Risk assessment: carcinogenic and mutagenic agents

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Abstract

Chemical agents are defined as all elements or chemical compounds, alone or as mixtures, in their natural or artificial state, used or released, as waste, by any employment, intentionally produced or not and present on the market. If the worker produces, manipulates, stores, transports or eliminates these substances there is an obligation for the employer to make a chemical risk assessment, in order to plan interventions to protect the health of workers. The carcinogenic risk assessment is today more difficult because there is often a chronic occupational exposure to carcinogens and mutagens, that could be easily underestimated. Occupational exposures to carcinogens and mutagens is both complex and varied, not only from an epidemiological point of view, but also from a clinical, social and economic. Complete and careful risk assessment is unquestionably the crucial point from which to adequate risk management itself and is the foundation for all subsequent steps. The Health Surveillance Protocol and prevention strategies, designed on the basis of the actual occupational risk, are an excellent tool for protecting workers’ health.

KEY WORDS: carcinogenic agent, health surveillance, mutagenic agent, prevention, risk assessment.

Introduction

In accordance to Legislative decree 81/08 art. 222, are defined as “Chemical agents” all elements or chemical compounds, alone or as mixtures, in their natural or artificial state, used or released, as waste, by any employment, intentionally produced or not and present on the market (1). These include “Hazardous chemical agents”, defined as chemical agents fulfilling the criteria of classification referred to the Regulation (EC) no. 1272/2008 of the European Parliament and of the Council. Are instead defined hazardous chemical agents those that represent a risk for the safety and health of workers due to their chemical and physical, chemical and toxicological properties, and because of the way they are used or are available in the workplace, including any chemical agent which has been assigned an occupational exposure limit value (Annex no. XXXVIII) (1).

If the worker produces, manipulates, stores, transports or eliminates these substances there is an obligation for the employer to make a chemical risk assessment, in order to plan interventions to protect the health of workers. Specifically (art. 223), the employer must previously determine the possible presence of hazardous chemical agents in the workplace and evaluate the risks for the safety and health of workers, arising from the presence of such agents, taking into account in particular:

a) their hazardous properties;
b) the health and safety information provided by the supplier on its security schedule, prepared according to the Regulation (EC) No. 1907/2006 of the European Parliament and of the Council;
c) the level, the manner and the duration of exposure;
d) the way the work is performed with these agents, considering the quantity of substances and mixture containing them or that can generate them;
e) the limit values for occupational exposure or biological limit values; the first list is included in the Annexs no. XXXVIII and no. XXXIX;
f) the effects of preventive and protective measures taken or to be taken;
g) where available, the conclusions drawn from any health surveillance actions already undertaken (1).

The risk assessment should include assets (maintenance and clearing included), for which it is expected the possibility of significant exposure or that, for other reasons, can cause harmful effects to health and safety, even after the adoption of all technical preventive measures.

In the case of activities involving the exposure to several hazardous chemical agents, the risks are assessed according to the risk involved in the combination of all such chemical agents (1).

The evaluation adopted for the chemical agents can not be taken in the case of jobs at risk in which are used carcinogens and mutagens; the Legislative decree no. 81/2008 and subsequent amendments (Title IX) provides 2 different chapters, one for chemicals and one for carcinogens and mutagens, with different modes of action (1).

Article no. 234 defines carcinogenic substance or mixture any agent that follows the criteria for classification as carcinogenic category 1 A or 1 B of Annex I of the regulation (EC) no. 1272/2008 of the European Parliament and of the Council; it defines a mutagenic substance or mixture corresponding to the criteria for classification as a germ cell mutagen of category 1 A or 1 B of the annex I to the regulation (EC) No. 1272/2008.

For the employer there is the obligation to replace, if technically possible, the carcinogen or mutagen with a harmless one or less harmful one to the health and safety of workers. If this is not possible, the employer must ensure that the production or use of a carcinogen or mutagen agent takes place in a closed system as long as technically possible. When even this is not possible, the employer shall ensure that the level of exposure of workers is reduced to as low as it is technically possible. The exposure shall not exceed the limit value indicated in the Annex no. XLIII (1).

The evaluation of the carcinogenic and mutagenic risk must be done according to the characteristics of processes, their duration and their frequency, the quantities of carcinogens or mutagens produced or used, their concentration, the capacity for them to penetrate into the body by the different routes of absorption, also in relation to their state of aggregation and, if it is in the solid state, whether in bulk or in flakes or compact into powder and whether or not contained in a solid matrix which reduces or prevents the leakage. The assessment must take into account all the possible exposition modes, including one in which there is absorption through the skin (1).

The evaluation of risk related to carcinogens and mutagens agents

Cancer is a leading cause of death worldwide; actually, unfortunately, the mortality rate for cancer is increasing. If in 1958 it was the second leading cause of death in Italy, since 2008 it occupies the first position (28.5% of deaths, compared with 27.8% of those for cardiovascular diseases and 10.9% for cerebrovascular disease) (2). It is intuitive to think that, in the workplace, an appropriate assessment of the carcinogenic risk allows to improve all the strategies aimed to the prevention and protection of workers’ health.

The Legislative decree no. 81/08 (Articles 17 and 28) provide that the employer has the obligation, that cannot be delegated to anyone, to assess all the risks to health and safety in the workplace and to develop a “risk assessment document” (1); so, the evaluation of the carcinogenic and mutagenic risk is up to the employer.

The carcinogenic risk assessment is today more difficult because there is often a chronic occupational exposure to carcinogens and mutagens, that could be easily underestimated. Furthermore, the occupational exposure limit value in the air is only suitable for three carcinogens (benzene, vinyl chloride monomer and wood dust) while the carcinogens that can be found in workplaces are definitely numerous. Recently it has been discovered that air pollution and particulate air pollution are carcinogenic to humans and the IARC classified them in the group 1 of carcinogens (3).

Reference values for the general population

In Italy the air quality is disciplined by the legislative decree no. 155/2010 (4), which define as:

- **Ambient air**: outdoor air in the troposphere, excluding the one present in the workplace (defined by the legislative decree no. 81/2008);
- **Pollution**: any substance in ambient air which can have harmful effects on human health and on the environment (art. 2 c. B);
- **Threshold level**: fixed on the basis of scientific knowledge, including those relating to the best available technology, in order to avoid, prevent or reduce the harmful effects on human health or on the environment, which should be achieved within a specific period, and must not be subsequently passed (art. 2 c. h);
- **Critical level**: fixed on the basis of scientific knowledge, above which there may be direct adverse effects on targets, such as trees, other plants or natural ecosystems but not on humans;
- **Tolerance limit**: a percentage of the limit value within which and admitted the limit violation to the terms of this decree;
- **Target value**: level fixed with the aim of avoiding, preventing or reducing harmful effects on human health or the environment, to be achieved, if possible, by a given date;
- **Alarm threshold**: level beyond which there is a risk to human health after brief exposure, the achievement of this limit requires the adoption of immediate protective measures;
- **Information threshold**: level beyond which there is a risk to human health from brief exposure for particularly sensitive people and whose achievement requires to ensure adequate and timely information;
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- **Long-term target**: level to be attained in the long term by means of proportionate measures in order to ensure an effective protection on human health and on the environment;
- **Average Exposure Indicator (AEI)**: average level to be determined on the basis of measurements taken from the cross-stations located at fixed sites of urban sampling at the entire national territory and which reflects population exposure. It allows to calculate the respect of national exposure reduction target and the exposure concentration;
- **Exposure concentration obligation**: level fixed on the basis of the average exposure in order to reduce the harmful effects on human health, to be achieved by a given date;
- **National exposure reduction target**: the reduction, expressed as a percentage, of average population exposure, fixed in relation to a given reference year, in order to reduce the harmful effects to human health, to be attained when possible, by a given date;
- **Fixed measurements**: measurements of pollutant’s levels carried in stations located at fixed sites, with continuous or discontinuous sampling, except for the indicative measurement;
- **Indicative measurements**: measurements of pollutant’s levels based on quality objectives, less restrictive than for fixed measurements, carried out in sampling stations located at fixed sites or by means of mobile measuring stations, or, for mercury, methods manual measurement as the diffusive sampling techniques;
- **Objective estimation techniques**: mathematical methods to calculate the concentrations from the measured values in places or times other than those referred to by the calculation, based on scientific knowledge about the distribution of concentrations;
- **Upper assessment threshold**: level below which the fixed measurements can be combined with indicative measurements or modeling techniques and, for arsenic, cadmium, nickel and benzo (a) pyrene, the level below which the fixed measurements or indicative sites can be combined with modeling techniques;
- **Lower assessment threshold**: level below which, even exclusively, is admitted the use of modeling techniques or objective-estimation.

It should also be considered another value, not covered by the law, called “Threshold Mixture Limit” that refers to mixtures of substances. In fact, in relation to chemical hazards, and in particular to carcinogenic and mutagenic risk, a lower exposure than indicated by TLV doesn’t guarantee the absence of health effects.

The carcinogenic risk assessment can not be separated from the integrated comparison of the limit values and the reference values:
- the risk is absent or not measurable if the levels of environmental or biological indicators of exposure to/ in the occupationally exposed population are below the limit values and fall within the variability of the reference ones;
- the risk is present but acceptable if the levels of exposure indicators are below the limit values but greater variability than those of reference;
- the risk is not acceptable if the exposure levels are above both the reference values that the limit values.

With regard to carcinogens and mutagens, in addition, the standards of good practice set out by the scientific community suggest to proceed with the execution of environmental and biological monitoring every three months for the first year, registering exposed workers in the appropriate register; then:
- if at the end of this period, they achieve the reference values for the general population, they will be canceled from the document, continuing their biological monitoring every six months;
- if at the end of this period they have higher values than expected for the general population, they will carry out the expected monitoring, i.e. every three months to one year;
- if at the end of this period, the reference values for the general population can not be compared because absent, they will be entered in the register of complaints. Health monitoring will be assessed on the basis of respect for professional tlv, if available.

The legislative decree no. 155/2010 lists the limit values and the exposure target values in the external environment for the general population for the following substances:
- Arsenic 6.0 ng/m³ - annual average (s.v.s. 3.6 ng/m³; s.v.i. 2.4 ng/m³);
- Cadmium 5.0 ng/m³ - annual average (s.v.s. 3 ng/m³; s.v.i. 2 ng/m³);
- Nickel 20 ng/m³ - annual average (s.v.s. 14 ng/m³; s.v.i. 10 ng/m³);
- Benzo (a) pyrene 1 ng/m³ - annual average (s.v.s. 0.6 ng/m³; s.v.i. 0.4 ng/m³);
- Lead 0.5 µg/m³ - annual average (s.v.s. 0.35 µg/m³; s.v.i. 0.25 µg/m³);
- Benzen 5 µg/m³ - annual average;
- PM 2.5 25 µg/m³ - for years;
- PM 10 40 µg/m³ - for years; 50 µg/m³ 24h not to be exceeded more than 35 times per year.
- PM 2.5 (r.v. 5-34 µg/m³) and I.P.A. (Benzo (a) pyrene r.v. 1 ± 0.6 ng/m³) were used as reference values for the general population, by some Authors, to evaluate the role of I.P.A. as a professional risk for the development of cardiovascular diseases for professional drivers (5).

The identification of the reference values for the general population is a complex process with multiple sources and methods of detection: legislation, qualified institutions (e.g. SCOEL: Scientific Committee on Occupational Exposure Limits), scientific literature, etc. In Italy the law indicates reference values for outdoor environment only, relating also to the reference values of the World Health Organization (WHO).
Retail application of reference values in outdoor environment

The following are the reference values in the air of certain chemicals:

**Carbon dioxide:**
- 100 mg/m³ average concentration over 24 hours (WHO)
- 20 g/m³ for 30 minutes (WHO)

**Arsenic:**
- 1 to 10 ng/m³ average concentration in the 24 hours in urban areas (WHO)
- 0.66 ng/m³ for a lifetime (cancer incidence 1:1,000,000) (WHO)
- 66 ng/m³ for a lifetime (cancer incidence 1:10,000) (WHO)
- 6 ng/m³ annual mean concentration (Legislative decree no. 155/2010)

**Benzene:**
- 1 mg/m³ average concentration over 24 hours (WHO)
- 1.7 g/m³ for a lifetime (cancer incidence 1:100,000) (WHO)
- 0.17 g/m³ for a lifetime (cancer incidence 1:1,000,000) (WHO)
- 5 mg/m³ annual mean concentration (Legislative decree no. 155/2010)

**Butadiene:**
- from 2 to 20 g/m³ 24-hour average concentration (WHO)

**Cadmium:**
- 5 ng/m³ 24-hour average concentration (WHO)
- 5 ng/m³ annual concentration (Legislative Decree no. 155/2010)

**Chrome:**
- from 5 to 200 ng/m³ average concentration in 24 hours (WHO)
- 0.025 ng/m³ for a lifetime (cancer incidence 1:1,000,000, hexavalent chromium WHO)
- 2.5 ng/m³ for a lifetime (cancer incidence 1:10,000, hexavalent chromium WHO)

**Formaldehyde:**
- 100 g/m³ for 30 minutes (WHO)
- from 2 to 4 g/m³ average concentration over 24 hours (WHO)

**Polycyclic aromatic hydrocarbons:**
- <1 ng/m³ average concentration over 24 hours in rural areas (WHO)
- 0.012 ng/m³ for a lifetime (cancer incidence 1:1,000,000) (WHO)
- 1.2 ng/m³ for a lifetime (cancer incidence 1:10,000) (WHO)
- 1 ng/m³ annual mean concentration (Legislative decree no. 155/2010)

**Hydrogen sulfide:**
- 7 g/m³ for 30 minutes (WHO)

**Manganese:**
- 0.15 g/m³ average concentration over 24 hours (WHO)

**Mercury:**
- 1 mg/m³ average concentration over 24 hours (WHO)

**Carbon monoxide:**
- from 0.06 to 0.14 mg/m³ 24-hour average concentration (WHO)
- 100 mg/m³ for 15 minutes (WHO)
- 60 mg/m³ for 30 minutes (WHO)
- 30 mg/m³ for 1 hour (WHO)
- 10 mg/m³ for 8 hours (WHO)

**Nickel:**
- 1 to 10 ng/m³ average concentration in 24 hours in urban areas (WHO)
- 2.5 ng/m³ for a lifetime (cancer incidence 1:1000000) (WHO)
- 250 ng/m³ for a lifetime (cancer incidence 1:10000) (WHO)
- 20 ng/m³ annual mean concentration (Legislative decree no. 155/2010)

**Lead:**
- 0.15 g/m³ average concentration over 24 hours in rural areas (WHO)
- 0.5 g/m³ annual mean concentration (Legislative decree no. 155/2010)

**Polychlorinated biphenyls (PCBs):**
- <3 ng/m³ average concentration in 24 hours (WHO)

**Polychlorinated dibenzodioxins (PCDDs) and Polychlorinated (PCDF):**
- 0.1 pg/m³ average concentration over 24 hours (WHO)

**Styrene:**
- <1 mg/m³ average concentration in 24 hours in rural areas (WHO)
- 70 g/m³ for 30 minutes (WHO)

**Toluene:**
- 5 mg/m³ average concentration over 24 hours in rural areas (WHO)
- 1 mg/m³ for 30 minutes (WHO)

**Vanadium:**
- 1 mg/m³ average concentration (WHO)

**PM 10:**
- 10 g/m³ per year (WHO)

**PM 2.5:**
- 10 g/m³ per year (WHO).

Application details of reference values in indoor environment (WHO)

In industrialized countries, people spend the 80/90% of their time in indoor environments; these environments are often perceived as risk-free, however, they expose the population to a prolonged contact with physical, chemical and biological agents. Some pollutants are more concentrated in closed rooms than outside. The most common sources of pollution are:
- people itself;
- the type of building materials and coatings;
- the furnishings;
- the air-handling systems;
- room’s clearing;
- indoor/outdoor interaction.

It must be remembered that the values of carcinogens and mutagens shall be reduced to the lowest possible
through the reduction or elimination of the activities that can produce them.

**Benzene:**
- 0.17 g/m³ for a lifetime (cancer incidence 1: 1,000,000)
- 17 g/m³ for a lifetime (cancer incidence 1: 10,000)

For benzene there is also a limit value for occupational exposure (TLV-TWA: 3.25 mg/m³ for 8 hours of work).

**Nitric Dioxide:**
- 200 g/m³ for 1 hour
- 15 g/m³ per year

**Formaldehyde:**
It is a carcinogen, so there is a threshold value, however, different threshold values are indicated:
- 100 g/m³ for 30 minutes

**Aromatic polycyclic hydrocarbons:**
- 0.012 ng/m³ for a lifetime (cancer incidence 1: 1,000,000)
- 1.2 ng/m³ for a lifetime (cancer incidence 1: 10,000)

**Carbon monoxide:**
The levels of exposure should not exceed the following values:
- 100 mg/m³ for 15 minutes
- 35 mg/m³ for 1 hour
- 10 mg/m³ for 8 hours
- 7 mg/m³ for 24 hours

**Styrene:**
- <10 mg/m³ average concentration over 24 hours
- 230 g/m³ for a lifetime (cancer incidence 1: 10,000)

**Legal-Medicine Appendix**

**Legislative decree no. 81/2008 (1)**

**Article 18: Obligations of the employer and the manager**

1. The employer, who shall exercise the tasks set out in Article 3, and the managers, who organize and manage the assets according to the functions and powers conferred on them, must:
   a) take all the appropriate steps to avoid that the technical measures adopted can cause risks to population’s health or environment’s deterioration, periodically verifying the continuing absence of risk;
   b) restrict to the minimum the number of workers exposed or likely to be exposed to carcinogens or mutagens, also isolating work in predetermined areas with adequate warning and safety signals, including “no smoking” signals, and only accessible to workers who must go there for reasons related to their job or with their functions. In these areas it is forbidden to smoke; he also designs, programs and monitors all the processes, so that there is no release of carcinogens or mutagens into the air. If this is not technically possible, the elimination of carcinogens or mutagens must be made as close as possible to the point of emission by local exhaust, in compliance with article 18, paragraph 1, letter q. The work environment must still be provided with a suitable ventilation system;
   c) provide for the measurement of carcinogens or mutagens in order to verify the effectiveness of the measures referred to in subparagraph c) and for early detection of abnormal exposures resulting from an unforeseeable event or an accident, with sampling and measurement methods conform to directions contained in the Annex no. XLI of this decree;
   d) assures the regular and systematic cleaning of the premises, equipments and installations;
   e) elaborates procedures for emergency cases that may involve high exposure;

2. The employer, who shall exercise the tasks set out in Article 3, and the managers, who organize and manage the assets according to the functions and powers conferred on them, must:
   a) communicate, in writing, at the meetings referred to in subparagraph c) and for early detection of abnormal exposures resulting from an unforeseeable event or an accident, with sampling and measurement methods conform to directions contained in the Annex no. XLI of this decree;
   b) assure the regular and systematic cleaning of the premises, equipments and installations;
   c) elaborates procedures for emergency cases that may involve high exposure;
Article 239: Information and training
1. The employer provides to employees, based on available knowledge, information and guidance, in particular as regards to:
   - carcinogenic or mutagenic agents present in the work cycles, their location, the health risks’ linked to their use, including the additional risks due to smoking;
   - precautions to be taken to prevent exposure;
   - hygienic measures to be observed;
   - the need for wearing and use of work clothes and protective clothing and personal protective equipment, and their proper use;
   - how to prevent the occurrence of accidents and the measures to be taken to minimize the consequences.
2. The employer assures to workers an adequate training in particular in relation to what is stated in paragraph 1.
3. The information and training referred to in paragraphs 1 and 2 shall be provided before workers are employed in such activities and must be repeated at least every five years, and any time there are changes in the processes that affect the nature and the degree of risk.
4. The employer shall also ensure that the labels of the facilities, containers and packages containing carcinogens or mutagens are legible and comprehensible. The signs used and other information must comply with the provisions of the legislative decree 3 February 1997, no. 52, and 14 March 2003, no. 65, as amended.

Article 241: Particular working operations
1. For works, such as the maintenance, for which it is expected, despite the adoption of all technically preventive measures, a significant exposure of workers to carcinogenic or mutagenic agents, the employer, after a consult with the safety representative:
   a) provides that only those workers can access to these areas also providing, where technically possible, the isolation of them and their identification by markings;
   b) provides special clothing and personal protective equipment that must be worn by workers employed in these operations.
2. The presence of the workforce in the areas referred to in paragraph 1 is in any case limited to the strictly necessary time to perform the process.

Article 242: Medical examinations and preventive and protective standards specifications
1. Workers for whom the evaluation referred to Article 236 has shown any risk to health must undergo health surveillance.
2. The employer shall adopt, upon advice of the occupational physician, preventive and protective measures for individual workers based on the results of the clinical and biological examinations carried out.
3. The measures referred to in paragraph 2 may include the withdrawal of the worker in accordance with the procedures of Article 42.
4. Where medical examinations have shown, in workers exposed to a single agent, the existence of an anomaly attributable to such exposure, the occupational physician shall inform the employer.
5. Following the information referred to in paragraph 4, the employer shall carry out:
   a) a new risk assessment in accordance with Article 236;
   b) if it is technically possible, a measurement of the concentration of the agent in the air and in any case the exposure to the agent, considering all the relevant circumstances and possible routes of exposure to test the effectiveness of the measures taken.
6. The occupational physician provides workers with adequate information on health surveillance which they are subject, particularly with regard to the opportunity to undergo health checks even after termination of employment.

Article 301: Applicability of the provisions set out in Article 20 and following of Legislative Decree 19 December 1994, no. 758
1. At fines on hygiene, health and safety at work provided for in this Decree and other provisions having the force of law, for which provision is made for alternative penalty of arrest or fine or the penalty of fine only; the provisions concerning the extinction of the offense are indicated in Articles 20 and followings of Legislative decree 19 December 1994, no. 758 (N).

Art Notes. 301 Article 301-bis: Facilitated extinction of administrative offenses as a result of regularization
1. In all cases of non-compliance with obligations punished with administrative fine, the offender, in order to settle the administrative offense, is allowed to pay a sum equal to the minimum extent permitted by law to regularize its position no later than the term assigned by the organ of surveillance of the first access inspection supervision.

Article 302 - Definition of offenses punishable by imprisonment alone
1. For the offenses punished by imprisonment, the court may, upon the defendant’s request, replace the sentence imposed in the limit of twelve months by paying a certain sum of their heights according to the criteria in Article 135 of the criminal code. The replacement can only occur when they are eliminated all sources of risk and the harmful consequences of the offense. The sum may not be less than 2000 €.
2. The exchange referred to in paragraph 1 is not allowed when the infringement has had a causal contribution to the occurrence of an accident at work from
which is derived the death or personal injury which has resulted in the inability to attend to the ordinary occupations for a period of more than forty days.

3. After a period of three years after the res judicata court judgment which operated the substitution referred to in paragraph 1 without the defendant has committed further crimes including those covered by this single text, or the offenses referred to in Article 589, second subparagraph and 590, third paragraph, of the criminal code, limited the allegation of infringement of the rules relating to the prevention of accidents at work, the offense is extinguished.

The penalty structure revision has greatly simplified the previous system and has graduated, and in many cases strongly attenuated than expected from the prior legislation.

In summary, we believe that it is expected a term of imprisonment (art. 55 paragraph 2) for the employer who has not carried out the risk assessment and has not prepared properly the risk assessment document in highly dangerous enterprises; exclusive arrest sentence is mitigated by the provisions of Article 302.

**Legislative decree no. 758/94: Extinction of fines on security and occupational health**

**Article 19**

1. The effects of the provisions referred to in this Title shall apply:
   a) offenses, offenses relating to safety and hygienic punished with the penalty of arrest or fine alternative under the standards in Annex I;
   b) supervisory board, the inspection staff in art. 21, third paragraph, of the Law of 23 December 1978, n. 833, subject to the various skills required by other standards.

2. The definition in paragraph 1, letter a), does not apply to the expected effects art. 60, first paragraph, and 127, in relation to art. 34, first paragraph, letter n) of the Law of 24 November 1981, n. 689, as well as Articles 589, second paragraph, and 590, third and fifth paragraphs, of the Criminal Code.

**Article 20**

1. In order to eliminate the fine established, the oversight body shall, in the exercise of judicial police functions in art. 55 of the Criminal Procedure Code, gives the offender a specific prescription, starting for a regularization term not exceeding the time period technically necessary. This deadline may be extended at the request of the offender, for particularly complex or to the objective difficulty of performance. In no case may it exceed six months. However, when specific circumstances not attributable to the offender result in a delay in the regularization, the period of six months may be extended only once, at the request of the offender, for a period not exceeding a further six months, with a reasoned decision which shall be notified immediately the prosecutor.

2. Copy the prescription is also served to the legal representative of the part or service which operates the offender.

3. Prescribing the supervisory authority may impose specific measures to put an end to the danger to the safety or health of workers at work.

4. The obligation of the supervisory board to report to the public prosecutor of a criminal offense relating to the contravention of the Article 347 of the Criminal Procedure Code.

The prescription under the ecree 758/94 art. 20 does not apply when it is scheduled to stop without alternative sanctions and is not mandatory in other cases (Supreme Court).

**Article 21**

1. No later than sixty days from the expiry of the deadline set in the prescription, the audit oversight body if the violation was eliminated in the manner and within the period indicated by the prescription.

2. When is the fulfillment of the prescription, the supervisory board allows the offender to pay to the administrative court, within thirty days, an amount equal to 1/4 of the maximum fine set for the offense committed. Within one hundred twenty days from the final date fixed in the prescription, the supervisory board shall inform the prosecutor fulfill the prescription, as well as any payment of the said sum.

When is the default prescription, the supervisory board shall inform the prosecutor and the offender within ninety days from the final date fixed in the prescription.

**Article 22**

1. If the prosecutor takes news of a contravention of its own initiative or receives it from private individuals or public officials or of a different public service by the supervisory board, it shall immediately notify the supervisory body for decisions related to the prescription that is needed in order to eliminate the fine.

2. In the case referred to in paragraph 1, the supervisory agency shall inform the prosecutor of its determinations within sixty days from the date on which he received notice of the news of crime by the prosecution.

**Article 23**

1. The process for the fine is suspended from the moment the news of crime in the register under art. 335 of the Criminal Procedure Code until such time as the prosecutor receives a communication in art. 21, paragraphs 2 and 3.

2. In the case provided by art. 22, paragraph 1, the process takes its course when the supervisory body informs the prosecutor who does not expect to issue a prescription, and in any case for a period fixed in art. 22, paragraph 2, if the supervisory board fails to inform the prosecutor of its determinations relating to the prescription. If the said period the supervisory board informs the prosecutor that he had given a prescription, the process is suspended until the date indicated in paragraph 1.

3. The stay of proceedings does not preclude the request for archiving. Also it does not prevent the taking of evidence with probative or urgent acts of preliminary investigation, nor the seizure in accordance with Articles 321 and following of the Code of Criminal Procedure.
Article 24
1. The offense is extinguished if the offender fulfills the prescription given by the supervisory board in the period laid down therein, and shall pay provisions of art. 21, paragraph 2.
2. The public prosecutor requires the filing if the offense is extinguished in accordance with paragraph 1.
3. The fulfillment in a time greater than that indicated in the prescription, but that is adequate in accordance with art. 20, paragraph 1, or the elimination of harmful or dangerous consequences of the offense in ways different from those indicated by the supervisory body, are valued for the purposes of art. 162-bis of the Penal Code. In this case, the sum payable is reduced to a quarter of the maximum fine set for the offense committed.

Article 25
1. For the offenses do not apply to current regulations on the subject of formal notice and arrangement.
2. The provisions of this Title shall not apply to proceedings pending at the date of entry into force of this decree.

Health surveillance

Health surveillance consists of a series of medical examinations (medical visits, laboratory tests, radiological tests, etc.) which the worker is subjected in order to protect the health and ensure the suitability to perform the duties which he was assigned. In addition, it is the instrument through which to monitor the health of the worker time to prevent, in the short term, the occurrence of long-term injuries and the occurrence of occupational diseases.

The purpose of health monitoring is to protect the health and safety of workers through:
- assessment of compatibility between health conditions and working tasks;
- identification of conditions of hypersusceptibility to occupational hazards;
- evaluation of the effectiveness of prevention measures implemented in the company.

According to the Legislative decree no. 81/08 art. 41 there are several types of medical examination (1):
- a preventive medical examination, carried out before and after taking assign the employee to the task, used to:
  - declare the absence of contraindications to work which the employee is intended to evaluate its suitability for specific tasks;
  - check the compatibility of the task entrusted with specific health conditions of the subject in an investigation;
  - to assess the worker’s state of health, which will be the base from which the subsequent follow-up;
  - the periodic medical examination which has as its objectives to control the state of health of workers and assess his fitness for the specific task. The frequency of inspections, if not required by the rules, is determined, as a rule, in once a year. This frequency can take on different basis, established by the occupational physician in accordance with the risk assessment. The supervisory board, in a reasoned opinion, can have content and schedule for the different health surveillance to those specified by the occupational physician. By periodically visit the company physician is able to evaluate the onset of any early changes of the health status of workers caused by exposure to specific occupational risk factors and checking the efficiency of preventive measures and risk protection;
  - the medical examination at the request of the worker, performed if it is judged by competent medical related to occupational hazards or her health condition, susceptible to deterioration due to the work performed, in order to express the judgment of suitability for specific tasks;
  - the medical examination on the occasion of change of job in order to verify the suitability of the employee for the specific task;
  - the medical examination upon termination of employment (as provided by law);
  - preventive medical examination during pre-underwriting that may be made, at the option of the employer, the occupational physician or the ASL prevention departments;
  - the medical examination to the resumption of work as a result of absence for health reasons for a period exceeding 60 consecutive days, in order to verify continuing suitability to the task (1, 5-8).

The above-mentioned visits, except for the end of the employment relationship and the worker’s request, are also aimed at the verification of the absence of alcohol-dependence conditions and use of psychotropic and narcotic substances, in all those jobs at risk (for themselves and for others) listed in the Order dated 16 March 2006 and in Intesa State-Regions 30/10/2007 (5, 9).

Periodic visits should also be also used to promote health and work skills through a few tips (correct behavior in the workplace, lifestyle and daily habits-promoting health; inclusion in health promotion activities in the workplace promoted by company affiliation; early identification of changes in health status or in the working capacity and consequent treatment and rehabilitation). Everything must always be carried out after obtaining the informed consent of the worker directly involved (5, 10).

Medical investigations as provided in the sanitary protocol must be approved in advance by the employee through the signing of informed consent: although every medical procedure should indeed be conducted in full compliance with the decision-making autonomy of the worker, that does not excuse the fact that it is considered to be acceptable from an ethical and legal point of view just because its consent was obtained. It is also useful to remember that the investigations are included in the health protocol must meet two criteria: the adequacy of scientific knowledge hitherto available and ensuring every decision has as its sole purpose the preservation and protection of workers’ health (11). All planned and implemented by the occupational physician are defined good quality if they improve the workers’ health or reduce the health risks.
Risk assessment: carcinogenic and mutagenic agents

Risk assessment: carcinogenic and mutagenic agents

precise rules, usually dictated by specific national reg-
such communication must take place according to
for specific tasks or specific requirements/restrictions;
about the results of the investigations to which a work-
tional physician must however inform the employer
and not to be disclosed to third parties. The occupa-
during the health monitoring visit is strictly personal
and respect the patient’s privacy; what was learned
For the physician in you have the obligation of secrecy
purpose of health surveillance data are physicians in
• to limit the exclusion from work for health reasons.
The results of the clinical investigations made for the
practice as early as possible any deterioration of the health
eters in fact help the occupational physician to know
quacy of the evaluation of risks and possible preven-
So, it is important to emphasize that the health proto-
workers should be as accurate as possible; however, there is
because you have to consider a large number of pa-
izations, in order to protect and respect the privacy of
ulations, in order to protect and respect the privacy of
Health monitoring of workers exposed to carcino-
genic risk
As far exposed, fair and efficient health surveillance should:
- include the assessment of individual and collective
status, recording and notification of occupa-
tional accidents, notification of sentinel events, in-
vestigations, surveys and inspections;
- describe the working population and socio-economic groups of health through the study of occup-
tional accidents, occupational diseases and work-related pathological events (frequency, severity, trends in mortality and morbidity, complaints, conditions work as well as experienced by
- stimulate epidemiological studies to identify and explain the negative health effects of causal fac-
tors of a physical, behavioral, organizational, psych-
ological and occupational exposure;
- predict the occurrence of work-related adverse
health events and have early warning capabilities
and alarm;
- preparing for action-oriented studies and re-
search, in order to eliminate causal factors through prevention;
- evaluate the effectiveness of control measures
previously implemented;
- provide guidance on policies and occupational
health programs to businesses, including data on
the funding of their implementation (5, 6).
So, it is important to emphasize that the health proto-
col of workers exposed to carcinogens and mutagens
be as accurate as possible; however, there is
no universal strategy that is applicable to all workers,
because you have to consider a large number of pa-
rameters, in particular the type of substance/s to
which the worker is exposed and the target organ that
they affect.
Based on what is stated so far it is clear that the occupa-
tional physician may hardly matter from making a
thorough history and an appropriate medical examina-
tion; they are in fact the first and essential medical
procedure to be applied to all workers regardless of
the substance in question. By medical history and
physical examination it is in fact possible to assess
over time the occurrence of changes or state of health
alterations of the worker, particularly in target organ.
Laboratory tests and biological monitoring are usually
a key part of the health surveillance program: they of-
fer to the physicians an useful tool in order to assess
not only the worker’s state of health, but also the ade-
quacy of the evaluation of risks and possible preven-
tive and ameliorative measures. The biological param-
eters in fact help the occupational physician to know
as early as possible any deterioration of the health
status of the worker and then implement all technically feasible strategies to further reduce occupational
health risks. The type of laboratory investigation obviously vary depending on substance and to which the worker is exposed and organs that affect and can be searched on different biological samples: the most commonly used are blood and urine for a variety of reasons, including wherein:
- low cost;
- less invasive for the worker;
- improved handling and practicality.
In addition to the foregoing, in the health protocol they are often also included instrumental examinations; as I said the investigation will vary depending on the carcinogenic substances and their target organs and so you can not draw up a commonly accepted international standard. However, the first-level instrumental tests most commonly performed in workers exposed to carcinogens are spirometry and chest radiography. An important aspect in the carcinogenic risk management is the health surveillance of the formerly exposed.
The debate on the subject is still running and controversial; in fact, if on one hand the implementation of a health protocol for former exposed would have clinical utility (early diagnosis), epidemiological, medical-legal (faster certification of occupational disease) and social, on the other hand this would result in a high financial commitment mainly borne by the National Health System, the risk of an excessive use of non appropriate examinations, the ability to create excessive concerns and false compensation expectations. Therefore, to date there is agreement on the need to implement health protocols in the former exposed to carcinogens (17).

Suitability for specific task

The health supervision visit and the related medical examinations have the ultimate goal of enabling the occupational physician to express their fitness for specific tasks assigned to the employee by the employer. Therefore, based on the results obtained, it is possible to express one of the following reviews:
- suitability (are not necessary corrective actions on the environment, work organization and man);
- fitness with prescriptions (the employee can carry out his work but only with special precautions);
- suitability limited (the worker can only perform certain tasks required by his job);
- temporary or permanent ineligibility: the pathology of which the worker is suffering from total to hamper his work task; in the case of expression of temporary unfitness temporal limits of validity should be specified. In the case of permanent inability of the employer must, if possible, assign the employer to another job, and for which he is qualified; if he is assigned to lower duties, it remains understood that the salary of the previous year and the original qualifying job (5) must be guaranteed.
The formulating their assessment of suitability for the specific task requires extreme caution on the part of the physician; in the expression of the eligibility decision in fact we must consider that every worker is different and that although the risk estimate can be the same, each person has certain individual risk factors and has a greater or lesser predisposition to cancer of a given disease (therefore speaks of individual hypersusceptibility).
The current legislation (art. 237 paragraph 1.i of Legislative decree no. 81/2008, as amended) emphasizes in this regard that, in the opinion of the occupational physician, special protective measures must be taken with the job categories for which exposure to certain carcinogens or mutagens has particularly high risks; to this job category they belong to workers with conditions hypersusceptibility primary or acquired.
The hypersusceptibility acquired conditions are abundantly discussed in literature; among the most common we have:
- habit of smoking;
- pathologies involving an increased absorption of xenobiotics (e.g. diseases of the digestive tract or skin integrity);
- pathologies involving a decreased excretion of xenobiotics (e.g. kidney and the urogenital tract or the digestive tract).
As regards the conditions of primary hypersusceptibility, to date there are two types of genetic testing, those for evaluating genetic variants high penetrance and those for the variants of low penetrance (Tab. 1) (18).

<table>
<thead>
<tr>
<th>Table 1 - High and low penetrance variants.</th>
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<tbody>
<tr>
<td><strong>High penetrance variants</strong></td>
</tr>
<tr>
<td>Rare</td>
</tr>
<tr>
<td>High risk of the cancer</td>
</tr>
<tr>
<td>Involve critical cellular functions (replication, apoptosis)</td>
</tr>
<tr>
<td>Do not involve interaction with environmental exposures (e.g. BRCA1, Li-Fraumeni syndrome, Von Hippel-Lindau)</td>
</tr>
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exposure to carcinogens. Parallel to this, it is reasonable to think that we can identify some situations in which particular individual pathological conditions render inadvisable even for some workers exposed to small concentrations in the workplace. It is clear that what has been set out is not an exact science: the medical literature is constantly changing and future evidence may one day confirm or deny the above.

Conclusions

Occupational exposures to carcinogens and mutagens is both complex and varied, not only from an epidemiological point of view, but also from a clinical, social and economic. Complete and careful risk assessment is unquestionably the crucial point from which to adequately risk management itself and is the foundation for all subsequent steps. The Health Surveillance Protocol and prevention strategies, designed on the basis of the actual occupational risk, are an excellent tool for protecting workers’ health. Nevertheless future and more and more up to date scientific research can make a future major changes and innovations in occupational medicine and, above all, more and more effectively protect the health of workers.

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