

# LESSONS LEARNED FROM JOINT WORKING GROUP REPORT ON ASSESSMENT AND MANAGEMENT OF CANCER RISKS FROM RADIOLOGICAL AND CHEMICAL HAZARDS

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## LEÇONS TIRÉES DU RAPPORT DU GROUPE DE TRAVAIL MIXTE PORTANT SUR L'ÉVALUATION ET LA GESTION DE RISQUES DE CANCER DUS AUX DANGERS PROVENANT DE CONTAMINANTS CHIMIQUES ET RADIOLOGIQUES

### RÉSUMÉ

La réglementation des dangers d'exposition de la population humaine aux rayonnements ionisants est grandement simplifiée par l'existence de la Commission internationale de protection contre les rayonnements (CIPR) (En anglais ICRP : International Commission on Radiological Protection). Les valeurs moyennes d'EBR (efficacité biologique relative) ou de facteurs de pondération (pour divers types de rayonnements) recommandées par la CIPR sont basées sur des données recueillies dans des études sur des organismes non humains. De plus, pour la CIPR, les mesures de contrôle de l'environnement requises pour la protection de la population humaine, au niveau jugé nécessaire actuellement par la Commission, sont suffisantes pour les autres espèces (traduction libre du texte ICRP). Cette prise de position de la CIPR est confirmée par des publications techniques d'autres organisations. Des membres du personnel de la Commission de contrôle de l'énergie atomique (CCEA) ont publié deux objections au sujet de la documentation appuyant la position de la CIPR, mais ces objections n'offrent pas de raisons suffisantes pour rejeter la prise de position de la CIPR.

Dans le présent exposé, un bref résumé du rapport du comité mixte sur le sujet en titre est présenté. On y note que la réglementation des substances chimiques cancérigènes ne tient pas compte, en général, des sources naturelles de contaminants, contrairement à la réglementation en protection radiologique. La plupart des espèces non humaines sont exposées à un équivalent de dose (de rayonnement ionisant) approximatif de 1 millisievert (mSv) par année provenant de sources naturelles. On note que le caribou et des organismes vivant en milieu souterrain sont exposés à des sources naturelles résultant en des équivalents de dose considérablement plus élevés.

Le biote naturel est en général doté d'une résistance remarquable, comme l'ont constaté de nombreuses études, en laboratoire autant que sur le terrain. L'Agence internationale de l'énergie atomique conclut qu'il est peu probable que des débits de dose inférieurs à un équivalent de dose de 400 mSv pour les humains puissent porter atteinte à la survie d'espèces non humaines.

On recommande d'agir avec prudence et sens commun dans les recherches futures sur la protection radiologique des espèces non humaines dans l'environnement au Canada. Aux États-Unis, plusieurs des projets de règlements proposés pour la protection de l'environnement contre les dangers posés par les produits chimiques et par les substances radioactives ne sont pas rentables. Il faut espérer qu'au Canada, nous ne glisserons pas dans un semblable bourbier d'irrationalité dans nos efforts pour protéger les espèces non humaines des dangers radiologiques potentiels.

## ABSTRACT

Regulation of radiological hazards to humans is greatly simplified by the existence of the International Commission on Radiological Protection (ICRP). The average RBE values or radiation weighting factors recommended by the ICRP are based on non-human data. The ICRP has also indicated that "the standard of environmental control needed to protect man to the degree currently thought desirable will ensure that other species are not put at risk." This statement appears to be supported by technical publications from other organizations. Two published objections by AECB staff to the scientific technical background of the ICRP statement do not offer any good reason to reject this ICRP statement.

A brief summary is given of the joint working group report on the topic indicated in the title. It is noted that regulators of cancer-causing chemicals have in general paid less attention to natural sources than have the regulators of radiological hazards. Most non-human species are exposed to about 1 millisievert (mSv) equivalent dose of radiation per year from natural sources. Caribou and organisms living underground are noted as examples where radiation exposures from natural sources are considerably higher.

The natural biota is in general remarkably resistant, both in the laboratory and in field studies, to the effects of high doses of radiation. A recent review by the International Atomic Agency concluded that dose rates below the equivalent of 400 mSv per year are unlikely to alter the survival of non-human species.

It is recommended that caution and common sense be applied in any future research on radiological protection of non-human species in the environment in Canada. Many of the proposed U.S. regulations to control chemical and radiation in the environment are not cost-effective. It is to be hoped that efforts to protect non-human species from potential radiological hazards in Canada do not slide into a similar kind of irrational quagmire.

## 1.0 INTRODUCTION

The Joint Working Group (JWG) of which I am co-chairman is not directly concerned with radiological risks to non-human species but rather with a comparison of methods of assessing and regulating risks to humans from radiation and from hazardous chemicals. My co-chairman is Dr. D. Krewski of Health Canada. Members of the Joint Working Group included representatives from Health Canada, the AECB Advisory Committee on Radiological Protection, the AECB Advisory Committee on Nuclear Safety, the AECB Group of Medical Advisors, the AECB itself, and the Ontario Ministry of Environment and Energy. Dr. P. Thompson, who is one of the instigators and speakers at this symposium, is also a member of the JWG. An earlier draft of this report was forwarded for comment to selected scientists in Canada, the U.S.A. and the U.K. as well as to federal and provincial representatives on the Committee on Environmental and Occupational Health in Canada. A great deal of valuable advice as thus received. The material in this report was essentially approved by the Joint Working Group in January 1996 with the proviso that it should be rewritten by a scientific editor to smooth out the style; this re-writing is still in progress.

## 2.0 PRINCIPLES INVOLVED IN RADIOLOGICAL PROTECTION

Regulation of radiological hazards to humans is greatly simplified by the existence of the International Commission on Radiological Protection (ICRP) which issues regular publications on this topic. AECB in 1991 issued a consultative document indicating its intention to adopt the most recent recommendations of the ICRP. In Canada, basic principles for radiation protection were established as early as 1945 and have of course evolved since then. We have thus a long tradition that radiation doses from all radionuclides received by humans from all

environmental pathways should be added up. In order to do this, average weighting factors for the relative biological effectiveness (RBE) of different types of radiation at low dose had to be established. Alpha-particles were assigned an average RBE value of 10 in Canada in 1945, based on laboratory studies on non-human species such as bean sprouts. This RBE of 10 for low doses of alpha particles was later increased to 20 by the ICRP in 1977. It should be emphasized that the current average RBE values (or radiation weighting factors) are all still based on studies on non-human species or, more recently, on cultured cells. There are no human data to establish RBE values, and there does not seem to be any good reason not to use the same average RBE values for non-human multicellular species. One should of course be cautious about applying the same radiation weighting factors to small unicellular organisms. The results can be expressed as an equivalent dose in sieverts but the authors must spell out clearly what they have done.

The ICRP also recommended in 1977 and 1991 the use of tissue weighting factors for exposure of selected tissues in humans to radiation. These values were derived from epidemiological studies on humans only. Equivalent values for non-human species do not exist, and indeed it seems nearly impossible to measure tissue weighting factors for each of the tens of thousands of non-human species that live in any given area of the world.

The most recent 1991 recommendations of the ICRP include the following statement: "The Commission believes that the standard of environmental control needed to protect man to the degree currently thought desirable will ensure that other species are not put at risk. Occasionally, individual members of non-human species might be harmed, but not to the extent of endangering whole species or creating imbalance between species." This rather powerful statement appears to be supported by technical publications from the International Atomic Agency (IAEA), the U.S. National Council on Radiation Protection (NCRP), the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), as well as by my own review of earlier literature.

Objections by AECB staff to the scientific technical background of this ICRP statement have been summarized by R. Chatterjee in a recent issue of the Bulletin of the Canadian Radiation Protection as follows: "... these conclusions are almost entirely based on the effects of exposure to external gamma radiation. Information on radiation effects of internally deposited alpha emitters is non-existent. Furthermore, AECB staff has noted that the differences in the radiosensitivity of various groups of organisms mentioned above practically disappear when genetic effects are considered." While both of these statements are true neither of them offer good reason to doubt the ICRP conclusion. If we know the radiation dose from internally deposited alpha emitters, we can easily compare this with the effects of the same radiation dose from external gamma radiation using internationally accepted RBE values or radiation weighting factors. The importance of genetic effects in non-human species is also highly debatable. In the first place, there is no evidence for a significant increase in genetic diseases in the children of Japanese bomb survivors who were exposed to high radiation doses at Hiroshima and Nagasaki in 1945. Secondly, and perhaps more importantly, serious detrimental genetic defects tend to be weeded out rather quickly by natural selection in populations of non-human species living under natural conditions in the wild. This situation is rather different from that for humans in technologically developed countries, where the tendency is generally to try to keep humans alive for as long as possible.

### **3.0 COMPARISON OF RADIATION AND CARCINOGENIC CHEMICALS**

A brief summary of our comparison of chemicals and radiation might be useful. (1) Regulators of genotoxic carcinogenic chemicals (i.e. chemicals which damage the DNA) generally use the same linear, non-threshold dose response relationship that is used for cancer induction by radiation. This is a theoretical assumption which cannot be proven at low doses of radiation or carcinogenic chemicals. Cancer development is a complex, multi-stage process and the latency period to development of an overt cancer frequently increases with decreasing dose. It is probable that, in certain cases, there is a practical threshold at low radiation doses due to the fact that humans and other animals do not live long enough for the cancers caused by very low radiation doses to develop.

Because the underlying theoretical assumption is similar, the JWG has chosen to focus on carcinogenic hazards from radiation and chemicals; potential hazards from other toxic effects of chemicals and bacteria are noted only briefly for purposes of comparison. (2) For both carcinogenic chemicals and radiation, the principle is applied of keeping all exposures as low as reasonably achievable, economic and social factors being taken into account. (3) Estimates of cancer risk for radiation are derived from human data; those for carcinogenic chemicals depend primarily on laboratory studies with rodents. (4) For radiation received from radionuclides, the general principle is to adopt a single dose limit for all radionuclides combined and to reduce actual exposure as far as reasonably achievable below this dose limit. For carcinogenic chemicals in municipal drinking water, the general principle is to reduce exposures as low as reasonably achievable and to set the dose limit for individual chemicals at this level. Potential hazards from individual carcinogenic chemicals are not summed. As a result, the dose limits for different individual carcinogenic chemicals in drinking water represent potential hazards which differ by a factor of 10,000 fold. (5) Dose limits for all radionuclides from all sources combined in drinking water are set at a level (0.1 mSv per year) where the estimated potential risk to humans is much higher than that for most man-made carcinogenic chemicals but lower than that for arsenic from natural sources in drinking water. Fortunately, the concentrations of radionuclides in drinking water from the Great Lakes are orders of magnitude lower than this dose limit. (6) Although both AECB and Environment Canada are very interested in the effects of radiation on non-human species, current radiation dose limits are based solely on potential hazards of radiation to humans. For toxic chemicals in water, effects on development of aquatic non-human species are also considered.

An additional problem might be noted. (7) Regulators of carcinogenic chemicals have in general paid less attention to natural sources than have the regulators of radiological hazards. One U.S. investigator has suggested that humans consume about 10,000 times more potentially carcinogenic pesticides from natural sources in foods than they do of the potentially carcinogenic synthetic pesticides which are closely regulated. Regulators of both radionuclides and carcinogenic chemicals appear to have done an outstanding job in as far as control of man-made or anthropogenic sources of both types of agents in the environment are concerned; more attention to non-regulated sources might be useful in future.

Although the issues dealt with in preparation of the JWG report were complex, and both co-chairmen learned a great deal from this exercise I believe, the complexities are small compared to those involved in looking at effects of radiation on non-human species. The effects of radiation on humans have been studied for more than nine decades. A great deal of information on non-human species has become available in the past five decades, but because of the very large number of non-human species that live in the world, this information will of course never be as complete for each species as that for humans. A search for the most radiation-sensitive species by looking at the relative populations of many different species in a radiation contaminated environment is in my opinion doomed to failure. There are far too many natural causes (droughts, forest fires, severe winters etc.) for normal wide fluctuations in the numbers of individuals in each species. Defining the average baseline for populations of all living organisms in a given area is very difficult and very expensive. It is also well known that millions of species have in the past become extinct (and been replaced) due to natural causes alone, long before the advent of humans in this world. The most radiation-sensitive species can be more reliably identified by review of the numerous laboratory and field studies that have already been published on this topic.

#### **4.0 RADIATION EXPOSURES**

The levels of radiation to which humans are exposed have been studied very extensively. On average in Canada, humans are exposed to about 1 mSv per year from natural sources such as cosmic rays, radiation from the soil and rocks, and radionuclides from ingested food and drinking water. Another 1 mSv per year on average, with major variations from one location to another, is due to inhalation of radon progeny from natural sources in the air in homes. A third contribution of about 1 mSv per year on average derives from medical applications, including x-rays and nuclear medicine, for the diagnosis of disease. Other man-made exposures are trivial by

comparison. For example, the maximum exposures to individuals living close to nuclear power stations in Canada are about 0.02 mSv per year, with doses to individuals living further away being very much less.

Radiation doses to non-human species are less certain. Average doses to most animals and birds will in general be about 1 mSv per year from natural sources since the contributions from radon in homes and from medical diagnoses are usually eliminated. The extra doses from nuclear power stations will also be very low since the major contributors, notably tritiated water and radioactive noble gases, do not accumulate in body tissues. However, there are some exceptions. Caribou frequently feed on lichens which have a very efficient system for trapping radon progeny from natural sources, and it appears that the caribou in northern Canada may receive large chronic radiation doses from this source. Secondly, it is well known that the concentrations of radon progeny in the soil are much higher than they are in surface air: organisms which spend all or most of their time below the surface of the soil (for example, some rodents, earthworms and plant roots) would thus be expected to receive much more than 1 mSv per year from this source. A detailed examination of these exposures is given in the 1996 UNSCEAR report. All of this has of course been going on for thousands of years under natural conditions.

## 5.0 EFFECTS OF RADIATION ON NON-HUMAN SPECIES

A great deal of work from various countries has been published dealing with the effects of radiation on non-human species both in the laboratory and in the field. These data have been reviewed by the IAEA, U.S. NCRP, and once by myself. A more recent review by UNSCEAR will be discussed by Dr. Woodhead at this symposium. My own interpretation of the earlier reviews will be summarized here.

The natural biota is in general remarkably resistant to the effects of high doses of radiation. Scientific visitors to the Bikini atoll in the South Pacific, where H-bombs were tested about 1960, had to hack their way through the jungle ten years later. A prompt increase in the number of eye-color genetic mutations in local fruit flies was noted but this increase in incidence died away fairly quickly after cessation of the H-bomb explosions. The genetic effects observed in fruit flies living on the Bikini atoll are consistent with the radiation effects noted earlier in laboratory studies on fruit flies. The natural incidence of another type of genetic mutation in fruit flies was approximately doubled by the chronic radiation dose of about 10,000 mSv per generation over many generations; this increase also decreased rapidly due to natural selection processes when radiation exposure was stopped. No significant genetic effects have been observed in the human children of the Japanese survivors of the atomic bomb explosions over Hiroshima and Nagasaki in 1945, even though the radiation dose required to double the natural mutation rate is believed to be similar in humans and in fruit flies.

In Canada, a study with a gamma-irradiator at the Whiteshell laboratories in Manitoba showed that pine trees in the forest were most susceptible to radiation effects. However, the radiation dose rate required to kill pine trees after a few years of chronic exposure was several orders of magnitude higher than the natural radiation exposure of 1 mSv per year. A variety of related studies on plant life have been carried out in the field in the U.S.A. One of the most sensitive endpoints appears to be the proportion of similar species in control and irradiated areas. The minimum dose rate required to produce a significant change in this proportion with 2 years was in the region of 180,000 mSv per year in an oak-pine forest. Many other endpoints have been studied in animals in the laboratory. The most sensitive endpoint here appears to be killing of 50% of immature egg cells (which does not in itself result in sterility) by about 40 mSv per year during the last trimester of fetal development in monkeys. Reproductive cells in lower organisms appear to be less sensitive to killing by radiation.

The IAEA reviews concluded that dose rates below about 400 mGy per year are unlikely to alter the survival of non-human species but that special consideration may be needed in the case of endangered species. The question of the survival of endangered species is of course a controversial topic. The survival of most non-human species

appears to become endangered through human activities such as over-fishing, over-hunting, clear-cutting of forest (including, for example, the preparation of human farmland and urban centres in Ontario) and sometimes war, not through the current regulated releases of radionuclides or carcinogenic chemicals from industrial sources. More attention to cost-benefit analyses of any proposed regulatory actions would be useful.

## 6.0 SUGGESTIONS FOR FUTURE RESEARCH

I have no specific suggestions for future research on radiological protection of non-human species in the environment. After discussing this question with Dr. D.B. Chambers of SENES Consultants, I would like to echo pleas for the application of caution and of common sense. There does not seem to be any point in recommending the expenditure of tens of millions of dollars on research projects that will not help us to solve any practical problems.

The calculation of cost-benefit ratios obviously needs to be encouraged, as it is in a 1994 draft statement on Managing Risks on Behalf of Canadians issued by the Treasury Board. There is considerable data available from the U.S.A. on the wide variations in cost-benefit ratios for various regulatory actions. The U.S. Environmental Protection Agency (EPA) and other government agencies have been criticized by the U.S. Office of Management and Budget for promulgating regulations which are not cost effective. This criticism was accompanied by a table indicating that the cost in millions of 1990 U.S. dollars per potential premature human death avoided varies by a factor of about 30,000,000 as a result of compliance with different EPA regulations. A more recent article by Tengs et al shows similar wide variations in cost per year to human life saved. Overall, the median medical intervention costs \$19,000 per life year saved, injury reduction \$48,000 per life year, and toxin (both chemical and radiation) control \$2,800,000 per life year. As noted by Tengs et al, this kind of variation is "unnerving." It is to be hoped that efforts to protect non-human species from potential radiological hazards in Canada do not slide into a similar kind of irrational quagmire. The costs of research and control and the potential benefits all need to be taken into account, as do the general principles of natural selection, and normal exposures to radiation and toxic chemicals from natural sources.

## 7.0 DISCUSSION

***Question No. 1: You touched briefly on the fact that carcinogenicity has been regulated in a different manner for radioactivity and for chemicals. This issue arises frequently. Do you have any suggestions on how to merge radiation protection and chemical methodology?***

Dr. Myers replied that the Joint Working Group had concluded that the two approaches to human carcinogenicity could not readily be harmonized, principally because of the different historical development of the two methods. However, in the case of ecological risk assessment there may be more opportunity for harmonization, since it is still quite early in the development of methods for both. In the case of radionuclides, it is the radiation dose that is toxic, not the isotope.

Mr. Maloney added a comment that the AECB's approach in the ecological risk assessment is to try to make the assessment endpoints as analogous to those used in traditional radiation protection as practical.

***Question No. 2: How I have attempted to harmonize the approaches in my own mind is to consider that a dose of 1 mSv, the annual public dose limit recommended by ICRP-60, represents a cancer risk of 5 in 100,000 based on the ICRP dose response curve. But in practice emissions are controlled so that actual doses are generally only a few percent of this or less. The risk limits applied to exposure to carcinogenic chemicals are typically around 1 in a million, so in comparison the risks are actually quite similar.***

Dr. Myers responded that in any such comparison it should be remembered that radiation dose limits apply to the total risk from all radionuclides, whereas chemical risk limits are applied separately to each individual chemical.

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