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**Radioactivity in Goods Supplied for Public
Consumption or Use:**

**Towards an Internationally Harmonized Regulatory
Framework**

**A discussion document prepared jointly by the
Autoridad Regulatoria Nuclear (ARN) of Argentina
and the
International Atomic Energy Agency**

PREFACE

(1) On 18 September 2015, the Nuclear Regulatory Authority of Argentina (Autoridad Regulatoria Nuclear or ARN) and the Secretariat of the International Atomic Energy Agency (IAEA) hereinafter termed ‘the Parties’, agreed on ‘*Practical Arrangements*’ setting forth the framework for non-exclusive cooperation between the Parties in the area of radiation safety and monitoring. The agreement was reconfirmed during a ceremony presided by the Chairman of ARN, Néstor Masriera, and the Deputy Director General of the IAEA, Juan Carlos Lentijo, with the presence of the Argentine Ambassador, Rafael Mariano Grossi, in the framework of the 60th Annual Regular Session of the IAEA General Conference, in Vienna, on 30 September 2016.

(2) The Practical Arrangements identify activities in which cooperation between the ARN and the IAEA may be pursued subject to their respective mandates, governing regulations, rules, policies and procedures. A relevant activity agreed to be pursued is the “*development and publication of a harmonized approach for managing radionuclide activity concentrations in food, drinking water and non-food commodities.*”

(3) The lessons learned from the aftermath of past nuclear and radiation accidents underline the need to resolve a longstanding and as yet unresolved radiation protection issue: the regulatory control of safe levels of radioactivity in everyday goods generally available for public consumption or use. Experience gained in responding to these accidents has emphasized the need to provide objective and easily comprehensible information to the affected population, to national authorities and to the public in general on the relevant safety standards dealing with these goods and how these standards should be applied.

(4) After the Chernobyl accident, the General Conference of the IAEA passed a resolution asking for a solution to this issue [1]; however, while progress has been made towards an international consensus on appropriate standards, further work is still necessary.

(5) Responding to the growing concerns raised and, as a result of the ARN/IAEA agreement, the Parties have prepared this discussion document on *Radioactivity in Goods Supplied for Public Consumption or Use: Towards an Internationally Harmonized Regulatory Framework*.

(6) In this document we identify issues of concern in order to raise awareness and generate further discussion among relevant parties. We do not propose a definitive solution to this problem that has until now not been solved internationally. The way forward is clearly articulated in the document around two central issues, as follows: (1) a more encompassing definition for goods generally available for public consumption or use; and (2) no longer using dosimetric quantities as the starting point of the regulatory framework for managing these goods. It is noted that whatever regulatory mechanisms are finally employed to address the different types of these goods, the need is to define what level of radioactivity should be subject to regulatory control for purposes of radiation protection and, conversely, what should not. The application of regulatory control should achieve a net benefit in public protection; otherwise, regulatory control would appear to be unjustified. Similarly, regulatory requirements should be applied in a manner that protection be the best under the prevailing circumstances, namely optimized.

(7) The document describes understandings reached between the Parties as to technical, operational or practical details relevant to the subject, and it is addressed to all professionals,

organizations and other parties interested in the field of controlling the amount of radioactivity in goods available to the public for consumption or use.

(8) It is noted that the issue is already being pursued within other work being undertaken by the IAEA, e.g.: a revision of the Safety Guide on Application for the Concepts of Exclusion, Exemption and Clearance [2], which will also address (in a separate Safety Report) international trade in non-food commodities containing radionuclides; a new project aimed at harmonizing the approach to managing radionuclides in food and drinking water in non-emergency situations; and various activities carried out by the IAEA Incident and Emergency Centre. The suggestions in this report should be viewed as contributing to all these efforts.

(9) The current approach to managing radionuclides in goods supplied for public consumption and use is complex and contains inconsistencies and is sometimes incoherent. There is a need for a consistent approach that is simple to use and understand. The purpose of this discussion document is to suggest options to achieve this.

(10) This document uses language that can be easily understood, even though this sometimes implies a divergence from the formal language used by professionals. We hope this will allow the document to be more widely discussed among non-experts and policy-makers than would otherwise be the case.

SECTION 1

INTRODUCTION

Background

(11) The fundamental safety objective of the safety standards established under the aegis of the IAEA is to protect people and the environment from harmful effects of ionizing radiation [3]. This objective needs to be achieved without unnecessarily restricting the many beneficial uses of radiation enjoyed by society.

(12) Radioactivity is a natural property of matter. Radioactive substances are found throughout the biosphere and are constantly exposing people to radiation. Uranium, thorium and potassium are chemical elements that are also radioactive – they have been present in the earth's crust since the formation of the earth and the radiation they emit continuously exposes all people. The amount of radiation exposure attributable to these naturally occurring sources is highly variable, depending on local geology and other factors. There are also many other natural radionuclides present in the environment, but these contribute much less to the natural background radiation exposure of humans.

(13) Since the discovery of X-rays and radioactivity more than 100 years ago, a wide variety of safe and beneficial uses of radiation has been developed in medicine, industry, agriculture and research. These uses of nuclear technology include improved food production and preservation, diagnosis and treatment of disease, and electricity production. Most of the radiation sources used for these applications are artificial in that they are produced with human intervention, normally under controlled conditions in nuclear reactors and accelerators.

(14) The use of and exposure from artificial radiation sources in medicine, industry, agriculture and research are strictly controlled. A properly established governmental, legal and regulatory framework for safety provides for the regulation of facilities and activities involving radiation exposure [4]. Moreover, a de facto international safety regime, under the aegis of the IAEA, establishes international intergovernmental radiation safety standards and provides for their application.

(15) Radionuclides are present in the environment due to various sources and therefore may be incorporated into goods supplied for public consumption and use, as follows:

- Cosmic radiation, which originates mostly in space, interacts with the earth's atmosphere to continuously generate radionuclides, some of which reach the earth's surface. Of particular interest are the radionuclides tritium and ^{14}C , both of which are also released to the environment by various regulated activities.
- Small amounts of radionuclides are discharged into the environment under strictly controlled conditions provided by the regulatory framework. These so-called 'authorized discharges' are associated primarily with operations that generate or use radionuclides, including the nuclear industry and nuclear medicine diagnosis and treatment as practised in hospitals around the world.
- Sometimes radionuclides are released to the environment under uncontrolled conditions that are not foreseen. Examples include the Kyshtym and Windscale accidents in 1957, the Three Mile Island accident in 1979, the Chernobyl accident in 1986, the Goiânia accident in 1987 and the Fukushima Daiichi NPP accident in 2011.

- There are a number of former mining and other sites around the world where waste material containing mainly naturally occurring radionuclides have not been appropriately controlled.
- Large amounts of radionuclides have been released into the environment as a result of military activities, notably nuclear weapons testing.

(16) It follows that many sources exist from which radionuclides can be transferred into the environment. These radionuclides may consequently be inadvertently incorporated into everyday goods that are consumed and used by people. For example: radionuclides may be present in water (including drinking water) and in soil from where they can transfer to crops and animal products so that foodstuffs may contain small, but detectable, amounts of radionuclides; in forests, radionuclides can be incorporated into the wood of trees and therefore be present in household furniture, sports equipment and other wood products in everyday use.

(17) In addition, there are also manufactured products that are supplied for public use into which radionuclides are deliberately incorporated to enable the products to function or to otherwise improve their efficiency or performance [5]. Examples include: ^{241}Am used in ionization chamber smoke detectors; thorium, ^{85}Kr and tritium used in high intensity lamps, (including car headlamps and lighting in sports arenas); thorium used in gas mantles; and, thoriated tungsten used in welding electrodes. The manufacture of certain artificial gemstones can also result in the production of short-lived radionuclides called ‘activation products’. These gemstones must be stored to allow these radionuclides to undergo radioactive decay before being cut and/or sold to the public.

(18) Given that so many items consumed and used in people’s daily lives contain radionuclides, and therefore deliver radiation doses, however minute, the question arises as to whether or not these items are intrinsically safe or if some form of restriction needs to be placed on their availability. At the same time, it is necessary to take into account whether any restriction, even if considered justified, can be applied effectively. Another way to look at the situation is to ask – what concentrations of radionuclides in goods that are provided for public consumption or use are considered ‘acceptable’ and therefore should be free of any regulation?

(19) Associated questions include whether to differentiate between:

- Naturally occurring radionuclides and artificial radionuclides;
- Goods to which radionuclides are artificially added and those (both naturally-occurring and artificial) that are present due to natural environmental processes;
- Goods that are consumed (such as foodstuffs) and items that are used by the general public for a variety of purposes;
- Goods that are considered edible and those which are not (taking onto account that edibility involve cultural issues and habits that change from people to people).

(20) Another challenging issue is whether goods that are consumed and used by people incorporating radionuclides from diverse initial situations should or should not be controlled differently. For instance, radionuclides could already be present in the environment and from there reach goods supplied for public consumption or use, or they can be there due to a *planned* and authorized discharge from a regulated activity, or they can be the result of a non-anticipated *emergency*. These give rise to exposure situations that have been identified in professional parlance as *existing*, *planned*, and *emergency* exposure situations and are subject to different regulatory approaches.

(21) IAEA Safety Standards Series No. GSR Part 3, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards [6] (commonly referred to as the BSS) are the current relevant international intergovernmental standards for radiation safety and apply to all facilities and all activities that give rise to radiation risks. The BSS are established under the aegis of the IAEA and jointly sponsored by the European Commission (EC), the Food and Agricultural Organization of the United Nations (FAO), the IAEA, the International Labour Organization (ILO), the OECD Nuclear Energy Agency (OECD/NEA), the Pan American Health Organization (PAHO), the United Nations Environment Programme (UNEP) and the World Health Organization (WHO). The current edition of the BSS was issued in 2014¹.

(22) The BSS are generally applicable to the regulatory control of radioactivity in goods generally available for public consumption or use. Therefore, following the BSS, and as discussed later in the document, a number of approaches were established for managing radionuclides in, and radiation doses from, everyday items that are consumed and used by people. But as it will be seen hereinafter, these approaches are not necessarily coherent or consistent and such incoherencies and inconsistencies may result in misunderstanding and confusion.

Structure of the document

- (23) Following this introductory text, the structure of the document is as follows:
- (a) Section 2 discusses some issues of semantics and terminology that have caused confusion in past discussions. It encapsulates the concept of goods provided for public consumption and use into a more generic term, which is defined precisely and used throughout the document.
 - (b) Section 3 summarizes the current situation with respect to controlling radionuclides in goods provided for public consumption and use. This includes (1) the relevant components of the system of radiological protection, with a particular analysis of the system's dosimetric approach and classification of exposure situations, and their applicability to goods provided for public consumption or use; (2) the scope of regulatory control, including the concepts of *exclusion* and *exemption*; (3) the approach to managing radionuclides present in food and drinking water in non-emergency situations, including a comparison of the documents produced by the FAO, the IAEA and the WHO.
 - (c) Section 4 summarizes views from States' relevant authorities arising from a meeting of Member States in the regions of Latin America and the Caribbean in 2015 and Asia and the Pacific in 2018.
 - (d) Section 5 discusses some of the problems with the current approach and brings forward recommendations that could help develop a better harmonized system that is easier to implement, but which still ensures a high level of radiation safety.
 - (e) Section 6 summarizes the suggestions from the common IAEA/ARN project, both in terms of an overall framework and more specific issues.

¹ Previous editions of the BSS were published in 1962, 1967, 1982 and 1996 (see footnotes 3,4,5 and 6).

SECTION 2

TERMINOLOGY

(24) The body of terms used for controlling the amount of radioactivity in goods generally available for public consumption or use have been an impediment for an internationally harmonized regulatory framework. People generally communicate with words rather than with gestures, and if the concept conveyed by the words used for this difficult issue is different to the usual meaning given by people to these words, understanding is diluted and harmonization became difficult. Some words have caused particular confusion, for instance *commodities*, *consumer products* and *contamination*.

Commodities

(25) The International Commission on Radiological Protection (ICRP) has used the related term commodity with the meaning of “products generally used or consumed by the public, such as foodstuffs and building materials, [that] can contain radioactive substances” para. 173 of Ref. [7]. The term was also used with a similar meaning by the IAEA General Conference [1]. However, the term commodity is commonly limited to denote a raw material or primary agricultural product that can be bought and sold, such as on the commodities markets. Moreover, the term is difficult to translate directly and it is either used with the English term or translated as a synonym of ‘basic product’.

Consumer products

(26) In common parlance all everyday goods supplied for public consumption or use are referred to as consumer products. The term consumer product is easily translatable and would be widely understood by most people. It therefore covers foodstuffs, household and daily-life goods, etc, that can be bought and sold and are widely available to members of the public. Radioactive substances may be inadvertently or purposely incorporated into these goods and there can be a societal expectation that these incorporations may need to be regulated.

(27) Notwithstanding this common understanding of the term consumer product, in the glossary of terms used in the IAEA safety standards [8], the term had been assigned the limited meaning of “a device or manufactured item into which radionuclides have deliberately been incorporated or produced by activation, or which generates ionizing radiation, and which can be sold or made available to members of the public without special surveillance or regulatory control after sale”. This is a much more limiting definition of the term than how it is understood in common usage. Basically, the IAEA definition constrains the term to products to which radioactive substances have been added on purpose for some beneficial outcome in its use. While these products exist in the market, they are extremely limited in number.

(28) To address these issues with terminology, throughout the remainder of this document, the term ‘consumer goods’² will be used with the following understanding:

Consumer goods are those products supplied for public consumption or use, including merchandise, edible and non-edible commodities, and other materials, goods and articles.

² The term ‘consumer goods’ was used in the 1962 edition of the BSS, but its use in IAEA safety standards was subsequently discontinued.

(29) A second term ‘radioactive consumer products’ will be used to describe those “*consumer goods to which radionuclides have been deliberately incorporated or produced by activation, or which generates ionizing radiation, and which can be sold or made available to members of the public without special surveillance or regulatory control after sale*”.

(30) These terms are used solely for the purpose of clarity in this document, specifically to avoid the use of the term consumer product with a restricted meaning that is different to the normal understanding of the term. In due course, preferable terminology may be identified.

Contamination

(31) The term (radioactive) contamination is usually employed to denote the presence of radioactivity and to quantify it, even if its amount is small. While the specific term ‘contaminated consumer goods’ is not common, reference is often made to contaminated water or contaminated food. It is also common to refer to a contaminated environment, which is the source of the presence of radioactive substances in many consumer goods.

(32) While the term contamination applied to food has a religious denotation (this is discussed further hereinafter), to most people it conveys the idea of danger. This connotation causes public concern, as people perceive it as a binary situation, namely either there is contamination, and therefore some danger, or there is not. The concept of ‘low levels of contamination’ is incomprehensible for many people. These undertones cause anxiety to people and confusion to the authorities when dealing with or discussing radioactivity in consumer goods.

(33) The term contamination is well established, although often confusedly used, within the radiation protection community. It formally means radioactive substances on surfaces, or within solids, liquids or gases (including the human body), where their *presence* is unintended or undesirable, or the *process* giving rise to their *presence* in such places. It has been recognized however that the term may have a connotation that is not intended, since it refers only to the presence of radioactivity, and gives no indication of the magnitude of the hazard involved. Its use is particularly unhelpful when talking about consumer goods in which, in general, the content of radioactive substances is low, and therefore the use of this term in this context is discouraged.

SECTION 3

BACKGROUND AND HISTORICAL PERSPECTIVE

The System of Radiological Protection

General

(34) The United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) is an intergovernmental scientific group established by the General Assembly of the United Nations in 1955. Its mandate in the United Nations system is to assess and report levels and effects of exposure to ionizing radiation. The reports of UNSCEAR provide the scientific basis for radiation protection and therefore for controlling consumer goods.

(35) The International Commission on Radiological Protection (ICRP) is a non-governmental charity established in 1928 to advance the science of radiological protection, in particular by providing recommendations and guidance on all aspects of protection against ionizing radiation. The ICRP's recommendations, which are based on a combination of science and value judgements, provide a general system for protection against radiation exposure, which has been universally used and form the basis of the international radiation protection standards and therefore for controlling consumer goods.

(36) In this regard, the relevant recommendations from the ICRP are those in ICRP Publication 104, *Scope of Radiological Protection Measures* [7]. These have been reflected in the Commission's current main recommendations, in ICRP Publication 103 [9], where two key concepts for the control of consumer goods are clearly defined: *exclusion*, namely the deliberate exclusion of a particular category of exposure from the scope of an instrument of regulatory control; and, *exemption*, namely the determination by a regulatory body that a source, practice or activity involving radiation need not be subject to some or all aspects of regulatory control. The issue of scope of radiological protection measures for consumer goods is discussed hereinafter.

(37) As indicated before, a consensual global system of radiation protection has been put in place through international intergovernmental standards established by relevant international organizations under the aegis of the IAEA. The system is based on the UNSCEAR estimates and takes account of the ICRP recommendations.

(38) The system of radiation protection is based on three basic principles, as follows: justification of actions involving radiation exposure, optimization of radiation protection and restrictions on individual risks. The principle of justification requires that decisions involving radiation exposure should do more good than harm. The principle of justification is not unique to radiological protection; all decisions involve a balancing of 'pros and cons'. Once a decision has been made that a particular action is justified, the principle of optimization is then applied. This requires that the selected radiation protection option be the best under the prevailing circumstances. Decisions on justification and optimization include societal, economic and environmental considerations. The third principle requires that regardless of the justification of actions or optimization of protection, individual risks should not exceed certain values. In many instances, the benefits considered in justification or in optimization accrue to society in general rather than to individuals. However, it is also appropriate that no individual be subject to unnecessary radiation risks.

(39) Over the years, the system of radiation protection has evolved in line with new scientific knowledge on the effects of radiation exposure. However, the system is not just

about science; ethics and the sense of what is acceptable have also changed and need to be appropriately reflected. As with many systems, new challenges often result in increased complexity. In this regard, the system of radiological protection has not been spared. The effort to develop one approach to cover all radiation exposure situations has not always been straightforward. While the system has been very successful for the regulatory implementation of relevant standards, particularly in occupational radiation protection, it is not specifically tailored to the needs of managing the very low levels of dose attributable to consumer goods. This is further discussed below.

Exposure situations

(40) In the past, the ICRP had recommended to divide situations involving radiation exposure of individuals into two broad categories: practices and interventions. A practice was (and still is) defined as any human activity that gives rise to an exposure to radiation that did not previously exist, whereas intervention was defined as human activity that reduces extant radiation exposures.

(41) However, in its Publication 103 [9], the ICRP redefined its recommendations introducing the concept of exposure situations, as follows:

- *Planned exposure situation*, which arises from the planned operation of a source or from a planned activity that results in radiation exposure.
- *Emergency exposure situation*, which arises as a result of an accident, a malicious act, or other unexpected event, and which requires urgent action in order to avoid or reduce adverse consequences.
- *Existing exposure situation*, which arises from extant situations where the exposure is already taking place when a decision on control has to be taken.

This classification was adopted into the international radiation safety standards.

(42) Planned exposure situations result from the introduction of practices that are eventually adopted as a matter of choice, usually in order to gain some individual or societal benefit. There is a conscious decision to adopt such practices, and therefore there can also be a conscious decision on whether or not the practice needs to be regulated.

(43) Conversely, emergency exposure situations and existing exposure situations are not generally a matter of choice. Since the situation already exists at the time when the protective measures are being considered, it is not tied to any particular societal benefit specifically related to it. Existing exposure situations are extant situations such as those caused by natural radiation, but also include, but are not limited to, prolonged exposures that may continue in the recovery phase following an emergency exposure situation.

(44) The clearest distinction between planned exposure situations and both existing and emergency exposure situations is the ability to choose a priori whether to accept a beneficial practice and its consequent exposures. If a choice is still available, the exposure situation can be planned and therefore controlled by regulation. If there is no choice, because the sources already exist, regulatory actions may or may not be undertaken to reduce exposures.

(45) Under the current system of radiological protection, regulatory control is applied to those radioactive consumer products that have radionuclides intentionally incorporated at the time of manufacture. This is clearly a planned exposure situation. In such cases, the three principles of justification, optimization and dose limitation can be applied. For consumer goods that arise from emergency exposure situations or existing exposure situations, the principle of justification applies only to the range of possible remedial actions that can be

taken to reduce exposures; optimization applies to those remedial actions that are deemed to be justified, which in turn defines the range of doses that are received.

(46) However, in general, radiation exposure from consumer goods does not always fall neatly into one of the three exposure situations. This is best demonstrated by the following examples:

- The deliberate incorporation of radionuclides into consumer goods at the time of manufacture is clearly a planned exposure situation, in that a formal decision is taken by the regulatory body to authorize, or not to authorize, the practice. However, after these products are exempted from regulatory control, and made available for normal use, the resulting doses received by the public could be considered an existing exposure situation in that the radionuclides are already *in situ* when the item is purchased for consumption or use.
- Radionuclides may be present in consumer goods as a result of (1) a regulated activity (planned exposure situation) such as authorized discharges from a nuclear facility or a hospital; (2) as a result of a nuclear or radiological accident (emergency exposure situation), during the emergency phase or after the emergency has ended; or (3) due to natural radioactivity in the environment or radionuclides remaining from unregulated past activities such as the testing of nuclear weapons or other unregulated releases to the environment (existing exposure situation). For any given radionuclide, it might not be possible to identify precisely its origin.

(47) It needs to be recognized that a consumer or user of consumer goods is not interested in the exposure situation that originated the presence of radioactivity in the product but on whether the product is safe to be consumed or used.

(48) Based on the above reasoning, it seems therefore that the categorization into planned, emergency and existing exposure situations does not fit into the concept of controlling consumer goods. It is suggested that this categorization should not be used when considering the need for controlling consumer goods.

Scope of regulatory control

(49) The history of the acceptability of radionuclides in consumer products is linked directly to the question of what is to be considered as 'radioactive' and therefore what the scope of regulatory action is to control the amount of radioactive substances in the product. Another way of looking at the issue is to ask the question: what should regulatory authorities control in consumer goods, in terms of its radioactivity content, and what they should exclude or exempt from control? This is therefore a fundamental issue to resolve.

(50) The earliest international radiation protection standards were very clear in this regard: they unambiguously distinguished what was radioactive from what was considered not radioactive, in spite of having some content of radioactive substances. The borderline between these two categories was clearly specified in terms of activity per unit mass. Those standards made no distinction between radionuclides except that the borderline was higher for natural radionuclides than for man-made ones. This could be construed to mean that the control criteria was based on the controllability of the content of radioactive substances rather than radiation dose. The clear intention of this approach was that items considered to be radioactive should be controlled, while items that were considered not to be radioactive need not be controlled, i.e. they should be excluded or exempted from regulatory control. The successive international basic safety standards present a long history in relation to these concepts, with the system becoming more complex with time.

(51) In fact, the 1962 edition of the BSS³ established that requirements of notification, registration and licensing could be waived if operations involved the use of radioactive substances at a concentration that did not exceed 0.002 $\mu\text{Ci/g}$ (74 000 Bq/Kg) or solid natural radioactive substances at concentrations exceeding 0.01 $\mu\text{Ci/g}$ (320 000 Bq/Kg). This criterion was not applied to medical uses or to the *intentional addition* of radionuclides “in the manufacture of consumer goods such as foodstuffs, pharmaceutical goods, cosmetics and toys” (i.e. a regulatory authorization was required in all cases). In addition, in order to limit radiation exposure through ingestion and inhalation, maximum permissible concentrations of single radionuclides in air and water (expressed in units of $\mu\text{Ci/cm}^3$) were established, with different values applying to workers and to the public.

(52) Essentially the same approach was maintained in the 1967⁴ and 1982⁵ editions of the BSS. The 1982 edition introduced the concept of consumer products and also noted that “the general exemptions formulated for radiological protection purposes, e.g. those adopted within the European Atomic Energy Community (EURATOM) [10] can be considered for further use by the competent authorities, until an evaluation conforming to the principles given in this document is performed”.

(53) By the end of the 1980s an international consensus on principles for the scope of regulatory control was being reached [11]. In 1988 the IAEA and the Nuclear Energy Agency of the Organization for Economic Co-operation and Development (OECD/NEA) jointly reached consensus on the criteria for determining which sources and practices may in a general sense be exempted from regulatory control because they present trivial radiation risks and detriments. Accordingly, the IAEA later published the document *Principles for the Exemption of Radiation Sources and Practices from Regulatory Control* [12], which established the general criteria for exemption, including values of trivial individual and collective dose for the purposes of radiological protection, and the OECD/NEA published a guide for controlling radioactive consumer products [13].

(54) Thus, in the 1996⁶ edition of the BSS, exemption values were developed using dose criteria as the starting point. While the general principles for exemption remained in place, these were interpreted in terms of individual radiation dose, as follows

“A practice or a source within a practice may be exempted without further consideration provided that the following criteria are met in all feasible situations:

- (a) the effective dose expected to be incurred by any member of the public due to the exempted practice or source is of the order of 10 μSv or less in a year; and
- (b) either the collective effective dose committed by one year of performance of the practice is no more than about 1 man.Sv or an assessment for the optimization of protection shows that exemption is the optimum option.”

(55) Using the dose criterion on 10 μSv in a year, conservative models were used to calculate values of activity concentration and of total activity below which compliance with the dose criterion was assured i.e. below these values, the individual dose was considered to be trivial, and therefore need not be regulated, and the criterion for collective dose would be met. Below these values of activity concentration exemption was applied without further consideration.

³ https://gnessn.iaea.org/Superseded%20Safety%20Standards/Safety_Series_009_1962.pdf

⁴ https://gnessn.iaea.org/Superseded%20Safety%20Standards/Safety_Series_009_1967.pdf

⁵ https://gnessn.iaea.org/Superseded%20Safety%20Standards/Safety_Series_009_1982.pdf

⁶ https://gnessn.iaea.org/Superseded%20Safety%20Standards/Safety_Series_115_1996_Pub996_EN.pdf

(56) It is important to note that, up to this time, the concept of exemption was focused specifically and solely on exempting practices and sources within practices from entering into the regulatory system. The concept of exempting radioactive sources and materials that were already inside the system but could be prospectively be exempted from it (e.g., because their radioactive content had decayed sufficiently) had not yet been introduced. This concept would be confusedly termed ‘clearance’⁷ [8] (which was translated as dispense, liberation, and release in different languages). Moreover, radioactivity in food, drinking water and non-edible commodities was not covered in these safety standards.

(57) On 22 September 2000, at its tenth plenary meeting, the forty-fourth regular session of the IAEA General Conference adopted Resolution GC(44)/RES/15 on Radiological Criteria for Long-Lived Radionuclides in Commodities (especially foodstuffs and wood), which requested the IAEA 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.

(58) International agreement on establishing radionuclide activity concentrations could not be achieved. Instead, a new Safety Guide on *Application of the Concepts of Exclusion, Exemption and Clearance* [2] was developed and published in 2004. This Safety Guide included values for exemption from regulatory control of bulk amounts of material and for clearance of material that no longer needed to be regulated. In order to ensure consistency in the regulatory approach, the same values of activity concentration were applied to both exemption and clearance.

(59) Reference [2] also recognized that certain exposures are not amenable to control. This is not an issue of the magnitude of the radiation dose received, but rather one of controllability. This concept was termed *exclusion*⁸ [8]. Thus, for example, exposure to cosmic radiation at the surface of the earth is excluded, in that there is no realistic action that could be taken to reduce such exposures. On the other hand, cosmic exposure of air crew is not excluded in that there are measures that could be taken to reduce exposures. However, if such actions are deemed not to be justified in terms of their economic and societal efforts, they may be exempted from some or all regulatory control.

(60) The specific topic of international trade in contaminated commodities referred to in GC(44)/RES/15 is addressed in paragraph 5.8 of Ref. [2], which states that “.....national and international trade in commodities containing radionuclides with activity concentrations below the values of activity concentration provided [in this Safety Guide] should not be subject to regulatory control for the purposes of radiation protection”.

(61) In 2007, ICRP issued recommendations on the scope of regulatory control [7], which suggested approaches to national authorities for their definition of the scope of radiological protection control measures through regulations, by using its principles of justification and optimisation. The document provided advice for deciding the radiation exposure situations that should be covered by relevant regulations because their regulatory control is justified,

⁷ In the IAEA Safety Glossary [8], ‘clearance’ is defined as ‘the removal of regulatory control by the regulatory body from radioactive material or radioactive objects within notified or authorized facilities and activities; namely, clearance can be viewed as an exemption from within the system.

⁸ In the IAEA Safety Glossary [8], ‘exclusion’ is defined as ‘the deliberate excluding of a particular type of exposure from the scope of an instrument of regulatory control on the grounds that it is not considered amenable to control through the regulatory instrument in question’.

and, conversely, those that may be considered for exclusion from the regulations because their regulatory control is deemed to be unamenable and unjustified. It also provided advice on the situations resulting from regulated circumstances, but which may be considered by regulators for exemption from complying with specific requirements because the application of these requirements is unwarranted, and exemption is the optimum option. Thus, the recommendations described exclusion criteria for defining the scope of radiological protection regulations, exemption criteria for planned exposure situations, and the application of these concepts in emergency exposure situations and in existing exposure situations. They also addressed specific exposure situations such as exposure to ‘commodities’. However, ICRP advised that the recommended quantitative criteria were intended only as generic suggestions to regulators for defining the regulatory scope, in the understanding that the definitive boundaries for establishing the situations that can be or need to be regulated will depend on national approaches.

(62) Thus, the concept of exemption was further developed in the 2014 edition of the BSS [6]. The exemption values that appeared in the 1996 edition were retained and it was specified that these applied to moderate amounts of material, specifically less than about 1 tonne. The number of radionuclides covered increased from less than 300 to over 700. The values for exemption of bulk amounts of material and for clearance, which had previously been developed in Ref. [2], were also included. One further change was to delete the criterion for exemption based on collective dose and, instead, to allow for individual doses up to 1 mSv in a year for ‘low probability scenarios’.

(63) The values for exemption of moderate amounts of material are widely used in Member States. The values for exemption of bulk amounts of material are also widely used, but primarily in relation to natural radionuclides generated by NORM industries. The values for clearance are also widely used, primarily in relation to decommissioning activities. All of the current values have been derived for situations where the radionuclide is an integral part of the material in question. No values have been developed for exemption or clearance in relation to surface-contaminated items.

(64) In summary, the IAEA safety standards contain values for exemption of moderate and of bulk amounts of material, and for clearance of material for which regulatory control is deemed to be no longer necessary. For consistency, the activity concentrations used for exemption of bulk amounts of material and for clearance are identical. In addition, it is suggested that these values are also appropriate for items in national and international trade. All values have been developed using conservative assumptions and (for artificial radionuclides) are based on an individual radiation dose of the order of 10 μ Sv or less in a year.

Radionuclides in Food and Water

(65) The early editions of the BSS referred to radioactivity in food and drinking water only in the context of monitoring to assess the impact of authorized discharges to the environment. As a result of the Chernobyl accident, the 1996 edition introduced the concept of intervention levels and action levels to be applied following an emergency. National authorities were required to specify “action levels for the withdrawal and substitution of specific supplies of food and drinking water” in their emergency plans.

(66) As a result of the publication of Ref. [2] and also changes to the system of radiological protection introduced in 2007 by the ICRP in its Publication 103 [9], the establishment of reference levels for commodities in existing exposure situations is addressed in the 2014 edition of the BSS [6], which states that national authorities are required to:

“...establish specific reference levels for exposure due to radionuclides in commodities such as construction material, food, feed and drinking water, each of which shall typically be expressed as, or based on, an annual effective dose to the representative person generally that does not exceed a value of about 1 mSv.”

(67) The subsequent paragraph states:

“the regulatory body or other relevant authority shall consider the guideline levels for radionuclides contained in food traded internationally that could contain radioactive substances as a result of a nuclear or radiation emergency, as published by the Joint FAO/WHO Codex Alimentarius Commission [14]. The regulatory body or other relevant authority shall consider the guideline levels for radionuclides contained in drinking water that have been published by the WHO [15].”

(68) Neither the BSS nor other IAEA safety standards clarify how such national reference levels⁹ [8] should be established and used for food, drinking water or commodities that are traded¹⁰ [16]. While Ref. [2] included text that suggested that the values for exemption and clearance could be appropriate for international trade in commodities, no such reference is included in the BSS. Experience suggests that the approach put forward in Ref. [2] would not be widely accepted by national authorities.

(69) The approach to managing radioactivity in these consumer goods is based on a radiation dose to an individual of 1 mSv in a year. This is in contrast with Ref. [2], where the dose criterion is 10 µSv in a year i.e. 100 times lower. However, it is important to note that the approach outlined in Ref. [2] has been developed specifically for practices i.e. sources that could potentially be regulated, such as radioactive consumer products to which radionuclides are added at the time of manufacture. Consumer goods that contain radionuclides as a result of natural environmental processes, such as uptake of radionuclides from soil to trees and its accumulation in wood, are now managed differently under the current system of radiological protection.

(70) What is also important is that, while the development of criteria for the control of radionuclides in food and drinking water are referred to in the IAEA safety standards, historically this function has been undertaken by the FAO and the WHO. As their documents are referenced in the BSS, it is important to understand their scope and applicability.

Food

(71) The presence of radioactive substances in food is particularly sensitive for members of the public. Naturally, they feel more vulnerable to radioactivity inside their bodies. Therefore, the regulation of the presence of radioactive substances in food is an important issue that presents many challenges.

(72) The first challenge is to define what we understand by food. In modern English, food replaces the archaic term, aliment, which is derived from *alere*, meaning to nourish. The Oxford English Dictionary defines food as “any nutritious substance that people eat or drink in order to maintain life and grow”.

⁹ In the IAEA Safety Glossary [7], a ‘reference level’ is defined as ‘the level of dose, risk or activity concentration above which it is not appropriate to plan to allow exposures to occur and below which optimization of protection and safety would continue to be implemented’.

¹⁰ Guidance on setting reference levels for building materials can be found in Ref [16].

(73) From this generic understanding a number of questions arise, as follows¹¹:

- The term food seems to include drinks. This would imply that water is also food if we consider it to be essential for nutrition. Should water be regulated in the same manner as other foods?
- The term food appears to be associated with nutrition and nourishment. Should substances that people eat for pleasure or vice, rather than because of its nutritious characteristics, be excluded from the regulation of food?
- The understanding of food has cultural connotations. Substances that are eaten in some cultures are considered unsuitable for eating in others. For instance, bovine intestines are a delicacy in many cultures and just used as suturing material in others. Similarly, seaweed is widely consumed in several countries but has just industrial uses in others. Should the regulation of food differ among cultures and should it be different depending on the intended use?
- Children and adults, women and men, have different sensitivities to radiation exposure, and therefore to the presence of radioactive substances in food. Moreover, food preferences and diet vary enormously between individuals. Some food is consumed primarily by infants and children, while others are consumed only by adults. How should these differences be accounted for when deciding what concentrations of radionuclides in food may require regulatory control?

(74) All these issues have been considered in many intergovernmental discussions on developing guidance for managing radioactive substances in food but have not been resolved. In fact, what has been achieved until now is a de facto pragmatic international guiding system established under two fundamental aegises: the FAO/WHO Codex Alimentarius Commission – and its various Codex Standards, and the WHO Guidelines for Drinking-water Quality. These two approaches are inconsistent, as discussed in the paragraphs below.

Joint FAO/WHO Codex Alimentarius Commission

(75) The Joint FAO/WHO Codex Alimentarius Commission (CAC) is the body charged with developing the Codex Alimentarius [14], 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. FAO and WHO both cosponsor the BSS.

(76) The CAC has developed both Guideline Levels and maximum levels for various chemical and other contaminants in food and feed. A Guideline Level is defined as “the maximum level of a substance in a food or feed commodity which is recommended by the CAC to be acceptable for commodities moving in international trade”. When the Guideline Level is exceeded, governments should decide whether, and under what circumstances, the food should be distributed within their territory or jurisdiction. The maximum level of a

¹¹ Another important question, as mentioned previously, is the connotation given to the presence of radioactive substances in food. This is confusedly termed ‘contamination’. Most languages have derived the term from the Latin *contaminare*, which means ‘made impure’, having a primeval religious meaning. A typical example of the religious understanding of food contamination is non-kosher food, or the presence of blood in Christian Eastern meals, namely food not satisfying the requirements of religious law with regard to its origin and preparation. However, in professional parlance, the term food contamination is used to denote the presence of radioactive substances, even if its amount is small; this subtlety is missed by most people. The public connotation of food contamination is different, and to most people it conveys the message of poisoned and they usually perceive it as a yes/no situation, namely either there is contamination, and therefore danger, or there is not. The concept of ‘low level’ food contamination is incomprehensible to most people. These undertones cause anxiety and concern to people and confusion to the authorities when handling situations involving food contamination

contaminant is defined as “the maximum concentration of that substance recommended by the CAC to be legally permitted in that commodity”.

(77) In response to the Chernobyl accident, the CAC developed, and in 1989 adopted, Guideline Levels for Radionuclides in Foods Following Accidental Nuclear Contamination for Use in International Trade [17]. At the time, no comprehensive guidance on international trade in food and feed containing radionuclides had been established. The radionuclides included were those important for uptake into the food chain and most likely to be present following a nuclear accident. For that reason, radionuclides of natural origin were excluded from consideration.

(78) Codex Guideline Levels were developed for six radionuclides, namely ^{90}Sr , ^{131}I , ^{134}Cs , ^{137}Cs , ^{239}Pu , and ^{241}Am , all of them relevant for nuclear accidents, but the Code is mute for other radionuclides relevant for other activities (e.g., medical practices) and natural radionuclides. Activity concentrations were derived for two different food groups: those destined for general consumption and milk and infant foods. The Guideline Levels were based on a dose criterion of 5 mSv in a year and using the assumption that 550 kg of food and 275 litres of milk – all of which was contaminated – is consumed in that year by adults and infants respectively.

(79) These Codex Guideline Levels were incorporated into the 1996 edition of the BSS, where they were referred to as action levels, specifying that they “...shall be applied to food as consumed, and to dried or concentrated food after dilution or reconstitution”. The BSS also noted that, “in certain circumstances, if food is scarce or there are other serious social or economic considerations, higher optimized action levelswould be expected to be used”.

(80) The Codex Guideline Levels were originally designed to be applicable for one year following a nuclear accident. They were based on conservative assumptions and intended for use only in international trade as values below which no food control restriction need be applied. In 1991, the CAC agreed to extend the period of application of the Guideline Levels indefinitely i.e. they would no longer apply only to the first year after a nuclear accident.

(81) As part of its response to General Conference resolution GC(44)/RES/15 referred to in the previous section, the IAEA requested the CAC to revise its Guidance Levels to address the following (1) consider levels that could be applied in the long-term; (2) increase the number of radionuclides covered; (3) take account of the most recent recommendations of the ICRP; and (4) apply the improvements in the assessment of radiation doses resulting from the human intake of radioactive substances that have become available since 1989.

(82) In response to this request, the CAC extended the list to 20 radionuclides and reduced the dose criterion to 1 mSv in a year. Based on statistical data on food production and import, it was now assumed that 10% of the diet consisted of food imported from the affected area, all of which was contaminated at the Guideline Level throughout the year. The remainder of the diet was assumed not to be contaminated. Consumption rates of 550 kg per year for adults and 200 kg per year for infants were assumed.

(83) In 2006 the CAC adopted revised Codex Guideline Levels to supersede those adopted in 1989. These were published in an updated version of the Codex General Standard for Contaminants and Toxins in Food and Feed [14]. These values, summarized in Table 1 below, continue to be valid today.

Table 1
Guideline Levels for Radionuclides in Food Contaminated following a Nuclear or Radiological Emergency for Use in International Trade

Product Name	Representative Radionuclides	Guideline Level (Bq/kg)
Infant foods*	^{238}Pu , ^{239}Pu , ^{240}Pu , ^{241}Am	1
	^{90}Sr , ^{106}Ru , ^{129}I , ^{131}I , ^{235}U	100
	$^{35}\text{S}^{**}$, ^{60}Co , ^{89}Sr , ^{103}Ru , ^{134}Cs , ^{137}Cs , ^{144}Ce , ^{192}Ir	1 000
	$^3\text{H}^{***}$, ^{14}C , ^{99}Tc	1 000
Foods other than infant foods	^{238}Pu , ^{239}Pu , ^{240}Pu , ^{241}Am	10
	^{90}Sr , ^{106}Ru , ^{129}I , ^{131}I , ^{235}U	100
	$^{35}\text{S}^{**}$, ^{60}Co , ^{89}Sr , ^{103}Ru , ^{134}Cs , ^{137}Cs , ^{144}Ce , ^{192}Ir	1 000
	$^3\text{H}^{***}$, ^{14}C , ^{99}Tc	10 000

* When intended for use as such.

** Represents the value for organically bound sulphur.

*** Represents the value for organically bound tritium.

(84) Of interest is the fact that the CAC has stated [17] that “the preferred format of a Codex standard in food or feed is a maximum level and that the existing Guideline Levels shall be reviewed for their possible conversion to a maximum level after a risk assessment [has been] performed”. This is to allow for the situation that still applies in several European countries whereby ^{137}Cs released to the environment following the Chernobyl accident is found in forest mushrooms, wild berries and game animals at activity concentrations well above the Guideline Levels.

(85) In addition to the above described standards for food, there are also specific Codex general standards for bottled/packageged drinking waters and for natural mineral waters. These are discussed below.

Water

(86) Water is essential for life. Water supply, sanitation and health are closely linked. In 2010, the United Nations General Assembly explicitly recognized the right to safe and clean drinking water and sanitation as a human right that is essential for the full enjoyment of life and all human rights. Direct or indirect use of water is a major source of food for humanity, with approximately 70% of the freshwater used by humans going to agriculture. Water is an excellent solvent for a wide variety of chemical substances and as such it is widely used e.g. in cooking. Water also plays an important role in the world economy. Large quantities of water, ice, and steam are used for cooling and heating, in industry and homes. Water is also central to many sports and other forms of entertainment, such as swimming.

(87) The control of radioactivity in water is of particular interest. However, this is one of the areas where the various consensus reached are not necessarily coherent and consistent among themselves.

(88) As regards international standards, water has been classified into a number of different categories as follows:

- ***Drinking water***

Guidelines for Drinking-water Quality [15] are provided by the World Health Organization. This international guidance is the basis for the setting of national regulations and standards for water safety in support of public health. However, the expression drinking water apparently excludes both packaged/bottled waters and natural mineral waters; the expression drinking water therefore seemingly refers to water from a public supply i.e. tap water.

- ***Packaged drinking waters (other than natural mineral waters)***

These packaged waters are waters for human consumption other than natural mineral waters, which may contain minerals, naturally occurring or intentionally added, and carbon dioxide, naturally occurring or intentionally added, but shall not contain sugars, sweeteners, flavourings or other foodstuffs [19]. These packaged waters must meet the requirements of the WHO Guidelines for Drinking Water Quality [15] and are either waters defined by origin, i.e. from specific environmental resources without passing through a community water system or 'prepared waters' which may originate from any type of water supply.

- ***Natural Mineral Waters*** are natural mineral waters offered for sale as food and not natural mineral waters sold or used for other purposes [20], which are:

- Waters clearly distinguishable from ordinary drinking water because they are characterized by its content of certain mineral salts and their relative proportions and the presence of trace elements or of other constituents;
- Obtained directly from natural or drilled sources from underground water bearing strata for which all possible precautions should be taken within the protected perimeters to avoid any pollution of, or external influence on, the chemical and physical qualities of natural mineral water, of the constancy of its composition and the stability of its discharge and its temperature, due account being taken of the cycles of minor natural fluctuations;
- Collected under conditions which guarantee the original microbiological purity and chemical composition of essential components, are packaged close to the point of emergence of the source with particular hygienic precautions and are not subjected to any treatment other than those permitted by international standards.

They are moreover classified as:

- naturally carbonated natural mineral water;
- non-carbonated natural mineral water;
- decarbonated natural mineral water;
- natural mineral water fortified with carbon dioxide from the source; or
- carbonated natural mineral water.

It is to be noted that the condition of natural mineral water should be recognized as such by the responsible authority of the State in which the natural mineral water has emerged.

(89) While drinking water (tap water) might not meet the general definition of a consumer good, both packaged waters and natural mineral waters appear to be classifiable as consumer goods. However, in international standards, the radiological criteria and guidance levels for drinking water (tap water) set out by the WHO apply also to packaged waters, but not to natural mineral waters. In the Codex Alimentarius, natural mineral waters are considered as being sold as a food.

(90) The relevant documents are summarized and discussed below.

WHO Guidelines for Drinking-water Quality

(91) In 1958, 1963 and 1971, the WHO published International Standards for Drinking Water. These were subsequently superseded by the document WHO Guidelines for Drinking-water Quality; editions of this document were published in 1983-1984, 1993-1997 and 2004, with the most recent edition being published in 2011 [15].

(92) It is to be noted that in the WHO Guidelines both packaged/bottled water and natural mineral waters, which are widely consumed all over the world, are not considered drinking water. It seems, although it is not clear, that the WHO guidelines apply only to tap water.

(93) Chapter 9 of the WHO Guidelines for Drinking-water Quality provides criteria with which to assess the acceptability of drinking water with respect to its radionuclide content. While the document is originally for application to naturally occurring radionuclides, it has been extended to include artificial radionuclides.

(94) The WHO recommends use of an individual dose criterion (IDC) of 0.1 mSv from one year's consumption of drinking water, regardless of whether the radionuclides are of natural or artificial origin. To assess compliance with the IDC, initial screening measurements of gross alpha and gross beta activity of the drinking water supply are carried out. If either of the screening levels of 0.5 Bq/L for gross alpha and 1 Bq/L for gross beta is exceeded, the concentration of individual radionuclides needs to be determined.

(95) The WHO has developed guidance levels in terms of activity concentrations for a range of common naturally occurring and man-made radionuclides. The guidance level for each radionuclide represents the concentration that, if present in the drinking water consumed throughout the year, would result in an individual dose of 0.1 mSv. These are summarized for selected radionuclides in Table 2.

(96) The WHO notes that "... guidance levels are conservative and should not be interpreted as limits. Exceeding a guidance level should be taken as a trigger for further investigation but not necessarily as an indication that the drinking-water is unsafe". Despite this caveat, in practice the WHO guidance levels are often used as limits.

(97) Uranium, is a chemically toxic element and its presence in drinking water is controlled through its chemical toxicity rather than its radioactivity. The guidance level recommended by the WHO has progressively increased from 2 µg/L in 1988 to 15 µg/L in 2004 and now 30 µg/L since 2011 [21]. Not all national authorities that have established standards for uranium in drinking water have adopted the WHO guidance level.

Table 2
Guideline Levels for Selected Radionuclides in Drinking Water¹²

Radionuclide	Guidance Level (Bq/L)
³ H	10 000
¹⁴ C	100
⁹⁰ Sr, ¹³¹ I, ¹³⁴ Cs, ¹³⁷ Cs, ²³⁸ U	10
²²⁶ Ra, ²²⁸ Th, ²³⁰ Th, ²³² Th, ²³⁴ U, ²³⁹ Pu, ²⁴¹ Am	1
²¹⁰ Pb, ²¹⁰ Po, ²²⁸ Ra	0.1

(98) One issue that causes much confusion is the relationship between the WHO's IDC of 0.1 mSv in a year and the IAEA's reference level of 1 mSv, also in a year. While the majority of drinking water supplies around the world comply with the IDC of 0.1 mSv, there are also many that are unable to do so. This issue is discussed in the WHO Guidelines for Drinking-water Quality [15] and also in TECDOC-1788 [22], but the need for two different values, and two different approaches, continues to be confusing to many national authorities. The WHO has recently developed additional guidance to clarify this issue [23].

Codex General Standard for Bottled/Packaged Drinking Waters

(99) One apparent omission in the Codex Alimentarius approach is the absence of Guideline Levels to be applied to water – while bulk water is generally not traded, bottled water most certainly usually contains some natural radionuclides and potentially also artificial radionuclides. However, this is dealt with in the Codex General Standard for Bottled/Packaged Drinking Waters [19], which stipulates that “all packaged water shall comply with the health-related requirements of the most recent Guidelines for Drinking-water Quality published by the World Health Organization”. But, it is not clear what is meant by health-related requirements and whether these include the guidance levels for selected radionuclides in drinking water. This standard appears to apply to all packaged/bottled water, and not just that contaminated following a nuclear accident.

Codex Standard for Natural Mineral Waters

(100) The provisions contained in the Codex Standard 227-2001 [19] does not apply to natural mineral waters. These are regulated by the Codex Standard for Natural Mineral Waters, Codex Standard 108-1981 [20]. This Codex Standard introduces health-related limits for certain substances in natural mineral water, establishing that in its packaged state they shall contain not more than specified amounts of certain chemical elements and substances. It also contains requirements for hygiene, including microbiological requirements, for packing, labelling and methods of analysis and sampling. But, surprisingly, it does not contain any restriction on radioactive substances. The impression given is that natural mineral water may contain any amount of radioactive substances provided that they originate at the natural source.

¹² ⁴⁰K, a radionuclide that occurs naturally in a fixed ratio to stable potassium, is not included. This is because potassium is an essential element for humans and its concentration in the body is controlled by metabolic processes. If the screening level of 1 Bq/l for gross beta activity concentration is exceeded, a separate determination of total potassium should be made and the contribution of ⁴⁰K to beta activity should be subtracted.

IAEA TECDOC-1788 [22]

(101) Despite the fact that much work had been carried out to develop criteria for the control of radionuclides in food and drinking water, at the time of the Fukushima Daiichi NPP accident in 2011 there was a lack of clarity as to what values should apply to international trade in food and non-food commodities. At the time, the concept of different exposure situations was relatively new and there was additional confusion as to criteria to be applied to consumer goods originating in an area being managed as an emergency exposure situation but being exported outside the affected area. This effectively reduced to the question of whether the activity concentrations applied by the Japanese government to consumer goods originating in Japan should also apply to the rest of the world.

(102) In addition to the CAC Guideline Levels for food in international trade, the IAEA has also developed values, referred as Operational Intervention Levels (OILs), for application in areas directly affected by a nuclear or radiological emergency [24]. OILs are used as a decision-making tool for restricting the consumption of food and drinking water. In general, for individual radionuclides the CAC Guideline Level and the corresponding OIL are different. This difference is explained by the fact that the values are used for different purposes, but this is not immediately understandable or easily explained to decision-makers and the public.

(103) In order to clarify the various international standards in place, the criteria under which they were developed and the circumstances to which they apply, the IAEA developed TECDOC-1788 on *Criteria for Radionuclide Activity Concentrations for Food and Drinking Water* [22]. The document is cosponsored by the Joint FAO/IAEA Division (representing the FAO) and the WHO.

(104) While Ref. [22] clarifies the existing international recommendations for food and drinking water and the circumstances in which these should be used, it also highlights that, when addressing the management of radionuclides in food and drinking water in non-emergency situations, the current international approaches are inconsistent in relation to scope, radiation protection criteria and terminology. This should perhaps not be surprising as these documents were developed at different times, by different organizations and for different purposes. Nevertheless, this inconsistency is problematic in terms of implementation by Member States.

(105) The differences highlighted in Ref. [22] are described below and summarized in Table 3.

Radiation Protection Criteria

(106) As mentioned above, the BSS requires the establishment of reference levels based on an annual effective dose of about 1 mSv. The Codex Alimentarius also uses a dose criterion of 1 mSv in a year for food in international trade, assuming that 10% of the food consumed in a particular country is imported. For drinking water, the WHO establishes a 'total indicative dose' of 0.1 mSv in a year.

(107) There is considerable confusion about how the reference level of 1 mSv in the BSS and the total indicative dose of 0.1 mSv in the WHO Drinking Water Guidelines are to be interpreted, especially in relation to exceedances of these values.

Scope

(108) The BSS does not clearly specify whether the reference level of 1 mSv applies to naturally-occurring radionuclides, to man-made radionuclides, or to both. The radionuclides included in the Codex Alimentarius are primarily of man-made origin. However, tritium and ^{14}C , which are included, also occur naturally in the environment. Naturally-occurring radionuclides such as ^{210}Po and ^{226}Ra are not covered by the Codex Alimentarius; both have industrial uses and it is not difficult to perceive circumstances where they could accumulate to high concentrations in food.

(109) The WHO Drinking Water Guidelines were initially developed to address naturally occurring radionuclides but have been extended to include artificial radionuclides. They therefore cover all possible radionuclides, which is very different to the limited scope of the Codex Alimentarius approach for food.

Activity Concentrations

(110) The BSS does not establish activity concentrations for radionuclides in food or drinking water but leaves it to individual Member States to establish values for use nationally. The Codex Alimentarius establishes activity concentrations for 20 radionuclides of importance for food that might be present following a nuclear or radiological emergency. Infant foods and non-infant foods are considered separately. The WHO has developed activity concentrations for both natural and artificial radionuclides in drinking water.

Trade versus national production and consumption

(111) Another concern in relation to the Codex Alimentarius is that the activity concentrations are developed for international trade in the event of a nuclear or radiological emergency. Experience has shown that, for the majority of foods, such concentrations are present only in the first year following the accident – subsequently much lower concentrations are present. However, there are certain speciality foods, such as forest mushrooms, berries and game, where activity concentrations can greatly exceed the values specified in the Codex Alimentarius and these values can persist for many years, even decades.

Terminology

(112) The BSS refers to reference levels, Codex Alimentarius uses the term guideline levels and the WHO uses guidance levels.

Table 3
Comparison of International Standards for Radionuclides in Food and Drinking Water

	International BSS	WHO DWG	CODEX 193-1995
Scope	Non-emergency	Non-emergency	Relevant only after an emergency
Dose Criteria	1 mSv in a year	0.1 mSv in a year	1 mSv in a year
Activity Concentrations (Bq/kg or Bq/l)	No	Yes	Yes
Age Groups	Representative person	Adults	Infants/Non-infants
Radionuclides	Not specified	Mainly natural; also covers man-made	20 radionuclides, mainly man-made
Terminology	Reference level	Guidance level	Guideline level

(113) These inconsistencies are recognized in the 2016 IAEA General Conference Resolution GC(60)/RES/9 dealing with Radiation Safety and Environmental Protection, where paragraph 75 mandates the Secretariat to cooperate with relevant international organizations in developing a harmonized framework for the control of radioactivity in food and drinking water.

(114) A revised resolution was agreed in 2017 and 2018, requesting the Secretariat to develop principles for harmonized guidance on radionuclide activity concentration values in food and drinking water, in continued cooperation with relevant international organizations and national authorities.

SECTION 4

FEEDBACK FROM NATIONAL AUTHORITIES

(115) The IAEA and the Nuclear Regulatory Authority of Argentina organized a Regional Workshop on Radioactivity in Food, Drinking Water and Commodities in Buenos Aires from 21 to 23 March 2017, to discuss the application of current international standards for managing radioactivity in food, drinking water and commodities in non-emergency situations¹³.

(116) The workshop, jointly supported by the IAEA, the Joint FAO/IAEA Division of Nuclear Techniques in Food and Agriculture, the Pan American Health Organization and the World Health Organization, was attended by 46 participants from 16 IAEA Member States and two non-Member States of IAEA (Aruba and St. Lucia). The participants included high level experts and senior staff from regulatory bodies, industry, research organizations and government ministries charged with the responsibility for establishing national standards for radioactivity in food, drinking water and commodities that are traded.

(117) The main purpose of the workshop was to seek feedback from countries in the Latin America and the Caribbean region on their experience in using the international standards, including the identification of any aspects requiring further clarification or development.

(118) A number of countries currently do not have programmes for monitoring radioactivity in food and drinking water. The workshop offered these countries an opportunity to learn from the experiences of others on how to design and implement an appropriate and cost-effective monitoring programme, including the management of situations where activity concentrations specified in standards are exceeded. The first step in designing such a monitoring programme is to undertake baseline studies describing the situation nationally.

(119) The workshop confirmed the desire for a universal and simple system of acceptable activity concentration levels for consumer goods and underlined the benefit of such a system in terms of consistency and communication. The participants considered that the current system was unnecessarily complex, but that at the same time it did not adequately address all the situations that exist in the region.

(120) There was a discussion around the differences between edible and non-edible consumer goods and if a fully unified system was realistic. While the ultimate ambition might be to have a small set of numbers (activity concentrations per kilogram, per litre or per square centimetre) for the key radionuclides that applied to all consumer goods, public perception might expect more restrictive values for consumer goods that are edible (food and drinking water) than for consumer goods that are not edible.

(121) It was noted that the exposure pathways for edible and non-edible consumer goods are different, and that while the dose modelling for edible products is straightforward the dose calculations for different scenarios of non-edible products could become very complex. It was suggested that, rather than starting with a dose criterion, perhaps a better approach would be to establish standards based on activity, activity concentration or activity per unit area, which might in turn be based on the observed concentrations in the environment (as least for edible consumer goods). However, it was recognized that some kind reference to notional individual doses would probably be necessary.

¹³ This event was implemented within the framework of the IAEA technical cooperation project RLA9078, which aims at enhancing effective regional capabilities for protecting the public and the environment in Latin American and Caribbean countries.

- (122) The participants reached the following conclusions:
- (a) There is a need to further harmonize the international standards in terms of scope, radiation protection criteria and terminology. The responsible organizations should work jointly to achieve this;
 - (b) In setting acceptable values for consumer goods, it is not necessary to differentiate between the three exposure situations recommended by ICRP and established in international standards;
 - (c) There must be flexibility to deal with unusual situations that arise in each country by allowing for national approaches;
 - (d) It is necessary to establish activity concentration values for managing non-edible commodities, taking into account the specific scenarios for their use by the public. Values also need to be developed for surface-contaminated non-edible commodities;
 - (e) Prior to the establishment of international standards for the regulatory control of radioactivity in consumer goods, it is essential to determine the values usually found in the environment for food, drinking water and non-edible commodities. This screening should include those items and situations where higher concentrations are to be expected;
 - (f) The same criteria for radioactive content should apply to tap water, bottled water and natural mineral water. Although mineral water often has a special status under national legislation, the consumer has the right to expect the same criteria for all water, regardless of source;
 - (g) Data on the natural radionuclide content of food produced in the region should be collected, both for comparison with radionuclides of artificial origin, and as a first step in considering the inclusion of natural radionuclides in international standards for food;
 - (h) The Codex Alimentarius lacks Guidance Levels for natural radionuclides in food. While the values established for certain radionuclides in the Codex were created in another context, it is now necessary to also establish values for natural radionuclides;
 - (i) It is important for the national authorities to identify foods that may be relevant in the diet, and to perform the screening described heretofore before establishing any value;
 - (j) In applying CAC values to food produced and consumed nationally or regionally, national authorities should not adopt and use the Codex values automatically but rather take account of any differences in consumption that may be different from those used by Codex;
 - (k) It would be helpful to carry out a realistic dosimetric evaluation, in order to know what a given concentration means in terms of dose. It is for this reason that countries are encouraged to carry out measurements of radionuclides at national level, to establish realistic consumption rates for different types of food, and based on these data, establish the dosimetric implication of these values. Many countries may already have such data;
 - (l) It is imperative not to use bands of values in the regulation of activity in consumer goods, since people and authorities usually believe that the minimum values are the safe ones. Currently both the Codex Alimentarius and the WHO DWG use absolute values rather than ranges, although of course the concept of reference levels allows flexibility in the numbers. This is a problem rather than a solution;

- (m) It is necessary to decide the status of any numbers that be finally established, namely: i.e. are they advisory, limits, upper bounds, lower bounds, action levels, trigger levels etc.;
- (n) With respect to the WHO total indicative dose of 0.1 mSv/y, this value is causing confusion vis-à-vis the reference level of 1 mSv/y in the IAEA safety standards. The reason for taking action if the 0.1 mSv/y value is exceeded is not understood. Moreover, some countries cannot comply with this value as they have higher values in their natural environment;
- (o) It is important to emphasize that the scenarios addressed by the transport regulations are used in another context, but the surface activity values are a useful starting point for developing appropriate values for commodities. However, situations should be avoided where items are not regulated but cannot be freely transported, and vice versa;
- (p) The control of non-edible commodities should be based on activity concentration values due to the fact that making dose estimates from activity concentrations can have a great deal of uncertainty because the parameters can have a large degree of variability.

(123) In November 2018, the Agency organized a workshop on Technical Challenges in Developing Guidance on Radionuclides in Food and Drinking Water in Non-Emergency Situations in Xi'an, China. The workshop was organized by the International Atomic Energy Agency (IAEA) in cooperation with the World Health Organization (WHO) and was hosted by the National Institute for Radiological Protection (NIRP), China Centre for Disease Control and Prevention (CDC). The workshop was attended by experts from Australia, China, Republic of Korea, New Zealand, United Arab Emirates and the United Kingdom. Many of the points mentioned above in relation to the control of radionuclides in food and drinking water were supported by participants.

SECTION 5

DISCUSSION

Introduction

(124) The preceding sections have described the relevant history that has brought radiation safety regulators to the current situation, namely that there is still not a clear and consistent view as to what criteria should be applied in deciding on the need to regulate radioactivity – either of natural or artificial origin – in consumer goods generally available for consumption and use by the public, either edible or non-edible.

(125) For the various types of consumer goods under consideration, the current approaches can be summarized as follows:

- (a) Radioactive consumer products to which radionuclides have been deliberately added for functional reasons are managed using the criteria for exemption of practices i.e. no individual should receive a dose above 10 μSv in a year. Products which fall into this category include ionization chamber smoke detectors, car headlamps and high-density lighting in sports arenas.
- (b) For other consumer goods, international standards specify that no individual should receive a radiation dose above a reference level of about 1 mSv in a year. Goods that fall into this category include products such as wood containing radioactivity following a nuclear accident, certain pottery containing elevated concentrations of naturally-occurring radionuclides, etc.
- (c) In the case of food, the Codex Alimentarius Commission has developed Guideline Levels for radionuclides in food destined for human consumption and traded internationally following a nuclear or radiological emergency. It is assumed that food imported from the affected area represents 10% of the total diet and that the remaining 90% of the diet is not contaminated. In such circumstances, the individual radiation dose is not expected to exceed 1 mSv in a year. Guideline levels have been developed for 20 primarily artificial radionuclides.
- (d) In the case of drinking water (tap water), the World Health Organization has established an individual dose criterion (IDC) of 0.1 mSv in a year, although bottled water and natural mineral waters seem to be excluded from this criterion. A systematic approach has been developed to assess compliance, or not, with the IDC, taking into account contributions from all naturally-occurring and man-made radionuclides. The IAEA has established a reference level of 1 mSv in a year for drinking water. The relationship between the WHO's IDC (0.1 mSv in a year) and the IAEA's reference level (1 mSv in a year) is seen as confusing.

(126) It is recognized that a fully integrated approach to managing radioactivity in both consumer goods and radioactive consumer products is highly desirable. To achieve this, the following need to be taken into:

- (a) Consumer goods, where the presence of radionuclides is due to natural environmental processes and, as such, is unplanned; and radioactive consumer products, for which radioactive substances are intentionally added at the time of manufacture;
- (b) Some consumer goods are ingested while others are external to the body. It is imperative to underline that protection criteria against internal exposure in international

approaches and standards result automatically in much higher protection than those criteria for external exposure. This is because the former is based on committed doses while the latter is based on immediate doses. In practice, this would imply stricter criteria for radionuclides in food and drinking water than for other consumer goods;

- (c) Depending on the approach applied to the control of consumer goods, there may be implications, as yet unforeseen, for other components of the system of radiological protection that would need to be considered.

(127) At the start of this document, several issues regarding commonality of language have been identified. One such confusion is caused by the definition of the term 'consumer product' in the IAEA safety standards and qualification of this term by the addition of the adjective radioactive may be considered for all international standards.

(128) The term 'contamination' is also problematic, particularly in relation to consumer goods. Its use in relation to food and drinking water is particularly detrimental because even where the associated radiation doses are extremely low, the use of this word can contribute to public anxiety about consuming 'contaminated' food and drinking water.

Non-edible consumer goods

(129) These consumer goods can contain natural and/or artificial radionuclides from several sources. The question is what concentration of radionuclides in these products used by people is considered acceptable and therefore should be exempted from any regulation. One approach is to simply adopt the exemption values that are already in the BSS. This has the advantage of consistency in numbers, although it is recognized that the associated individual radiation doses may be very different for each product, depending on how it is used.

(130) Another approach would be to derive generic exemption values, based on an individual dose of 1 mSv in a year, for these non-edible consumer goods. This would result in another set of possibly higher exemption values, adding further complication to the current system. It is recognized that further technical work may be necessary before a final decision can be made on the most appropriate set of exemption values.

(131) It is recognized that the current basis for deriving exemption values is highly conservative in relation to both the models used and the values applied to individual parameters within the models. This means that the actual doses received are considerably lower, sometimes by an order of magnitude or more, than those calculated by the models. The current system can therefore be seen as unduly restrictive in relation to non-edible consumer goods, which argues in favour of a new set of numbers.

(132) Reference [2] provides values of activity concentration that may be used for exemption (as well as for exclusion and for clearance) of radionuclides of natural origin and bulk amounts of material containing radionuclides of artificial origin. In the case of natural radionuclides, a value of 1 Bq/g is proposed, based on consideration of the worldwide distribution of activity concentrations for these radionuclides. This represents a precedent for the approach suggested in this document.

(133) For the reasons discussed heretofore, the starting point for controlling radionuclides in non-edible consumer goods does not need to be the identification of the associated exposure situations from which they are derived, nor a dose criterion. A much more sensible and useful approach would be to adopt the same set of activity concentrations for the exemption from regulatory control of all non-edible consumer goods.

(134) Currently there are no accepted international values for the control of surface contamination of consumer goods. This is a gap in the current system that needs to be addressed.

Radioactive consumer products

(135) A special case is the deliberate incorporation of radionuclides into products at the time of manufacture to improve their performance, e.g., smoke detectors, gas mantles, high intensity lamps, and others. The control of these products occurs at the time of manufacture and it is part of a wider system of regulatory control based on the principles of radiation protection, including justification and optimization. This ensures that these radioactive consumer products can be sold directly to the public with the understanding that no further regulation is necessary.

Edible consumer goods – food and drinking water

(136) Reference [22] clearly identifies the fact that the relevant documents produced by the Joint FAO/WHO Codex Alimentarius Commission, the IAEA and WHO are inconsistent in relation to scope, radiation protection criteria and terminology.

(137) In several recent IAEA General Conference Resolutions, the IAEA Member States requested the Secretariat, in cooperation with relevant international organisations, to develop principles for harmonized guidance on radioactivity in food and drinking water.

(138) In terms of moving towards a harmonized approach, there are several inconsistencies to be addressed. The WHO Guidelines for Drinking-water Quality [23] apply to both naturally-occurring and artificial radionuclides, while the Codex Alimentarius approach for food addresses only selected artificial radionuclides. Moreover, while the WHO guidelines apply to drinking water (tap water) and, through the CAC, to packaged waters, there are no international guidelines for radionuclides in natural mineral waters.

(139) Given that, in non-emergency situations, naturally-occurring radionuclides are the larger contributor to our ingestion dose, it would seem appropriate to take account of at least the more important naturally-occurring radionuclides in any dietary dose assessment, just as they are for drinking water. It is therefore recommended that an assessment be undertaken of the distribution of the key naturally-occurring radionuclides in foods worldwide, and the associated radiation doses received by different population groups.

(140) It is to be expected that there are at least some sub-groups of the population who, because of the dietary preferences, receive a radiation dose in excess of the reference level of 'about 1 mSv' established in the BSS. To avoid unnecessary anxiety on behalf of consumers and unnecessary enforcement actions by the national authorities, it is recommended that the standards for natural radionuclides in food be established on the basis of actual measured concentrations i.e. what is often referred to as background levels. Thus, individual dose no longer becomes the starting point for assessment.

(141) An important consideration in relation to naturally-occurring radionuclides in food is how to deal with doses due to ^{40}K . Potassium is an essential element in regulating many bodily functions such as digestion, heart rate and the water content of cells. The potassium content of the body is kept constant by metabolic processes. In the case of drinking water, the dose due to ^{40}K is disregarded in any dose assessment, simply because it is not controllable. Using this approach, it is recommended that ^{40}K in food should also be excluded from regulatory control.

(142) Another important issue is that the Codex Alimentarius values reflect those likely to be present in foodstuffs in the first year after a nuclear accident. As such, they are considerably higher than the activity concentrations likely to be found in most foods on sale in commercial outlets. This would suggest that the Codex values are not a 'quality standard' for non-emergency situations. However, the development of a different set of numbers requires careful consideration and discussion in terms of the potential impact on both trade and consumer confidence.

(143) There are other inconsistencies in the approach to managing radionuclides in food that need to be addressed. While the criteria for drinking water also apply to bottled water in international trade, the situation regarding natural mineral waters is not yet resolved. In many countries, natural mineral waters are covered by different legislation.

(144) It is recommended that the same standards apply to consumer goods that are nationally produced, consumed and used and to those that are traded. It is recognized that, in exceptional circumstances, national authorities may wish to, and should have the right to, establish values of activity concentrations for consumer goods produced nationally for national consumption and use that are higher than internationally agreed values. Examples of such exceptional circumstances include management of the recovery phase following a nuclear accident where elevated activity concentrations are present in forest foods over an extended period.

(145) What is not so clear is whether agreed international standards should apply only to consumer goods available in large commercial outlets, or if it should also apply to those bought at local markets and to those produced by individuals for personal consumption. Here the key issue is controllability, and the extent to which national authorities can, or feel they need to, regulate personal habits of the population. One argument is that the same standards should apply to all consumer goods, regardless of its source, while the contrary argument is that such standards are not enforceable in all situations.

(146) Another potential problem is that Guideline Levels are provided for both infant and non-infant foods in the Codex Alimentarius. Except for the case of food that is exclusive for children, this differentiation is difficult to be applied in practice. In the international radiation safety standards, the accepted approach is to base standards on the 'representative person', defined as an individual receiving a dose that is representative of the doses to the more highly exposed individuals in the population. The underlying philosophy is that if those who receive the highest radiation doses are adequately protected, the rest of the population will also be protected. But inherent in the definition of 'representative person' is the acceptance that certain individuals might receive higher doses. It is recommended that the numerical criteria for controlling consumer goods do not introduce differences between adults and children. Criteria should be based on identification of the representative person. Normally – but not always – this will be children and those levels that are considered safe for children should be used also for adults.

(147) In the case of drinking water, there is a need to explain and clarify the application of the reference level of 1 mSv in the BSS, and the individual dose criterion of 0.1 mSv in the WHO Drinking Water Guidelines.

(148) The bulk of water for human consumption worldwide is covered by drinking water (tap water) and packaged waters. The former is normally not traded, whereas the latter is traded both nationally and internationally. The radiological criteria outlined in the WHO Guidelines [19] apply to both these categories of water, but there are still two issues to be resolved. Firstly, the 0.1 mSv IDC seems to be unduly restrictive for many supplies

worldwide; and, secondly, the CAC text and philosophy linking radiological criteria for packaged waters to those of drinking water (tap water) are unclear.

(149) This leaves natural mineral waters, for which there are presently no specific restrictions on radionuclides in the standards of CAC. In some countries, natural mineral water is consumed in large amounts and represents a significant component of overall consumption. Natural mineral waters are also traded extensively and, under CAC, are regarded as a food. In principle, the radionuclide content of natural mineral waters could be controlled as a food but, Guidance Levels have not yet been developed for radionuclides in food, except for food affected by a nuclear or radiological emergency. Finally, it seems reasonable that the public would expect that the same radiological criteria be applied to all types of intentionally ingested water, thereby providing coherence and simplicity. This issue needs further consideration at the international level.

Overall framework

(150) Experience has shown that a relatively limited number of radionuclides – both naturally-occurring and artificial – are likely to be present in consumer goods. In terms of developing a framework for managing radionuclides in consumer goods, it does not seem necessary to include all 700+ radionuclides listed in the BSS, but rather it would be better to focus on a sub-set of these that include only the radionuclides of interest.

(151) The approach adopted by the Codex Alimentarius for food is to establish a grouping of radionuclides based on similar dose-conversion factors (radiotoxicity group). Although the radionuclides considered are different, a similar approach has been used by the WHO in relation to drinking-water. In the case of non-food commodities, exemption values have been derived for each radionuclide individually.

(152) As a starting point, the CAC and WHO activity concentrations for radionuclides could be consolidated into one table. This should then be reviewed to determine if all listed radionuclides are indeed relevant and if the listing should be extended to include additional radionuclides. The ideal outcome would be to have the same numerical value of activity concentration apply to all consumer goods within each radiotoxicity group. The implications of this approach will need to be evaluated in terms of the associated radiation doses, and their acceptability.

(153) It is thought that the dosimetric approach, which has been very successful in operational radiation protection, mainly in relation to the control of occupational exposures, is an impractical starting point for decisions on which consumer goods should be exempted from regulatory control. Individual radiation doses that might be incurred from consumption and use of consumer goods are not directly measurable in a practical way and therefore not the most appropriate target for establishing controls. It could be worthwhile to consider simplifying the current system by using activity concentrations as the starting point. This is quite clear in the specific case of naturally occurring radionuclides in food, and it is recognized that further work is required to extend this approach to encompass all consumer goods.

(154) It is also possible to consider dealing separately with edible and non-edible consumer goods. It would be a considerable improvement on the current situation to have one set of values for edible consumer goods (food and drinking water) and another set for non-edible consumer goods (those to which radionuclides are intentionally added at the time of manufacture and those in which the presence of radionuclides is due to natural environmental processes). Ideally, the numerical values should be related in some way (e.g. higher/lower by a fixed factor). Using the philosophy and approach discussed in this document, such an

outcome is certainly realistic and the minimum that should be expected. In any case, even with this approach, a number of consumer goods will remain in limbo because they are edible in some countries and not edible in others. This also needs to be addressed.

CHAPTER 6

CONCLUSIONS AND RECOMMENDATIONS

(155) Many national authorities have identified a need for further harmonization of the existing international standards on the control of radionuclides in consumer goods and radioactive consumer products, including scope, radiation protection criteria and terminology. They seem to consider that the current system is unnecessarily complex, inconsistent and in some instances also incoherent.

(156) The history of the current status of the control of consumer goods containing radionuclides has been described heretofore. This has been followed by a discussion on the inconsistencies that exist in the current system. From this, recommendations have been developed to assist in establishing clear criteria and approaches for defining the level of radioactivity in consumer goods that can be, or needs to be, the subject of regulatory requirements for the purposes of radiation protection. The recommendations in this document are intended for wider discussion within the radiation protection scientific and regulatory communities.

(157) In the preceding section many issues of detail, important nonetheless, were discussed. These issues clearly need to be addressed and resolved in due course. However, it is recognized that the first step is to develop an overall framework for the regulatory control of consumer goods and radioactive consumer products. It is recommended that the following criteria be an integral part of such a framework:

- The term ‘consumer products’ should be replaced by the term *consumer goods* defined as follows:

Consumer goods are those products supplied for public consumption or use, including merchandise, edible and non-edible commodities, and other materials, goods or articles.

This new definition does not include items to which radioactive substances are intentionally added, for which the existing term consumer products, now qualified by the addition of the adjective *radioactive* should be used.

- The use of the term contamination should be avoided when referring to consumer goods. Rather than referring to contaminated consumer goods, reference should be made to ‘the presence of radionuclides in consumer goods’.
- It is questionable whether it is reasonable, for practical and epistemological reasons, to use dosimetric quantities as the primary basis for controlling the presence of radioactivity in consumer goods. These quantities are generally unmeasurable in relation to the consumption or use of consumer goods and their estimation requires modelling, often with substantial subjective uncertainties. Instead, it is considered sufficient to use the physical quantity of (radio)activity, and its derivatives, e.g., (radio)activity per unit volume or per unit weight or per unit surface area of the relevant consumer good, which are measurable and therefore can be directly quantified.
- The presence of radionuclides in consumer goods should be regulated coherently and consistently, regardless of the origin of the radionuclides, inter alia because notional

radiation risks are basically independent of the origin of the radioactivity. Specifically, consumer goods containing naturally occurring radionuclides and those containing artificial radionuclides should be regulated using the same criteria and regulations. Notwithstanding this, regulations should also take account of the amenability of control, and possibly also the social expectations of those affected.

- The amount of natural radionuclides present in widely available consumer goods could serve as a good indicator of acceptable levels of radioactivity of any origin in consumer goods. It is important to establish the variability that exists in the concentrations of various radionuclides in consumer goods (including food and water currently freely available on the market).
- Due to the ubiquity and general global distribution of consumer goods, national frameworks should be coherent and consistent with consensual international guidance established by governing bodies of relevant international intergovernmental organizations.
- It is not always possible to identify exactly either the radiation exposure situation (i.e. planned, emergency or existing exposure situation) that has generated the presence of radioactivity in consumer goods. Additionally, for the consumer it is irrelevant which type of exposure situation has given rise to the presence of radioactivity in consumer goods. Therefore, the regulation of consumer goods should neither be based on the exposure situation from which they are derived nor on the type of exposure being incurred, i.e. all those affected by consumer goods should be considered members of the public undergoing an exposure situation without qualification.
- The separation of consumer goods between those that are edible and those that are not is not universal because the definition of edibility involves cultural attitudes. Thus, the control criteria for consumer goods should in principle be independent of their edibility. However, since consumer goods generally recognized as edible may be of particular concern to people; in such cases, an ad hoc approach dealing separately with edible and non-edible consumer goods might be considered.
- Criteria for controlling consumer goods that introduce differences among gender or age are difficult to implement in practice. However, because women and children are generally more sensitive to radiation, those levels that are considered safe for women and children should be used as the main criteria, which should be established based on consideration of a notional 'person' representative of those at higher risk.
- National systems for controlling consumer goods could be framed taking into account the following criteria:
 - States should establish the levels of radioactivity under which consumer goods can be excluded from regulatory control, because such control is unamenable. For example, the doses received from ^{40}K in the diet is normally excluded from regulatory control because of the fact that it is homeostatically controlled in the body.

- Regulators should establish the levels of radioactivity under which consumer goods can be exempted from some or all regulatory control requirements because such regulatory requirements are unwarranted.

(158) The suggested basic criteria for controlling radioactivity in consumer goods are intended to establish the generic framework for defining the scope of regulatory control of consumer goods, with flexibility being given to national authorities to manage specific situations.

(159) It is expected that these suggestions will be an important step forward in clarifying a number of issues related to the control of radioactivity in consumer goods. Until now, these issues have not been properly resolved and have been the subject of differing interpretations and confusion.

(160) Finally, it is important that the relevant intergovernmental international bodies address and resolve the many issues arising from this document.

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