception

of the sixth paragraph, or referred to in Article 407, paragraph 2, letter a), number 5) of the Code of Criminal Procedure, are included among the relevant offences.

The commission of these crimes involves the maximum of the penalties provided for both in the form of a fine of up to 1,000 shares, and in the form of disqualification sanctions, including a perpetual ban on the exercise of the activity.

Art. 25 – EMBEZZLEMENT, UNDUE USE OF MONEY OR MOVABLE PROPERTY, BRIBERY, UNDUE INDUCEMENT TO GIVE OR PROMISE BENEFITS, CORRUPTION

Together with Article 24, it constitutes, in its original wording entitled "Bribery and corruption", the original core of the offences provided for by Legislative Decree no. 231/01 and, like that, pertains to the sphere of relations with the Public Administration.

Law no. 190 of 6 November 2012 (2), known as the "anti-corruption law", has modified the heading of this article following the introduction by the same law 190 of the crime of "Undue inducement to give or promise benefits" (Article 319 quarter of the Criminal Code) where the public official or the person in charge of public service manifests a hypothesis of advantage for anyone in exchange for giving or promising benefits. The person who, by accepting the mere proposal made by the public official, actually gives or promises utility, commits a crime relevant for the purposes of the administrative liability of entities, pursuant to Legislative Decree no. 231/01.

Further amendments were made by Legislative Decree no. 75 of 14/07/2020 in implementation of EU Directive 2017/1371 (the so-called PIF Directive) which intervened both on the heading of the article (inserting the crimes of Embezzlement and Abuse of Office) and on its content by inserting "embezzlement" and "abuse of office" among the predicate crimes. In relation to these newly introduced crimes, the administrative liability of entities is limited to cases of damage to the financial interests of the European Union.

Recently, "the improper allocation of money or movable property" (art. 314-bis of the Criminal Code) *has been introduced into the Criminal Code and considered among the predicate crimes of liability pursuant to Legislative Decree 231/2001* (art. 9, paragraph 1 of Legislative Decree no. 92 of 4 July 2024, converted with amendments by Law no. 112 of 8 August 2024).

² Law no. 190 of 6 November 2012 "Provisions for the prevention and repression of corruption and illegality in the public administration" published in the Official Gazette no. 265 of 13/11/2012.

THE "**NORDIO LAW**" (**LAW NO. 114 OF 9 AUGUST 2024**) ALSO REPEALED THE CRIME OF "*Abuse of office*" PREVIOUSLY CONTEMPLATED AMONG THE PREDICATE CRIMES OF LIABILITY PURSUANT TO LEGISLATIVE DECREE 231/2001. The financial penalties for the commission of these offences can reach up to 800 quotas and involve the application of all disqualification sanctions for a period of not less than one year.

Art. 25-bis - COUNTERFEITING OF COINS, PUBLIC CREDIT CARDS, REVENUE STAMPS AND IDENTIFICATION INSTRUMENTS OR SIGNS

Law no. 409 of 23 November 2001 (3), converting Legislative Decree no. 350/2001 containing urgent provisions in view of the euro, a few months after the issuance of the first version of Legislative Decree no. 231/01, introduced, in art. 4, the new article of the Decree (art. 25bis) relating to counterfeiting of coins, public credit cards and revenue stamps, which Law 99/2009, containing provisions for the development and internationalisation of companies, as well as in the field of energy and containing amendments to Legislative Decree no. 81 of 8 June 2001, will then amend by introducing letter f bis) in paragraph 2 and with it the offences related to the infringement of trademarks, distinctive signs and patents as well as the introduction into the State and trade in products with false signs. This is the same rule that will then also introduce crimes against industry and commerce and crimes of copyright infringement.

The penalties for the violations referred to in Article 25bis are provided for in the maximum amount of 800 quotas and all disqualification sanctions for a maximum period of one year.

Art. 25.bis1 - CRIMES AGAINST INDUSTRY AND COMMERCE

As reported in the commentary on the previous article, crimes against industry become relevant for the purposes of the administrative liability of entities as a result of Law 99/2009, containing provisions for the development and internationalization of companies, as well as in the field of energy and containing amendments to Legislative Decree 8 June 2001, no. 81. The related penalties can reach up to 800 quotas and involve the application of all disqualification sanctions.

Article 25-ter - CORPORATE CRIMES

³ Law no. 409/2001 published in the Official Gazette no. 274 of 24 November 2001.

The introduction of this article, which took place with Legislative Decree no. 61/2002 (4), which added art. 25-ter to Legislative Decree no. 231/01, extending administrative liability to certain types of corporate crimes. On 15 June 2015, the changes in the field of corporate crimes came into force with the amendment to art. 25ter which implements the amendments made to the crime of false corporate communications, introduced by art. 12 of Law no. 69 of 27 May 2015 "Provisions on crimes against the public administration, mafia-type associations and false accounting".

The news on the predicate crime concerns:

- different classification of the crime: the conduct qualifying the crime today is, the conscious exposure to profit from it, of untrue facts (or omission of relevant facts) in the financial statements or in other corporate communications on the economic, equity or financial situation of the Company or the group to which it belongs, in a way that is concretely capable of misleading others. Therefore, falsehood with the intent to achieve an unfair profit and no longer the intention to deceive the shareholders or the public;
- increase in the financial penalty for the company compared to the past: in the event of a conviction of the legal person, the financial penalty now ranges from 200 to 400 shares;
- introduction of the crime of false corporate communications with minor facts. The financial penalty to be paid by the company ranges from 100 to 200 shares.
- introduction of the crime of false corporate communications of listed companies. The financial penalty to be paid by the company ranges from 400 to 600 shares.

Art. Article 25-ter regulates, in particular, the offences of: falsification of the financial statements in the reports and other corporate communications, forgery of the prospectus, falsity in the reports or communications of the auditing firm, impeded control, undue return of contributions, illegal distribution of profits and reserves, unlawful transactions on shares or quotas of the company or of the parent company, transactions to the detriment of creditors, failure to disclose the conflict of interest, fictitious formation of capital, undue distribution of company assets by the liquidator,

⁴ Legislative Decree no. 61/2002 on the regulation of criminal and administrative offences concerning commercial companies. The decree was published on 11 April 2002 in the Official Gazette - General Series no. 88 of 15 April 2002. With this measure, the Government has implemented art. 11 of the enabling law on the reform of company law (Law no. 366/2001), approved on 3 October 2001. The aforementioned rules were subsequently amended by Law no. 262/2005 cited below.

corruption between private individuals, unlawful influence on the shareholders' meeting, rigging, obstruction of the exercise of the functions of the public supervisory authorities.

In the past, interventions aimed at amending the rules on the administrative liability of entities have been implemented with the Community Law for 2004 (5art. 9) which, among other things, transposed Directive 2003/6/EC of the European Parliament and of the Council of 28 January 2003 on insider dealing and market manipulation (so-called market abuse) by means of immediately applicable rules. and with the law "Provisions for the protection of savings and the regulation of financial markets", which made some changes to the regime of administrative liability of legal persons with regard to certain corporate crimes.

The new legislation on market abuse has expanded the scope of application of Decree 231, making the cases of insider trading and market manipulation fall within the category of "prerequisite" offences for the administrative liability of entities.

The 2004 Community Law, in particular, intervened both on the Civil Code and on the Consolidated Law on Finance (TUF).

Law no. 262/2005 (6) on the protection of savings, on the other hand, extended the liability of entities to the new offence of failure to disclose the conflict of interest of directors, concerning only listed companies, and amended the rules on false corporate communications and false prospectuses.

As for the Civil Code, art. 2637, which sanctioned the crime of rigging committed on both listed and unlisted financial instruments. The rule now applies only to cases of rigging carried out with reference to unlisted financial instruments or for which no request for admission to trading on a regulated market has been submitted, and not to listed ones, to which the rules of the TUF on market manipulation apply. On the other hand, the new case of insider trading (or abuse of inside information) refers only to inside information relating to issuer companies governed by the TUF.

⁵ Law no. 62 of 18 April 2005, containing "Provisions for the fulfilment of obligations deriving from Italy's membership of the European Communities. Community Law 2004". The measure was published in the Official Gazette no. 96 of 27 April 2005 - Ordinary Supplement no. 76.

⁶ Law no. 262 of 28 December 2005 on "Provisions for the protection of savings and the regulation of financial markets", published in the Official Gazette no. 301 of 28 December 2005 - Ordinary Supplement no. 208.

Finally, in November 2012, the aforementioned "Anti-Corruption Law" (7) introduced, among the offences relevant for the purposes of the liability of entities, the offence of "Corruption between private individuals" through the amendments to Article 2635 of the Civil Code and its reference in letter s-bis of paragraph 2. Art. 25 ter letter s-bis was then replaced by art. 6 of Legislative Decree no. 38 of 15.03.2017 with effect from 14.04.2017, following the introduction of the new offence of "Instigation to Corruption between private individuals" (art. 2635 bis).

The penalties for the crimes referred to involve a maximum sanction of 600 shares, which can be increased by one third in the event of the achievement of a "significant profit". For the crime of Corruption between Private Individuals (art. 2635 of the Italian Civil Code) and of Incitement to Corruption between Private Individuals (art. 2635 bis of the Italian Civil Code), the disqualification sanctions provided for by art. 9, paragraph 2 of Legislative Decree 231/2001.

On 7 March 2023, Legislative Decree no. 19 of 2 March 2023 was published in the Official Gazette no. 56, containing "Implementation of Directive (EU) 2019/2121 of the European Parliament and of the Council of 27 November 2019 amending Directive (EU) 2017/1132 as regards cross-border conversions, mergers and divisions", which expands the range of predicate crimes to the liability of entities.

Art. 55 of the new legislation intervenes on art. 25-ter of Legislative Decree 231/2001, entitled "Corporate crimes", extending the punishability of the legal person also in relation to offences provided for not only by the Civil Code, but also by "other special laws".

A new "s-ter" letter is also added, which provides for the application of financial penalties to the entity: "for the crime of false or omitted declarations for the issuance of the preliminary certificate provided for by the legislation implementing Directive (EU) 2019/2121, of the European Parliament and of the Council, of 27 November 2019, the financial penalty from one hundred and fifty to three hundred shares" (the preliminary certificate is the document accompanying extraordinary cross-border transactions).

Art. 25-quarter - CRIMES WITH THE PURPOSE OF TERRORISM OR SUBVERSION OF THE DEMOCRATIC ORDER

The law of "Ratification and execution of the International Convention for the Suppression of the Financing of Terrorism" made in New York on December 9, 1999 (8) inserted a new art. 25quarter

⁷ See note 2.

⁸ Law no. 7/2003, in the Official Gazette no. 21 of 27 January 2003.

to decree 231, which establishes the liability put in place in violation of the provisions of article 2 of the International Administrative Convention of the entity also in relation to the commission of crimes with the purpose of terrorism or subversion of the democratic order. The law also applies (art. 25quarter, ult. co.) with reference to the commission of crimes, other than those expressly mentioned, "which were in any case for the repression of the financing of terrorism made in New York on December 9, 1999".

The penalties provided for are up to 1,000 shares and the application of all disqualification sanctions, including the definitive prohibition from exercising the activity.

Art. 25-quarter 1 - FEMALE MUTILATION

Law no. 7/2006 (9), which prohibits and punishes the so-called infibulation practices, has extended the scope of application of Legislative Decree no. 231/2001 to the new crime of mutilation of the female genital organs (Article 583bis of the Criminal Code).

The financial penalties applied reach a maximum of 700 shares and can lead to the definitive prohibition of the activity.

Art. 25-quinquies - CRIMES AGAINST THE INDIVIDUAL PERSONALITY

The law containing "Measures against trafficking in persons" (10) then introduced a new article to the decree, 25quinquies, which extends the regime of administrative liability of the entity also in relation to the commission of crimes against the individual personality governed by section I of Chapter III of Title XII of Book II of the Criminal Code.

Law no. 38 of 6 February 2006 (11), containing "Provisions on the fight against the sexual exploitation of children and child pornography also via the Internet", modified the scope of application of the crimes of child pornography and possession of pornographic material (respectively, articles 600ter and 600quarter of the Criminal Code), for which the liability of the

⁹ Law no. 7 of 9 January 2006 on "Provisions concerning the prevention and prohibition of female genital mutilation practices", published in the Official Gazette no. 14 of 18 January 2006.

¹⁰ Law no. 228 of 11 August 2003 on "Measures against trafficking in persons". The measure was published in the Official Gazette no. 195 of 23 August 2003.

¹¹ Law no. 38 of 6 February 2006, containing "Provisions on the fight against the sexual exploitation of children and child pornography also via the Internet", published in the Official Gazette no. 38 of 15 February 2006.

entity pursuant to Legislative Decree no. 231/01 was already envisaged, also including cases in which the pornographic material used represents virtual images of minors (so-called "virtual child pornography").

Article 3 of Legislative Decree no. 39 of 4 March 2014 inserted, in paragraph 1 letter c), the reference to article 609undecies of the Criminal Code, thus introducing the solicitation of minors among the relevant cases.

Finally, Law no. 199 of 29 October 2016, in amending art. 603bis of the Criminal Code on "Illegal intermediation and exploitation of labour", has also amended art. 25quinquies of Legislative Decree 231/2001 by inserting in letter a) of paragraph 1 the provision of the financial penalty also for the crime referred to in art. 603 bis of the Criminal Code.

The financial penalties applied reach a maximum of 1,000 shares and can lead to the definitive prohibition of the activity.

Art. 25 – sexies – MARKET ABUSE

The article and the related references to the crimes of insider dealing and market manipulation were introduced by the aforementioned Law 62/2005 (12).

For comments on the introductory provisions, please refer to the comment on the previous article 25ter of the Decree.

The fine can be up to 1,000 shares or be increased up to 10 times the profit from the crime. There are no disqualification sanctions.

Art. 25-septies – HEALTH AND SAFETY IN THE WORKPLACE

Law no. 123 of 3 August 2007, with the introduction of art. 25septies in the regulatory framework of Legislative Decree no. 231/2001, further extended the scope of application of the administrative liability of entities to the crimes of manslaughter and serious or very serious culpable injuries that

¹² See note 6 above.

occur in connection with the violation of the rules for the prevention of accidents at work or relating to the protection of hygiene and health at work (13).

The penalties provided for are up to 1,000 shares and the application of all disqualification sanctions for a maximum period of one year.

Article 25-octies - RECEIVING STOLEN GOODS, MONEY LAUNDERING AND USE OF MONEY, GOODS OR UTILITIES OF ILLEGAL ORIGIN AS WELL AS SELF-LAUNDERING

By Legislative Decree No. 231 of 21 November 2007, the legislator implemented Directive 2005/60/EC of the European Parliament and of the Council of 26 October 2005 on the prevention of the use of the financial system for the purpose of money laundering and terrorist financing (the so-called III Anti-Money Laundering Directive) (14). Art. 72 of Legislative Decree 231/2007, introducing this art. 25-octies, was amended by art. 5 Legislative Decree 25/05/2017 n. 90 with effect from 04/07/2017.

Law no. 186 of 15 December 2014, which introduced Article 648 ter of the Criminal Code, entitled "Self-laundering", has simultaneously referred to the same within this article.

Recently, with Legislative Decree No. 195 of 8 November 2021, the Italian legal system has implemented the European Directive 2018/1673 on the fight against money laundering. Specifically, the Decree intervenes on the Criminal Code in two directions: firstly, it extends the catalogue of predicate offences of the various types of money laundering, also including culpable crimes and contravention offences; secondly, it reshapes the penalties of the various cases.

It follows that the entity is punishable for the crimes of receiving stolen goods, money laundering, use of illicit capital and self-laundering, even if carried out in a purely "national" context, provided that an interest or advantage for the entity itself derives.

¹³ Law no. 123 of 3 August 2007 on "Measures on the protection of health and safety at work and delegation to the Government for the reorganisation and reform of the relevant legislation", published in the Official Gazette no. 185 of 10 August 2007.

¹⁴ Legislative Decree no. 231/2007, on "Implementation of Directive 2005/60/EC on the prevention of the use of the financial system for the purpose of money laundering and terrorist financing, as well as Directive 2006/70/EC on implementing measures", was published in the Official Gazette no. 290 of 14 December 2007 - Ordinary Supplement no. 268. The text has been in force since 29 December 2007.

The penalties provided for are of a pecuniary nature up to 1,000 shares and the application of all disqualification sanctions for a maximum period of two years.

Art. 25-octies.1 – CRIMES RELATING TO NON-CASH PAYMENT INSTRUMENTS AND FRAUDULENT TRANSFER OF VALUABLES

Article 25-octies.1 identifies the financial penalties that apply to the Entity in relation to the commission of the crimes provided for by the Criminal Code regarding payment instruments other than cash and fictitious attribution to others of the ownership or availability of money, goods or other utilities. The financial penalty reaches a maximum of 800 shares and the application in some cases of the **disqualification sanctions** provided for in Article 9, paragraph 2.

Art. 25-novies - CRIMES RELATING TO COPYRIGHT INFRINGEMENT

Law 99/2009, containing provisions for the development and internationalization of companies, as well as in the field of energy and containing amendments to Legislative Decree no. 81 of 8 June 2001, in addition to intervening on articles 25bis and 25bis 1 of Legislative Decree 231/01, introduces a further art. 25novies "Inducement not to make declarations or to make false declarations to the judicial authority" with reference to Article 377bis of the Criminal Code.

The penalties provided for are up to 500 quotas and the application of all disqualification sanctions for a maximum period of one year.

Art. 25-decies - INDUCEMENT NOT TO MAKE DECLARATIONS OR TO MAKE FALSE DECLARATIONS TO THE JUDICIAL AUTHORITY

Law No. 116 of 3 August 2009 - Ratification and implementation of the United Nations Convention against Corruption, adopted by the UN General Assembly on 31 October 2003 with Resolution No. 58/4, signed by the Italian State on 9 December 2003, as well as internal adaptation rules and amendments to the Criminal Code and the Code of Criminal Procedure, inserts in Legislative Decree no. 231/01 the reference to the offence referred to in art. 377bis of the Criminal Code, so that even the inducement not to make statements by means of violence, threats or offer or promise of money or other benefits, constitutes a prerequisite crime for the administrative liability of entities.

The penalties for the offence referred to entail a maximum fine of 500 shares. There are no disqualification sanctions.

Art. 25-undecies - ENVIRONMENTAL CRIMES

The inclusion of environmental crimes among the "predicate crimes" for which the liability of companies can arise took place with the insertion of a new additional article (15) in the legislative provision containing the specific discipline on the administrative liability of entities. The list of crimes introduced is particularly extensive; in fact, it relates to numerous offences, both criminal and contraventive, contained in the Criminal Code and recently expanded with the provision of new offences introduced by Law no. 68/2015 (Law on Eco-offences) in the Environmental Code (16), in the provisions for the protection of endangered animal and plant species (17), by the regulations for the protection of ozone (18) and in the provisions relating to pollution caused by ships (19).

The financial penalties reach a maximum of 1,000 shares and the disqualification sanctions, where applicable, can also lead to the definitive prohibition of the exercise of the activity.

Article 25-duodecies - EMPLOYMENT OF ILLEGALLY STAYING THIRD-COUNTRY NATIONALS

Art. 2 of Legislative Decree 109/2012 introduced the new article "25-duodecies" (Employment of illegally staying third-country nationals) within Legislative Decree 231/01. Art. 30 Law no. 161 of 17/10/2017 added to the original article 25 duodecies of Legislative Decree no. 231/2001, a further three paragraphs with effect from 19.11.2017 and relating to the predicate crime of promoting, directing, organizing, financing, or carrying out the transport of illegal immigrants, and to that of aiding and abetting the stay of illegal foreigners, referred to in art. 12 of Legislative Decree no. 286/1998 paragraphs 3, 3-bis, 3-ter and 5. The new Article 25 duodecies provides that

¹⁵ Article 25-undecies of Legislative Decree no. 231 of 8 June 2001.

¹⁶ Legislative Decree no. 152 of 3 April 2006 - Environmental regulations.

¹⁷ Law No. 150 of 7 February 1992 - Regulation of offences relating to the application in Italy of the Convention on International Trade in Endangered Species of Animals and Plants, signed in Washington on 3 March 1973, referred to in Law No. 874 of 19 December 1975 and Regulation (EEC) No. 3626/82 and subsequent amendments, as well as rules for the marketing and possession of live specimens of mammals and reptiles that may constitute a danger to health and safety Public.

¹⁸ Law no. 549 of 28 December 1993 - Measures for the protection of stratospheric ozone and the environment.

¹⁹ Legislative Decree no. 202 of 6 November 2007 - Implementation of Directive 2005/35/EC on pollution caused by ships and consequent sanctions.

"1. In relation to the commission of the crime referred to in art. 22, paragraph 12-bis, of Legislative Decree no. 286 of 25 July 1998, a fine of between 100 and 200 shares is applied to the entity, within the limit of 150,000 euros. 1-bis. In relation to the commission of the crimes referred to in art. 12, paragraphs 3, 3-bis and 3-ter, of the consolidated text referred to in Legislative Decree 25/07/1998 n. 286, as subsequently amended, a financial penalty of between four hundred and one thousand shares is applied to the entity. 1-ter. In relation to the commission of the crimes referred to in art. 12, paragraph 5, of the consolidated text referred to in Legislative Decree no. 286 of 25/07/1998, as amended, a fine of one hundred to two hundred shares is applied to the entity. 1-quarter. In cases of conviction for the crimes referred to in paragraphs 1-bis and 1-ter of this article, the disqualification sanctions provided for in article 9, paragraph 2, shall apply for a duration of not less than one year".

Therefore, if the employer employs foreign workers without a residence permit, with an expired residence permit whose renewal has not been requested within the terms of the law, revoked or cancelled, in addition to the criminal liability for the employer's natural person, the 231 liability for the company will also be triggered if the aggravating circumstances referred to in paragraph 12 bis of art. 22 of Legislative Decree 286/98 explained below:

- there are more than three workers employed;
- employed workers are minors of non-working age;
- Employed workers are subject to the other particularly exploitative working conditions referred to in the third paragraph of art. 603-bis of the Criminal Code.

In the same way, if the entity derives interest or advantage from the commission by top management or subordinates of crimes of promotion, management, organization, financing, or carrying out the transport of illegal immigrants or aiding and abetting the stay of illegal foreigners, in addition to the criminal liability for the natural person who committed the crime, the 231 liability for the Company will also be triggered.

The financial penalty reaches a maximum of 1,000 shares. For the crimes referred to in paragraphs 1-bis and 1-ter, the disqualification sanction referred to in art. 9, paragraph 2, for a duration of not less than one year.

Art. 25-Terdecies – RACISM AND XENOPHOBIA

Article 5 of Law no. 167 of 20/11/2017 introduced with effect from 12.12.2017 the new article 25 Terdecies of Legislative Decree 231/2001. The predicate crime is the crime referred to in art. 3, paragraph 3-bis (Propaganda/incitement/incitement based on the apology of crimes of genocide, against humanity and war), introduced in Law no. 654 of 13/10/1975, by art. 1 of Law no. 115 of 16/06/2016 and then amended by art. 5 of Law no. 167 of 20/11/2017. The financial penalty provided for by the Authority reaches a maximum of 800 shares. In the case of a permanent establishment with the sole or predominant purpose of allowing or facilitating the commission of crimes, the definitive disqualification sanction from the exercise of the activity pursuant to Article 16, paragraph 3 of Legislative Decree no. 231/2001 is envisaged.

Art. 25-quaterdecies - FRAUD IN SPORTS COMPETITIONS, ABUSIVE EXERCISE OF GAMING OR BETTING AND GAMES OF CHANCE EXERCISED BY MEANS OF PROHIBITED MACHINES

Law no. 39 of 3 May 2019 on the "Ratification and execution of the Council of Europe Convention on sports manipulation, made in Magglingen on 18 September 2014", extended the liability of entities pursuant to Legislative Decree no. 231/2001 to the crimes of fraud in sports competitions and abusive exercise of gaming or betting activities. It then introduced in Legislative Decree 231/2001 art. 25 quaterdecies, according to which:

"1. In relation to the commission of the offences referred to in Articles 1 and 4 of Law No. 401 of 13 December 1989, the following financial penalties shall apply to the entity: for offences, a fine of up to 500 shares; for contraventions, a fine of up to 260 shares.

2. In cases of conviction for one of the offences referred to in paragraph 1, letter a) of this article, the disqualification sanctions provided for in art. 9, paragraph 2, for a duration of not less than one year".

Specifically, the crime of sports fraud (art. 1 L. 401/1989) criminalizes "anyone who offers or promises money or other benefits or advantages to any of the participants in a sports competition organized by recognized federations, in order to achieve a result other than that resulting from the correct and fair conduct of the competition, or carries out other fraudulent acts aimed at the same purpose" as well as "the participant in the competition who accepts the money or other benefit or advantage, or accepts its promise".

Art. 4 of the same regulatory structure, on the other hand, contemplates various cases related to the exercise, organization, sale of gaming and betting activities in violation of authorizations or administrative concessions.

Art. 25-quinquiesdecies- TAX CRIMES

During the session of 17 December 2019, the Senate gave the final go-ahead to the Law converting – with amendments – the Legislative Decree no. 124 of 26 October 2019, containing "Urgent provisions on tax matters and for non-deferrable needs" (the so-called Tax Decree). Among the novelties, the introduction of some tax crimes stands out among the predicate crimes of the "administrative" liability of the former entities Legislative Decree no. 231/2001. In particular, the catalogue of predicate offences will become part of the catalogue of predicate offences, in art. 25-quinquiesdecies, the offences of:

- fraudulent declaration through the use of invoices or other documents for non-existent transactions referred to in Article 2, comma 1, D.lgs. 74/2000, for which a fine of up to 500 shares is envisaged;
- fraudulent declaration through the use of invoices or other documents for non-existent transactions referred to in Article 2, comma 2-bis, D.lgs. 74/2000, for which a fine of up to 400 shares is envisaged;
- fraudulent declaration by means of other artifices referred to in Article 3, Legislative Decree 74/2000, for which a fine of up to 500 shares is envisaged;
- issuance of invoices or other documents for non-existent transactions referred to in article 8, comma 1, D.lgs. 74/2000, for which a fine of up to 500 shares is envisaged;
- issuance of invoices or other documents for non-existent transactions referred to in Article 8, comma 2-bis, D.lgs. 74/2000, for which a fine of up to 400 shares is envisaged;
- concealment or destruction of accounting documents referred to in Article 10, for which a fine of up to 400 shares is envisaged;
- fraudulent evasion of the payment of taxes provided for in Article 11, for which a fine of up to 400 shares is envisaged.

Legislative Decree no. 75 of 14/07/2020 implementing EU Directive 2017/1371 (the so-called PIF Directive) supplemented art. 25 quinquiesdecies in question, introducing a new paragraph 1-bis which provides:

- the penalty of up to 300 shares, for the crime of unfaithful declaration;

- the penalty of up to 400 shares, for the crime of failure to declare;
- the sanction of up to 400 shares, for the crime of undue compensation;
- and the application of disqualification sanctions also for the new cases introduced.

It then provides, as conditions for sanctionability, that the conducts be carried out:

- in the context of cross-border fraudulent schemes;
- in order to evade value added tax for a total amount of not less than € 10,000,000.

(*) From 1 January 2026, Legislative Decree No. 74 of 10 March 2000 will be repealed and the corresponding provisions of Legislative Decree No. 173 of 5 November 2024 (Consolidated Law on Administrative and Criminal Tax Sanctions) will apply pursuant to art. 101, paragraph 1, letter z), of the Consolidated Law annexed to Legislative Decree no. 173 of 5 November 2024. For the repeal of art. 21-bis and 21-ter, as of 1 January 2026, see art. 130, paragraph 1, letter f), of the Consolidated Law annexed to Legislative Decree No. 175 of 14 November 2024.

Art. 25-sexiesdecies SMUGGLING

Legislative Decree no. 75 of 14 July 2020, implementing EU Directive 2017/1371 (the so-called PIF Directive), with the aim of providing the most complete possible protection for the financial interests of the European Union, introduced this new article, aimed at providing for the liability of the entity for the committal, in its interest or advantage, of smuggling offences provided for by the national provisions complementary to the Union Customs Code, referred to in the legislative decree issued pursuant to Articles 11 and 20, paragraphs 2 and 3, of Law No. 111 of 9 August 2023, and by the consolidated text of the legislative provisions concerning taxes on production and consumption and related criminal and administrative sanctions, referred to in Legislative Decree No. 504 of 26 October 1995. Following the establishment of the customs union between EU member states, customs duties represent an own resource of the European Union, helping to define its budget.

One of the latest innovations in the 231 area is dictated by the new **Legislative Decree No. 141 of 26 September 2024**, bearing "*Supplementary national provisions to the Union Customs Code and revision of the system of penalties for excise duties and other indirect taxes on production and consumption*" which repealed the Decree of the President of the Republic of 23 January 1973, no. 43 Consolidated text of the legislative provisions on customs (so-called "TULD"). The customs

reform has repealed the TULD, now providing for Annex 1 containing precisely the penalties of a criminal nature in the field of smuggling.

One of the main innovations brought about by the new legislation consists in the redefinition of customs violations divided into criminal offenses and administrative offenses.

The Decree in question also made changes to art. 2 sexiesdecies of Legislative Decree no. 231/2001 which now also provides for the applicability of the disqualification sanctions referred to in art. 9 of the decree, namely:

- the prohibition from exercising the activity
- and the suspension or revocation of authorizations, licenses or concessions functional to the commission of the offense.

With reference to these cases, a fine of up to 200 shares is envisaged, or up to 400 shares if the border fees due exceed 100,000 euros. In any case, the disqualification sanctions referred to in art. 9, paragraph 2, letters c), d) and e).

Art. 25-septiesdecies CRIMES AGAINST CULTURAL HERITAGE

Law no. 22 of 9 March 2022 containing the provisions on crimes against cultural heritage has been published in the Official Gazette with the aim of strengthening the protection tools, with particular reference to movable property, through the introduction of new types of crime, the expansion of the scope of application of confiscation and the inclusion of some crimes against cultural heritage among the predicate crimes of the administrative liability of the entities of referred to in Legislative Decree no. 231/2001.

In particular, the law identifies the following offences:

- the theft of cultural property;
- the receipt of cultural goods;
- the use of cultural property deriving from crime;
- the laundering of cultural property;
- the self-laundering of cultural goods;

- the falsification of private deeds relating to cultural heritage;
- the violation of the alienation of cultural property;
- the illicit exit or export of cultural goods;
- destruction, dispersion, deterioration, disfigurement, soiling and illegal use of cultural or landscape property;
- devastation and looting of cultural and landscape assets.

The law provides for the administrative liability of legal persons when crimes against cultural heritage are committed in their interest or to their advantage. The reform has therefore integrated the catalogue of crimes with the insertion of two new articles:

This Article 25-septiesdecies which provides in relation to:

- Article 518-ter (misappropriation of cultural property), Article 518-decies (illegal importation of cultural property) and Article 518-undecies (illegal exit or export of cultural property) the application of an administrative fine of between 200 and 500 quotas;
- Article 518-sexies of the Criminal Code (laundering of cultural property) the application of an administrative fine ranging from 500 to 1,000 shares;
- Article 518-duodecies (destruction, dispersion, deterioration, defacement, soiling and illegal use of cultural and landscape property) and Article 518-qua terdecies of the Criminal Code (counterfeiting of works of art) the application of an administrative fine ranging from 300 to 700 shares;
- Article 518-bis (theft of cultural property), Article 518-quarter (receiving stolen cultural property) and Article 518-octies (forgery of private deeds relating to cultural property) the application of the administrative fine ranging from 400 to 900 shares.

In the event of conviction for the crimes listed above, the new provision provides for the application of disqualification sanctions to the entity for a duration not exceeding two years;

The law then introduced the article referred to in the following paragraph.

Art. 25-duodevicies- LAUNDERING OF CULTURAL PROPERTY AND DEVASTATION AND LOOTING OF CULTURAL AND LANDSCAPE PROPERTY

In relation to the crimes of laundering cultural property (Article 518-sexies) and devastation and looting of cultural and landscape property (Article 518-terdecies), this article provides for the application of a fine of 500 to 1,000 shares to the entity. In the event that the entity, or one of its organizational units, is permanently used for the sole or predominant purpose of allowing or facilitating the commission of such crimes, the sanction of permanent disqualification from exercising the activity is applied.

TRANSNATIONAL CRIMES

Law no. 146/2006 ratifying and implementing the Palermo Convention against transnational organized crime of 15 November 2006²⁰ established the application of Decree 231 to **TRANSNATIONAL ORGANIZED CRIME CRIMES**. The new provisions have provided for the liability of entities for administrative offences dependent on the crimes of criminal association, money laundering and use of money and goods of illegal origin, migrant trafficking and obstruction of justice²¹.

The customs reform referred to in Legislative Decree No. 141 of 26 September 2024 has redefined the contents of Art. 291-quarter of Presidential Decree no. 43 of 23 January 1973 on the subject of " *Criminal conspiracy to smuggle foreign manufactured tobacco*".

²⁰ Law no. 146 of 16 March 2006 on "Ratification and implementation of the United Nations Convention and Protocols against transnational organised crime, adopted by the General Assembly on 15 November 2000 and 31 May 2001", published in the Official Gazette of 11 April 2006, no. 85 Suppl. Ord. no. 91.

²¹ The provision relating to the crimes of money laundering and use of money and goods of illegal origin having a transnational character was subsequently repealed by Legislative Decree no. 231 of 21 November 2007.

1.3. The Subjective Profile of Administrative Liability and the Exemption Hypotheses

From the point of view of the recipients, the law indicates "*entities with legal personality, companies with legal personality and companies and associations, including those without legal personality*" (Article 1, paragraph 2).

The descriptive framework is completed by the indication, of a negative nature, of the subjects to whom the law does not apply, i.e. "*the State, local public bodies as well as entities that perform functions of constitutional importance*" (art. 1, para. 3).

It should be remembered that this new liability arises only on the occasion of the commission of certain types of crimes by persons linked in various ways to the entity and only in the hypothesis that the unlawful conduct has been carried out in the interest or to the advantage of it.

Therefore, not only when the unlawful conduct has led to an advantage, financial or otherwise, for the entity, but also in the event that, even in the absence of such a concrete result, the offence is justified in the interest of the entity.

A second aspect of particular importance in order to correctly define the cases in which the discipline in question is applied, concerns the identification of the subjects who, by committing a crime, may give rise to liability on the part of the entity to which they belong.

In this regard, Article 5 of the decree identifies two different categories of employees and collaborators of the company.

This distinction, however, is not merely formal, but takes on particular importance in order to understand how the company can prevent and avoid the application of sanctions against it. The two categories of subjects who can determine, due to the crimes they have committed, the onset of liability against the company are:

- persons who hold representation, administration or management functions of the entity or of one of its organisational units with financial and functional autonomy as well as persons who exercise, even de facto, the management and control of the same (the so-called persons in "*top positions*");
- persons subject to the management or supervision of one of the subjects mentioned in the previous letter (in fact employees and lower-level collaborators).

Article 6 of the measure in question, however, provides for a form of "**exemption**" from liability of the entity if it is demonstrated, during criminal proceedings for one of the crimes considered, that it has adopted and effectively implemented Organization, Management and Control Models pursuant to Legislative Decree 231/01 suitable for preventing the commission of the criminal offences considered; to have appointed a

body with autonomous powers of initiative and control with the task of supervising the functioning and compliance with the Model and taking care of its updating; that the crime was committed by fraudulently circumventing the Model.

The system provides for the establishment of an internal control body within the entity with the task of supervising the real effectiveness of the model. Finally, the law establishes that trade associations can draw up codes of conduct, on the basis of which individual organisational models will be drawn up, to be communicated to the Ministry of Justice, which has thirty days to formulate its observations.

It should be emphasized, in this regard, that, as also reiterated below, the exemption from the responsibilities of the Entity passes through the **judgment of the suitability of the internal system of organization and controls**, a judgment that the criminal judge is called upon to formulate. Therefore, the formulation of the Models must aim at the positive outcome of this assessment of suitability and - in line with the UNI ISO Guidelines - at an integrated compliance risk management system that favours coordination and collaboration between company subjects and the implementation of transversal procedures for the prevention of the widest spectrum of risks.

1.4. Scope of application of the Organisational Model: the natural persons required to comply with it

It is of particular importance to limit the application of the discipline in question, identifying the subjects who, by committing a crime, can give rise to liability on the part of the entity to which they belong. Article 5 of the decree identifies two different categories of employees and collaborators of the company: top management and subordinates.

This distinction, however, is not merely formal, but takes on particular importance in order to understand how the Company can prevent and avoid the application of sanctions against it. The two categories of subjects who, pursuant to the provisions of Legislative Decree 231/2001, can determine, due to the crimes they have committed, the onset of liability for the company are:

- persons who hold representation, administration or management functions of the entity or of one of its organisational units with financial and functional autonomy as well as persons who exercise, even de facto, the management and control of the same (the so-called persons in "*top positions*");
- persons subject to the management or supervision of one of the subjects mentioned in the previous letter (in fact employees and lower-level collaborators).

In an integrated vision of all the actors expressing the Entity's actions, the approach of the Organizational Model, for an easier application expenditure, is to distinguish the natural persons required to comply with the Organizational Model into:

A) SUBJECTS WITHIN THE INSTITUTION:

- those who perform, even de facto, management, administration, management, control functions, as well as functions of a disciplinary, consultative and propositional nature in the company or in one of its autonomous organizational units;
- those who have powers of representation of the company;
- employees of the company, even if seconded abroad to carry out the activities;
- all those subjects who collaborate with the company by virtue of a para-subordinate employment relationship, such as project collaborators, temporary workers, temporary workers.

B) SUBJECTS EXTERNAL TO THE INSTITUTION:

- Suppliers (differentiating between raw material suppliers and subcontractors);
- Consultants;
- Outsourcer functions;
- VAT numbers;
- Counterparties to a service contract;
- Agents/representatives;

who are subjects external to the company organization, but linked to the Entity by a contractual and/or mandate relationship. On the other hand, the UNI ISO 37301 compliance risk assessment also highlights the importance of a system of compliance with the law in the supplier qualification process.

For each of these, the Special Part of the Model will take into account the further distinction between:

B.1) INTERNAL RISKS OF THE ENTITY: WHEN IT IS THE RELATIONSHIP ITSELF WITH THE SUPPLIER THAT IS AN INSTRUMENT OF CONDUCT AT RISK OF CRIME 231 (E.G. CORRUPTION, MONEY LAUNDERING, ...) AND THE SUPPLIER IS ONE OF THE ACTORS OF THE CRIME. In this case, the recipient of the Model is the internal entity that manages the relationship with the supplier.

B.2) RISKS EXTERNAL TO THE ENTITY: when the conduct at risk of crime is part of the activity carried out by the supplier on behalf of the Entity (e.g. environmental crimes, OSH crimes, crimes against industry and commerce, ...): in this case the crime is not of the Entity, but committed for the Entity.

It is the prerogative of the Special Part of the Organisational Model, once this assessment has been carried out and the existence of an external risk has been ascertained, to prepare the appropriate containment protocols, to create the tools to verify its compliance (flow to the Surveillance Body (or "SB") / the SB's power of verification), to contractually bind the external party to the Code of Conduct, to the specific containment protocols and to safeguard rules.

1.5. The Organizational Model as an essential part of the compliance and prevention system

In view of the purpose of the rule, which is to stimulate economic entities to prevent the commission of crimes, the legislator has provided, in Articles 6 and 7 of the decree, that companies may preventively adopt guidelines such as to reduce or exclude liability (and consequently the sanctions) provided for by Decree 231/01.

In particular, the two articles cited separately provide for the procedures to be observed in order to protect oneself from consequences in the two different cases referring to crimes committed by persons in top positions or by employees and collaborators.

As regards the first hypothesis, Article 6 provides that the company is not considered liable if it proves that:

- a) the management body has adopted and effectively implemented, before the commission of the act, organizational and management models suitable for preventing crimes of the kind that occurred;
- b) the task of supervising the functioning and observance of the models, of taking care of their updating has been entrusted to a body of the entity with autonomous powers of initiative and control;
- c) the persons committed the crime by fraudulently circumventing the organizational and management models;
- d) there has been no omission or insufficient supervision by the body referred to in letter b).

Article 7, on the other hand, focusing on the hypothesis of crimes committed by persons subject to the supervision of others, establishes that the company is liable if the commission of the crime was made possible by the failure to comply with the management or supervisory obligations, it being understood that the failure to comply with these obligations is excluded a priori if the entity, before the commission of the crime, has adopted and effectively implemented an Organization Model, Management and Control suitable for preventing crimes of the kind that occurred.

As is evident, therefore, the two pivots around which the system of exclusion of liability revolves are the adoption of Organizational Models suitable for preventing the commission of crimes and the supervision of these models by a special body of the company.

As regards the implementation of the Organisational Model, art. 6, paragraph 2, of Legislative Decree no. 231/2001, indicates the essential characteristics for the construction of an Organization, Management and Control Model.

In particular, letters a) and b) of the aforementioned provision expressly refer, albeit with the use of terminology and exposition extraneous to business practice, to a typical risk management system²². The risk assessment activity is also considered by UNI ISO 11961 to be the most important: only a correct, careful and adequate risk analysis and assessment process can make it possible to identify the cornerstones that allow the organization/entity to build a Compliance Management System, compliant with ISO standards, or to build an Organization Model, Management and Control pursuant to Legislative Decree no. 231/2001.

Art. 6 expressly indicates the two main phases in which such a system must be articulated:

- **the identification of risks:** i.e. the analysis of the company context to highlight where (in which area/sector of activity) and in what ways events may occur that are detrimental to the objectives indicated by Legislative Decree no. 231/2001;
- **the design of the control system** (so-called protocols for the planning of the formation and implementation of the decisions of the entity), i.e. the evaluation of the existing system within the entity and its possible adjustment, in terms of its ability to effectively counteract, i.e. reduce to an acceptable level, the identified risks. From a conceptual point of view, reducing a risk implies having to intervene (jointly or severally) on two determining factors: i) the probability of occurrence of the event and ii) the impact of the event itself.

However, in order to operate effectively, the system briefly outlined cannot be reduced to a one-off activity, but must be translated into a continuous process (or in any case carried out with an adequate periodicity), to be reiterated with particular attention in times of business change (opening of new offices, expansion of activities, acquisitions, reorganizations, etc.). Also pursuant to UNI ISO 37301, *"When the organization determines the need for changes to the management system for compliance, these must be carried out in a planned manner. The organization must take into account: - the purpose of the changes and their potential consequences; - the design and operational effectiveness of the compliance management system; - the availability of adequate resources; - the allocation or reallocation of responsibilities and authority."*

²² "In relation to the extension of delegated powers and the risk of committing crimes, the forms referred to in letter a), paragraph 1, must meet the following requirements:

- a) identify the activities in the context of which crimes may be committed;
- b) provide for specific protocols aimed at planning the formation and implementation of the decisions of the entity in relation to the crimes to be prevented".

With regard to the risk of unlawful conduct in the field of health and safety at work, this system must necessarily take into account the prevention legislation in force.

This set of regulations, in fact, itself outlines a "system" of binding principles and mandatory obligations whose declination in terms of application management - where appropriately integrated/adapted according to the "organizational model" provided for by Legislative Decree no. 231/2001 - may be suitable to reduce to an "acceptable" level, to the exempting effects of the same Legislative Decree no. 231/2001, the possibility of conduct constituting the extremes of the crime of homicide or serious or very serious culpable injuries committed in violation of the prevention rules.

1.6. The definition of "Acceptable Risk"

An absolutely nodal concept in the construction of a preventive control system is that of acceptable risk.

In the design of control systems to protect business risks, defining acceptable risk is a relatively simple operation, at least from a conceptual point of view. The risk is considered acceptable when the additional controls "cost" more than the resource to be protected (for example: common cars are equipped with an anti-theft device and not also with an armed vigilante).

In the case of Legislative Decree no. 231/2001, however, the economic logic of costs cannot be a reference that can be used exclusively. It is therefore important that, for the purposes of applying the provisions of the decree, an effective threshold is defined that allows a limit to be placed on the quantity/quality of the prevention measures to be introduced to avoid the commission of the crimes in question.

In the absence of a prior determination of the acceptable risk, the quantity/quality of preventive controls that can be instituted is in fact virtually infinite, with the predictable consequences in terms of business operations.

Moreover, the general principle, which can also be invoked in criminal law, of the concrete enforceability of the conduct, summarized by the Latin brocardo *ad impossibilia nemo tenetur*, represents an indispensable reference criterion even if, often, it seems difficult to identify its limit in practice.

With regard to the preventive control system to be built in relation to the risk of committing the offences contemplated by Legislative Decree no. 231/2001, the conceptual threshold of acceptability, in cases of intentional crimes, in line with the provisions of the Guidelines drawn up by Confindustria (and approved by the Ministry of Justice), is represented by a prevention system such that it cannot be circumvented except fraudulently.

This solution is in line with the logic of the "*fraudulent avoidance*" of the organizational model as expressed by the aforementioned legislative decree for the purpose of excluding the administrative liability of the entity (art. 6, para. 1, letter c), "*the persons*

have committed the crime by fraudulently circumventing the organizational and management models").

On the other hand, in cases of crimes of manslaughter and culpable personal injury committed with violation of the rules on health and safety at work, the conceptual threshold of acceptability, for the purposes of exemption from Legislative Decree no. 231/2001, is represented by the implementation of a conduct (not accompanied by the will of the event-death/personal injury) violating the organisational prevention model (and the underlying mandatory obligations prescribed by the prevention regulations) despite the punctual compliance with the supervisory obligations provided for by Legislative Decree no. 231/2001 by the appropriate body.

This is because the fraudulent circumvention of organizational models appears incompatible with the subjective element of the crimes of manslaughter and culpable personal injury, referred to in art. 589 and 590 of the Criminal Code.

1.7. Confindustria and Fise – Assoambiente Guidelines and the UNI ISO 11961/2024 and 37301/2021 Guidelines

In order to offer concrete help to companies and associations in the development of the Models and in the identification of a control body, Confindustria was the first to draw up Guidelines, which contain a series of indications and measures, essentially drawn from company practice, considered in the abstract suitable to meet the needs outlined by Legislative Decree no. 231/2001.

The Guidelines therefore aim to provide concrete indications on how to implement these Models, since it is not possible to propose the construction of decontextualized cases to be applied directly to individual operating realities.

The Guidelines therefore play an important inspiring role in the construction of the Model and the Control Body with the related tasks by the individual entity, which, however, in order to better pursue the purpose of preventing crimes, may also deviate from them, if specific business needs require it, without this being possible to assume that the requirements necessary for the drafting of a valid organizational model have not been fulfilled. management and control.

The first version of the document was drawn up in 2002 by the Working Group on the Administrative Liability of Legal Persons set up within the Tax, Finance and Business Law Unit of Confindustria. Representatives of the territorial and trade associations of the Confindustria system, representatives of member companies, as well as academics and professionals who are experts in the field participated in the work of the Group.

The Guidelines were sent to the Ministry of Justice, which in the communication sent to Confindustria (December 2003) considered them "overall adequate to achieve the purpose set by art. 6, paragraph 3, of Legislative Decree no. 231/2001", identifying only minor profiles, on which it requested further clarifications and additions.

The Guidelines have therefore been updated to incorporate the observations of the Ministry – which definitively approved them in June 2004 – but also to introduce the adjustments suggested by the application experience carried out by associations and companies in these early years, as well as to adapt them to the new internal structures of corporations, outlined by the reform of company law.

Subsequently, the Working Group set up at Confindustria provided for periodic updates to the Guidelines, the last of which was in June 2021, in consideration of the evolution of the reference regulatory framework, the new discussions on integrated compliance, the new control systems in the field of tax compliance, and the updates on *Whistleblowing* reports and other updates that have occurred over the years. New operational guidelines on Whistleblowing were issued by Confindustria in October 2023 following the transposition by the Italian legislator, with Legislative Decree 24/2023, of the European directive on the protection of reporting entities.

In February 2016, FISE-ASSOAMBIENTE also drew up guidelines for the construction of the Models pursuant to Legislative Decree 231/2001 for the specific section aimed at the prevention of environmental crimes, also following the innovations introduced in 2015 by the Legislator on Ecocrimes.

In December 2024, the UNI 11961 Guidelines for the integration of the UNI ISO 37301:2021 compliance management system were also published in support of the Organizational Management and Control Models and the Supervisory Bodies in accordance with Legislative Decree 231/2001. These indications establish coordination by themes between the indications of UNI ISO 37301/2021, the indications of Legislative Decree 231/2001 and those of the Confindustria Guidelines, for the benefit of the construction of organizational models and control activities of the Supervisory Bodies.

The preparation of the update of the Company's Organisational Model (which, as better specified below, concerned exclusively the offences referred to in Articles 24, 25, 25 ter, 25 octies, 25 quinquiesdecies and 25 sexiesdecies of Legislative Decree 231/01) was carried out on the basis of the indications provided by all the above documents in the version available at the date of drafting²³, operating the necessary "customization" aimed at applying general rules to a single operational and business context.

1.8. The Approach of the Company Aptuit (Verona) S.r.l. to the "231" regulation

Aptuit (Verona) S.r.l. (hereinafter referred to as "Aptuit" or the "Company") is a company active in the field of pharmaceutical research on behalf of third parties (so-called "Aptuit"). "Contract Research Operations" or "CRO"), born from the acquisition in 2010 by the Aptuit Group of the research and development business unit of

²³ The latest version of the Guidelines was updated in March 2014 and, on 21 July 2014, received final approval from the Ministry of Justice.

GlaxoSmithKline S.p.A.. Following this transaction, the Aptuit Group proceeded with an overall reorganization of the research services for third parties to adapt the service provided to the needs of the market and ensure sustainability for the research and development center in Verona. In January 2012, the Company adopted the first version of the Organisation, Management and Control Model pursuant to Legislative Decree 231/2001. The Company's organisational choices were thus part of the broader policy pursued by the Aptuit Group, aimed at promoting the values of fairness, transparency and legality in corporate management as expressed in the Group's Code of Conduct. In this first historical phase, the life of the Company appeared to be characterized by a deep commitment aimed at the progressive organizational reorganization of the Company, by numerous changes in top management figures, by the essential need to focus most of the company's energies on business. At the same time, the Company nevertheless considered it appropriate to proceed with the update of Mod. pursuant to Legislative Decree 231/2001. Therefore, considering the framework of the complex changes taking place, the constant commitment to the most scrupulous compliance with the rules also on the health and safety of workers, the frequent and penetrating controls by various public and private bodies, the mandatory subjection for Pharmaceutical Research to fundamental ethical principles for development, the manufacture, safety and efficacy of drugs, with particular regard to Good Standard Practice (GXP), decided, with Board of Directors Resolution of 20/01/2016, to update Model 231 in the areas of activity and risk considered most sensitive, making a selective choice of the predicate offences and "limiting the updating activity as well as the operation of the Model and, consequently, the obligations and charges of the SB to the following offences: a) Bribery, Undue inducement to give or promise benefits and Corruption referred to in art. 25 of Legislative Decree 231/2001 b) Corruption between private individuals referred to in art. 25ter, letter s-bis) of Legislative Decree 231/2001 (Board of Directors Resolution 20/01/2016).

The new corporate structure and organization determined following the acquisition of the Company by the company Evotec AG of Hamburg (now Evotec SE) with consequent entry into the Evotec Group from August 2017, has led the Company to resume the project of completion of the organizational structure pursuant to Legislative Decree 231/2001. With the Board of Directors Resolution of 12 December 2018, the company therefore decided

“ ... as a result of the changed regulatory framework, as well as assessments shared by the directors, it is necessary to update and extend the Company Model to the following offences: a) Corporate offences referred to in Article 25 ter of Legislative Decree 231/2001 in the new wording amended by Legislative Decree no. 38 of 15/03/2017 art. 6, in force since 14/04/2017. These offences are not currently covered by the Model; b) Crime of Corruption between private individuals referred to in art. 25-ter, letter s-bis) of Legislative Decree 231/2001, already provided for in the current organizational model but to be updated in the new formulation of the rule amended by Legislative Decree 15/03/2017 n. 38 art. 6 in force from 14/04/2017; c) Undue receipt of disbursements, fraud to the detriment of the State or a public body or to obtain public disbursements and computer fraud to the detriment of the State or a

public body pursuant to Legislative Decree 231/2001 art. 24. These offences are not currently covered by the Model. “

In 2021, given the introduction by the legislator in 2019 of the new predicate crimes of liability (tax crimes and smuggling crimes) with arts. 25 quinquiesdecies and 25 sexiedecies of Legislative Decree 231/2001, with the Board of Directors Resolution of 20 March 2021, the Company decided to proceed with a new update of the Organisational Model with regard to the scope of the new predicate offences thus introduced. It also resolved, with a view to completing its organisational path for the areas not yet covered, to proceed with the extension of the Organisational Model to predicate offences in the field of health and safety in the workplace and in environmental matters.

In December 2023, the Company resolved to further update the General Part of the Model in light of the legislator's amendments to predicate offences and the mandatory information following the new whistleblowing system referred to in Legislative Decree no. 24 of 2023.

The update of the Model referred to in this document concerns the following profiles:

1. the reformulation of the risk analysis according to the best practices of the process approach, including the predicate offences introduced in Legislative Decree 231/01 after the last update of the Organisational Model in 2021 and identification of the related safeguards with possible gap analysis;
2. the rewriting of Special Parts 1 and 1 bis by creating a single Special Part 1 document, together with the related risk matrix;
3. the integration of the predicate offences referred to in art. 25-octies of Legislative Decree 231/2001 ("Receiving stolen goods, laundering and use of money, goods or utilities of illegal origin, as well as self-laundering") and related risk analysis (crimes already existing at the time of approval of the previous Organizational Model).

The current framework is therefore given by the supervision of the crimes of Legislative Decree 231/2001 limited to **articles 24** (Undue receipt of disbursements, fraud to the detriment of the State, a public body or the European Union or for the achievement of public disbursements, computer fraud to the detriment of the State or a public body and fraud in public supplies), **25** (embezzlement, undue use of money or movable property, bribery, undue inducement to give or promise benefits and corruption), **25 ter** (Corporate crimes), **25 septies** (Crimes of manslaughter and serious or very serious culpable injuries, committed in violation of accident prevention regulations and on the protection of hygiene and health at work), **25 octies** (Receiving stolen goods, laundering and use of money, goods or utilities of illegal origin, as well as self-laundering), **25 undecies** (Environmental crimes), **25 quinquiesdecies** (Tax crimes) and **25 sexiesdecies** (Smuggling) of Legislative Decree 231/01.

In particular, the path undertaken for the implementation of the "231" project by the Company was aimed at:

- identify the risk profiles through the mapping of the activities/processes existing within the scope of the activity carried out, the subsequent analysis and monitoring of the functional and organizational peculiarities and the identification of the areas that represent the main potential sources of criticality in relation to the crimes listed in point 1.1 above;
- assess the compatibility of the existing organisational and control mechanisms with the requirements expressed by the Decree;
- identify any deficiencies and define an Improvement Plan to overcome them;
- implement an Organizational Model in compliance with the provisions of the legislation and with the indications of Confindustria.

Leaving aside the strictly legal-sanctioning aspect, which was mentioned above, the adoption of a system of rules aimed at reaffirming the compliance of the entity not only with respect to legal rules, but also to ethical values can represent an opportunity.

The adoption of an Organisational Model that makes internal procedures more transparent and increases accountability, as well as guaranteeing exemption from administrative liability, **is in fact an opportunity for growth and development** for the parties concerned, improving, on the one hand, their relationship with the company and, therefore, their public image and, on the other, reducing the transaction costs deriving from any legal actions and bargaining processes.

Aware of these advantages, the Company has adopted: **a)** a Code of Conduct since 2012 (at the time of the adoption of the first version of the Model pursuant to Legislative Decree 231/2001); since January 2020 the Code of Conduct adopted by the entire Evotec group, in its subsequent and periodic updates, and which has replaced the local Code of Conduct. The current Code of Ethics and Business Conduct of the Evotec Group, as of the last update of 2024, contains an appendix called "*Ethical Rules of Aptuit (Verona) s.r.l.* ", valid only for the Italian Company in application of Legislative Decree 231/2001; **b)** an Organisation, Management and Control Model pursuant to Legislative Decree 231/01 (also the "Organisational Model" or "Model" or "Model 231"), in order to implement the organisational system through the adoption of behavioural models that are now of considerable importance in competition on the markets and which are often decisive, like sophisticated corporate governance rules, in influencing the performance of the company; **(c)** of a specific Whistleblowing Procedure of Aptuit (Verona) S.r.L., in application of local legislation (Legislative Decree 24/2023) flanked in line with the Whistleblowing procedures of the Evotec Group

All the above-mentioned documents are available on the website of the Parent Company Evotec SE, in the "Ethics & Compliance" section.

The commitment to ethical values must therefore be perceived as a means to achieve better performance, improve one's organizational structure and give a positive image of oneself.

The "*moralization*" of the entity and the pursuit of the "integrity" of the entity itself therefore represents a sure moment of enhancement of entrepreneurial activities.

2. THE METHODS OF DRAFTING THE ORGANIZATIONAL MODEL

2.1. The Principles for defining the procedure for drafting the Model

In the creation/updating of the Company's Organisational Model, the indications provided by the current regulatory framework were followed, also in the light of the interpretation given by the most recent jurisprudence, as well as the procedural indications drawn up by Confindustria and reported in the Guidelines, already assessed and deemed suitable by the Ministry of Justice.

In fact, the Ministry has specified that "in addition to containing a summary illustration of the contents of the legislative decree that introduced the administrative liability of companies, the guidelines in fact provide members with clear and precise indications on almost all the aspects that the aforementioned Article 6 lists for the purpose of preparing business organization models, proposing various alternatives for each of these aspects, warning of the possible dangers or disadvantages deriving from the adoption of certain business strategies, punctually identifying the areas of risk for each type of crime".

The question that each subject must ask himself when deciding to adopt an Organizational Model for the purpose of excluding liability pursuant to Legislative Decree 231/2001, in fact, is that of **the assessment of the suitability of such a Model to achieve the purpose for which it is adopted**, i.e. to prevent the commission of crimes and therefore, as a mediated effect, to exclude the liability of the entity on the basis of the similar assessment that the judge will subsequently have to make of this Model.

Obviously, this evaluation must be made *ex ante*, i.e. basing the examination on experience data and lowering the Organizational Model into the reality of each individual subject, with specific reference to the structure considered and the activity actually carried out.

The implementation phase of the Organisational model, therefore, followed the scheme followed in the elaboration of the Guidelines for the construction of the models, based, as already mentioned, on the most widespread risk assessment and risk management processes normally implemented in companies.

It is clear, however, that the concrete preparation of the Organisational Model, in order to achieve the result of ensuring sufficient preventive effectiveness, has been defined and concretely implemented on the basis of the characteristics of the subject to which it applies.

The risk of crime, in fact, is strictly dependent on the economic sector in which one operates, the corporate structure, the operating procedures adopted in practice, and the size of the entity.

Consequently, the structure and articulation of the Organizational Model that will be outlined later in the special part have taken into account all these specificities.

2.2. The essential phases of implementation of the Organizational Model

This Organisational Model must be suitable for preventing the offences envisaged by Legislative Decree 231/2001 included in the scope approved by the Board of Directors.

Consequently, the first objective for the construction of an Organizational Model is the proceduralization of activities that involve a risk of crime, or alternatively the identification of specific control points, in order to avoid their commission.

It should be noted, in this regard, that it is clear that the same crimes can still be committed even once the Model has been implemented but, in this case, where they are intentional crimes, they can only be committed if they are really intended by the agent both as conduct and as an event, regardless of the internal directives that the entity has adopted.

In this case, the Model and the related measures must therefore be such that the agent must not only "*want*" the criminal event (e.g. bribe a public official) but will be able to implement his criminal purpose only by fraudulently circumventing (e.g. through artifices and/or deceptions) the indications of the entity. The set of measures that the agent, if he wants to commit a crime, will be forced to "*force*", must be carried out in relation to the specific activities of the entity considered at risk and to the individual crimes hypothetically linked to them.

This logic is consistent with the consolidated international references in terms of internal control and corporate governance and is the basis of the best risk self-assessment systems (Control Self Assessment).

The international reference commonly accepted as a reference model in terms of governance and internal control is the Internal Control Integrated Framework ("CoSO Report"), produced in the USA in 1992 by the Committee of Sponsoring Organizations of the Treadway Commission updated in May 2013 on the internal control system and the Enterprise Risk Management Framework (so-called ERM), also issued by the CoSO

in 2014 on risk management. of which the latest version of the Application Guidelines was released in November 2020²⁴.

In the case, on the other hand, of culpable crimes, they must be desired by the agent only as conduct and not also as an event.

Despite the necessary customization of the implementation procedures and the characteristics of the model, it is still possible to identify the fundamental characteristics of the correct methodology for the implementation of a risk management system.

In this regard, it is appropriate to recall that, with reference to the extension of Legislative Decree no. 231 to the crimes of manslaughter and serious or very serious culpable personal injury committed in violation of the rules on health and safety at work, the current legislative discipline of the prevention of occupational risks dictates the essential principles and criteria for the management of health and safety at work in the company and therefore, in this context, the Organizational Model cannot disregard this precondition.

More generally, the update to the Model prepared by the Company is the result of the documented methodological application of the indications that will now be outlined, depending on the internal (organisational structure, territorial structure, size, etc.) and external (economic sector, geographical area) operating context, as well as the individual offences hypothetically linked to the specific activities of the entity considered to be at risk, but within the scope of update outlined by the Board of Directors, which, as specified above, includes only intentional crimes. From now on, therefore, the discussion will refer exclusively to the crimes of the perimeter.

The concrete implementation methods will be subsequently and in detail identified in the Special Parts of this Model.

Here, however, the procedural rules followed for the definition of the Model will be described, regardless of the concrete application to the company reality.

In particular, the operational phases carried out are as follows:

a) Inventory of the company's areas of activity by understanding and mapping the organization and its context.

The performance of this phase involves, in particular, an exhaustive review of the company's reality, with the aim of identifying the areas that are affected by the potential cases of crime.

As part of this procedure for the review of processes/functions at risk, it is appropriate to determine the scope of application of the 231 preventive system by identifying the subjects subject to the monitoring activity which, with reference to intentional crimes,

²⁴ <https://www.coso.org/Documents/Compliance-Risk-Management-Applying-the-COSO-ERM-Framework.pdf>

in certain particular and exceptional circumstances, could also include those who are linked to the company by mere para-subordination relationships, such as agents, or other collaborative relationships.

Finally, it should be emphasized that each company/sector has its own specific areas of risk that can only be identified through a precise internal analysis. A position of obvious importance for the purposes of the application of Legislative Decree no. 231/2001, however, is played by the processes of the financial area. The law, probably for this very reason, highlights them with a separate treatment (Article 6, paragraph 2, letter c)), although an accurate evaluation analysis of the business areas "at risk" should still bring out the financial one as one of certain importance.

b) Analysis of potential risks

The analysis of potential risks must take into account the possible methods of implementing the crimes in the various business areas (identified according to the process referred to in the previous point).

The analysis, preparatory to a correct design of preventive measures, must result in an exhaustive representation of how the types of crime can be implemented with respect to the internal and external operating context in which the company operates.

c) Evaluation/construction/adaptation of the preventive control system

The activities described above in points a) and b) are completed with an assessment of any existing preventive control system and its adaptation where necessary, with a view to an integrated approach between existing procedures and control systems to guarantee general corporate compliance.

The system of preventive controls must be such as to ensure that the risks of committing crimes, according to the methods identified and documented in the previous phase, are reduced to an "acceptable level", according to the definition set out above.

In essence, it is a matter of designing what Legislative Decree no. 231/2001 defines as "specific protocols aimed at planning the formation and implementation of the decisions of the entity in relation to the crimes to be prevented".

The components of an internal control system (preventive), for which there are consolidated methodological references, are many and must be integrated into an organic system, in which not all of them necessarily have to coexist and where the possible weakness of one component can be counterbalanced by the strengthening of one or more of the other components in a compensatory key.

What has just been said applies especially in consideration of the size of the company,

However, it should be reiterated that, for all entities, whether large, medium or small, the system of preventive controls must be such that the same, in the case of intentional crimes, can only be circumvented intentionally.

2.3. Control Principles at the basis of Aptuit's Organizational Model

The procedures described above for the implementation of the Organisational Model are aimed at creating a system of suitable preventive controls.

These control mechanisms, however, must necessarily be organically integrated into a system architecture that respects a series of **control principles**.

The principles underlying the Organisational and Management Model adopted by the Company are as follows:

"Every operation, transaction, action must be: verifiable, documented, consistent and congruous".

For each operation there must be adequate documentary support on which checks can be carried out at any time that certify the characteristics and reasons for the operation and identify who authorised, carried out, recorded and verified the operation itself.

"No one can manage an entire process independently."

The system must ensure the application of the principle of separation of functions, according to which the authorization to carry out an operation must be under the responsibility of a person other than the person who accounts, operationally executes or controls the operation.

In addition, it is necessary that:

- no one is to be given unlimited powers;
- the powers and responsibilities are clearly defined and known within the organization;
- the authorization and signing powers are consistent with the organizational responsibilities assigned.

"Documentation of controls".

The control system should document (possibly through the drafting of reports) the performance of controls, including supervision.



2.4. The main phases of implementation of the Model

After its drafting/updating, the Model is submitted for approval to the Company's Administrative Body which, at the same time, identifies and appoints the Surveillance Body, as specified in more detail in the following paragraph⁴, with the allocation of compensation and budget.

The Company, considering it essential to fully disseminate and disseminate the Model to all interested parties, whether internal or external, undertakes to ensure that the contents of the same and, in particular, of the Code of Conduct, are the subject of specific information and training activities, using all the tools and methods available. For the operating procedures, please refer to the specific procedures included in the Special Section.

Finally, the monitoring of initiatives for the dissemination of knowledge and understanding of the Model is one of the tasks assigned to the Surveillance Body, as better explained below.

3. COMPANY PROFILE

In accordance with the requirements of the Confindustria Guidelines and on the basis of the indications provided by the best case law on the subject, the Organisational Model adopted by the Company has been conceived and designed in relation to the specific characteristics of the company, from which the risk profiles and the most consistent structuring of internal controls and protocols aimed at the prevention of relevant crimes inevitably derive.

3.1. The History and Activities of the Company

As mentioned above, Aptuit is a company born from the acquisition in 2010 by the Aptuit Group of the research and development business unit of GlaxoSmithKline S.p.A. and, since then, has mainly carried out pharmaceutical research activities on behalf of third parties (so-called pharmaceutical research on behalf of third parties). "Contract

Research Operations" or "CRO"). Following this acquisition, the Aptuit Group proceeded with an overall reorganization of the research services for third parties to adapt the service provided to the needs of the market and ensure sustainability for the research and development center in Verona, allowing

the Company to maintain the scientific expertise of the research center in the field of neuroscience, cardiovascular, infectious diseases and, in general, of all the scientific disciplines necessary for the discovery and development of new drugs to offer customers a highly integrated and articulated service.

Since August 2017, the Company has become part of the multinational group Evotec SE, a company based in Germany, which will be discussed in more detail later.

The Company's core business is basically to create and develop new drugs. The mission is to create value for shareholders and other stakeholders in a sustainable way, integrating with the other legal entities of the Evotec Group and exploiting the resulting synergies, in any case respecting the code of conduct adopted at Group level. To this end, the company offers a comprehensive set of integrated solutions for drug development, focusing on (i) scientific excellence, (ii) excellent service, and (iii) leveraging a team of some of the industry's leading scientific professionals.

The Company is authorized by the Ministry of Health to operate as an establishment for the use of animals for scientific purposes and therefore also operates through research on animal experimentation in full compliance with current regulations. As a result, the Company, over the last few years, has been exposed to repeated objections by animal rights associations that pursue the ultimate goal of putting an end to scientific research activities with the use of animals in Italy, despite the fact that animal tests are legally (and scientifically) necessary for the authorization of drugs on the market. It is currently involved in several investigations and disputes, which also concern its exponents for the alleged crime of "*animal abuse*"

. Even on the date of approval of this Model, a heated debate on the subject is underway. In the event of an evolution of the predicate offences under 231 in a pertinent sense, the Company may revise the risk analysis by also considering the offence in question.

On the date of approval of this Model, the Company has approximately no. 800 employees, most of them highly specialized researchers, which allow it to be considered a center of excellence in pharmaceutical research in Italy. It is also characterized by the presence of the following Business Areas, which are divided as follows:

- **Integrated Drug Discovery and Drug Discovery Services (collectively understood as "Discovery Sciences")**, engaged in the validation processes of innovative biological targets for the treatment of diseases with unmet therapeutic needs, in the identification, development and synthesis of innovative and patentable chemical molecules, suitable for development as new drugs;

- **Preclinical Sciences**, engaged in preclinical activities aimed at characterizing molecules to allow experimentation in compliance with the specifications required by current national and international legislation. These activities include, among other things, the evaluation of the safety or possible toxicity of the drug, the development of bio-analytical techniques to measure the concentrations of drugs in biological matrices, the studies necessary to understand the phenomena of absorption, distribution, metabolism and elimination by complex living organisms and the identification of therapeutic doses to be evaluated in research;
- **Pharmaceutical Sciences**, engaged in activities aimed at the production of pharmaceutical ingredients and products according to the so-called "Pharmaceutical Sciences". Good Manufacturing Practice (GMP). The latter are necessary to guarantee the safety requirements of pharmaceutical products for their experimentation in human beings and to identify the most suitable chemical synthesis routes and pharmaceutical forms for the transfer of production processes to an industrial scale

In carrying out the specific pharmaceutical research and development activity, in order to proceed with the experimentation and development phases of the final product, the Company is subject to stringent controls and authorizations by various Public Bodies with which it constantly interacts, among which are the Ministry of Health, the National Institute of Health, AIFA (Italian Medicines Agency), EMA (European Medicines Agency), ULSS and others.

3.2. The Organization

A – Aptuit as part of the Evotec Group

Aptuit belongs, as previously mentioned, to the German multinational group Evotec. In particular, the Company is subject to the management and coordination of others by Evotec SE (indirect control) and Aptuit Global LLC (direct control). In this regard, in order to accurately photograph and allocate the decision-making dynamics, the particularly pervasive nature of this management and coordination activity by the Parent Company should be highlighted: the directives for the most important strategic, entrepreneurial and financial decisions are issued by the Parent Company on an ongoing basis. The composition of the Board of Directors itself is significant in this regard, given that directors of the same Parent Company also sit on it.

Evotec SE is a multinational company headquartered in Hamburg (Germany), 22419, Manfred Eigen Campus, Essener Bogen 7, a company particularly active in the field of "Drug Discovery" as well as a development partnership company focused on innovative product approaches in rapid evolution with major pharmaceutical and biotechnology companies.

Evotec SE, already listed on the Frankfurt Stock Exchange, has also been listed on the Nasdaq since November 2021 and therefore, by virtue of this latest listing, the Company

is required to operate from 1 January 2022 in accordance with the Sarbanes-Oxley Procedures.

The Evotec Group has as its core business that of pharmaceutical research for third parties.

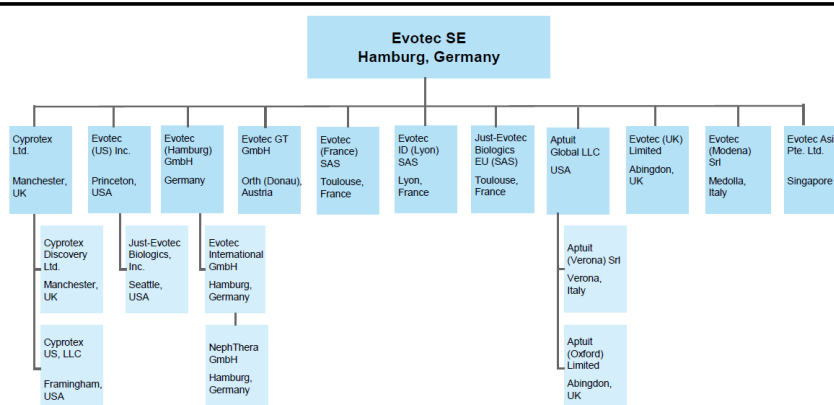
The entire share capital of the Company, equal to Euro 8,010,000.00, is held by the Sole Shareholder Aptuit Global LLC, a US company with registered office at 303B COLLEGE ROAD EAST, PRINCETON, NJ 08540, USA. In turn, Aptuit Global LLC is a wholly owned subsidiary of Evotec SE. Aptuit's local procedures, referred to as risk containment measures in this Organisational Model, are always consistent with the corresponding group procedures and are reviewed at least once a year.

The following diagram shows the structure of the Evotec Group at the date of drafting of this Model:



The Evotec Group

Legal structure



Status January 2025

The Company has in place with the other companies of the Evotec Group – Aptuit Division and Evotec Division, intra-company service contracts, annually renewed, by virtue of which the aforementioned Companies mutually exchange services of various kinds.

B - The internal operating structure

With regard to the Company's operating structure, reference is made to the Company's Organization Chart, which is periodically updated and available on the company intranet. It highlights lines of reporting and functional dependency which, as is typical of integrated groups, disregard the logic of the single legal entity to embrace integrated group management.

C- Internal Administration and Control System

The administration system adopted is that of the Board of Directors. There are currently four members of the Board of Directors, with equal powers attributed by the Board of Directors itself, one of whom is Chairman of the Board of Directors. Pursuant to the Articles of Association, the directors are assigned the legal representation of the Company within the limits of the powers received. The Directors hold powers with single or joint signature with other directors or First Level managers identified by subject matter and/or value, which can be delegated pursuant to the Articles of Association. The Chairman of the Board of Directors is identified as the Employer pursuant to art. 2 lett. B of Legislative Decree no. 81/2008; another Director is delegated for the purposes of processing personal data.

The **First Level Managers** are identified and appointed by means of a board resolution reported in the company profile, which also highlights certain **attorneys of company areas considered particularly sensitive**.

The **external control system** is entrusted, as far as legality control is concerned, to the Statutory Auditors composed of three standing members and two alternate members and, as regards accounting control, to a leading Independent Auditors.

The graphic representation of the various company functions is expressed by the Organization Chart available on the company intranet, with regard to the definition of the roles relevant to the application of internal procedures.

4. THE SURVEILLANCE BODY

4.1. Identification, Composition and Appointment

Given that the Surveillance Body is responsible for monitoring and proposing the updating of the Model and the Code of Conduct, it should be noted that the Company pays attention to ensuring that the skills expressed by it are particularly qualified in matters relevant to the Decree and in possession of the integrity requirements referred to in art. 109 of Legislative Decree 85/93. The Company also establishes that it is endowed with autonomous powers of intervention in the areas of competence, involving internal personnel and/or external collaborators to ensure the continuous

performance of the verification of the adequacy and suitability of the Model. The specific skills are identified according to the risks of crime that this Model aims to prevent.

For the checks and actions requested from the Surveillance Body and relating to specific issues, the same may make use of professionals identified at its discretion, informing the Administrative Body in advance. Financial coverage will be ensured by the expenditure budget made available to him at the time of appointment, with only the obligation to report on the expenditure.

4.2. Requirements

The requirements that characterize the Surveillance Body and make it effective are:

- **autonomy and independence**, as clarified in the Confindustria Guidelines, the position of the Surveillance Body in the Entity "must guarantee the autonomy of the control initiative from any form of interference and/or conditioning by any body of the Entity", including the management body. The Surveillance Body must be guaranteed hierarchical independence and its members must not be directly involved in management activities that are subject to control by the same Body or linked to the managers of the Entity or to the Entity by any parental ties, significant economic interests (shareholdings) or by any situation that may generate a conflict of interest;
- **professionalism**, to this end, the members of the aforementioned Body must have specific knowledge in relation to any technique useful for preventing the commission of crimes, to discover those already committed and identify their causes, as well as to verify compliance with the Organizational Model by members of the company organization and, when necessary, propose the necessary updates to the Organizational Model;
- **continuity of action**, through a structure dedicated to constant supervision of compliance with the Organisational Model, capable of constantly verifying the effectiveness and effectiveness of the Model and providing for its continuous updating. This structure must be characterized by limited revocability and limited renewability. Furthermore, the duration of the office must be long enough to allow a stable and professional exercise of the function, but not so much as to create strong ties with the top management from which situations of conditioning could arise;

In consideration of the above and the specificities of its corporate reality, with particular regard to the current internal legal competences and the opportunity to externalize those of a corporate nature, the Company has deemed it appropriate, in light of the characteristics of the Organizational Model adopted, to establish a collegial Surveillance Body composed of two members with proven experience, competence and professionalism, as indicated below:

- a) **an external member** with specific skills in supervision, auditing and legal;
- b) **an internal member** with specific legal skills, contact person for the Legal area, who is in no way involved in the management activity of the Company and who ensures a high level of professionalism and autonomy.

The persons who will assume the role of members of the Company's Surveillance Body must carry out their duties with the diligence required by the nature of the assignment, the nature of the activity carried out and their specific skills.

The members of the Company's Surveillance Body must meet the **integrity requirements provided for by Article 109 of Legislative Decree No. 385 of 1 September 1993**. Failure to meet these requirements shall result in the ineligibility and/or forfeiture of the Surveillance Body and its members.

In particular, the following constitute grounds for ineligibility and/or forfeiture:

- the conditions referred to in Article 2382 of the Italian Civil Code;
- the conviction with a sentence, even if not final, or the plea bargain sentence, for having committed an offence among those provided for by Legislative Decree 231/01;
- the imposition of a sanction by CONSOB, for having committed one of the administrative offences in the field of market abuse, referred to in the TUF.

It should be noted that the spouse, relative and relative within the fourth degree of the directors of the Company, the directors, the spouse, the spouse, the relative and the relative within the fourth degree of the directors of the companies controlled by the Company, of the companies that control it and of those subject to common control may not be appointed as a member of the Surveillance Body and if appointed, the spouse, the relative and the relative within the fourth degree of the directors of the companies controlled by the Company, of the companies that control it and of those subject to common control.

The appointed persons must self-certify that they are not in any of the conditions indicated above, expressly undertaking to notify the Board of Directors of any changes to the content of this declaration, as soon as they occur.

In cases of particular and proven gravity, the Board of Directors, subject to the positive opinion of the Company's Board of Statutory Auditors, may in any case order the suspension of the powers of the Surveillance Body and the appointment of an interim body.

The appointment and dismissal of the Surveillance Body is the exclusive responsibility of the Company's Board of Directors.

In order to ensure the effective and constant implementation of the Model, as well as continuity of action, the term of office of the Surveillance Body is set at three financial years expiring upon approval of the financial statements referring to the last of the three, renewable, by resolution of the Company's Board of Directors. The termination of the Surveillance Body due to expiry of the term takes effect from the moment it is reconstituted by resolution of the Board of Directors, subject to any renewal.

The Board of Directors of the Company reserves the right to establish for the entire duration of the office the annual remuneration, adequately remunerative of the skills and professionalism expressed, as well as the frequency and characteristics of the verification activities provided for by the Model for the participation of individual members in the Surveillance Body.

The Board of Directors of the Company may revoke the members of the Surveillance Body only for just cause. In the event of revocation or forfeiture, the Board of Directors of the Company shall promptly replace the revoked or lapsed member, subject to ascertaining that the new member meets the subjective requirements indicated above.

In order to give the Surveillance Body the ability to obtain information and therefore to act effectively with regard to the Company's organisation, this Model also establishes the methods of information flows to and from the Surveillance Body.

4.3. Functions and Powers

The Surveillance Body, with regard to the provisions of the Decree, is called upon to perform the following **functions**:

- ensure constant and independent monitoring of compliance **with** and **adequacy** of the Company's procedures and processes in order to prevent, as established in the Resolution of the Board of Directors of 20/01/2016, the commission of offences limited to a) Bribery, Undue inducement to give or promise benefits and Corruption referred to in art. 25 of Legislative Decree 231/2001 b) Corruption between private individuals referred to in art. 25ter, letter sbis) of Legislative Decree 231/2001 and identified in the Company's risk mapping, in accordance with the provisions of the Decree;
- ascertain the **effectiveness** of the Model, i.e. ensure that the conduct envisaged therein is consistent with the Company's actual operations;
- verify the **functionality** of the Model, i.e. its ability to effectively prevent the commission of crimes;
- analyze the applicability of the Model in order to assess, over time, its **maintenance** of solidity and functionality;
- take care of the necessary **updating**, in a dynamic sense, of the Model, both through the presentation of adaptation proposals to the Governing Body, and then

ascertaining the implementation and functionality of the proposals made and accepted;

- verify the real **effectiveness** of the Model, in relation to the structure of the Company, in preventing the commission of the identified crimes;
- verify the adequacy of the **sanctioning system** in relation to its applicability, effective application and effectiveness;
- monitor initiatives for the **dissemination of knowledge** and understanding of the Model and preparation of the internal documentation necessary for its operation, containing instructions, clarifications or updates;
- manage whistleblowing reports in the event of appointment as a manager;
- **report periodically**, or promptly if necessary, to the Administrative Body on the implementation of the Model's policies, with reference to the activities carried out, the reports received, the corrective actions implemented and the possible corrections or implementations to the Model.

Therefore, as part of the above activities, the Surveillance Body will provide for the following **obligations**:

- verify in the context of the Company the knowledge and understanding of the principles outlined in the Model and, in particular, of the Code of Conduct;
- establish specific "dedicated information channels", aimed at facilitating the flow of reports and information to the Body by the Company's employees or other recipients of the directives issued by the Company through the adoption of the Model itself, also due to the new Article 6 of Legislative Decree 231/2001, paragraphs 2-bis, 2-ter and 2-quarter ("*Whistleblower*") inserted by Art. 2 of Law no. 179 of 30/11/2017 with effect from 29/12/2017;
- promote, when necessary, the periodic review of the Code of Conduct and the mechanisms of its implementation.

In order to adequately and concretely carry out the functions, tasks and obligations listed above, the Surveillance Body is granted the **powers** to:

1. access directly, or by delegation on their behalf, to any and all documents relevant to the performance of the functions assigned to the Surveillance Body pursuant to the Decree, granting them appropriate discretion for this purpose within the scope and limits of the purposes of their activity;
2. carry out periodic checks, even if not pre-agreed, on the application and compliance with the Model by all recipients with regard to the requirements established in relation to the different types of crimes contemplated by the Decree;
3. conduct reconnaissance on the Company's activities for the purpose of updating company procedures;

4. propose training programmes for staff on the Model and its contents in collaboration with the directors/department managers;
5. collect, process and store the relevant information regarding compliance with the Model, as well as update the list of information that must be transmitted to him or kept available to him, constituting the "formal" database of internal control activities;
6. coordinate with the other company functions in carrying out the monitoring activities for which they are responsible and provided for in the procedures;
7. verify the adequacy of the internal control system in relation to these regulatory requirements, also making use of specific legal advice;
8. to check the actual presence, regular maintenance and effectiveness of databases and archives in support of the activity deriving from compliance with the Decree;
9. if appointed as a whistleblowing manager, access to any data or system necessary for the management of Whistleblowing reports.

Furthermore, in order to allow the Body to correctly exercise the tasks and powers attributed to it, within the limits and under the conditions required by law, it is established that:

- the Surveillance Body must always be kept informed about the organisational, managerial and operational structure of the Company, in particular with regard to the facts listed in the following paragraph dedicated to the flow of information to the Surveillance Body;
- the Surveillance Body is assigned an autonomous expenditure budget that can and must be used exclusively for disbursements that may be necessary for the performance of verification and control activities;
- all the Company's Bodies, employees, consultants, "project" collaborators and third parties acting on behalf of the Company in any capacity, are required to provide the utmost collaboration in facilitating the performance of the functions attributed to the Surveillance Body;
- taking into account, on the one hand, the purposes of investigation and verification related to the tasks assigned to the Surveillance Body and, on the other hand, the structure of the Company, the control activity carried out by the Surveillance Body also concerns the work of the Administrative Body;
- the Surveillance Body is obliged to maintain absolute confidentiality with regard to any and all information that it may become aware of in the exercise of its functions, including all whistleblowing information pursuant to Legislative Decree 24/2023 from which the identity of the reporting person, the person involved and the person in any case mentioned in the report can be derived, as well as the content of the report and related documentation;

- the same Surveillance Body has its own regulations for the performance of the tasks and functions required.

4.4. Information Flow Directed to the Surveillance Body

The Recipients of the Model are required to promptly report to the Surveillance Body those acts, behaviors or events that may constitute relevant unlawful conduct pursuant to Legislative Decree 231/2001 and/or determine a violation of the Model or, more generally, are relevant for the purposes of prevention/sanctioning the crimes provided for by Legislative Decree 231/2001.

The Surveillance Body is bound to secrecy with regard to the news and information acquired in the exercise of its functions.

As for the **information flows towards the Surveillance Body**, the latter must be promptly informed or receive adequate documentation regarding:

- Reports of conduct and/or news relating to the violation of the Organizational Model / Code of Conduct
- Measures and/or news from the Judicial Police or any other authority from which it is clear that investigations have been carried out against persons operating for the Company and also against unknown persons, for the offences provided for by the Organisational Model
- Access for inspection purposes or for the issuance of authorizations and licenses by Public Administration bodies or private certifiers, distinguishing those scheduled from those not scheduled
- Reports relating to the effective application of disciplinary sanctions imposed for violation of the Organizational Model
- Reports of risky transactions capable of altering the risk predetermined in the Organisational Model
- Reports relating to the Company's customers under investigation for crimes pursuant to Legislative Decree 231/01
- Reports relating to the Company's suppliers under investigation for crimes pursuant to Legislative Decree 231/01
- Changes in organizational structure
- Changes in the organizational structure – EHS organization chart
- Minutes of the meetings of the Board of Directors / Shareholders' Meeting

Transmission of a short report on tenders and construction sites started and their management

- Changes in the system of delegations and powers
- Report audits interni
- Report audits interni – EHS
- Issue of procedures relevant for the purposes of 231
- List of purchase orders for an amount greater than Euro 50 thousand and less with an unclear description of the activity (in excel format)
- List of consultancy contracts signed during the period with evidence of counterparties, amounts and duration (in excel format)
- Reports of authorizations to pay for work meals exceeding the procedural limits
- Evidence of the situation of collections from customers and reporting of any outstanding payments
- **HR sector:** accident report
- (Note: since the paper register has been repealed, only the online communication/complaint could be attached. Agreed in the SB to request a copy of the register for trim. and the latest online communication)
- **EHS sector:** analysis of accidents, illnesses, near misses and adverse events
- **Environment Sector:** news of any adverse environmental events
- Transmission of the list of applicable legal requirements
- Communication of updating documentation relating to risk assessment in general and assessments for specific risks including comments on the main changes and improvement plans (DVR)
- Information on active tenders and construction sites
- Transmission of EHS internal audit reports and monitoring
- Transmission of the minutes of the periodic meeting pursuant to Article 35 of Legislative Decree 81/08
- Transmission of the evacuation test report
- Trasmissione Training MATRIX EHS
- Environment Sector: Results of the supervision carried out during the calendar year prior to the periodic meeting

- Environment Sector: Risk analysis of the commission of crimes after each update

The SB may propose to the Board of Directors any changes to the list indicated above.

4.5. Periodic checks by the Surveillance Body

The Model provides for four types of periodic checks:

- checks **on the deeds**, i.e. on all those procedures that involve the Company's commitment;
- checks **on internal procedures, regulations and instructions**, or on the documentation containing the indications to outline the prevention activities for the purposes of the Decree according to the procedures established by the Surveillance Body;
- checks **on whistleblowing reports**, i.e. on what has been reported by any interested party regarding any event considered at risk or harmful;
- checks **on the degree of transposition of the Model**, i.e. on the level of awareness and knowledge of the staff on the hypotheses of crime contemplated in the Decree, also through personal interviews.

As already stated in the previous paragraphs, the Surveillance Body prepares a report for each audit, keeping any supporting documentation under its care.

4.6. Reporting methods and periodicity

As already mentioned with regard to the functions assigned to it, the Surveillance Body reports **at least annually**, or promptly if necessary, to the Administrative Body and the Board of Statutory Auditors on the implementation of the policies of the Model, with reference to:

- the activities carried out;
- the reports received;
- the corrective actions implemented;
- possible corrections or implementations to the Model;
- the possible application of the disciplinary system, in the event of violation of the Model or of the duties of direction and supervision by top management.

The Administrative Body may request the convocation of the Surveillance Body at any time. Likewise, the Surveillance Body may, if necessary, request the convocation of the

Administrative Body to report on any offences or serious deficiencies found. A special report of each meeting with each other will be drawn up by the Surveillance Body.

4.7. Management Review

The procedural apparatus and the organization set up to oversee the identified risks are periodically subjected to verification of their effectiveness and adequacy at least once a year during the Review Meeting. Such a Meeting, unless otherwise provided, is convened by the Site Head and the Surveillance Board participates as an invitee. It will also take into account in its Annual Report the information acquired in these forums. In the individual Special Sections it is indicated:

- the person required to convene the meeting;
- the subjects to be summoned;
- the points to be addressed.

4.8. Criminal profiles of the liability of the Surveillance Body

The general duty of supervision placed at the head of the Surveillance Body has a role of absolute centrality in the effectiveness of the Model, to the point that its non-compliance would result in the inapplicability of the exemption from liability for the Company. In this regard, however, it must be said that the obligation to supervise does not imply the obligation to prevent the crime. The Surveillance Body is not vested with the obligation to supervise the commission of crimes but the operation and compliance with the Model, taking care of its updating and possible adaptation, being it, in essence, the advisory body of the Company's Administrative Body which is solely responsible for amending the Model, according to the indications and proposed by the Surveillance Body itself.

That said, the legislator had placed specific monitoring and reporting obligations on the Surveillance Body in the field of anti-money laundering, as provided for the case of failure to report relevant facts pursuant to Article 52 of Legislative Decree 231/07, the non-compliance with which constituted a crime. Following Legislative Decree 90/2017 and its amendments to Legislative Decree 231/2007 and with particular reference to the new Article 46 of Legislative Decree 231/2007 (Reporting Obligations), the SB's obligation to supervise compliance with the specific anti-money laundering legislation has been eliminated with consequent exemption from any criminal liability.

5. VIOLATIONS AND WHISTLEBLOWING REPORTING SYSTEM PURSUANT TO LEGISLATIVE DECREE NO. 24 OF 10 MARCH 2023 AND INTERNAL REPORTING CHANNEL

In implementation of the Directive (EU) 2019/1937, was issued on D.Lgs. n. 24 of 10 March 2023 in force from 15 July 2023, concerning "*the protection of persons who report breaches of Union law and laying down provisions concerning the protection of*

persons who report breaches of national law", which completely replaced the previous Whistleblowing legislation pursuant to Legislative Decree 231/2001.

The Decree applies, among others, to private sector entities that adopt Organisational and Management Models pursuant to Legislative Decree 231/2001, which must provide for internal reporting channels in the Organisational Model.

The main innovations contained in the new regulations are:

- the specification of the subjective scope with reference to public law bodies, to those under private law and the extension of the range of the latter;
- the expansion of the number of natural persons who can be protected for notices, complaints or public disclosures;
- the expansion of the objective scope, i.e. of what is considered a relevant violation for the purposes of protection and which, in the specific case of the Company (a company with more than 50 employees and equipped with the 231 Model) consist of: **a) crimes pursuant to Legislative Decree 231/2001 and violation of the 231 Organizational Model; b) violations of EU law; c) violations, non-compliance and retaliation in the field of whistleblowing;**
- the distinction between what is subject to protection and what is not;
- the regulation of three reporting channels and the conditions for accessing them: internal (in entities with a dedicated person or office or through an external party with specific skills), external (managed by ANAC) as well as the channel of public disclosure;
- the indication of different methods of submitting reports, in written or oral form;
- the detailed regulation of confidentiality obligations and the processing of personal data received, managed and communicated by third parties or to third parties;
- clarifications on what is meant by retaliation and expansion of the related cases;
- the discipline on the protection of whistleblowers or persons who communicate retaliatory measures offered by both ANAC and the judicial authority and more information on the responsibility of the whistleblower and on the exculpatory factors;
- the introduction of special support measures for reporting persons and the involvement, to this end, of Third Sector entities that have adequate skills and that lend their activities free of charge;
- the revision of the discipline of sanctions applicable by ANAC and the introduction by private entities of sanctions in the disciplinary system adopted pursuant to Legislative Decree no. 231/2001.

On 21 December 2023, the Board of Directors, in compliance with the new Whistleblowing legislation pursuant to Legislative Decree 24/2023, the Anac Guidelines and the Confindustria Guidelines, resolved on the new "Whistleblowing system" adopted by the Company, giving formal notice to the trade union representatives, consisting of the adoption:

- local Whistleblowing procedures ("*Procedure for sending/receiving Whistleblowing reports*" and the "*Procedure for managing whistleblowing reports*"), alongside the Group Whistleblowing procedure;
- the Group's shared internal channel for "231 reports" and whistleblowing in both written and oral form, through an encrypted IT platform (EQS platform called by the Group "EVOWhistle platform" - link <https://evotecgroup.integrityline.org>) and with dedicated and segregated channels for each Company;
- a Whistleblowing Reporting Manager, identified in an Ethics Committee composed of two members, identified as the Senior Legal Counsel and internal member of the Company's SB and the SVP Global Employee Relations & Work Council Management, Head of HR Italy;

in addition to having proceeded, as already mentioned above, to update the General Part of the Organizational Model for regulatory references and for interventions on the sanctioning system.

On the date of approval of this Model, the Company is proceeding to finalize the new local Whistleblowing procedure, in accordance with the local Whistleblowing legislation (Legislative Decree 24/2023), replacing the first set of local procedures mentioned above, in line with and alongside the Group Whistleblowing procedures.

The link to the platform for Whistleblowing reports, together with the Procedures and the Information on the processing of personal data, is available on the Parent Company's website in the Ethics & Compliance section.

It is the responsibility of the Company to provide all interested parties with specific training on the system for reporting offences adopted.

Furthermore, the disciplinary system, illustrated as the last chapter of this document, has expressly provided for any violation and non-compliance in the field of whistleblowing.

5.1. Prohibition of retaliatory behaviour

In compliance with the provisions of Legislative Decree 24/2023, any behavior, act or omission, even if only attempted or threatened, carried out by reason of the report, the complaint to the judicial or accounting authority or public disclosure and which causes or may cause the reporting person or the person who filed the report, directly or indirectly, is prohibited. An unjust damage.

In the context of any procedure concerning the ascertainment of prohibited conduct, acts or omissions towards reporting parties, it is presumed that they have been carried out due to the report. The burden of proving that such conduct or acts are motivated by reasons unrelated to the report, public disclosure or denunciation is borne by the person who carried them out.

In the case of a claim for damages submitted to the judicial authority by the reporting parties, if those persons prove that they have made, pursuant to this decree, a report, a public disclosure or a complaint to the judicial or accounting authority and that they have suffered damage, it shall be presumed, unless proven otherwise, that the damage is a consequence of such reporting, public disclosure or complaint to the judicial or accounting authority.

The following are certain cases that constitute retaliation:

- (a) dismissal, suspension or equivalent measures;**
- b) demotion in rank or non-promotion;**
- c) the change of functions, the change of the place of work, the reduction of salary, the modification of working hours;**
- d) the suspension of training or any restriction of access to it;**
- e) negative notes of merit or negative references;**
- f) the adoption of disciplinary measures or other sanctions, including financial sanctions;**
- (g) coercion, intimidation, harassment or ostracism;**
- h) discrimination or in any case unfavourable treatment;**
- (i) the failure to convert a fixed-term employment contract into an employment contract of indefinite duration, where the worker had a legitimate expectation of such conversion;**
- l) the non-renewal or early termination of a fixed-term employment contract;**
- (m) damage, including to the person's reputation, in particular on social media, or economic or financial harm, including loss of economic opportunity and loss of income;**
- (n) improper listing on the basis of a formal or informal sectoral or industry agreement, which may result in the person not being able to find employment in the sector or industry in the future;**
- o) the early conclusion or cancellation of the contract for the supply of goods or services;**
- (p) the cancellation of a licence or permit;**
- q) the request for psychiatric or medical examinations.**

5.2. Whistleblowing and protection of personal data

The implementation of the whistleblowing regulations and the related procedure is coordinated with the new rules introduced by the European Regulation on the protection of personal data of natural persons no. 679/2016 (so-called "Whistleblowing"). GDPR) and by Legislative Decree 196/2003 (so-called GDPR). Italian Privacy Code), as amended by Legislative Decree 101/2018. To this end, the specific processing of personal data is classified and managed by the technical and organizational measures implemented to comply with the processing of personal data by the Company with the provisions of the GDPR and the Italian Privacy Code, with particular attention to:

- assess the risk of data breach and its consequences;

- define the roles attributed to the various actors involved from the point of view of the privacy organization chart;
- enter the processing in the Register of Processing;
- ensure adequate security measures for the personal data processed;
- identify the conditions for the lawfulness of the processing;
- provide ad hoc information to data subjects;
- identify the scope of application of the processing by limiting it only to the unlawful acts indicated by the legislation and not to any type of complaint;
- regulate the right of access of the reported person and possibly limit it to reconcile his right with the obligation to protect the confidentiality of the identity of the whistleblower, as established by the new Article 2-undecies, letter f) of the Italian Privacy Code;
 - carry out the Impact Assessment on the process of receiving and managing whistleblowing reports;
 - draw up a joint controllership agreement pursuant to Article 26 of the GDPR between the group companies that share the internal whistleblowing reporting channel.

To this end, the Company also complies with the specific indications contained in Legislative Decree no. 24/2023.

5.3. Whistleblowing and protection of confidentiality

The first protection placed by the legislator in favor of the whistleblower is the obligation to guarantee the confidentiality of his identity and any other information, including any attached documentation, from which he can directly or indirectly trace the identity of the whistleblower. The same guarantee is provided in favour of the persons involved and/or mentioned in the report, as well as the facilitators, in consideration of the risk of retaliation.

This obligation is required:

- the persons responsible for receiving and managing reports;
- ANAC;

- the administrative authorities (Department for Public Administration and National Labour Inspectorate) to which ANAC transmits, for competence, the external reports received.

Confidentiality must be guaranteed for each method of reporting, therefore, even when it takes place orally.

6. DISCIPLINARY SANCTIONS AND SANCTIONING SYSTEM

An aspect of particular importance in the construction of the Model is the provision of an adequate sanctioning system for the violation of the rules of the Code of Conduct, as well as the procedures provided for by the Model.

More precisely, for the purposes of applying the penalty system, "*violation*" means:

- violations of the provisions of the Model and Code of Conduct, the rules of conduct, protocols or procedures referred to therein;
- unlawful conduct relevant pursuant to Legislative Decree 231/01 (crimes, administrative offences or acts suitable for the implementation of the same) and based on precise and concordant factual elements;
- breaches of EU law and national transposition rules;
- whistleblowing violations, non-compliances and retaliation;

Such violations in fact damage the relationship of trust established with the entity, also on the basis of the provisions of art. 2104 and 2105 of the Italian Civil Code. which establish obligations in terms of diligence and loyalty of the employee towards his employer and may, consequently, lead to disciplinary action, regardless of the possible initiation of criminal proceedings in cases where the conduct constitutes a crime.

The disciplinary assessment of the conduct carried out by employers, except, of course, for any subsequent control by the labour court, does not necessarily have to coincide with the judge's assessment in criminal proceedings, given the autonomy of the violation of the Code of Conduct and internal procedures with respect to the violation of the law that involves the commission of a crime. The employer is therefore not required, before acting, to wait for the end of any criminal proceedings in progress.

The principles of timeliness and immediacy of the sanction make it not only unnecessary, but also inadvisable to delay the disciplinary complaint pending the outcome of any trial instituted before the criminal court.

As for the type of sanctions that can be imposed, it should be noted at the outset that, in the case of an employment relationship, any sanction must comply with the procedures provided for by art. 7 of Law no. 300/70 (the so-called Workers' Statute) and/or by special regulations, where applicable, characterized, in addition to the principle of typicality of violations, also by the principle of typicality of sanctions.

Failure to comply with the provisions of the Code of Conduct and, more generally, with the protocols adopted with the Organisation, Management and Control Model pursuant

to Legislative Decree no. 231/2001, constitutes a disciplinary offence both in the event that it is carried out by an employee of the Company and in the event that the misconduct is committed by a collaborator, compatibly with the activities that may be carried out by them.

Due to their disciplinary value, the Code of Conduct and the procedures adopted in the context of the Organisation, Management and Control Model pursuant to Legislative Decree no. 231/2001, failure to comply with which constitutes a disciplinary offence, are formally declared binding for all employees at the time of communication of the adoption of the Model.

The Disciplinary System, an integral part of the Organisation, Management and Control Model pursuant to Legislative Decree no. 231/2001, is described below, containing the disciplinary sanctions as well as the related procedural aspects applicable as a result of conduct that violates the provisions of the Code of Conduct or the protocols of the Company's Model.

6.1. Disciplinary sanctions and protection of confidentiality

In the context of the disciplinary proceedings initiated by the entity against the alleged perpetrator of the reported conduct, the identity of the whistleblower cannot be revealed, where the challenge to the disciplinary charge is based on separate and additional investigations with respect to the report, even if consequent to the same. If, on the other hand, the complaint is based, in whole or in part, on the report and the identity of the whistleblower is indispensable for the defence of the person who has been charged with the disciplinary charge or of the person involved in the report, the latter will be used for the purposes of disciplinary proceedings only with the express consent of the reporting person to the disclosure of his or her identity. In such cases, prior notice shall be given to the reporting person by written communication of the reasons that make it necessary to disclose the confidential data. If the reporting party denies his/her consent, the report cannot be used in the disciplinary proceedings which, therefore, cannot be initiated or continued in the absence of further elements on which to base the complaint. In any case, the right of the entity to proceed with the complaint to the judicial authority remains unaffected, if the conditions are met.

6.2. Disciplinary sanctions for employees

In relation to employees, the Company must comply with the limits set out in art. 7 of Law 300/1970 (the so-called Workers' Statute) and the provisions contained in the National Collective Labour Agreement (CCNL) applied, both with regard to the sanctions that can be imposed and the methods of exercising disciplinary power.

The following penalties may be imposed on employees:

- i) verbal warning;
- ii) written warning;
- iii) fine;

- iv) suspension from work;
- v) dismissal.

The ascertainment of any violations may result in the worker being suspended from work as a precautionary measure.

These sanctions will be imposed on the basis of the importance of the individual cases considered and will be proportionate according to their seriousness.

In order to explain in advance the criteria for correlation between workers' violations and the disciplinary measures adopted, it should be noted that:

- An employee who:
 - a. violates internal procedures or behaves in a way that does not comply with the provisions of the Code of Conduct and the rules of conduct contained in this Model (e.g. that he/she does not comply with the prescribed procedures, fails to notify the Surveillance Body of the prescribed information, fails to carry out checks, etc.), such conduct being considered as a non-execution of the orders given by the Company;
 - b. commits violations of the Model pursuant to Legislative Decree 231/2001, excluding those unequivocally aimed at committing an offence sanctioned by Legislative Decree 231/2001;
- the employee incurs the disciplinary measures **terminating**:
 - a. that adopts, in carrying out activities in the areas deemed at risk by the Company, a conduct that does not comply with the requirements contained in the Model and in the Code of Conduct, unequivocally aimed at committing an offence sanctioned by Legislative Decree 231/2001, since such conduct must be considered an infringement of discipline and diligence in the workplace, so serious as to damage the company's trust in the employee himself;
 - b. that adopts, in carrying out activities attributable to areas at risk, a conduct that is clearly in contrast with the provisions contained in the Model and in the Code of Conduct, such as to determine the concrete application to the Company of the measures provided for by Legislative Decree 231/2001, since such conduct must be considered an act that causes serious moral and material damage to the Company that does not allow the continuation of the relationship, not even temporarily;

The Company may not take any disciplinary action against the employee without having previously challenged the charge and without having heard him in his defense. Except for a verbal warning, the complaint must be made in writing and disciplinary measures cannot be imposed before five days have elapsed, during which the worker may present his justifications.

If the measure is not imposed within ten days following these justifications, they will be considered accepted. The worker may also present his justifications verbally.

The imposition of the disciplinary measure must be justified and communicated in writing.

Disciplinary measures may be appealed by the worker to the trade unions, according to the applicable contractual rules. The dismissal may be challenged according to the procedures provided for by art. 7 of Law no. 604 of 15 July 1966, confirmed by article 18 of Law no. 300 of 20 May 1970.

Disciplinary measures two years after their imposition will not be taken into account for any purpose.

The principles of correlation and proportionality between the violation committed and the sanction imposed are guaranteed by compliance with the following criteria:

- seriousness of the violations committed;
- the employee's task, role, responsibility and autonomy;
- predictability of the event;
- intentionality of conduct or degree of negligence, recklessness or inexperience;
- overall conduct of the offender, with regard to the existence or absence of disciplinary precedents;
- other particular circumstances that characterize the violation.

Disciplinary sanctions (as provided for by Article 7 of Law 300/70) and the Code of Conduct are brought to the attention of the worker on the website of the Parent Company Evotec SE, Ethics & Compliance section.

6.3. Disciplinary sanctions for management staff

In general, the following penalties may be imposed on managerial staff:

- i) fine;
- ii) suspension from work;
- iii) early termination of the employment relationship.

The manager incurs **precautionary disciplinary measures** in the following cases:

- a. violates internal procedures or behaves in a way that does not comply with the provisions of the Code of Conduct and the rules of conduct contained in this Model (e.g. that he/she does not comply with the prescribed procedures, fails to notify the Surveillance Body of the prescribed information, fails to carry out checks, etc.), such conduct being considered as a non-execution of the orders given by the Company;
- b. commits violations of the Model pursuant to Legislative Decree 231/2001, excluding those unequivocally aimed at committing an offence sanctioned by Legislative Decree 231/2001;

In these cases, in consideration of the seriousness of the conduct, workers with managerial qualifications may be suspended, as a precautionary measure, without prejudice to the manager's right to remuneration, as well as, again on a provisional and precautionary basis for a period not exceeding three months, the assignment to different positions in compliance with art. 2103 of the Italian Civil Code.

The manager incurs the **decisive disciplinary measures** in cases where:

- a. adopts, in carrying out activities in the areas deemed at risk by the Company, conduct that does not comply with the requirements contained in the Model and the Code of Conduct, unequivocally aimed at committing an offence sanctioned by Legislative Decree 231/2001, since such conduct must be considered an infringement of discipline and diligence in the workplace, so serious as to damage the company's trust in the employee himself;
- b. adopts, in carrying out activities attributable to areas at risk, a behaviour that is clearly in contrast with the provisions contained in the Model and in the Code of Conduct, such as to determine the concrete application to the Company of the measures provided for by Legislative Decree 231/2001, since such behaviour must be considered an act that causes serious moral and material damage to the Company that does not allow the continuation of the relationship, not even temporarily;

In these cases, the Company, in consideration of the seriousness of the conduct, may proceed with the early termination of the employment contract in accordance with the provisions of the applicable law and the CCNL.

6.4. Measures against directors

The Surveillance Body shall promptly inform the Administrative Body as a whole so that it may take or promote the most appropriate and appropriate initiatives, in relation to the seriousness of the violation detected and in accordance with the powers provided for by current legislation and the Articles of Association.

The administrator incurs **precautionary measures** in the following cases:

- a. violates internal procedures or behaves in a way that does not comply with the provisions of the Code of Conduct and the rules of conduct contained in this Model (e.g. that he/she does not comply with the prescribed procedures, fails to notify the Surveillance Body of the prescribed information, fails to carry out checks, etc.), such conduct being considered as a non-execution of the orders given by the Company;
- b. commits violations of the Model pursuant to Legislative Decree 231/2001, excluding those unequivocally aimed at committing an offence sanctioned by Legislative Decree 231/2001;

In these cases, the Administrative Body may proceed directly to the imposition of the sanctioning measure of the formal written warning or the revocation of the powers of attorney conferred, depending on the seriousness of the fact.

The administrator incurs the **resolving measures** in the following cases:

- a. adopts, in carrying out activities in the areas deemed at risk by the Company, conduct that does not comply with the requirements contained in the Model and the Code of Conduct, unequivocally aimed at committing an offence sanctioned by Legislative Decree 231/2001, since such conduct must be considered an infringement of discipline and diligence in the workplace, so serious as to damage the company's trust in the employee himself;
- b. adopts, in carrying out activities attributable to areas at risk, a behaviour that is clearly in contrast with the requirements contained in the Model and in the Code of Conduct, such as to determine the concrete application to the Company of the measures provided for by Legislative Decree 231/2001, since such behaviour must be considered an act that causes serious moral and material damage to the Company that does not allow the continuation of the relationship, not even temporarily;

In this case, the sanctioning measures (such as, by way of example, temporary suspension from office and, in the most serious cases, revocation from the office) will be adopted by the Shareholders' Meeting.

6.5. Subjects having contractual/commercial relationships and "para-subordinated" subjects

Violation of the provisions and principles established in the Code of Conduct by persons having contractual or commercial relationships or partnership agreements with the Company, including the professional in charge of the role of Surveillance Body, may determine, in accordance with the provisions of the specific contractual relationship, the termination of the relevant contract, or the right to withdraw from the same, without prejudice to the right to request compensation for the damage occurring as a result of such conduct, including damage caused by the application by the judge of the measures provided for by Legislative Decree 231/2001.

In particular, the contracts entered into by the Company with self-employed workers, collaborators and consultants may provide for a specific declaration of knowledge of the existence of the Code of Conduct and its principles, of the obligation to comply with these, or, if it is a foreign person or operating abroad, to comply with international and local regulations for the prevention of risks that may determine liability resulting from the commission of crimes against the Company.

6.6. Penalties for whistleblowing violations

CONSERVATIVE disciplinary sanctions Against **employees, managers, directors** or shareholders who ascertain:

- a. have breached confidentiality obligations regarding the identity of the whistleblower;
- b. have violated the prohibition of retaliatory or discriminatory acts against the whistleblower;
- c. obstructed or attempted to obstruct a report;
- d. have not established, having been mandated, the reporting channels or procedures for making and managing reports or adopt procedures that do not comply with those referred to in Articles 4 and 5 of Legislative Decree 24/2023;
- e. have not reported to the SB the information flows on whistleblowing and the disciplinary measures adopted.

DECISIVE disciplinary sanctions against **employees, managers or directors** or shareholders when it is ascertained:

- f. , including by first instance judgment, the criminal liability of the whistleblower for the offences of defamation or slander or in the event that such offences are committed by reporting to the judicial or accounting authority;
- g. civil liability for the same reason for wilful misconduct or gross negligence.

In the event of violations by shareholders, the Board of Directors reserves the right to take the most appropriate measures.

With regard to **persons having contractual/commercial relationships and "para-subordinate"** subjects, the violations referred to in the previous letters may determine, in accordance with the provisions of the Special Part of this Model and possibly governed by the specific contractual relationship, the termination of the relevant contract, or the right to withdraw from the same, without prejudice to the right to request compensation for damages incurred as a result of such behavior.

6.7. Application of penalties

The Board of Directors is responsible for the necessary investigations, the initiation of disciplinary proceedings and the imposition of sanctions, following any violation

of the Model. The Company also keeps adequate documentation to support any sanctions imposed.

The Surveillance Body, given its function of monitoring the effective implementation and compliance with the Model and all its components, will have the task of making the appropriate reports of possible violations found or of which it has become aware in the performance of its activities, and of verifying, in the event of a positive ascertainment of the violation, the actual imposition, by the Company, of the proportionate sanction.