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Possible Trends in the Management of Radiological Materials and Hazardous Chemicals Authorised for Release to the Environment



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Committee on Radiation Protection and Public Health

POSSIBLE TRENDS IN THE MANAGEMENT OF RADIOLOGICAL MATERIALS AND HAZARDOUS CHEMICALS AUTHORISED FOR RELEASE TO THE ENVIRONMENT

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Radiological Protection

Possible Trends in the Management of Radiological Materials and Hazardous Chemicals Authorised for Release to the Environment

Report to the 69th CRPPH Meeting (17-19 May 2011) Prepared for the ad-hoc Expert Group on RP of the Environment (EGRPE) by Dr. Jack Valentin

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SUMMARY

At its 68th meeting, the CRPPH approved a short questionnaire concerning possible trends in the management of radiological materials and hazardous chemicals authorised for release to the environment. The key issue to be analysed was whether NEA member countries are moving towards bringing closer together their regulation of radioactive substances and toxic chemical substances in the environment. The questionnaire was distributed by the NEA Secretariat to the CRPPH membership, and responses were obtained from twelve member countries (in two cases, from several different regulatory agencies within a member country).

Of the twelve countries that responded, five flatly observed that no such trend towards a unification of the regulatory approaches existed in their countries; a similar reply from a sixth country added that agencies collaborate to combine (but not align) different requirements. Four countries indicated various stages of development towards some future harmonisation of legislation and/or protection goals. Two countries mentioned limited current alignment of protection goals and felt that this had resulted in some improvement of protection of the environment.

Thus, 6 out of 12 countries do not seem to expect or plan for any harmonisation of their regulatory systems for health effects of radioactive or chemical releases to the environment. However, 6 countries do anticipate some developments in this direction, and two of them have already taken some small steps towards unification. Furthermore, earlier information to the EGRPE from two countries hints that one of them does not anticipate unification anytime soon while the other one begins to arrange for a degree of harmonisation.

Those countries that are considering some alignment of their systems mention anticipated advantages in terms of administration (and concomitant costs to operators) as well as sustainability: duplication of requirements avoided, conflicting requirements avoided, a more holistic approach leading to improved protection of the environment.

In conclusion, the survey shows that there are some trends towards unification, but the trends are not universal. In the consultant's opinion, this could be an area where CRPPH may wish to continue to be active in the future.

1. Introduction

The CRPPH has for some time been interested in the radiological protection of the environment, in particular since the Taormina workshop (2002), and the issuance of ICRP Publication 91 (2004). The CRPPH discussed this topic at its 66th and 67th meetings (in 2008 and 2009), and agreed that it would be useful to create a small ad-hoc Expert Group on the Radiological Protection of the Environment, EGRPE, to explore the regulatory implications of this question to see whether the CRPPH could effectively contribute in this area.

At the 68th CRPPH meeting (2010), the EGRPE reported that a number of important issues were already being addressed by other organisations, and recommended that the CRPPH should continue to monitor progress, but did not propose any concrete actions that the Committee should undertake with respect to those issues.

However, the EGRPE also noted that there were signs of a tendency to explore how the regulation of chemical pollution of the environment and radiological pollution of the environment

could be brought closer together. Because of this, the EGRPE proposed that the CRPPH should explore trends and approaches in this area, taking account of recent work performed within the PROTECT project of the Euratom 6th Framework, through the use of a simple questionnaire that had been drafted by the group. Initially, the idea would be to see if such tendencies exist in many NEA member countries, and if so what approaches are being pursued.

The CRPPH agreed to approve to send the questionnaire to CRPPH members, and this was effected in 2010. The present report summarises the responses received and outlines the conclusions that could be inferred.

2. Results

To date, responses have been received from twelve countries, viz., Austria, Canada, the Czech Republic, Denmark, Germany, Iceland, Ireland, Japan, Norway, Sweden, Switzerland, and the United States. Table 1 provides a very brief summary of these responses. In addition, at the stage when the questionnaire was devised, Spain and the United Kingdom provided input which was described in the 2010 EGRPE report to CRPPH and which is relevant in this context.

The questionnaire

In addition to contact details, respondents were asked to provide information concerning:

- The regulatory and advisory responsibilities of their organisation;
- Any trend in their countries to combine the environmental regulation, in legislation or organisational structure, of radiological and chemical hazards;
- Any trend in their countries to combine advisory capacity for environmental protection, in legislation or organisational structure, concerning radiological and chemical hazards;
- Any improvement in their countries of protection of the environment from the regulatory standpoint due to such trends.

The respondents

The pattern of different kinds of respondents is quite varied, ranging from government ministries over regulatory authorities to purely advisory organisations. Table 2 summarises how these organisations described themselves in terms of competence and regulatory and/or advisory roles.

The questionnaire invited recipients whose organisations are only dealing with radiation to collaborate, if possible, with colleagues from pertinent other regulatory bodies. The responses from the Czech Republic and from Ireland, but no other country, include such supplementary information from non-radiation bodies.

Country	Respondent	Brief summary of replies
AUSTRIA	FedMin Agricult, Forestry, Env, Water	No common legislation, no trend towards alignment of protection goals

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CANADA	CNSC	No common legislation but some organisational co- ordination and some alignment of protection goals; some resulting improvement of protection of the environment
CZECH REPUB.	 MinEnv D of Water Protection MinEnv D of Environmental Hazards State Office for Nuclear Safety, D of RP 	No common legislation, collaboration between agencies to include different requirements in the same licence, but no alignment of protection goals
DENMARK	Ntl Inst of RP	No common legislation, no trend towards alignment of protection goals
GERMANY	BMU	No common legislation but some organisational co- ordination; discussions towards more alignment of protection goals are under way
ICELAND	GR (IRSA)	No common legislation, no trend towards alignment of protection goals
IRELAND	1. RPII 2. HSA 3. EPA	As yet, no common legislation, collaboration between agencies to avoid duplication or conflicting requirements; existing collaboration may lead to some future alignment of protection goals
JAPAN	NIRS	No common legislation, no trend towards alignment of protection goals
NORWAY	NRPA	Revised legislation being developed to harmonise radiological/chemical protection, formal collaboration but no direct co-ordination of organisations
SWEDEN	SSM	Integrated safety and RP legislation being developed and will probably be part of the Environmental Code, potentially facilitating future alignment of protection goals, but no immediate plans for such alignment
SWITZERLAND	BfG	No common legislation, no trend towards alignment of protection goals
USA	EPA	Cleanup under Superfund to meet combined risk criteria, otherwise mostly no common legislation and no combination of organisations but mature and effective protection programs

Table 2 should be regarded with some caution. It is obvious that most responses concerning competence were adapted directly to the questionnaire questions where it was asked whether they were responsible for radioactive materials, hazardous chemicals, or both. A few organisations

described themselves as responsible for ionising radiation in general; this is probably true also of many of the organisations that just mentioned radioactive substances.

Country	Organisation	Area of expertise	Regulatory role	Adviso ry role
AT	Fed. Min. of Agriculture, Forestry, Environment and Water Management	Hazardous chemicals & radioactive substances (in different Depts, advisory responsibility shared with the 9 provinces	Yes	Partly
CA	Canadian Nuclear Safety Commission	Nuclear & hazardous substances, physical stressors, prot. of the env. & health & safety of persons for nuclear facilities	Yes	Yes
CZ	Min. of Environment, Dept of Water Protection	Hazardous chemicals (incl. chemical toxicity of radioactive mtrl)	Yes	Yes
	Min. of Environment, Dept of Environmental Hazards	Hazardous chemicals	Yes	No
	State Office for Nuclear Safety, Dept of Radiation Protection	RP, peaceful uses of nuclear energy & radioactive mtrl	Yes	Yes
DK	National Institute of Radiation Protection	RP and radioactive substances	Yes	Yes
DE	BMU: Fed. Min. for the En- vironment, Nature Conserv- ation & Nuclear Safety	Unit: Radioactive substances Entire Ministry: Fundamental environmental policy issues	Yes	Yes
IS	GR: Icelandic Radiation Safety Authority	Radioactive substances (licensing, inspections, etc)	Yes	Yes
EI	Radiological Protection Institute of Ireland	lonising radiation	Yes	Yes
	Health & Safety Authority	Hazardous chemicals	Yes	Yes
	Environmental Protection Agency	Hazardous chemicals at industrial sites & waste facilities	Yes	Yes
JP	National Institute of Radiological Sciences	Radioactive substances	No	Yes
NO	Norwegian Radiation Protection Authority	Radioactive substances	Yes	Yes
SE	SSM: Swedish Radiation Safety Authority	Radioactive substances	Yes	Yes
СН	BfG: Fed. Office of Public Health	Hazardous chemicals & radioactive substances	Yes	Yes
US	Environmental Protection Agency	Hazardous chemicals & radioactive substances	Yes	Yes

Table 2 Respondent structure	(as described by respondents)
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Likewise, the descriptions of regulatory roles were probably influenced by the questionnaire, and perhaps at times by the responding person's vantage point. Probably, the regulatory arrangements are more complex in almost all of the responding countries than what transpires from the questionnaire. Ministries might be responsible for written regulations and therefore perceive themselves as regulators even if licensing and inspection are performed by separate authorities. Several different authorities are often involved, depending on the type of radiation, the exposure situation, and/or other factors. In federations, some or all of the licensing and inspection may be performed by state authorities even if regulations are written at the federal level.

The answers concerning the advisory role of the responding organisations also reflect considerable variation in the interpretation of this question. Advice to whom, and what kind of advice?

Advice from a supporting organisation to a regulatory body was probably what the questionnaire constructors had in mind primarily. Among respondents, the NIRS in Japan is an example of such a supporting organisation with no direct regulatory function; other such organisations include, e.g., the IRSN in France and the HPA CRCE in UK. In some countries, such separation of duties is regarded as quite important, while in other countries, the practicality of integrating advisory and regulatory functions is regarded as overriding.

Advice from a regulatory body to licensees is a difficult and touchy issue. General advice is uncontroversial; for instance, Approved Codes of Practice provide examples of methods that operators can apply to ensure that they are in compliance with regulations. However, specific advice to an individual operator could transfer responsibility from the operator to the regulator and should, in principle, be avoided. At the same time, it would be counterproductive and outright silly if inspectors refused to engage in constructive discussions with operators who bring a problem to the regulator's attention.

Advice to the general public is usually the responsibility of both regulatory and advisory organisations, where such a division exists, and consistency between such organisations as well as between different regulatory bodies is usually achieved through Memoranda of Understanding or similar instruments.

Thus in summary the spectrum of respondents is far from 'Cartesian', and probably does not provide a very accurate insight into the regulatory structure. However, while an in-depth study of this might be interesting in its own right, it does not appear to be important in the present context. As long as it is recalled that the present study does not purport to summarise regulatory and advisory arrangements in general, the observations regarding the main issue at hand, i.e., trends of alignment of the handling of radiological and chemical hazards to health of releases into the environment, should be valid.

The responses received

A. No trends towards alignment were observed in six countries: Austria, the Czech Republic, Denmark, Iceland, Japan, and Switzerland.

The Dept. of Water Protection in the *Czech Republic* points out that nevertheless, agencies do collaborate at the administrative level: if a substance is hazardous both chemically and radiologically, a single licence from a 'chemicals' agency may include pertinent requirements from 'radiological' authorities. However, the actual requirements or legislation are not aligned. The *Swiss* Federal Office of Health mentions that as a single organisation, it is responsible for both radioactive substances and hazardous chemicals, but still notes that the two scopes are strictly separated.

B. A trend towards some future alignment was observed in four countries, viz., Germany, Ireland, Norway, and Sweden.

The *German* Environment Ministry mentions that (like the Swiss Federal Office of Health) it is responsible for both radiological and chemical issues, and goes on to say that a first expert discussion on the different regulatory approaches used in radiological protection and in environmental protection against hazardous chemicals has started. However, legislation concerning the two areas remains strictly separated. With respect to advisory trends, the Ministry does 'not yet' see any trend towards alignment.

A recent workshop at the Ministry with supporting advisory bodies observed similarities between approaches to the two areas, noted a need for better harmonisation of toxicological terminology (not least in connection with risk communication), and suggested that the dialogue between the expert communities should be expanded. They pointed out that national natural resources should be integrated explicitly in radiological protection, and regarded precautionary actions as a means towards sustainability, although scales and concepts permitting quantification are needed.

The Radiological Protection Institute of *Ireland* says that it is 'not to date' observing any trend towards combining environmental regulation of the two areas, but then says that guidance documents on waste disposal have already been drafted together with the Irish EPA. The RPII notes that it has Memoranda of Understanding with 'chemical' agencies, the intent of which is to co-operate, even to the point of developing regulations to ensure that duplication or conflicting requirements are avoided. Legislation is not being combined, but with respect to advisory tasks the RPII states that at the agency level there is a strong focus on working together, for instance on issues relating to radioactive waste. Thus the RPII concludes by saying that it sees trends towards future development of common/similar legislation, regulation, and risk assessment approaches.

The Irish Health & Safety Authority concurs that there is not to date any trend towards combining environmental regulation, but points out that more and more health and safety legislation is including the environmental impact of chemicals and that such legislation focuses on hazard identification and risk assessment and does not differentiate between chemical and radiological substances. With respect to combining advisory capacity, the HSA says 'again, not as yet', but notes that genuine cross-over / overlap issues have been identified. The HSA recommends the use of combined expert groups to develop legislation, and identifies a problem: differing priorities of the various bodies concerned often leads to key issues being disregarded and to skewed, incomplete country responses.

The Irish Environmental Protection Agency again states that there is no current combination of environmental regulation. but points out that overlaps are becoming apparent at the operational level and are addressed by ad hoc working groups between competent authorities. Several examples of improved environmental protection are, according to the EPA, already seen: various kinds of waste management, investigations of combined storage facilities for chemically hazardous waste and low-level radioactive waste, shared ambient monitoring facilities, assessment of safe radiation levels in groundwater, and discharges of low-level radioactive waste to sewers.

The *Norwegian* Radiation Protection Authority describes legislative work in progress that aims to harmonise the assessment of radioactivity discharges and waste with those for non-radioactive pollutants and to provide clearer guidelines for the management of radioactive pollution and waste at all stages of the process in a similar fashion to other dangerous substances. There is close technical and legal co-operation with the Climate and Pollution Agency, with a formal agreement in the pipeline, but no organisational change is anticipated.

The emphasis of the harmonisation is on waste. The trends for future alignment are on common/similar protection goals, legislation, and regulation, while no such trend is seen for merging of organisations, or for common/similar risk assessment approaches. More unified regulation of different sectors, resulting in a better control of waste, is mentioned as an improvement of protection due to these emerging trends.

The *Swedish* Radiation Safety Authority quotes current legislative work, primarily aimed at merging nuclear safety and radiological protection regulations, but also integrating the resulting legislation into the Environmental Code which would provide potential links to hazardous chemicals legislation. However, there is no active process or task to achieve such links, and the practical regulation practices could still be kept different for the two types of contaminant.

The trend towards future alignment that could be seen is for risk assessment for non-human biota, where the EC Euratom Framework project series FASSET / ERICA / PROTECT considered harmonisation of radiological and chemical assessments. National development will take account of these projects and of the framework suggested by ICRP. The conclusion is that international development of environmental protection, including assessment approaches, protection goals, and the ICRP protection system framework, have already led to improved possibilities of a more direct assessment of environmental protection.

C. A limited but distinct current alignment was observed in two countries, viz., Canada and the United States.

The *Canadian* Nuclear Safety Commission explains that the environmental regulation of radiological and hazardous substances was combined in the Nuclear Safety and Control Act in 2000. With respect to advisory alignment, there are Memoranda of Understanding with pertinent other regulatory bodies. This concerns regulation of effluent discharges, contaminated lands, waste disposal, and general environmental protection.

Current trends observed by the CNSC include the development of common/similar protection goals (to the extent allowed by the different legal mandates). The Memoranda of Understanding are cited as examples of merging of authorities, although this is a less stringent interpretation of merging than that used by other respondents. There is no development of common/similar legislation or regulations, or of common/similar risk assessment approaches, but there is a common approach to environmental assessments in general. A formal procedure is being developed for establishing release limits that meet both pollution prevention criteria and the requirement of 'adequate control' of (nuclear and chemical) releases from nuclear installations.

According to the CNSC, an improved protection has resulted from the use of a science-based holistic approach to environmental regulation of nuclear facilities. This has identified areas requiring performance improvement for previously unregulated issues, resulting in regulatory action.

The US Environmental Protection Agency notes that the control of radiological and hazardous substances at operating facilities is most often regulated separately. Regulation of effluent discharges to water and air and cleanup of contaminated land tend to consider radiological and hazardous chemical components together under media-specific laws and regulations (i.e., contaminated water, contaminated air, etc.). Radioactive waste disposal and hazardous chemical disposal are regulated independently under separate laws and regulations.

However, the EPA says, the risks from radioactive and hazardous components are considered together when setting cleanup objectives at contaminated 'Superfund' sites. Thus, for cleanup of land

with both types of contaminant, the Superfund program requires that the cancer risks from all contaminants combined after cleanup meet a predetermined acceptable risk level, generally less than a one in ten thousand risk of lifetime excess cancer for a designated 'receptor' (worker, on-site resident, or other designated person).

With respect to advisory capacity, the EPA considers that there is no current trend towards alignment. There is no effort at present to merge or combine regulatory or advisory organisations. There are some commonalities for those laws that apply to both hazardous and chemical material. The human health risk assessment approaches for hazardous chemicals and for radioactive material are essentially the same in the US. The EPA provides guidance and risk coefficients for both. The underlying assumptions may differ somewhat depending on the organisation conducting the assessment and the specific situation being analysed.

The EPA does not identify any major improvements of protection that would be due immediately to any alignment trends. Nevertheless, environmental and radiation protection programs in the US are mature and effective. Protection of the environment has evolved from being a means to protect human health to being a strategy for protecting humans and biota alike, reflecting the move towards promoting a sustainable environment. The tools available for assessing environmental protection are evolving and improving. The ecological risk assessment model of the EPA looks at all the stressors in an ecosystem or community and evaluates their interrelationships when determining cleanup criteria.

Additional information obtained apart from the questionnaire

The EGRPE obtained some information already at the stage when the questionnaire was devised, and this information was provided in the EGRPE report to the 68^{th} (2010) CRPPH meeting.

Thus, the CIEMAT, an advisory expert organisation in *Spain*, clarified that Spain is not developing any new policy, framework or regulation on the radiological protection of the environment. Spain, being a member of the EU, follows the European legislation on environmental protection. In other words, Spain clearly belongs to *Group A* above: no trend towards any unification of the regulatory approaches.

In the *United Kingdom*, the creation of the Centre for Radiation, Chemical and Environmental Hazards of the Health Protection Agency meant that the chemical and radiation branches of the advisory expert organisation system were brought together. The Environment Agency summarised developments relating to radiological protection in the UK environment in terms of habitats assessments, ICRP Committee 5 support, IAEA EMRAS 2 participation, and participation in the revisions of the international and European Basic Safety Standards. While the report was not tailored to the questions asked in the present study, it still seems to place the UK in *Group B* above, i.e., a trend towards some future alignment.

3. Analysis

Limitations of the study

With responses from twelve countries, plus pertinent information from two additional countries, inevitably there are questions about sample sizes and representativeness.

It is somewhat unfortunate that most of the responses are from European and North American countries. However, the actual number of replies is probably sufficient to demonstrate the overall patterns. The responses fall neatly into three groups: two roughly equally sized groups of countries

where no alignment is being anticipated and countries with beginning trends towards a future alignment, and a smaller third group where some initial steps towards alignment have already been taken. This is a plausible and internally consistent result, and it seems unlikely that a larger sample would have revealed any completely different situation.

Why alignment?

Countries where a trend towards some kind of alignment is seen offer different reasons why such alignment could be useful (not surprisingly, since there are different kinds of alignment).

For example, Ireland anticipates that enhanced collaboration between agencies will avoid duplication or conflicting requirements. Similar advantages of collaboration are hinted also by the Czech Republic, even though they do not see themselves as part of any alignment trend. Thus, one reason for organisational co-ordination is that it simplifies administration (and hence reduces costs for agencies and operators).

More importantly in terms of radiological protection, alignment of assessment approaches and protection goals is expected to result in an improvement of the protection of the environment. Several respondents point out the management of hazardous waste as an area where alignment is particularly likely to be useful. Canada, Germany, and Ireland report that increased organisational co-ordination is expected to lead to such alignment and concomitant improvement of protection. Ireland also anticipates some future alignment of legislation / regulation; such developments are already under way in Norway and to some extent in Sweden. Again, improved protection and administrative simplification are quoted as reasons for the alignment. In the US, one particular area (cleanup activities under Superfund) is fully integrated such that combined risk criteria must be met.

In addition, alignment may lead to some conceptual 'cross-fertilisation' between radiological and chemical experts. In some cases, mechanisms of hazardous action and exposure to hazards are so different that closer integration does not seem desirable. However, there are also cases where there are genuine scientific reasons for a closer integration. Germany, in particular, reports that high-level discussions between the two groups of experts have revealed that both groups will be able to learn from each other, and that a continued dialogue with a view to possible further alignment is desirable.

Finally, in the discussions leading up to the present report, it was pointed out that care should be taken to avoid any negative effects of co-ordination of regulatory efforts. As an example of a potential problem, improving protection of the public through co-ordination should not be at the cost of impaired protection of exposed workers.

4. Suggested Way Forward

The initial question was whether member countries are moving towards bringing closer together their 'regulation' of environmental releases of substances that are chemically or radiologically hazardous to human health. The answer seems to be 'some but not all of them, in some but not all respects'. Some countries are merging, to some extent, regulatory organisations (but Switzerland where the same body regulates both problems does not expect any trend towards further integration). Some more countries are harmonising some of their assessment and protection approaches, with or without revising their legislation, and are expecting this to lead to improved protection of the environment and reduced administrative burdens.

Conditions for different hazardous materials, and in the various CRPPH member countries, differ vastly and it is unlikely that any 'one-for-all' solution is feasible or even desirable. However, judging

from the survey results, it seems likely that in several member countries, a closer integration (legally, organisationally, or both) could be useful for selected issues, such as the management of hazardous waste. This seems to be an issue that is not already being pursued by other international organisations, and therefore it is possible that the NEA could contribute to a simplification of such processes.

Therefore, it is proposed that the CRPPH considers the following possible additional actions:

- Extending the mandate of the EGRPE to follow more closely the integration processes in the countries that are beginning to experience trends towards some alignment.
- Planning for the possibility of NEA/CRPPH taking an active future role in achieving any benefits, while avoiding unnecessary costs, of harmonisation.

5. CRPPH Decision

Dr. Jack Valentin, former ICRP Scientific Secretariat and consultant to the NEA, presented the results of this survey to the CRPPH at its May 17-19 2011 meeting. He noted that the objective of the survey was to examine an apparent trend by national regulatory authorities to move towards an approach, at some level, for the common management of chemical and radiological effluents to the environment. He then summarised the survey results as indicating that in some countries such a trend was occurring, and was felt to bring some advantages:

- Enhanced collaboration thus helping to avoid duplication and conflicting requirements,
- Simplified administration = less costly for all
- Improved protection of the environment
- Conceptual cross-fertilisation, experts learn from each other

Jack concluded from the survey that:

- Some member countries are moving towards aligned regulations, but not in all respects
- Complete integration is neither feasible nor desirable, but legal and/or organisational integration of selected issues may be useful, particularly for waste management

Dr. Jill Meara (HPA, United Kingdom) suggested that this was a good topic, and suggested that balancing regulatory approaches by focusing on public health aspects would be a good way forward. Dr. Ingemar Lund (SSM, Sweden) suggested that there was ongoing work on this in Sweden, but that legislation was not complete. Peter Johnston (ARPANSA, Australia) reported that the jurisdiction over environmental protection and public health issues varied from State to State. Dr. Ciara McMahon (RPII, Ireland) reported that the trend to merge regulatory approaches had a significant financial savings motivation, but that it was not yet clear if there would be a common focus for chemical and radiological aspects of effluent management approaches. Dr. Clive Williams (EA, United Kingdom) agreed that the report was interesting, and to send input for England, Scotland and Wales.

Mr. Mike Boyd (EPA, United States) noted that the EGRPE had been disbanded by the 2010 CRPPH meeting, and that any further work on this topic would require a different Terms of Reference than the EGRPE had used. Dr. McGarry agreed with this, and noted that the ICRP would be putting a new recommendation, on RP of the environment, on the web for comment in the not-too-distant future. As such, she proposed the following, with which the Committee agreed:

- As decided at the 2010 CRPPH meeting, the EGRPE should remain disbanded. No further work in this area is needed by the CRPPH at this time, although the Committee may at some time in the future request further watching briefs, or other actions, with regard to radiological protection of the environment.
- The report summarizing the survey questionnaire should be completed and submitted to the CRPPH. The draft report should be submitted to the responding countries before finalization, and should be reviewed by the Bureau for approval before publication.
- The EGRPE members should be informed once the ICRP draft recommendation on RP of the environment becomes available on the ICRP web for comment, and should be invited to participate in the EGIR meeting to review the ICRP recommendation.

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ANNEXES

Questionnaire on Trends in Environmental Regulation of Radionuclides and Toxic Chemicals

Based on preliminary studies by the CRPPH it seems that several NEA member countries are moving somewhat towards bringing closer together their regulation of radioactive substances and toxic chemical substances in the environment. To explore the nature and extent of such a trend the CRPPH Expert Group on the Radiological Protection of the Environment has developed the following questionnaire, and the CRPPH at its 68th meeting in May 2010 approved its mailing to members.

I would very much appreciate your completing this questionnaire, if possible in collaboration with your colleagues from other regulatory authorities in your country should your organisation not have jurisdiction over the environmental regulation of toxic chemicals. The results of this survey will be submitted to the CRPPH for review and approval, and are intended to assist members to share their experience in this area, and to identify any further areas, should there be any, where the CRPPH could usefully contribute.

Austria

Contact details Name: Helmut Fischer Organisation: Federal Ministry of Agriculture, Forestry, Environment and Water Management Radiation Protection Division Address: Radetzkystraße 2, Abt. V/7- Radiation Protection, 1031 Vienna, Austria Phone/Fax/email details: +43 1 71100 4868/+43 1 712 2331/helmut.fischer@lebensministerium.at Your role in organisation: Radiation protection expert

1. Regulatory role

What are the regulatory responsibilities of your organisation?

• hazardous chemicals & radioactive substances \rightarrow the above mentioned ministry has the regulatory responsibilities for both topics; however in two different divisions

What are the advisory responsibilities of your organisation?

• chemical & radioactive substances \rightarrow in Austria the advisory responsibilities are divided between the state and the nine self-governing federal Provinces

Trends in Regulation

1. Is there a trend in your country to combine the environmental regulation, either in legislation or organisational structure, of radiological and hazardous chemical substances? If so, please describe.

NO

2. Is there a trend in your country to combine national technical advisory capacity for environmental protection, either in legislation or organisational structure, with respect to the regulation of radiological and hazardous chemical substances? If so, please describe.

NO

- 3. If yes, for either 1 or 2 above, in what areas?
 - Regulation of effluent discharges:
 - Regulation of contaminated lands?
 - Regulation of waste disposal?

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- Other?
- 4. If yes, for either 1 or 2 above, what trends are you experiencing?
 - Development of common/similar protection goals
 - Merging or combining of regulatory or advisory organisations
 - Development of common/similar legislation
 - Development of common/similar regulation
 - Development of common/similar risk assessment approaches
 - Other
- 5. If yes, for either 1 or 2 above, what changes, in your view, have improved protection of the environment from the regulatory standpoint?

Canada

Contact details

Name: Michael Rinker Organisation: CNSC Address: 280 Slater Street Ottawa Phone/Fax/email details: +1 613-943-9935 Your role in organisation: Director, Environmental Risk Assessment Division

1. Regulatory role

What are the regulatory responsibilities of your organisation?

- Nuclear and hazardous substances, and physical stressors
- Protection of the environment and health and safety of persons for nuclear facilities

What are the advisory responsibilities of your organisation?

- We advise the Commission on licensing decisions for nuclear facilities
- We advise panels formed under the Canadian Environmental Assessment Act
- We provide advice to other Canadian Government departments and the Canadian Standards Association

Trends in Regulation

1. Is there a trend in your country to combine the environmental regulation, either in legislation or organisational structure, of radiological and hazardous chemical substances? If so, please describe.

The environmental regulation of radiological and hazardous substances was combined in the Nuclear Safety and Control Act (NSCA) in 2000.

2. Is there a trend in your country to combine national technical advisory capacity for environmental protection, either in legislation or organisational structure, with respect to the regulation of radiological and hazardous chemical substances? If so, please describe.

We have existing memoranda of understanding (MOUs) with Environment Canada and the Province of Saskatchewan on harmonizing regulation of nuclear facilities. Initiatives are underway to develop MOUs with other governmental organizations. Note, however, that the CNSC is the main statutory authority to regulate nuclear facilities in Canada.

- 3. If yes, for either 1 or 2 above, in what areas?
 - Regulation of effluent discharges
 - Regulation of contaminated lands
 - Regulation of waste disposal
 - Other? Environmental protection under Canadian Environmental Protection Act (CEPA), Canadian Environmental Assessment Act (CEAA), Fisheries Act.
- 4. If yes, for either 1 or 2 above, what trends are you experiencing?
 - Development of common/similar protection goals Yes to the extent that the different legislative mandates allow
 - Merging or combining of regulatory or advisory organisations Yes, CNSC MOUs with Environment Canada and the Province of Saskatchewan; others in progress
 - Development of common/similar risk assessment approaches No, but through the CEPA and CEAA guidance, there is a common approach to environmental assessments in general.

- Other There is an ongoing initiative to develop and document a formal procedure for establishing release limits that meet the CEPA principles of pollution prevention, and the NSCA requirement for "adequate control" of releases (nuclear and hazardous substances) from nuclear facilities.
- 5. If yes, for either 1 or 2 above, what changes, in your view, have improved protection of the environment from the regulatory standpoint?

Use of a science-based holistic approach to environmental regulation of nuclear facilities has identified areas requiring performance improvement for previously unregulated issues, resulting in regulatory action under the NSCA.

Czech Republic

Contact details

Name: Viktor Kliment Organisation: Ministry of the Environment Department of Water Protection Address: Vršovická 65, Prague 10 Phone/Fax/email details: viktor.kliment@mzp.cz Your role in organisation: expert Director of department: Václav Dvořák Phone/Fax/email details: vaclav.dvorak@mzp.cz

1. Regulatory role

What are the regulatory responsibilities of your organisation?

- hazardous chemicals Protection of water from the point of human health and water environment based on substance toxicity, persistency and bioaccumulation
- radioactive substances Radioactive substances are followed only from the point of view of their chemical toxicity by the Ministry of the Environment.
- hazardous chemicals & radioactive substances
 If the substance is both, hazardous and radioactive
 Ministry has responsibilities only for before mentioned modes of action (substance toxicity,
 persistency and bioaccumulation)

Our organization is in charge of hazardous chemicals, which are treated according to Directives No. 2006/11/(EC), 2000/60/(EC), 76/464/(EEC), 91/271/(EEC), 76/160/(EEC), 75/440/(EEC) a 78/659/(EEC) implemented in the national legislation.

What are the advisory responsibilities of your organisation?

- hazardous chemicals in water and respective matrixes Sediment, biota, SPM
- radioactive substances Radioactive substances are followed only from the point of view of their chemical toxicity.
- chemical & radioactive substances
 If the substance is both, hazardous and radioactive Ministry has responsibilities only for
 before mentioned modes of action

Trends in Regulation

1. Is there a trend in your country to combine the environmental regulation, either in legislation or organisational structure, of radiological and hazardous chemical substances? If so, please describe.

No because of division of competencies in water sector, ministry has responsibility only for "hazardous" modes of action. If substance has both modes of action, and permission for emission must be set out, radioactive requirements are set in the permission but based on other authority.

2. Is there a trend in your country to combine national technical advisory capacity for environmental protection, either in legislation or organisational structure, with respect to the regulation of radiological and hazardous chemical substances? If so, please describe.

No, competences in water sector are divided – radiological requirements are set by other authority The regulatory authority in the field of radiation protection is the State Office for Nuclear Safety (www.sujb.cz).

- 3. If yes, for either 1 or 2 above, in what areas?
 - Regulation of effluent discharges
 - Regulation of contaminated lands?
 - Regulation of waste disposal?
 - Other?
- 4. If yes, for either 1 or 2 above, what trends are you experiencing?
 - Development of common/similar protection goals
 - Merging or combining of regulatory or advisory organisations
 - Development of common/similar legislation
 - Development of common/similar regulation
 - Development of common/similar risk assessment approaches
 - Other
- 5. If yes, for either 1 or 2 above, what changes, in your view, have improved protection of the environment from the regulatory standpoint?

Contact details

Name: Ing. Karel Bláha, CSc. Organisation: Ministry of the Environment of the Czech Republic Department of Environmental Hazards Address: Vršovická 1442/65, Praha 10, 100 10 Phone/Fax/email details: karel.blaha@mzp.cz Your role in organisation: Director of department

1. Regulatory role

What are the regulatory responsibilities of your organisation?

- hazardous chemicals
- radioactive substances
- hazardous chemicals & radioactive substances,

Our organization is in charge of hazardous chemicals, which are treated according to Directives (EC) No 1907/2006, Regulatory (EC) No 1272/2008 implemented in the national legislation.

What are the advisory responsibilities of your organisation?

- hazardous chemicals
- radioactive substances
- chemical & radioactive substances

The department has no advisory responsibilities for hazardous chemicals.

The regulatory authority in the field of radiation protection is the State Office for Nuclear Safety (www.sujb.cz).

There is a division of competencies between the Ministry of Environment and the State Office for Nuclear Safety. The Ministry has responsibility only for "hazardous" substances, the State Office for Nuclear Safety for radioactive substances.

Contact details

Name: Ing. Jan Horyna, CSc. Organisation: State Office for Nuclear Safety Department of Radiation Protection Address: Senovážné náměstí 9, Praha 2, 110 00 Phone/Fax/email details: jan.horyna@sujb.cz Your role in organisation: Inspector

1. Regulatory role

What are the regulatory responsibilities of your organisation?

- hazardous chemicals
- radioactive substances
- hazardous chemicals & radioactive substances,

The State Office for Nuclear Safety is in charge of regulating peaceful use of nuclear energy and ionizing radiation. Radiation protection provisions are implementation of the Directive (EC) No. 29/1996 in the national legislation. The State Office for Nuclear Safety has no regulatory responsibility for hazardous chemicals.

The responsibility and competences of the State Office for Nuclear Safety are given by the Atomic Act No. 18/1997 as amended. The implementing regulation is the Decree No. 499/2005, on radiation protection.

What are the advisory responsibilities of your organisation?

- hazardous chemicals
- radioactive substances
- chemical & radioactive substances

We have not the advisory responsibilities for hazardous chemicals.

Advisory responsibility for radioactive substances in the environment the State Office for Nuclear Safety (www.sujb.cz).

There is a division of competencies between the Ministry of Environment and the State Office for Nuclear Safety. The ministry has responsibility only for "hazardous" substances, the State Office for Nuclear Safety for radioactive substances.

Trends in Regulation

Is there a trend in your country to combine the environmental regulation, either in legislation or organisational structure, of radiological and hazardous chemical substances? If so, please describe.

There is no trend in our country to combine the environmental regulation of radiological and hazardous chemical substances.

Is there a trend in our country to combine national technical advisory capacity for environmental protection, either in legislation or organisational structure, with respect to the regulation of radiological and hazardous chemical substances? If so, please describe.

There are no trends to combine the environmental regulation of radiological and hazardous chemical substances as well as technical advisory capacities.

If yes, for either 1 or 2 above, in what areas?

- Regulation of effluent discharges
- Regulation of contaminated lands?
- Regulation of waste disposal?

• Other?

No

If yes, for either 1 or 2 above, what trends are you experiencing?

- Development of common/similar protection goals
- Merging or combining of regulatory or advisory organisations
- Development of common/similar legislation
- Development of common/similar regulation
- Development of common/similar risk assessment approaches
- Other

No

If yes, for either 1 or 2 above, what changes, in your view, have improved protection of the environment from the regulatory standpoint?

No

Denmark

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1. Regulatory role

What are the regulatory responsibilities of your organisation?

• radioactive substances

What are the advisory responsibilities of your organisation?

• radioactive substances

Trends in Regulation

1. Is there a trend in your country to combine the environmental regulation, either in legislation or organisational structure, of radiological and hazardous chemical substances? If so, please describe.

NO

2. Is there a trend in your country to combine national technical advisory capacity for environmental protection, either in legislation or organisational structure, with respect to the regulation of radiological and hazardous chemical substances? If so, please describe.

NO

- 3. If yes, for either 1 or 2 above, in what areas?
 - Regulation of effluent discharges
 - Regulation of contaminated lands?
 - Regulation of waste disposal?
 - Other?
- 4. If yes, for either 1 or 2 above, what trends are you experiencing?
 - Development of common/similar protection goals
 - Merging or combining of regulatory or advisory organisations
 - Development of common/similar legislation
 - Development of common/similar regulation
 - Development of common/similar risk assessment approaches
 - Other
- 5. If yes, for either 1 or 2 above, what changes, in your view, have improved protection of the environment from the regulatory standpoint?

Germany

Contact details

Name: Johannes Kuhlen Organisation: (BMU) (Federal Ministry for the Environment, Nature Conservation and Nuclear Safety) Address: P.O. Box 1206, 53048 Bonn /Germany Phone/Fax/email details: phone +49 (0) 3018 305 – 2970/johannes.kuhlen@bmu.bund.de Your role in organisation: Regierungsdirektor (civil servant, advisor)

1. Regulatory role

What are the regulatory responsibilities of your organisation? Deputy Head of unit "Radioecology, Environmental Radioactivity Surveillance, Emergency Preparedness and Response"

• radioactive substances

What are the advisory responsibilities of your organisation? Fundamental environmental policy issues including: "Chemicals safety, environment and health", "Radiological protection", "Nuclear supply and disposal", "Safety of nuclear facilities", "Precautions against emergencies in industrial plants" and "Air quality control"

- hazardous chemicals
- radioactive substances
- chemical & radioactive substances

Trends in Regulation

- 1. Is there a trend in your country to combine the environmental regulation, either in legislation or organisational structure, of radiological and hazardous chemical substances? If so, please describe.
 - a.) *Yes:* Regarding the organizational structure BMU is responsible for both radiological and chemical issues.
 - b.) *Partly:* A first discussion by experts on the different approaches in the fields "radiation protection" and "substance related environmental protection" has started.
 - c.) *No:* Regarding the legislation there is a (more or less strict) disconnection both fields.
- 2. Is there a trend in your country to combine national technical advisory capacity for environmental protection, either in legislation or organisational structure, with respect to the regulation of radiological and hazardous chemical substances? If so, please describe.

Not yet (see above). Regarding the potential combination there was a workshop at BMU in June 2010. Details of the findings see below (**ADDENDUM**)

- 3. If yes, for either 1 or 2 above, in what areas?
 - Regulation of effluent discharges
 - Regulation of contaminated lands?
 - Regulation of waste disposal?
 - Other?
 - (see above)
- 4. If yes, for either 1 or 2 above, what trends are you experiencing?
 - Development of common/similar protection goals
 - Merging or combining of regulatory or advisory organisations
 - Development of common/similar legislation
 - Development of common/similar regulation
 - Development of common/similar risk assessment approaches
 - Other

- (see above)

5. If yes, for either 1 or 2 above, what changes, in your view, have improved protection of the environment from the regulatory standpoint?

- (see above)

ADDENDUM

The "Protection of the Environment" working group of the Federal Environment Ministry's Commission on Radiological Protection held a workshop in Bonn on 8 and 9 June 2010 entitled "Radioactivity as carcinogenic nitrogen oxides – interface between radiation protection and environmental protection". Most of the 30 participants were representatives of national expert institutions (BMU, BfS, UBA and BGR), universities and scientific institutions (e.g. Helmholtz Zentrum). The workshop <u>focused</u> on three major topics:

- 1. Comparison of environmental protection and radiation protection concepts in the field of contamination evaluation.
- 2. Values for the assessment of carcinogenic substances with a view to tolerable or acceptable risks.
- 3. Sustainability and precautionary action.

In terms of <u>substance</u> the 13 presentations covered aspects such as the following:

- a) Risk assessment and risk evaluation of carcinogenic substances in soil conservation.
- b) Test values for radioactive soil contamination.
- c) Caps for genotoxic-carcinogenic nitrogen oxides in drinking water and ground water.
- d) DALY concept for the evaluation of Disability Adjusted Life Years.
- e) Risk assessment and risk evaluation of carcinogenic substances in air quality legislation.
- f) Evaluation of radioactive emissions in radiation protection legislation.
- g) Evaluation of radon and other radioactive nitrogen oxides in ambient air.
- h) Precautionary principles in environmental protection and sustainability and precautionary action in radiation protection.
- i) Sustainability of environmental rehabilitation, general sustainability and precautionary action in radiation protection, risk assessment aspects and risk assessment and sustainability regarding radio nuclides in drinking water in particular.

Some of the <u>results and conclusions</u> of the workshop:

- 1) In Germany radiation protection and substance-related environmental protection are characterised by similar approaches and concepts.
- 2) With regard to our knowledge about carcinogenic potential, radio nuclides can be well categorised, but both the toxicological basis and terminology and concepts should be better harmonised: it is in particular necessary to introduce comparable risk terminology and to focus more strongly on the potential dangers of risk communication.
- 3) The "chemical experts' group" should receive better input on new radiation impact mechanisms, the "radiological experts' group" should receive better input on the further development of the DALY concept.
- 4) The dialogue between "radiation protectionists" and "environmental protectionists" should be expanded.
- 5) Assets such as water, soil and air should be explicitly integrated into radiation protection in national provisions (e.g. by applying approaches and methods in soil conservation with regard to radiologically contaminated sites).
- 6) Precautionary action may be considered a means to guarantee sustainability. However, there is a need for information on concepts and scales which enable precautionary action to be quantified.

Iceland

Contact details

Name: Sigurður M. Magnússon Organisation: IRSA Address: Phone/Fax/email details: smm@gr.is Your role in organisation: Director

1. Regulatory role

What are the regulatory responsibilities of your organisation?

• radioactive substances – competent authority, licensing, inspections etc.

What are the advisory responsibilities of your organisation?

• radioactive substances – wide advisory responsibility towards users, other authorities etc.

Trends in Regulation

1. Is there a trend in your country to combine the environmental regulation, either in legislation or organisational structure, of radiological and hazardous chemical substances? If so, please describe.

NO

2. Is there a trend in your country to combine national technical advisory capacity for environmental protection, either in legislation or organisational structure, with respect to the regulation of radiological and hazardous chemical substances? If so, please describe.

NO

- 3. If yes, for either 1 or 2 above, in what areas?
 - Regulation of effluent discharges
 - Regulation of contaminated lands?
 - Regulation of waste disposal?
 - Other?
- 4. If yes, for either 1 or 2 above, what trends are you experiencing?
 - Development of common/similar protection goals
 - Merging or combining of regulatory or advisory organisations
 - Development of common/similar legislation
 - Development of common/similar risk assessment approaches
 - Other
- 5. If yes, for either 1 or 2 above, what changes, in your view, have improved protection of the environment from the regulatory standpoint?

Ireland

Contact details

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1. Regulatory role

What are the regulatory responsibilities of your organisation?

• radioactive substances – The RPII is responsible for licensing and regulating the use of ionising radiation in the medical, veterinary, educational and industrial sectors. The RPII also regulates the exposure of aircrew to cosmic radiation and, where appropriate, work activities involving Naturally Occurring Radioactive Materials (NORM)

What are the advisory responsibilities of your organisation?

radioactive substances – The RPII provides advice to Government and to the public, the
principal work areas covered are nuclear safety, emergency preparedness and radon. It also coordinates dose assessment studies in areas such as occupational exposure to naturally
occurring and artificial radiation.

Trends in Regulation

1. Is there a trend in your country to combine the environmental regulation, either in legislation or organisational structure, of radiological and hazardous chemical substances?

Not to date, however the RPII has Memoranda of Understanding (MoU's) with other Irish State agencies such as the Irish Health and Safety Authority (HSA) and the Irish Environmental Protection Agency (EPA). The HSA is the body with regulatory responsibility with respect to chemical hazards and the EPA is the body with responsibility for environmental protection. The intent of these MoU's are to co-operate even to the point of developing regulations to ensure that there is no duplication or conflicting requirements between the state bodies. Work has already been undertaken with the EPA on guidance documents to implement regulations such as the waste of electrical and electronic equipment (WEEE) Directive, storage and disposal of radioactive waste and management of uranium and thorium salts.

2. Is there a trend in your country to combine national technical advisory capacity for environmental protection, either in legislation or organisational structure, with respect to the regulation of radiological and hazardous chemical substances? If so, please describe.

At present, legislation in Ireland is not being combined but, at the agency level, there is a strong focus on working together. For example, the RPII has been working with the EPA and other state bodies on the issues relating to radioactive waste.

In addition, number of Irish government agencies including the RPII, EPA and HSA are working together as part of an Irish Department of Environment, Heritage and Local Government high level group on waste management.

- 3. If yes, for either 1 or 2 above, in what areas?
 - Regulation of waste disposal? Yes, guidance documents have been drafted in conjunction with the Irish EPA to handle WEEE

- 4. If yes, for either 1 or 2 above, what trends are you experiencing?
 - Development of common/similar legislation
 - Development of common/similar regulation
 - Development of common/similar risk assessment approaches
- 5. If yes, for either 1 or 2 above, what changes, in your view, have improved protection of the environment from the regulatory standpoint?

Contact details

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1. Regulatory role

What are the regulatory responsibilities of your organisation?

hazardous chemicals

What are the advisory responsibilities of your organisation?

• hazardous chemicals

Trends in Regulation

1. Is there a trend in your country to combine the environmental regulation, either in legislation or organisational structure, of radiological and hazardous chemical substances?

Not to date however more and more health and safety legislation is including the environmental impact of use, exposure to and disposal of hazardous chemicals – REACH / COMAH. Health and Safety legislation is premised on hazard identification and risk assessment in the workplace and therefore will not differentiate between hazardous chemical substances or radiological substances impacting on the safety, health and welfare of those exposed. Radon is an example of this overlap. Where all of these factors are affecting employee welfare at the workplace then the risk assessment should account for each of these factors and control accordingly.

2. Is there a trend in your country to combine national technical advisory capacity for environmental protection, either in legislation or organisational structure, with respect to the regulation of radiological and hazardous chemical substances? If so, please describe.

Again not as yet. Technical advisory capacity to date has been compartmentalised into three distinct strands – HSA for hazardous chemicals, EPA for the environmental impact and RPII for the radiological aspects. However recent legislative models from Europe have been assigning differing competent authorities where genuine overlap / cross-over issues have been identified. Examples would include REACH where the EPA and the Pesticide Control Service are also listed as competent authorities alongside the HSA. To date all advice around radiological substances stems from the RPII and they have been recognised as the competent authority for Class 7 materials under the European Agreement concerning the International Carriage of Dangerous Goods by Road while the HSA are responsible for 7 of the remaining 9 classes.

- 3. If yes, for either 1 or 2 above, in what areas? N/A
 - Regulation of effluent discharges
 - Regulation of contaminated lands?
 - Regulation of waste disposal?

- Other?
- 4. If yes, for either 1 or 2 above, what trends are you experiencing? N/A
 - Development of common/similar protection goals
 - Merging or combining of regulatory or advisory organisations
 - Development of common/similar legislation
 - Development of common/similar regulation
 - Development of common/similar risk assessment approaches
 - Other
- 5. If yes, for either 1 or 2 above, what changes, in your view, have improved protection of the environment from the regulatory standpoint?

In my opinion assigning responsibility for certain aspects of these legislative instruments to differing expert groups is the way to proceed. The problem unfortunately is that often the organisations involved have starkly differing priorities and engagement between disparate organisations with differing strains on resources all too often results in key issues not being addressed or the overall country response is skewed and incomplete.

Contact details Name: Jonathan Derham and Theresa Doherty Organisation: EPA Ireland Address: Environmental Protection Agency, Johnstown Castle Estate, Wexford, Ireland Phone/Fax/email details: j.derham@epa.ie Your role in organisation: Senior Inspector

1. Regulatory role

What are the regulatory responsibilities of your organisation?

- hazardous chemicals The EPA regulate industrial site that hold/use/produce hazardous chemicals. We regulate waste facilities that may Dispose & Recover hazardous chemicals
- radioactive substances The EPA only regulates Recovery facilities that may have radioactive material associated (e.g. smoke detectors)

What are the advisory responsibilities of your organisation?

- hazardous chemicals Recovery & Disposal, Storage and handling at regulated industrial & waste sites
- radioactive substances Recovery (where associated with other controlled waste, e.g. smoke detectors in WEEE)

Trends in Regulation

1. Is there a trend in your country to combine the environmental regulation, either in legislation or organisational structure, of radiological and hazardous chemical substances?

Article 2 of the REACH Regulation states that this Regulation shall not apply to radioactive substances within the scope of Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation. However, overlaps are becoming more apparent at operational level. Ad Hoc working groups have been established between competent authorities to deal with areas of mutual interest.

2. Is there a trend in your country to combine national technical advisory capacity for environmental protection, either in legislation or organisational structure, with respect to the regulation of radiological and hazardous chemical substances? If so, please describe.

See above.

- 3. If yes, for either 1 or 2 above, in what areas?
 - Regulation of effluent discharges
 - Regulation of contaminated lands?
 - Regulation of waste disposal?
 - Other?

NORM in groundwater used for potable supply.

- 4. If yes, for either 1 or 2 above, what trends are you experiencing?
 - Development of common/similar protection goals
 - Merging or combining of regulatory or advisory organisations
 - Development of common/similar legislation
 - Development of common/similar regulation
 - Development of common/similar risk assessment approaches
 - Other

Development of inter-agency liaison groupings operating under a formal Memorandum of Understanding between the organisations, who are tasked to deal with issues of mutual interest/concern.

5. If yes, for either 1 or 2 above, what changes, in your view, have improved protection of the environment from the regulatory standpoint?

Cooperation on management of waste containing radioactive material

Cooperation on the management of certain WEEE

Cooperation in relation to investigation of combined storage facilities for hazardous waste and low-level radioactive waste

Cooperation in relation to shared national ambient monitoring facilities

Cooperation in relation to assessment of safe radiation levels (from NORM) in groundwater Cooperation in relation to discharge of low level radioactive waste to sewer.

Japan

Contact details

Name: Kazuo Sakai Organisation: National Institute of Radiological Sciences Address: 4-9-1 Anagawa, Inage-ku, Chiba-shi, Chiba 263-8555, JAPAN Phone/Fax/email details: +81 43 206 6190/+81 43 206 4134/kazsakai@nirs.go.jp Your role in organisation: Research Programme Management (Director of the Research Center for Radiation Protection)

1. Regulatory role

What are the regulatory responsibilities of your organisation?

N/A

What are the advisory responsibilities of your organisation?

• radioactive substances

Trends in Regulation

1. Is there a trend in your country to combine the environmental regulation, either in legislation or organisational structure, of radiological and hazardous chemical substances? If so, please describe.

No

2. Is there a trend in your country to combine national technical advisory capacity for environmental protection, either in legislation or organisational structure, with respect to the regulation of radiological and hazardous chemical substances? If so, please describe.

No

- 3. If yes, for either 1 or 2 above, in what areas?
 - Regulation of effluent discharges
 - Regulation of contaminated lands?
 - Regulation of waste disposal?
 - Other?

N/A

- 4. If yes, for either 1 or 2 above, what trends are you experiencing?
 - Development of common/similar protection goals
 - Merging or combining of regulatory or advisory organisations
 - Development of common/similar legislation
 - Development of common/similar regulation
 - Development of common/similar risk assessment approaches
 - Other

N/A

5. If yes, for either 1 or 2 above, what changes, in your view, have improved protection of the environment from the regulatory standpoint?

N/A

Norway

Contact details

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1. Regulatory role

What are the regulatory responsibilities of your organisation?

• radioactive substances

What are the advisory responsibilities of your organisation?

• radioactive substances

Trends in Regulation

1. Is there a trend in your country to combine the environmental regulation, either in legislation or organisational structure, of radiological and hazardous chemical substances? If so, please describe.

The Ministry of Environment has the constitutional responsibility for pollution. By Royal Decree of 10 November 2006, the Ministry of Environment was delegated the role of authority for the regulations in the Radiation Protection Act which deal with radioactive pollution.

There is now work in progress to bring Norway's "Pollution Control Act" into force for radioactivity and to remove provisions relating to environmental protection from the "Act on Radiation Protection and Use of Radiation". The goal is to harmonise the assessment of radioactivity discharges and waste with those for non-radioactive pollutants and to provide clearer guidelines for the management of radioactive pollution and waste at all stages of the process in a similar fashion to other dangerous substances. The revised regulation for radiation protection and the new regulation on radioactive pollution and waste are planned to enter into force in 2011.

2. Is there a trend in your country to combine national technical advisory capacity for environmental protection, either in legislation or organisational structure, with respect to the regulation of radiological and hazardous chemical substances? If so, please describe.

The NRPA is cooperating closely with the Climate and Pollution Agency, both on technical and legal issues, and we will seek to formalise this cooperation in an agreement between these two bodies. No organisational changes will be made.

- 3. If yes, for either 1 or 2 above, in what areas?
 - Regulation of effluent discharges
 - Regulation of contaminated lands?
 - Regulation of waste disposal?
 - Other?

All of the above. The emphasis is on waste.

- 4. If yes, for either 1 or 2 above, what trends are you experiencing?
 - Development of common/similar protection goals

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- Development of common/similar legislation
- Development of common/similar regulation
- 5. If yes, for either 1 or 2 above, what changes, in your view, have improved protection of the environment from the regulatory standpoint?

Better ways to declare waste, and more specific regulations on handling and delivery, clearance etc.

The new regulations will include all kinds of radioactive waste.

More unified regulation of different sectors and therefore a better control of waste.

Sweden

Contact details

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1. Regulatory role

What are the regulatory responsibilities of your organisation?

• radioactive substances

What are the advisory responsibilities of your organisation?

• radioactive substances

Trends in Regulation

1. Is there a trend in your country to combine the environmental regulation, either in legislation or organisational structure, of radiological and hazardous chemical substances? If so, please describe.

There is an ongoing review of the legislation concerning radiation safety in Sweden. The aim is to combine the act on nuclear activities and the act on radiation protection. One possibility that is under consideration is to include the combined radiological legislation in the Swedish Environmental Code. In that case there would be potential links between legislation regarding hazardous chemicals and that regarding radioactive substances. However it would still be possible to keep the practical regulation praxis different for the two types of contaminants.

2. Is there a trend in your country to combine national technical advisory capacity for environmental protection, either in legislation or organisational structure, with respect to the regulation of radiological and hazardous chemical substances? If so, please describe.

No

- 3. If yes, for either 1 or 2 above, in what areas?
 - Regulation of effluent discharges
 - Regulation of contaminated lands?
 - Regulation of waste disposal?
 - Other?

The review of the legislation is not yet concluded. Potentially the regulation of all areas could become more similar between hazardous chemicals and radioactive substances if all the legislation is contained within the same environmental code, but there is no active process or task to achieve this.

- 4. If yes, for either 1 or 2 above, what trends are you experiencing?
 - Development of common/similar protection goals
 - Merging or combining of regulatory or advisory organisations
 - Development of common/similar legislation
 - Development of common/similar regulation
 - Development of common/similar risk assessment approaches
 - Other

Risk assessment approaches for non human biota, as discussed by e.g. the EU-projects FASSET/ERICA/PROTECT was considering harmonisation with the chemical side. SSM will be continuing the national development in line with these considerations and the framework suggested by ICRP.

5. If yes, for either 1 or 2 above, what changes, in your view, have improved protection of the environment from the regulatory standpoint?

Again, the international development in the area of environmental protection, including assessment approaches, protection goals, protection system framework (ICRP), has been considering harmonisation with chemicals regulations and has improved the possibilities to assess current environmental protection in a more direct way.

Switzerland

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1. Regulatory role

What are the regulatory responsibilities of your organisation?

• hazardous chemicals & radioactive substances

What are the advisory responsibilities of your organisation?

• chemical & radioactive substances

Trends in Regulation

1. Is there a trend in your country to combine the environmental regulation, either in legislation or organisational structure, of radiological and hazardous chemical substances? If so, please describe.

No, these two scopes are strictly separated.

2. Is there a trend in your country to combine national technical advisory capacity for environmental protection, either in legislation or organisational structure, with respect to the regulation of radiological and hazardous chemical substances? If so, please describe.

No.

- 3. If yes, for either 1 or 2 above, in what areas?
 - Regulation of effluent discharges
 - Regulation of contaminated lands?
 - Regulation of waste disposal?
 - Other?
- 4. If yes, for either 1 or 2 above, what trends are you experiencing?
 - Development of common/similar protection goals
 - Merging or combining of regulatory or advisory organisations
 - Development of common/similar legislation
 - Development of common/similar regulation
 - Development of common/similar risk assessment approaches
 - Other
- 5. If yes, for either 1 or 2 above, what changes, in your view, have improved protection of the environment from the regulatory standpoint?

USA

Contact details

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1. Regulatory role

What are the regulatory responsibilities of your organisation?

- hazardous chemicals
- radioactive substances
- hazardous chemicals & radioactive substances

The Environmental Protection Agency (EPA) operates under a number of statutory authorities addressing different contaminants or environmental media. Under the Clean Air Act and Clean Water Act, EPA regulates the discharge of hazardous chemicals into air and water, both through monitoring of permitted releases and through enforcement actions to stop or prevent pollution of the environment. Under the Resource Conservation and Recovery Act and Toxic Substances Control Act, EPA also regulates the storage and treatment of toxic chemicals and hazardous waste and sets waste acceptance criteria for disposal of waste containing hazardous chemicals in permitted land disposal facilities.

Under the Atomic Energy Act, EPA sets "generally applicable standards" for radioactivity in the environment. Many of these standards are enforced by the U.S. Nuclear Regulatory Commission (NRC) or by individual States. The Act requires that civilian uses of nuclear materials and facilities be licensed, and it empowers the NRC to establish and enforce regulations in order to protect health and safety and minimize danger to life or property. The NRC has no jurisdiction over non-radioactive hazardous chemicals and assumes that its licensees will comply with the relevant EPA regulations covering non-radioactive substances. The Clean Air Act gives EPA enforcement authority for radionuclide air emissions from facilities not licensed by the NRC. Under the Safe Drinking Water Act, EPA also establishes maximum contaminant limits for radionuclides and hazardous chemicals in public drinking water.

Mixtures of hazardous and radioactive substances ("mixed waste") may be subject to dual regulation by NRC and EPA when disposed of (i.e., mixed waste needs to meet disposal criteria standards of both agencies). For cleanup of land with both hazardous and radioactive contaminants, EPA's Superfund program (implemented under the Comprehensive Environmental Response, Compensation, and Liability Act) requires that the cancer risks from all contaminants combined after cleanup meet a predetermined acceptable risk level, generally one posing less than a one in ten thousand risk of lifetime excess cancer for a designated receptor. Depending on the future land use of the site, the receptor could be a worker, an on-site resident, or meet some other description. For decommissioning of licensed facilities, NRC's regulations consider 0.25 mSV per year total effective dose equivalent (TEDE) acceptable for residual radioactivity remaining on site and that the levels of radioactivity are reduced to as low as reasonably achievable (ALARA). NRC regulations do not address the cleanup of non-radioactive substances.

While a primary objective of EPA's regulations is the protection of human health, there are also specific additional requirements for protecting the environment. For example, an ecological risk assessment could result in stricter cleanup limits being applied to a site if the contaminant levels acceptable for protecting human health pose an unacceptable risk to either communities of resident biota or to individual members of threatened or endangered species.

What are the advisory responsibilities of your organisation?

- hazardous chemicals
- radioactive substances
- chemical & radioactive substances

EPA plays an advisory role in reviewing environmental impact statements required for most new land use applications. EPA provides non-binding guidance to other federal agencies on the formulation of radiation standards. The agency also provides standardized methodologies and look-up tables of coefficients for performing both radionuclide-specific dose and risk assessments and hazardous chemical risk assessments. The NRC makes every attempt to follow EPA's guidance concerning standardized methodologies and coefficients for radionuclides.

Trends in Regulation

1. Is there a trend in your country to combine the environmental regulation, either in legislation or organisational structure, of radiological and hazardous chemical substances? If so, please describe.

Environmental legislation in the U.S. tends to be media specific and EPA is the primary agency charged with implementing these statutes. Hence, we have the Clean Air Act, Safe Drinking Water Act, and various laws governing treatment and disposal of solid waste. In most of these laws, radioactive material is considered a hazardous substance whose release to the environment is to be controlled. However, control of radiological and hazardous substances at operating facilities is most often regulated separately. For example, the Atomic Energy Act gives NRC the authority to license and regulate the use of radioactive material, whereas EPA has the authority to regulate most hazardous emissions from these NRC-licensed facilities. As previously described, the risks from radioactive and hazardous components are considered together when setting cleanup objectives at contaminated Superfund sites.

2. Is there a trend in your country to combine national technical advisory capacity for environmental protection, either in legislation or organisational structure, with respect to the regulation of radiological and hazardous chemical substances? If so, please describe.

Technical advisory capacity is assumed to mean non-regulatory guidance on radiological and hazardous chemical issues. At the national level in the U.S., guidance from regulatory agencies tends to follow the same pattern as for regulations as described above. Non-governmental advisory bodies tend to be more specialized. The National Council on Radiation Protection and Measurements (NCRP) has published comparisons of hazardous and radioactive waste management, for example, but their focus is almost exclusively on radiation-related issues. Similarly, the U.S. National Academy of Sciences (NAS) refers most radiation-related issues to its Nuclear and Radiation Studies Board, and would handle hazardous chemical issues through a different Board.

- 3. If yes, for either 1 or 2 above, in what areas?
 - Regulation of effluent discharges
 - Regulation of contaminated lands?

- 4. Regulation of waste disposal?
 - Other?

These areas are covered in the response to question 1 above. Regulation of effluent discharges to water and air and cleanup of contaminated land tend to consider radiological and hazardous chemical components together under media-specific laws and regulations. Radioactive waste disposal and hazardous chemical disposal are regulated independently under separate laws and regulations.

- 5. If yes, for either 1 or 2 above, what trends are you experiencing?
 - Development of common/similar protection goals
 - Merging or combining of regulatory or advisory organisations
 - Development of common/similar legislation
 - Development of common/similar risk assessment approaches
 - Other

Regulation of hazardous chemicals in the U.S. is usually risk based, whereas regulation of radioactive material is either risk based (e.g., for determining cleanup levels) or, more commonly, dose based. Where individual sources are regulated, dose limits typically fall in the range of 40 microsieverts/a (i.e., EPA's drinking water limit) to 250 microsieverts/a plus ALARA (e.g., NRC's license termination rule for decommissioning). Risk-based limits are in the range of one in one million excess cancers to no more than around one in ten thousand excess cancers, estimated over a lifetime. The upper end of this risk range equates to a cumulative lifetime dose of one to a few millisieverts, a somewhat similar protection goal to that for hazardous contaminants when constraints or ALARA goals are applied to radiation dose limits.

There is no effort at present to merge or combine regulatory or advisory organizations. As described, there are some commonalities for those laws that apply to both hazardous and chemical material.

The human health risk assessment approaches for hazardous chemicals and for radioactive material are essentially the same in the U.S. EPA provides guidance and risk coefficients for both. The underlying assumptions may differ somewhat depending on the organization conducting the assessment and the specific situation being analyzed.

6. If yes, for either 1 or 2 above, what changes, in your view, have improved protection of the environment from the regulatory standpoint?

Neither 1 nor 2 above qualify for a strong yes response. Nevertheless, environmental and radiation protection programs in the U.S. are mature and effective. Protection of the environment has evolved from being a means to protect human health to being a strategy for protecting humans and biota alike, reflecting the move towards promoting a sustainable environment. The tools available for assessing environmental protection are evolving and improving. EPA's ecological risk assessment model looks at all the stressors in an ecosystem or community and evaluates their interrelationships when determining cleanup criteria.