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The role of ecotoxicology in the health impact assessment: an innovative ecosystem approach for the protection of human health in Italy

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Abstract

Background. The Health Impact Assessment (HIA) is a procedure with the aim to protect the populations exposed to the impacts deriving from the establishment or upgrading of large industrial enterprises, i.e. large combustion plants (>300 MWth). In Italy a guideline for the HIA procedure has been published in compliance with the 2014/52/EU Directive on the Environmental Impact Assessment (EIA) requirements.

Italian HIA procedure. An ecotoxicological approach has been included for the first time in the HIA procedure with the aim to detect toxic effects caused by unknown not-monitored contaminants or mixtures in the ecosystem components affected by the potential emissions, discharges and releases of large industrial enterprises. Ecotoxicology plays an important bridge role between environment and human health in the scoping and monitoring step of the HIA procedure with a key function of early warning system and screening. The aim of this paper is to present the Italian experience in the first three years of the application of the new approach, proposing recommendations on specific case studies.

Conclusion and future perspective. 80% of enterprises, that applied HIA, have delivered a robust, integrated and detailed documentation in relation to the ecotoxicological assessment, this positive feedback will generate environmental and human health benefits to the areas where the plants are established.

Key words

- Health Impact Assessment
- ecotoxicology
- mixtures
- gas-fired power plant
- early warning system

BACKGROUND

Over the past decade the focus on biodiversity protection, sustainable development, climate changes and ecosystems health, has become the main key driver in European and international policy making.

Human health depends ultimately upon ecosystem products and services (such as availability of fresh water, food, pharmaceuticals, pollination) and significant direct and indirect human health impacts can occur if ecosystem services are no longer adequate to meet social needs, this concept is also embedded in the new European chemical strategy for sustainability that has been launched by the European Commission in October 2020 [1].

It is now well known that multiple substances occur simultaneously in the environment: a substance-by substance risk assessment therefore can underestimate the total chemical risk, as it does not take into account the fact that several substances present at the same time may have the same effects or modes of action and act additively or synergistically. The European chemical strategy recommends that "the effect of chemical mixtures needs to be taken into account and integrated more generally into chemical risk assessments" and plans to "introduce or reinforce provisions to take account of the combination effects in other relevant legislation, such as legislation on water, air, soil". The EU Action Plan "Towards zero pollution for air, water and soil" published in 2021 [2] sets out an integrated vision for 2050 to reduce environmental pollution to levels that are no longer harmful to human health and natural ecosystems. This means reducing the risk not only from single chemicals, but also the risk arising from their combined presence in the environment.

In this context every public and private project should therefore consider and limit the impact on environment of chemical and physical stressors including erosion, compaction and sealing. Specifically, the European Directive 2014/52/EU on the environmental impact assessment [3] aims to assure a high level of protection of

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the environment and it highlights the importance of the protection of human health, through the establishment of minimum requirements for the assessment of the environmental impact of public and private projects. The Italian Legislative Decree 104/2017 has implemented the European Directive. The National Decree prescribes for new plants belonging to a specific category (e.g., large combustion plants, refineries) to carry out a Health Impact Assessment (HIA) procedure to protect the populations from the potential impacts caused by these plants, considering the economic development opportunities. In particular, it requires carrying out a HIA for new plants belonging to the categories of large combustion plants (>300 MWth), crude oil refineries, re-gasification and liquefaction plants or for plants that can have strong impacts on the land in relation to their production activity. Plants such as gas-fired power stations [4], steel industries and refineries can release in air, soil and water several chemical contaminants in low quantities, but their interaction can generate unpredictable effects for ecosystems and human health, for this reason tools and procedures are needed to detect and evaluate these effects earlier. In relation to air emissions a relevant pathway is also the atmospheric deposition on soil and surface waterbodies located around the plants. In this context, ecotoxicology [5] represents a valid and recognized instrument at European level which is fundamental for the management and understanding of the potential adverse effects resulting from multiple exposure to contaminants including those not covered by the legislation (emerging) and the mixtures. The aim of this paper is to present the Italian experience in the first three years in the application of the ecotoxicological approach in the context of HIA procedure and to propose recommendations.

THE ITALIAN HIA PROCEDURE

As reported by European Directive 2014/52/EU, in order to ensure a high level of protection of the environment and human health, screening procedures and environmental impact assessments should be considered the impact of the whole project, including, where relevant, its subsurface and underground, during the construction, transport and, where relevant, during the demolition phases. The Italian HIA guideline published in compliance with the law requirements [6] recommends that the proposers should compile a technical dossier with all information included in relation to several aspects relevant to the human health protection: description of the pressures and geographical area, exposure assessment, epidemiological and toxicological aspects. The dossier must be subsequently evaluated by the Competent Authority responsible for issuing the authorizations.

The procedure includes 5 phases among which the ecotoxicological assessment should be applied in the scoping and monitoring phase:

- *screening,* at this phase, it is assessed whether a HIA needs to be applied for the project subjected to EIA determining the potential health implication impact, through the identification of the exposed population, health profile of the exposed population, evaluation of the overlap of existing impacts with new ones determined by the work;
- *scoping,* health determinants are identified and addressed by the HIA such as the characterization of the area of interest, the exposed population, assessment of the state of health of the exposed population before the construction, definition of the socio-economic profiles of populations and communities and ecotoxicological evaluation;
- *assessment and appraisal,* the health effects determined by the realization of the project must be quantified and therefore a risk assessment (including an extensive exposure assessment) will be carried out. The conclusion of this stage determines the acceptability and feasibility of the project on the territory, the identification of the actions / technologies to be adopted to reduce the exposure of population;
- *monitoring,* definition of the health monitoring plan in relation to the environment to verify the assessments (toxicological, epidemiological, ecotoxicological and other health determinant evaluation) that have been carried out;
- *reporting,* drafting of the detailed report of the activities carried out: from bibliographic research to criteria for selecting the scientific literature consulted, models, environmental data health care utilized, the evaluation procedures adopted, the uncertainty levels of the estimates, the monitoring and control plan prepared.

THE ROLE OF ECOTOXICOLOGY IN HIA PROCEDURE

The ecotoxicological assessment has the aim to detect and assess before and after the building/upgrading of the plant effects caused by mixtures or pollutants not directly monitored. In a recent European technical document [7] drawn up in the context of the common implementation strategy of the EU Water Framework Directive 2000/60/EC [8] the use of effect-based methods (EBMs) (bioassays *in vivo* and *in vitro* and biomarkers) for ecosystems monitoring is recommended by a group of European experts in particular for their role as early warning systems and screening. Effects caused by chemical substances detected in ecosystems (e.g. genotoxic, embryotoxic, neurotoxic, endocrine disrupting effects) can indeed occur also in humans [9-11]. The HIA is an interdisciplinary procedure that is based on toxicological, epidemiological and ecotoxicological assessment. Ecotoxicology is connected to the exposure assessment of the HIA, for example the data related to the quality status of waterbodies (surface and ground) and soils are useful information to select the EBM that should be applied. If effects are detected in the ecosystems, this information will be considered also in the context of the other key evaluations (toxicological, epidemiological) foreseen by the HIA.

The importance of ecotoxicological assessment in environmental monitoring to support human health protection it is a requirement for the enterprises in two steps of the HIA procedure: scoping and monitoring *(Figure 1)*. In the scoping phase, when the pre-existing anthropogenic pressures on the territory are known the

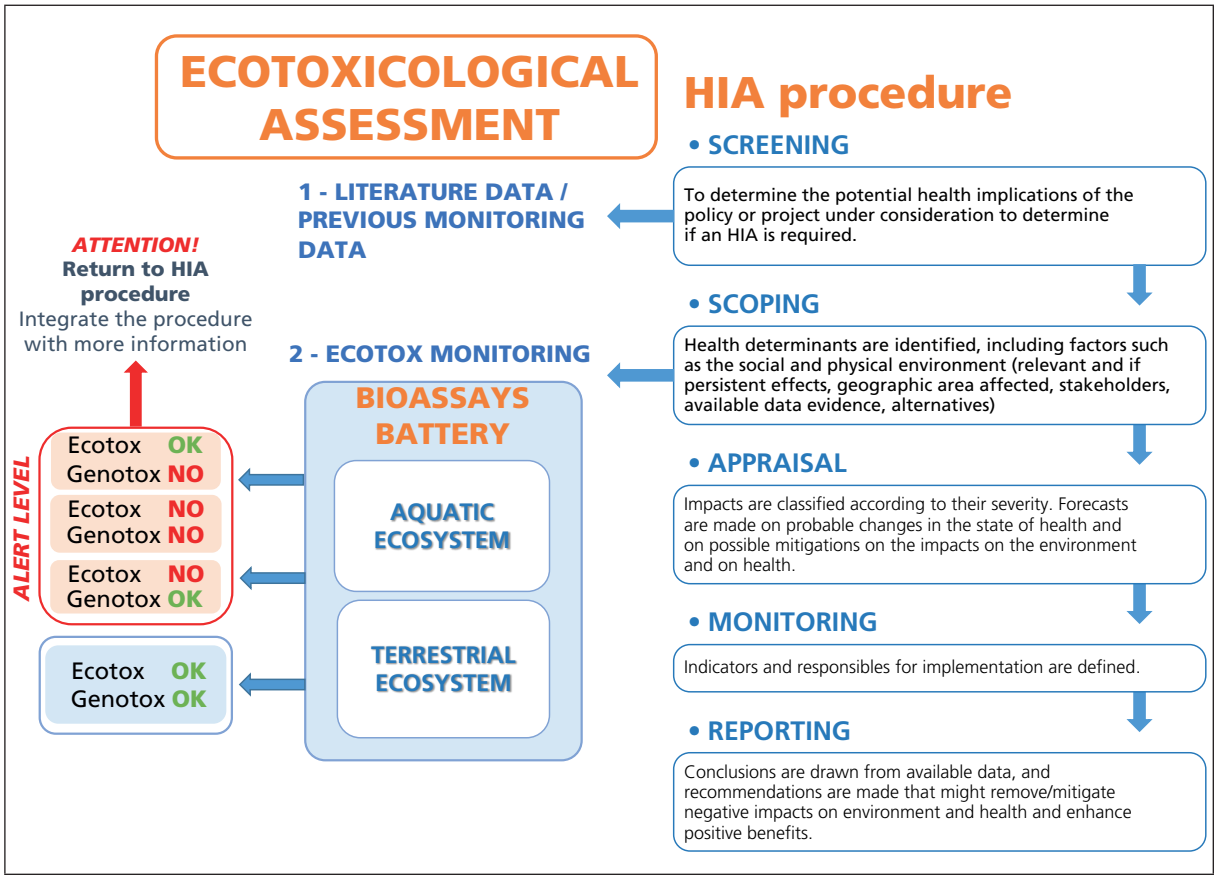

Figure 1
Ecotoxicological assessment flow scheme in the HIA procedure (modified from Dogliotti *et al.* [6]).

possibility of carrying out ecotoxicological investigations will be evaluated *ante-operam*; this is important in order to evaluate the trend of the effects after the construction/upgrading of the plant. During the monitoring phase a correct frequency and site selection strategy of application of effect-based methods should be performed.

The ecotoxicological investigation should be based on an appropriate choice of a site-specific bioassay battery (at least on three trophic levels) including acute, chronic ecotoxicity tests and eco-genotoxic tests since the mutagenic/genotoxic effects are closely related to human health [12, 13]; *in vitro* tests are recommended also because they are in line with the 3R (replacement, reduction, refinement) principle for animal welfare and also because they can detect very low levels of chemical contaminants. The bioassays should be selected following essential elements: the ecosystem in which the plant will be built (natural environment, urban environment, type of water bodies, aquatic or terrestrial ecosystems), type of industrial cycle and potential pollutants discharged and the routes of exposures for the population (drinking water, irrigation, agricultural and zootechnical activity). Testing should be conducted by the enterprises according to the main national, international guidelines (e.g. OECD) or validated protocols. On the basis of the results obtained through the ecotoxicological assessment, different scenarios may occur: 1) if no presence of ecotoxicity and eco-genotoxicity is detected, no warning for HIA should be reported; 2) if ecotoxicity or eco-genotoxicity is detected there is the need to integrate the information acquired within the HIA and investigate the pollutants released in greater detail; in case of acute ecotoxicity the alert level is higher; 3) if ecotoxicity and eco-genotoxicity are detected, that is the maximum warning, there is the need to develop and apply adequate risk reduction measures such as more advanced treatment systems.

The ecotoxicological assessment must be site specific and the choice of bioassays will be different in relation to the environmental information acquired on site, also in relation to the human epidemiological and toxicological information required by the HIA procedure.

PRELIMINARY RESULTS OF THE APPLICATION

The Italian National Institute of Health (ISS) has evaluated several projects in the first 3 years, the requests for HIA procedures belong mainly to power-fired gas plants (90%) distributed throughout the whole Italian territory: 54% the northern, 14% the southern, 14% the central part of Italy, 18% Sardinia and Sicily. The HIA projects concern the extension, renovation and partial or total replacement of the old plants. The majority of them referred to the conversion of coal-fired power plants into natural gas-fired power plants, 10% of

Table 1
List of the main bioassays applied by the enterprises

Surface inland waters	Transitional waters	Marine waters	Soil
		Ecotoxicological bioassay	
Daphnia magna - Acute immobilisation test (OECD 202)	*Artemia franciscana* - Acute test (APAT CNR IRSA 29 2003)	Marine algae Chronic assay (UNI EN ISO 1053-2016)	Earthworms - Acute test (OECD 207)
Selenastrum capricornutum - Freshwater Alga and Cyanobacteria - Growth inhibition test (OECD 201)	*Phaeodactylum tricornutum* - Marine algal Growth inhibition test (UNI EN ISO 1053:2016)	*Vibrio fischeri* - Determination of the inhibitory effect of water samples on the light emission luminescent bacteria test (ISO 11348-3)	*Lepidium sativum, Sorgum saccaratum, Sinapis alba* - Determination of the inhibition of germination and root elongation (UNICHIM N. 1651: 2003)
Zebrafish embryos test (OECD 236)	Fish embryos (i.e. *Dicentrarchus labrax)* (OECD 236)	Sea urchin - Acute embryo test with (EPA/600/R-95/136)	
		Eco-genotoxicological assay	
Comet assay (validated methods)	Comet Assay (OECD 489)	MicroNucleus Test on mytilus	Comet Assay (validated methods)
	Bacterial reverse mutation test - Ames test (OECD 471)		Bacterial reverse mutation test - Ames test (OECD 471)

the projects are related to steel industries. At the beginning of the assessment the ecotoxicological approach was never applied neither in the scoping phase nor in the monitoring phase as required by the guideline, this was expected due to the novelty of the procedure. In the second submission, 80% of enterprises have delivered a robust, integrated and detailed documentation in relation to the ecotoxicological assessment.

The typology of bioassays applied by the enterprises until now cover different trophic levels and also endpoints such as genotoxicity, embryotoxicity and neurotoxicity *(Table 1)*. The bioassays applied are mainly acute and chronic aquatic and terrestrial bioassays *in vivo* (e.g., test with earthworms, algae, crustaceans, fish embryos), eco-genotoxicological assays such as the Ames test, Comet Assay and the micronucleus tests. For the marine sites the methods applied are mainly the same that are foreseen by the Italian National Decree about dredging activities N.173/2016, integrated by an eco-genotoxicological assay.

CASE STUDY

Power plants for regasification of liquefied natural gas (LNG) are proposed now in Italy due to the urgent energy demand; in particular the government has recently approved the installation of an FSRU (Floating Storage and Regasification Unit) in the city of Ravenna on the Adriatic Sea in Central Italy. In the context of the HIA that has been carried out for this plant a complete ecotoxicological assessment has been recommended in order to prevent the possible effects for the ecosystems and indirectly for human health. In this assessment EBM will be applied in coastal marine waterbodies (included sediments) to detect the potential effects of the FSRU and in surface waters and soils that are located in proximity of the pipelines for the furniture of the gas. The EBM applied are *in vivo* and *in vitro* assays and will cover several endpoints included genotoxicity and embryotoxicity, they will be performed in the phases of scoping and monitoring of the health impact assessment.

CONCLUSIONS AND FUTURE PERSPECTIVES

The ISS has issued several opinions on HIA submitted in the last 3 years. In agreement with the Ministry of Health, the ISS has also organized training courses, events and specific meetings with stakeholders, to increase awareness and facilitate the application of guidelines. The enterprises have acquired all information and understood the importance of ecotoxicology in this context. Several enterprises have already applied the ecotoxicological assessment in the scoping phase submitting a complete monitoring plan. In the recent European Commission proposal for the protection water resources is included the need to apply EBMs for the detection of endocrine disrupting effects, this is an important step towards the inclusion of ecotoxicity for the evaluation of the status of European aquatic ecosystems [14]. In Italy there is availability of several EBMs that can cover a large range of effects. The economic effort of the EBMs can be advantageous in many cases in comparison to the chemical analysis, the capacity of Italian and European labs to use them is increasing. In future a more accurate procedure about the setting of trigger values/evaluation criteria for the interpretation of the results will be necessary, this is also an important step that will be considered at European level in the context of the EU Water Framework Directive. It is expected in future also an increasing of the use of *in vitro* methods in compliance with the ethical testing requirements. The inclusion of the ecotoxicological aspects in the HIA in Italy will have an important role as early warning and screening system and will contribute

to apply the appropriate preventive measures needed to eliminate or reduce the potential effects and impacts of the industrial chemical emissions on human health.

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Conflict of interest statement

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