Società Nazionale Operatori della Prevenzione

Pescara 31 gennaio 2017

SNOP is an Italian scientific society connecting prevention professionals, mainly operating in public health services, listed among the founders of C.I.I.P. (Consulta Interassociativa Italiana per la Prevenzione - Council of Italian Societies for Prevention) (http://www.ciip-consulta.it), active for more than 30 years in the fields of risk communication, education, health and safety promotion, incentive and proposal towards institutional subjects, paying particular attention to occupational cancer themes (http://www.snop.it/index.php?option=com_content_HYPERLINK_).

We are aware that an ongoing project is bent on modifying the current CE Carcinogens and Mutagens Directive and that Mrs Marita Ulksvog proposed many amendments aimed to ameliorate the Directive (coming from chiefly from EEP - PPE, GUE/NGL and Greens/EFA groups).

We have studied and fully agree with the document recently issued, regarding the occupational cancers themes, by ETUC (European Trade Union Confederation); we believe it needs just a limited integration and modification, as follows.

"*Workers who have been exposed to carcinogens and mutagens should be entitled to a health assistance program, based not only upon medical surveillance, even after the end of the exposure and the end of their employment. Ad hoc medical surveillance should be implemented and maintained only when evidence supports reasonable hypothesis that a subject could receive health advantages from early identification of a cancer or of a precancerous condition: but when such evidence exists, any subject has the right to be granted with free of charge diagnosis and treatment. Any subject exposed to carcinogens and mutagens has the right to receive counseling and any other useful support, in front of necessities of coping with anxiety for disease and death too*."

In the same way we have studied and fully agree to the letter recently sent, regarding occupational cancers themes, by Mme Thebaud Mony, honorary research director at the French INSERM, and signally her concerns about the direction along with the reappraisal of the CE Carcinogens and Mutagens Directive seem to go as follows.

1 - The numbers of cancers in Italy

For years Italy has had its own public system for registering and analyzing the *"cancer phenomenon"*, based upon a web of regional registries of cancer cases arising in the local populations; cancer registries meeting strict criteria for accreditation enter an *ad hoc* scientific society called AIRTUM, regularly publishing detailed reports freely available on the Net, among which is the one titled ***"I numeri del cancro in Italia" ("The numbers of cancers in Italy")***.

By way of this source we know that in Italy, excluding skin cancers other than melanomas (roughly 70.000 *per annum*), around 365.000 new cancer cases are diagnosed *per annum*. In Italy the death rate for all cancers stands at around 60 %, leading to around 216.000 cancer deaths *per annum*.

2 - Which kind of occupational cancers and how many occupational cancer cases in Italy ?

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Based upon the available and practically exploitable occupational exposures profiles (i.e. the data provided by the European project CAREX and by a selection of the scientific literature indexed for PubMed), we can reasonably assume that even now we deal with several thousand cancer cases deriving from occupational exposures arising in Italy every year: following different assessment criteria, between at least 4.000 and something over 20.000 *per annum* (a very wide interval estimate, unavoidably affected by differences between the approaches adopted to define a cancer case as *"of occupational origin"*, or not).

Based upon the datasets released by the Italian National Registry of Mesotheliomas - Registro Nazionale Mesoteliomi (ReNaM), we can assume that occupational exposure to asbestos causes at least 700 of the more than 1000 fully diagnosed mesotheliomas arising in Italy every year.

Lung carcinomas caused by asbestos arising in Italy every year are at least as numerous as asbestos - caused mesotheliomas (probably greater in number).

Based upon the datasets released by the Italian National Registry of Sinonasal Cancers - Registro Nazionale dei Tumori Naso-Sinusali (ReNaTuNS), we can assume that at least 200 out of about 360 fully diagnosed sino-nasal cancers arising in Italy every year derive from one or more occupational exposures.

However, mainly as a consequence of the lack of practical enforcement of the National Registry of Low Occupational Etiological Fraction Tumors - Registro Nazionale dei Tumori a Bassa Frazione Eziologica Occupazionale (even if provided for by law - Article 244 of the Dlgs 81/08), our information is, at present, insufficient to issue quantitative estimates about the frequency of other cancer types deriving from occupational exposures in Italy, e.g. lung carcinomas from aromatic polycyiclic hydrocarbons (PAHs), bladder carcinomas from aromatic amines and PAHs, hemolymphatic neoplasms from benzene, skin cancers from ultraviolet (UV) radiation, and so on.

The pattern of our current knowledge about occupational cancers in Italy is clearly different from the "zero" level, but is still largely inadequate: it permits us to classify occupational cancer as a persistent relevant criticality, it calls upon us to cope with it, it directs us towards a list of specific neoplasms deserving particular attention and preventive actions, but certainly much more information is needed.

So we retain a mandatory public intervention aimed at :
i) enforcing and crowning a web of disease / patient registries committed to work-related neoplasms;
ii) promoting *ad hoc* epidemiological studies (both of the cohort and of the case-control types), also examining the effects of widespread *"low exposures"* and of synergies between multiple exposures to different carcinogens.

In this respect, we consider as a very precious resource the experience of the Finnish Tumors Registry (ASA Register), where health information is connected to datasets of occupational exposure to carcinogens.

In parallel, we consider it mandatory that public institutions realize systemic monitoring programs devoted to current and previous occupational exposures to carcinogens, approaching the matter by means of time- and area- specific job exposure matrices (JEMs), adequately socializing their results: in this respect, we can find very useful references by looking at French (Matgéné) and Finnish

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(FINJEM) experiences.

3 - Proposal about the actions we consider mandatory to regulate and carry out the prevention of occupational cancers at work

In practical terms, the project presented for the 28th February session, aimed at modifying the CE Carcinogens and Mutagens Directive, deals solely with the item of the Occupational Exposure Limit Values (OELVs): certainly a crucial one, but certainly not exhausting the whole subject of actions needed to be carried out and maintained over time in order to prevent occupational cancer .

It is fundamental that the European Union does not forget the founding principles at the base of social legislation, and seeks to ensure that health protection is not subject to constraints imposed by the market; especially in the face of a severe, widespread and painful phenomenon like cancer (carrying heavy economic consequences too), we want the CE to maintain a position of reasonable prudence, i.e applying what is universally known as the *"precautionary principle"* detailed in Article 191 of the Treaty on the Functioning of the European Union (EU).

The OELV values that have been proposed for several important agents, although intended solely as *"pragmatic" rather than "health-based"* limits, can not be considered adequate to the necessities and to the present possibilities for preventing occupational cancers, considering both available scientific knowledge and technological feasibility. This statement particularly applies to crystalline silica (quartz) and hexavalent chromium (Cr VI); regarding the latter, the OELV proposed at the European Commission stands at a very high level of 25 micrograms per cubic meter of air, corresponding to a risk of an additional lung cancer case amongst every ten exposed workers during their whole working life. In France, Netherlands and Germany an OELV of 1 microgram per cubic meter for Cr VI has been adopted and gives hope for a relevant risk abatement.

It will be central that the European legislation regarding occupational exposures to carcinogens adopts, as a direct consequence of the general precautionary principle, the specific principle ALARA (As Low As Reasonably Possible) on *"tolerated"* or *"accepted"* exposures levels, ensuring an effective application of the best available practices.

We can not forget that no reasonable outcome has been achieved by the efforts conducted by many to exactly define a DNEL (Derived No-Effect Level), i.e. a threshold, an exposure level below which the exposure to a given carcinogen certainly has no consequences upon the web of causation of one or more cancer types.

We can not forget that the division of labour and the unequal allocation of the exposures bring about a very unequal allocation of the cumulative hazard, with the majority of deleterious effects being found in precarious population groups such as multipurpose workers and poor workers in general, especially those assigned to jobs such as maintenance, cleaning, waste management and those entering high-risk processes entailing high cumulative exposure to carcinogens, especially in marginal and scarcely controlled areas in which the productions that represent the highest risk to human health and the environment are to be found. So, at present too, many workers undergo relevant multiple exposures to carcinogens (concurrently and / or sequentially), raising their personal risk of falling ill to a cancer.

We stress that an adequate assessment of *"pragmatic"* OELVs for carcinogens must not to be and

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cannot be the sole tool being adopted by the European Community to cope with the occupational cancer issues: the issue of regulations about OELVs needs to be accompanied by systemic actions in the fields of independent scientific research, controls upon market, production processes and practical working conditions, public monitoring of exposures (job-exposure matrices - JEM) and diseases (Cancer Registries), education and counseling for employers and workers, assistance both for "at risk" subjects and patients, conscious community participation in the web of all useful actions for cancer prevention and health promotion.

We fully support the amendments proposed by Mrs Ulksvog, together with other CE Members of Parliament, namely:

- the enlargement of the field of application of the Directive to reprotoxic agents (***amendments 12 and 13***);
- the placement at the value of 0,05 mg/m^3, i.e. 50 micrograms/m^3, of the OELV for the exposure to crystalline silica (***amendment 23***);
- the placement at the value of 0,001 mg/m^3, i.e. 1 microgram/m^3, of the OELV for the exposure to Cr VI (***amendment 20***);
- the placement at the value of 1 mg/m^3 of the OELV for the exposure to wood dusts, regardless of distinctions about the nature of the wood species on a case-by-case basis involved - *"hard"* or not (***amendments 18 and 19***);
- the placement at the value of 0,1 mg/m^3 of the OELV for the exposure to ceramic fibers (***amendments 21 and 22***);
- the placement at the value of 1,12 mg/m^3, i.e. 0,5 ppm, of the OELV for the exposure to 1-3 Butadiene (***amendment 25***);
- the necessity to include diesel exhausts inside the field of application of the CE Carcinogens Directive (Annex 1) and the assessment, for them, of an OELV of 0,1 mg/m^3 in the context of Annex 3 (***amendments 191 and 192*** presented by Mrs Karima Delli);
- the necessity to ensure the transparency of the processes for estimating the number of cancer cases practically *"tolerated"* or *"accepted"* correspondingly to given exposure values considered in the aim to define a DMEL (Derived Minimal Effect Level) (***amendment 5***);
- the assessment of an obligation assuring that all workers exposed to carcinogen, mutagen and reprotoxic risks will receive a dedicated, affordable and effective sanitary, both when they are at work and after retirement (***amendment 14)***;
- the assessment of an obligation to update the Carcinogens Directive at regular intervals, taking into consideration both the present scientific knowledge and technology and their evolution, and remembering that at present there are just under 50 agents that ETUC has pointed out as of particularly high concern (***amendments 1 and 6***);
- the assessment of an obligation to identify and permanently monitor the workers' exposures to carcinogens and to evaluate them inside the context of the actions addressed to the labour, publishing the results at a European level, according to the regulations established by the CE Directive in 1989 (***amendment 4***).

We strongly support a solicitation to the European Community so that, on the occasion of the revision of the Carcinogens Directive, in its full autonomy of judgement the European Community newly and authoritatively deals with the problems posed by the exposures, not only in work environments, to two widespread agents like glyphosate and formaldehyde: with

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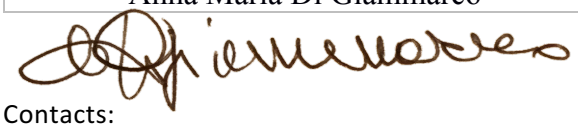
resepect to both, we seek proper regard to the robust scientific positions advanced by IARC, following assessments issued by its Working Groups formed by independent experts.

Please, do not hesitate to request any elucidations and technical details you may consider useful to your action; we will be glad to meet you too and to deal with your arguments and necessities, and to discuss with you the dossier going to the debate on February 28 2017 at the Social Affairs European Commission.

Yours sincerely

La Presidente
Anna Maria Di Giammarco



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