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TRANSLATION OF PROF. MALTONI'S ARTICLE
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PVC BOTTLES : THE GREEN LIGHT

"COOP" is the most powerful large-scale distribution chain in Italy, this chain, of communist origin has been characterized up to now by incisive "eco-marketing", going as far as to rule out PVC packaging in some regions of Italy. It plays a leading role in Italy and can be compared with MIGROS in Switzerland.

Prof. MALTONI is one of their scientific consultants.

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MINERAL WATER IN PVC BOTTLES

César Maltoni(*)

Plastics and foodstuffs, a controversial marriage. Studies seem to give PVC the go-ahead. Similar studies should be made for PET and for glass.

THE GREEN LIGHT

Can plastics be used as packaging materials or for manufacturing bottles for mineral water or other beverages ?

This question has been discussed very often in the last few years, regularly submitted to public opinion and still remaining very actual.

The problem is that soluble impurities in these plastics might migrate into food or beverages or might be formed through contact with the contents (water for instance).

These substances likely to migrate contain monomers (which are small basic molecules that constitute polymers), products of different types added to optimize the type of plastic according to the different uses and other products formed during the use of the plastics.

The plastic material that, among different types of plastics used by the food and beverage industries, has been, rightly or wrongly, the subject of major concerns and controversy, is without any doubt PVC. Why ?

The reason for this particular attention is that vinyl chloride, the monomer constituting PVC, has proven to be carcinogenic and that the consideration of the carcinogenicity triggered off a real revolution in the sector of toxicology and industrial carcinogenicity and environment, not only for the assessment of the dimension of industrial carcinogenicity as a public health hazard, but also for scientific methodologies, the approach of the problem and the norms.

TWENTY YEARS OF VINYL CHLORIDE

Thanks to a project of experimental studies having no historic precedent, neither by its size nor by its systematic approach, launched in 1971 and lasting several years and conducted by the Experimental Laboratories of the Institute of Oncology of Bologna at the Bentivoglio Castle, it was proven in 1972-1974 that vinyl chloride is carcinogenic for different animal species and for many organs and tissues both by inhalation (VCM is indeed a gas) and by ingestion, diluted in oil.

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The tumor more specifically related to vinyl chloride was a rare form of malignant neoplasia, a tumor of the liver blood vessels, i.e. hepatic angiosarcoma. Our Institute's data have oriented and encouraged epidemiological studies that have confirmed the carcinogenic effect of this component on human beings, in particular thanks to the discovery of angiosarcomas in factory workers who had been exposed.

The experiments of the Institute of Oncology of Bologna have also supplied information on the carcinogenicity of VCM with respect to the doses; these data have constituted to a great extent the basis of the standards on the acceptable levels of this component.

Two lessons were drawn from the history of VCM carcinogenicity :

- 1) experimental studies can predict the carcinogenic effect of agents man is in contact with.
- 2) such studies can give indications that can be used to determine standards and to develop a specific technology, they can thus be considered as a development research.

In view of the results concerning the carcinogenicity of VCM and the technological and economic importance of PVC, industry has taken a series of technical measures (of unprecedented extent and rapidity) to reduce the VCM concentration in workshop atmosphere and to cut drastically the levels of this component in plastics for packaging foodstuffs and pharmaceuticals.

Until the VCM was found out to be carcinogenic, it had been present in high concentrations in plastics used for the food industry. I remember very well how the situation was clearly described at the time.

After having published our data on the risk of this component, we got a letter from a representative of the whisky production and distribution. He told us that he was very worried about the fact that a VCM concentration of 20 ppm had been found in PVC barrels (simulating wood). He also asked us to comment on the possible risks.

COMPARISON BETWEEN MINERAL WATER IN GLASS BOTTLES AND IN PVC BOTTLES

There is a principle in Research and thus also in bio medical Research saying that Science has only one basis : the datum, and only one language : figures.

A datum is the more precise as it reproduces and thoroughly analyzes the situation that is the subject of research.

In order to know whether PVC bottles with low concentrations of VCM and other additives that may migrate, are compatible with public health, there was only one direct way : to make sure by adequate experiments that the ingestion of water contained in PVC bottles increased the occurrence of tumors or other effects on health in comparison with water packaged in traditional bottles, i.e. made of glass.

In November 1988, five years ago, a mega-experiment was started in the experimental laboratories of the Institute of Oncology of Bologna at Bentivoglio Castle to assess the carcinogenic hazards of carbonated or non carbonated mineral water from PVC bottles compared to the same type of water from glass bottles.

A research was made on 2,000 rats. 1,000 animals (50 % females, 50 % males) were fed with PVC-bottled water from birth till death (check-group).

The mothers of these rats had drunk PVC bottled water before the conception and during pregnancy. This water had been bottled at least 1 or 2 months before and PVC tablets had been added of the same type as the one used for the bottles (eliminated before watering the animals) in order to intensify later on the possible migration of soluble contaminants.

We can speak here, for the group of animals treated, of global and intensified feeding with water packaged in plastic bottles.

The quantity of VCM found in the water contained in the PVC bottles was 10 to 150 ppt, i.e. 0.01 to 0.15 parts per billion of water.

The biological phase of the Study lasted more than 3 years and was followed by an elaboration phase of 18 months.

The animals were checked during their whole life as to their weight, behaviour and pathology. After their decease, they were submitted to a complete autopsy and a systematic histological examination.

For each rat, a systematic histopathological examination of at least 60 tissues and organs was carried out; so, this Study included the execution and examination of about 130,000 histologic sections.

The research was carried out on a model animal well known by researchers. The latter have a long experience of mega tests, which as a model of biomedical research, have been almost perfected by the Laboratory of Bentivoglio.

The study of mineral water in PVC bottles represents a prototype of controlled mega-experience that is the only scientific tool we have at our disposal to assess (mainly low potential) diffuse carcinogenic risks. The definition of diffuse oncological risks, the characteristics and the functions of the mega-experiments developed to identify them are shown in the attached table.

The data have been completely analyzed and worked out a few weeks ago and the results can be summarized as follows :

- 1) among the 1,000 animals fed with mineral water packaged in PVC bottles and those fed with mineral water in glass bottles there were no noticeable differences concerning survival, weight, health conditions during the tests, typology and especially the effect on tumors.

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- 2) the result of the carcinogeneticity test is therefore negative; in other words, if there should be any risk, it is below the sensitivity limits of the mega-experiment carried out.
- 3) concerning the tumors, their effect among treated animals compared to control animals is the same, i.e 40.9 % for animals fed with glass-bottled water and 39 % for those fed with PVC-bottled water.

GLASS AND PET TO BE EXAMINED

At least as far as PVC bottles are concerned, we can say that we have today a convincing powerful experimental study which, since it has yielded negative results gives us satisfactory safety margins. But foodstuffs and beverages are also marketed and distributed in containers made of materials for which we do not have any study saying they are less hazardous. I am referring especially to glass and other plastics (besides PVC).

Glass often contains components that can migrate, namely metal impurities. The quality of glass may vary depending on its origin or typology.

The entity of these impurities should be studied - their risks should be better assessed and definite standards should be set for them, when the glass is to be used for foodstuffs and beverages. For plastics used for the manufacturing of bottles for beverages and food containers, still other types of polymers are used besides PVC : in particular for water bottles, PET is the secondly most widely used plastic material, after PVC in the bottle manufacturing sector.

Regarding the toxicity and, the carcinogenicity of monomers constituting plastics other than PVC none have been studied like VCM and for many of them there are no studies or if they exist, they are inadequate; it is the case for those dealing with PET.

We are convinced that it is imperative without any delay to submit also bottles made of plastics other than PVC and, in particular PET, to the same kind of studies as those that have characterized the biomedical research on VCM and PVC.

In this connection we are now carrying out an experimental test of carcinogenity on acetaldehyde added in variable doses to drinking water : this compound migrating in water is indeed present as impurity in PET and moreover forms when PET is brought into contact with water.

Note : the tables mentioned in this articles do not appear in COOP's journal.

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LONG-TERM CARCINOGENICITY BIOASSAYS OF POLYVINYLCHLORIDE (PVC)
ADMINISTERED BY INGESTION (GAVAGE) ON SPRAGUE-DAWLEY RATS

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CURRICULUM VITAE OF PROFESSOR CESARE MALTONI, MD

Born in Faenza (Ravenna) Italy, on November 17, 1930. Graduated in Medicine and Surgery at the University of Bologna. Docent in General Pathology and Oncology. Director of the Institute of Oncology of Bologna since 1964. Professor at the school of Oncology of the University of Bologna.

Past President and Honorary President of Italian Society of Tumor Prevention, Detection and Therapy. Member of the Italian National Board of Health, and of the Italian Commission of Carcinogenesis, Teratogenesis and Mutagenesis. Past Chairman of International Committee of Human Tumor Characterisation. Member of the Académie Internationale de Lutèce, and of the "Académie des Sciences, des Arts et des Lettres". General Secretary of Collegium RAMAZZINI.

He is author of more than 320 scientific publications, and co-editor and contributing editor of several scientific series of books, and scientific journals.

His major contributions were :

1. the promotion of large scale screenings for early diagnosis of tumors,
2. the promotion of health surveillance of groups at carcinogenic risk,
3. the foundation of the Tumor Registry of Bologna, and,
4. the setting up of a large Experimental Unit of Industrial, Occupational and Environmental Carcinogenesis (when it was shown that :
 - 1) vinyl chloride is experimentally a multipotential carcinogen, causing, among other tumors, angiosarcoma of the liver,
 - 2) benzene is an experimental multipotential carcinogen, and,
 - 3) many other widely produced and used compounds are carcinogens on experimental system.

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