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Measures to Strengthen International Co-operation in Nuclear, Radiation and Transport Safety and Waste Management

Radiological Criteria for Radionuclides in Commodities

Report by the Director General

Summary

- The Annex to this document describes the outcome of the actions taken pursuant to General Conference resolution GC(44)/RES/15 entitled "Radiological criteria for long-lived radionuclides in commodities (especially foodstuffs and wood)".

Recommended Action

It is recommended that the Board:

- approve the use of the radiological criteria for radionuclides in commodities presented in the Annex to this document in the application of the *International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources* (the BSS)[1], and
- request the Director General to report the Board's decision to the General Conference, indicating that the request made in resolution GC(44)/RES/15 has been complied with.

[1] The BSS were established by the Agency and are jointly sponsored by the Food and Agriculture Organization of the United Nations (FAO), the International Labour Organization (ILO), the Nuclear Energy Agency of the Organisation for Economic Co-operation and Development (OECD/NEA), the Pan American Health Organization (PAHO) and the World Health Organization (WHO).

Radiological Criteria for Radionuclides in Commodities

A. Background

A.1. The General Conference's request

1. In September 2000, in resolution GC(44)/RES/15, the General Conference requested the Secretariat "to develop, using the Agency's radiation protection advisory mechanisms and in collaboration with the competent organs of the United Nations and with the specialized agencies concerned, … *radiological criteria for long-lived radionuclides in commodities, particularly foodstuffs and wood*, and to submit them to the Board of Governors for its approval".

A.2. The Secretariat's response

2. Pursuant to the request made in resolution GC(44)/RES/15, the Secretariat and other specialized agencies within the United Nations system took a number of actions that are summarized in the Attachment to this Annex and the final stages of which are described in the following paragraphs.

B. The radiological criteria

3. The outcome of the Secretariat's response are the radiological criteria for all significant radionuclides (not just long-lived ones) in commodities presented below:

(a) At its latest regular session, held from 7 to 9 June 2004, the Commission on Safety Standards - following approval by the Radiation Safety Standards Committee (RASSC – in which the specialized agencies of the United Nations that co-sponsor the BSS are invited to participate) and the Waste Safety Standards Committee (WASSC) in the light of extensive consultations held with Member States and with the Transport Safety Standards Committee (TRANSSC) - endorsed the publication of a Safety Guide entitled *Application of the Concepts of Exclusion, Exemption and Clearance.* This created a basis for the derivation of values of activity of radionuclides (both natural and artificial) and values of activity concentration in bulk amounts of materials and provided for the application of the values to trade, proposing a graded approach in such application and for verification. The Safety Guide is being issued by the Agency as IAEA Safety Standard (Safety Guide) RS-G-1.7 and is already available on the Agency's website under http://www-ns.iaea.org/downloads/drafts/ds161.pdf . The Safety Guide establishes the activity concentration values for radionuclides of artificial and natural origin in bulk amounts of materials that are given in Table 1. These levels are to be used for guidance in fulfilling requirements of the BSS for radionuclides of artificial and natural origin in bulk amounts of materials that relate to:

- *exclusion* (BSS, paragraph 1.4);
- *exemption* (BSS, paragraphs 2.17 and 2.18, and Schedule I – particularly sentence (d) in footnote 36); and
- *clearance* (BSS, paragraph 2.19).

A graded approach consistent with the requirements of optimization of protection established in the BSS should be applied (reference should also be made to BSS paragraph 2.8) in the event of values exceeding the levels prescribed in Table 1.

Table 1: Criteria for Radionuclides in Bulk Amounts of Materials

Radionuclides	Level (Bq/g)
I-129	0.01
Na-22; Sc-46; Mn-54; Co-56; Co-60; Zn-65; Nb-94; Ru-106; Ag-110m; Sb-125; Cs-134; Cs-137; Eu-152; Eu-154; Ta-182; Bi-207; Th-229; U-232; Pu-238; Pu-239; Pu-240; Pu-242; Pu-244; Am-241; Am-242m; Am-243; Cm-245; Cm-246; Cm-247; Cm-248; Cf-249; Cf-251; Es-254	0.1
C-14; Na-24; Cl-36; Sc-48; V-48; Mn-52; Fe-59; Co-57; Co-58; Se-75; Br-82; Sr-85; Sr-90; Zr-95; Nb-95; Tc-96; Tc-99; Ru-103; Ag-105; Cd-109; Sn-113; Sb-124; Te-123m; Te-132; Cs-136; Ba-140; La-140; Ce-139; Eu-155; Tb-160; Hf-181; Os-185; Ir-190; Ir-192; Tl-204; Bi-206; Th-232 [1], U-233; U-235 [2]; U-238 [3] Np-237; Pu-236; Cm-243; Cm-244; Cf-248; Cf-250; Cf-252; Cf-254	1
Be-7; F-18; Cl-38; K-40; K-43; Ca-47; Mn-51; Mn-52m; Mn-56; Fe-52; Co-55; Co-62m; Ni-65; Zn-69m; Ga-72; As-74; As-76; Sr-91; Sr-92; Zr-93; Zr-97; Nb-93m; Nb-97; Nb-98; Mo-90; Mo-93; Mo-99; Mo-101; Tc-97; Ru-97; Ru-105; Cd-115; In-111; In-114m; Sn-125; Sb-122; Te-127m; Te-129m; Te-131m; Te-133; Te-133m; Te-134; I-126; I-130; I-131; I-132; I-133; I-134; I-135; Cs-129; Cs-132; Cs-138; Ba-131; Ce-143; Ce-144; Gd-153; W-181; W-187; Pt-191; Au-198; Hg-203; Tl-200; Tl-202; Pb-203; Po-203; Po-205; Po-207; Ra-225; Pa-230; Pa-233; U-230; U-236; Np-240; Pu-241; Cm-242; Es-254m	10
H-3; S-35; K-42; Ca-45; Sc-47; Cr-51; Mn-53; Co-61; Ni-59; Ni-63; Cu-64; Rb-86; Sr-85m; Sr-87m; Y-91; Y-91m; Y-92; Y-93; Tc-97m; Tc-99m; Rh-105; Pd-109; Ag-111; Cd-115m; In-113m; In-115m; Te-129; Te-131; I-123; I-125; Cs-135; Ce-141; Pr-142; Nd-147; Nd-149; Sm-153; Eu-152m; Gd-159; Dy-166; Ho-166; Er-171; Tm-170; Yb-175; Lu-177; Re-188; Os-191; Os-193; Ir-194; Pt-197m; Au-199; Hg-197; Hg-197m; Tl-201; Ra-227; U-231; U-237; U-239; U-240; Np-239; Pu-234; Pu-235; Pu-237; Bk-249; Cf-253; Es-253; Fm-255	100
Si-31; P-32; P-33; Fe-55; Co-60m; Zn-69; As-73; As-77; Sr-89; Y-90; Tc-96m; Pd-103; Te-125m; Te-127; Cs-131; Cs-134m; Pr-143; Pm-147; Pm-149; Sm-151; Dy-165; Er-169; Tm-171; W-185; Re-186; Os-191m; Pt-193m; Pt-197; At-211; Th-226; Pu-243; Am-242; Cf-246	1000
Co-58m; Ge-71; Rh-103m; Fm-254	10 000

[1] The thorium series, headed by thorium-232 and constituted by ^{228}Ra, ^{228}Ac, ^{228}Th, ^{224}Ra, ^{220}Rn, ^{216}Po, ^{212}Pb, ^{212}Bi, ^{212}Po, ^{208}Tl, and ^{208}Pb.

[2] The actinium series, headed by uranium-235 and constituted by ^{231}Th, ^{231}Pa, ^{227}Ac, ^{227}Th, ^{223}Fr, ^{223}Ra, ^{219}Rn, ^{215}Po, ^{211}Pb, ^{211}Bi, ^{207}Tl, and ^{207}Pb.

[3] The uranium series, headed by uranium-238 and constituted by ^{234}Th , ^{234}mPa, ^{234}U, ^{230}Th, ^{226}Ra, ^{222}Rn, ^{218}Po, ^{214}Pb, ^{214}Bi, ^{214}Po, ^{210}Pb, ^{210}Bi , ^{210}Po, and ^{206}Pb.

(b) Following a recommendation by RASSC and WASSC to request "the FAO/WHO Codex Alimentarius Commission[2] (the CAC) to develop appropriate levels for artificial and natural radionuclides in foodstuffs", the Secretariat requested the CAC to broaden the Guideline Levels for Radionuclides in Foods Following Accidental Nuclear Contamination for Use in International Trade (ref: CAC/GL 5-1989)[3], which have been established in the BSS (BSS Table V-I), to other radionuclides and to consider the establishment of guideline levels for radionuclides for long-term use as new work. The 50th Session of the CAC's Executive Committee (in June 2002) considered a request of the Secretariat The Executive Committee referred the issue to the Codex Committee on Food Additives and Contaminants (CCFAC) for consideration along with further input from the IAEA in regard to the scope of the work. The 35th Session of the CCFAC (in March 2003) agreed to request the Agency to prepare a revised version of the Codex Guideline Levels for Radionuclides in Foods Following Accidental Nuclear Contamination for Use in International Trade for circulation, comment and further consideration at its 36th Session. The 26th Session of the Codex Alimentarius Commission (CAC) approved the revision of the Codex Guideline Levels for Radionuclides in Foods Following Accidental Nuclear Contamination for Use in International Trade (ref: CAC/GL 5-1989), including Guideline Levels for Long-Term Use, as new work for the Committee. In response to this request, the Agency convened a consultants meeting at the Agency's Headquarters from 18-22 August 2003 to revise the Codex Guideline Levels for Radionuclides in Foods to other radionuclides and to consider the establishment of guideline levels for long-term use, which was attended by representatives of the WHO and FAO. Subsequently, the Agency convened a consultants meeting of a high-level group of experts to advise the Agency on radiological criteria for radionuclides in food moving in international trade at the Agency's Headquarters from 19-21 January 2004. The high-level group of experts was chaired by the Chairman of the International Commission on Radiological Protection (ICRP) and was attended by the Secretary of the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), the Director of the State Research Centre of the Russian Federation Institute of Biophysics, the Chairman of the (Hiroshima) Radiation Effects Research Foundation, representatives of the European Commission and representatives of FAO. The CAC Committee on Food Additives and Contaminants, at its 36th session, held from 22 to 26 March 2004, approved revised Guideline Levels for Radionuclides in Foods for Use in International Trade (ALINORM 04/27/12, Appendix XXII); accessible under www.codexalimentarius.net/web/reports.jsp), which contains new guideline levels for radionuclides in foods. Once the CAC formally adopts these levels as a revised and final Codex text, which are given in Table 2, they may be applied for long-term use in lieu of the generic action levels for foodstuffs given in Table V-1 of the BSS.

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[2] The Codex Alimentarius Commmission is a body of the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) charged with developing the *Codex Alimentarius*, or the food code, which has become the seminal global reference point for consumers, food producers and processors, national food control agencies and the international food trade. Both FAO and WHO cosponsor the BSS. The Codex Alimentarius provides the basis for the BSS generic action levels of radioactivity for foodstuffs.

[3] The Codex Alimentarius Commission at its 18th Session (Geneva, 1989) adopted Guideline Levels for Radionuclides in Foods Following Accidental Nuclear Contamination for Use in International Trade (CAC/GL 5-1989) applicable for six radionuclides (^{90}Sr, ^{131}I, ^{137}Cs, ^{134}Cs, ^{239}Pu and ^{241}Am), which were incorporated into the BSS as generic action levels for foodstuffs to be used in interventions.. The Guideline Levels were designed to be applicable for one year following a nuclear accident. Since that time, the need to establish guideline levels for more than six radionuclides and for a longer time period than one year after a major nuclear or radiological event or due to routine radionuclide discharge to the environment has been recognised. In addition, and as presented in the attached Scientific Justification for Proposed Draft Guideline Levels for Radionuclides in Foods, significant improvements in the assessment of radiation doses resulting from the human intake of radioactive substances have become available.

Table 2: Guideline levels for radionuclides in foods

Radionuclides in foods	Guideline Level (Bq/kg)
^{238}Pu, ^{239}Pu, ^{240}Pu, ^{241}Am	1
^{90}Sr, ^{106}Ru, ^{129}I, ^{131}I, ^{235}U	100
^{35}S, ^{60}Co, ^{89}Sr, ^{103}Ru, ^{134}Cs, ^{137}Cs, ^{144}Ce, ^{192}Ir	1000
^{3}H*, ^{14}C, ^{99}Tc	10000

* This represents the most conservative value for tritium (organically bound).

(c) It is to be noted that the World Health Organization (WHO), with the collaboration of the Secretariat, has developed specific guidance levels for radionuclides in drinking-water. The levels have been accepted by the WHO's task force for the finalization of the Guidelines for Drinking-Water Quality, third edition.[4] WHO is expecting to issue these Guidelines around the time of the September meetings of the Board. (Publication has been embargoed by WHO until they are officially launched and officially put on the WHO website.) Once WHO formally issue these levels they may be applied in lieu of the generic action levels for drinking-water established in BSS Table V-I.

[4] WHO published the first edition of *Guidelines for drinking-water quality* in 1984 and 1985. In 1993, a second edition was published. The third edition of the Guidelines has been recently approved and is expected to be published by WHO in September 2004. The Agency has been involved in the development of the guidance levels for radionuclides in drinking-water contained in the revised Guidelines.

Actions taken by the Secretariat and others pursuant to the request made in resolution GC(44)/RES/15

1. In September 2000, in resolution GC(44)/RES/15, the General Conference requested the Secretariat "to develop, using the Agency's radiation protection advisory mechanisms and in collaboration with the competent organs of the United Nations and with the specialized agencies concerned, during the next two years and within available resources, *radiological criteria for long-lived radionuclides in commodities, particularly foodstuffs and wood,* and to submit them to the Board of Governors for its approval".

2. As reported in August 2001 in document GOV/2001/29-GC(45)/12, in November 2000 the Secretariat convened a group of consultants who developed, for a number of commodities, some criteria and quantitative proposals for intervention exemption levels which were numerically different from the exemption levels established in the *International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources* (the BSS) and the clearance levels that had been recommended within the context of the Agency and the European Commission. In view of the confusion which might arise from this diversity of levels, the Secretariat considered that an attempt at rationalization was necessary and that the process might also help in responding to the request made of it in resolution GC(44)/RES/15. Consequently, in February 2001 it convened a meeting of senior experts with a view to obtaining advice on a strategy for determining unequivocally the scope of regulatory control of radiation exposure. The senior experts concluded that it would be sensible to use a single set of radionuclide-specific activity concentration levels for the purpose of defining the scope of regulatory control of radiation exposure. Moreover, they recommended an approach that could be adopted in developing this set of levels, which would automatically serve for responding to the request made of the Secretariat in resolution GC(44)/RES/15.

3. Meanwhile, the Secretariat had also convened in late February 2001 a Technical Committee to continue work on the specific issue of radiological criteria for long-lived radionuclides in commodities. The Technical Committee discussed the intervention exemption levels for commodities vis-à-vis both the established exemption levels and the recommended clearance levels for materials and, specifically, intervention exemption levels for foodstuffs vis-à-vis the established generic action levels for foodstuffs (for example, the guideline levels for radionuclides in food moving in international trade established by the Codex Alimentarius Commission (the CAC) of the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) and the guideline values for drinking water established by WHO).

4. The advice received by the Secretariat from the various bodies which it had convened was considered by the Agency's Radiation Safety Standards Committee (RASSC) and Waste Safety Standards Committee (WASSC) at a joint meeting in April 2001. RASSC and WASSC endorsed the idea of rationalizing the definition of the scope of the regulatory control of radiation exposure and thereby clarifying the scope of the BSS. In addition, they confirmed the dose criteria on which to base the calculation of appropriate levels of activity concentration and recommended that particular consideration be given to radionuclides of natural origin because of their ubiquity. They stressed that regulatory authorities should continue to have the power to exempt practices (and sources within practices) involving levels which exceeded those used in defining the scope of the BSS. They recommended that the Secretariat engage in further consultations with the objective of making proposals for the definition of the scope of the regulatory control of radiation exposure. The outcome

of the RASSC and WASSC discussions was considered by the Agency's Commission on Safety Standards (CSS) in May 2001. Immediately after the CSS's meeting, the Secretariat, pursuant to the recommendation of RASSC and WASSC, convened a group of consultants which developed, for a number of radionuclides, a set of activity concentrations that could be used in defining the scope of regulatory control of radiation exposure and therefore in dealing with the issue of intervention exemption levels for international trade in commodities.

5. Following the lengthy consultation process summarized above, the Secretariat convened, during 23-26 July 2001, a Technical Committee which arrived at recommendations to the Secretariat regarding the main direction for responding to the request made of the Secretariat in resolution GC(44)/RES/15. The report of the Technical Committee was transmitted to Member States under cover of Note by the Secretariat 2001/Note 16 dated 1 August 2001.

6. The main conclusions of the Technical Committee are summarized below:

(a) The Secretariat should complete the work currently in progress on specifying general clearance levels and activity concentration levels for use in international trade in commodities, particularly foodstuffs and wood. The resulting report(s) should be published for critical review and comment as soon as possible. They could serve as interim guidance in meeting the objectives of the General Conference.

(b) It is a matter of concern that several different sets of values, each intended to define the scope of some aspects of regulatory control, will exist at the international level. Their existence could lead to confusion and contradiction in the implementation and enforcement of regulations. The Technical Committee therefore proposed an approach for rationalization through a re-examination of the bases for exclusion, exemption and clearance and for international trade in commodities.

(c) The relevant radiological protection criteria are currently described in publication IAEA Safety Series No. 89 (1988), publication No. 60 (1990) of the International Commission on Radiological Protection (ICRP) and the BSS (1996), somewhat differently in each. The inconsistencies should be addressed.

(d) The objective should be to establish a coherent system of radionuclide-specific levels (expressed in terms of total activity and of activity concentration) for defining the scope of regulatory standards. Schedule I of the BSS would then be superseded.

(e) Natural radionuclides should be included; a basis for exemption and clearance was suggested by the Technical Committee.

7. At the Board meetings preceding the 2001 session of the General Conference, the Deputy Director General for Nuclear Safety (now Deputy Director General for Nuclear Safety and Security) said that

> 'The issue of intervention exemption levels for commodities, raised at the 44th session of the General Conference, had proved to be very complex, owing to its link to the broader issue of the scope of regulatory control of radiation exposure. The objective was to establish a coherent system of radionuclide-specific levels for defining the scope of regulatory standards. In that broader context, the Secretariat wished to continue working on the General Conference's request that it should develop "radiological criteria for long-lived radionuclides in commodities, particularly foodstuffs and wood".'

The Chairman of the Board, summing up the Board's discussion, took it that the Board, noting the difficulties encountered by the Secretariat in responding to resolution GC(44)/RES/15, wished the Secretariat "to continue working towards meeting the request made of it in that resolution, taking into account the recommendations set out in paragraph 17 of the document [See para. 6 above, which is para. 17 of document GOV/2001/29-GC(45)/12.], using the mechanisms based on RASSC, WASSC and the Commission on Safety Standards and inviting relevant international organizations as appropriate."

8. At its 2001 session, the General Conference took note of the difficulties encountered in responding to resolution GC(44)/RES/15 and endorsed the decision of the Board to request the Secretariat to continue working towards meeting the request made of it in that resolution.

9. Following the 2001 session of the General Conference, a group of consultants and a Technical Committee convened by the Secretariat met – in December 2001 and February 2002 respectively – for the purpose of continuing with the effort to produce a consensus on the issues which needed to be resolved in order that the request made by the General Conference in September 2000 might be met.

10. The Technical Committee, in which FAO and WHO were represented, recommended that the safety guidance developed by the various bodies convened by the Secretariat not include radiological criteria for foodstuffs and drinking water. In addition, it concluded that the current values in the Codex Alimentarius, which related to the period immediately following a nuclear accident, were not directly applicable to the control of normal commerce involving foodstuffs, and it recommended that the CAC, which is responsible for specifying maximum activity concentrations of radionuclides in foodstuffs, review the foodstuff issue and develop guidance. The CAC did so in cooperation with the Secretariat. At the same time, WHO reviewed its standards relating to radionuclides in drinking water.

11. The outcome of the meetings of the group of consultants and the Technical Committee was a draft Safety Guide relating to commodities other than foodstuffs and drinking water that was submitted to RASSC and WASSC, which considered it in a joint meeting held in March 2002.

12. RASSC and WASSC agreed that the draft Safety Guide should be sent to Member States for comment as the next step in the process prescribed for the approval of Agency safety standards. The draft Safety Guide, entitled "Radionuclide content in commodities not requiring regulation for purposes of radiation protection", was sent to Member States on 9 May 2002, with a request that comments be submitted to the Secretariat by 15 September 2002 at the latest.

13. At the Board meetings preceding the 2002 session of the General Conference, at which the Board and the General Conference had before them a report contained in Attachment 3 to document GOV/2002/35-GC(46)/11, the Deputy Director General for Nuclear Safety (now Deputy Director General for Nuclear Safety and Security) said that the Secretariat shared the concerns voiced [in the Board] about the 'scope-defining levels' in the draft Safety Guide (draft Safety Guide 161) and that the Secretariat intended to ensure that that important issue was thoroughly ventilated. The Chairman of the Board, summing up the Board's discussion, said that it had been emphasized that the establishment of radiological criteria for long-lived radionuclides in commodities "was a very sensitive issue owing to its implications for radiological protection and to the considerable impact which the criteria might have on the domestic and international trade in commodities, and that the Secretariat should proceed carefully, without undue haste and with full consideration of the views of Member States."

14. At its 2002 session, the General Conference took note of the steps taken by the Secretariat, pursuant to resolution GC(44)/RES/15, towards developing radiological criteria for long-lived radionuclides in commodities, described in Attachment 3 to document GOV/2002/35-GC(46)/11.

15. Following the 2002 session at the General Conference, the Secretariat – as stated in Annex 2 to document GOV/INF/2003/15-GC(47)/INF/4 issued in August 2003 – revised draft Safety Guide 161 in the light of the nearly 300 comments received by it from Member States and submitted the revised draft Safety Guide (entitled "Radioactivity in material not requiring regulation for purposes of radiation protection") to RASSC, WASSC and the Transport Safety Standards Committee (TRANSSC), which recommended that it also be sent to Member States for comment. The deadline for the receipt of comments was set at 15 August 2003, after which all comments received were duly taken into account. The work in question included Action 4, "Develop an internationally accepted and harmonized approach for controlling the removal of materials and sites from regulatory control", of the actions in the area of radioactive waste management whose implementation was described in Annex 7 to document GOV/INF/2003/15-GC(47)/INF/4.

16. As reported in document GOV/2002/35-GC(46)/11, the CAC had been requested to review radiological criteria for foodstuffs and WHO had been consulted with regard to criteria for drinking water. In March 2003 the 35th Session of the CAC Committee on Food Additives and Contaminants recommended that criteria for the transboundary movement of foodstuffs be developed, and the Secretariat participated – together with FAO and WHO – in their development.

17. WHO prepared draft criteria for drinking water containing radioactive material. The draft criteria have been approved and the approved criteria are expected to be published in mid-September 2004.

18. At its 2003 session, the General Conference encouraged the development of radiological criteria for long-lived radionuclides in commodities, noting "the need to consider carefully the implications for radiological protection and international trade".