Radioactivity in Goods Supplied for Public Consumption or Use: Towards an Internationally Harmonized Regulatory Framework

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Abstract: The objective of this paper is to present a discussion document, jointly prepared by the Argentine Nuclear Regulatory Authority and the International Atomic Energy Agency, which provides suggestions for moving towards an internationally harmonized regulatory framework for controlling radioactivity in goods supplied for public consumption or use. Its concluding recommendations are: (1) the terms *commodities* and *consumer products* should be replaced by *consumer goods*, i.e. products supplied for public consumption or use; (2) the term *contamination* should be avoided when referring to consumer goods;. (3) the quantity for regulating consumer goods should be the activity, and its derivatives; (4) consumer goods should be regulated, regardless of the origin of the radionuclides; (5) the amount of natural radionuclides in widely available consumer goods could serve as indicator of acceptable levels of radioactivity; (6) national frameworks should be coherent and consistent with consensual international guidance established by the governing bodies of relevant international intergovernmental organizations; (7) 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; (8) the control criteria should take into account conflicting views on *edibility*; (9) activity levels in consumer goods that are considered safe for women and children should be used as the main criteria, based on consideration of a notional 'person' representative of those at higher risk; and (10) national systems for controlling consumer goods could be framed on the following criteria: (i) States should establish the levels of radioactivity under which consumer goods can be excluded from regulatory control, because such control is and (ii) 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.

KEYWORDS: radiation protection; consumer goods; consumer products; commodities; international regulations; IAEA; WHO; FAO; Codex Alimentarious; Drink Water Guidelines.

1. INTRODUCTION

The objective of this paper is to present a discussion *document* (hereinafter referred to as the document), which suggests moving towards an internationally harmonized regulatory framework for controlling radioactivity in goods supplied for public consumption or use.

On 18 September 2015, Argentine Nuclear Regulatory Authority (ARN) [Autoridad Regulatoria Nuclear] and the Secretariat of International Atomic Energy Agency (IAEA) agreed on 'Practical Arrangements' setting forth the framework for non-exclusive cooperation between the Parties in the area of radiation safety and monitoring. A relevant activity agreed to be pursued under the 'Practical Arrangements' was the "*development and publication of a harmonized approach for managing radionuclide activity concentrations in food, drinking water and non-food commodities*."

On 29 January 2019, ARN and the OIEA finalized and published a jointly prepared document under the title ***'Radioactivity in Goods Supplied for Public Consumption or Use: Towards an Internationally Harmonized Regulatory Framework*** [1], clearly indicating that it was just a discussion document.

2. BACKGROUND

There is an international need for simple and consensual approaches for regulating radioactivity in goods supplied for public consumption and use of universal distribution. The current approaches are complex and contain inconsistencies and incoherencies.

One regulatory difficulty relates to problems of semantics and terminology, which resulted in the absence of encompassing understandings for such goods.. An additional challenge has been the use of dosimetric quantities for the basic paradigm of control. Such dosimetric quantities are not directly measurable and control should be based in radioactivity quantities. These quantities have to be related trough models that are unreliable.

Moreover, there are a number of basic questions that have not been fully addressed and need a clear answer. For instance: whether to differentiate between goods that contain radionuclides artificially added and those presenting naturally-occurring and/or artificial radionuclides added due to natural environmental processes; or between good that are consumed and those that are only used; or between those that are considered edible and those which are not; or between those that are consumed or used preferently by a given sex or a given age group and those consumed or used indistinctly of sex or age; or between those that have incorporated radionuclides from given initial exposure situation (extant, planned, or emergency situation) and those for which the initial situation is unknown. With reference to the last question is convenient to recall that radionuclides in consumer goods could already be present in the environment and from there reach the goods (i.e., from an existing or extant situation), or be there due to an authorized discharge from a regulated activity (i.e., from a planed situation), or be the result of a non-anticipated situation (i.e., an emergency situation); in the current international standards, these situations are subject to different regulatory approaches!

3. SEMANTICS AND TERMINOLOGY

A number of terms have been used for regulating consumer goods that have caused some uncertainty. Particularly confusing have been the terms *commodity* and *consumer product* and *consumer good*, and also their main components for public consumption, foodstuff and water. Another confusion term that has been cause of serious harm is the term *contamination*, in particular when it is applied to food or water.

3.1. Commodity and consumer product *vis-à-vis* consumer good

The English term *commodity* has been widely used: in the recommendations of the International Commission on Radiological Protection (ICRP) [2]; in the international standards been established under the aegis of the IAEA [3]; and, even in resolutions of the IAEA General Conference [4]. It has been generally defined as products generally used or consumed by the public that can contain radioactive substances**.** However in its conventional use, commodity refers to raw material or primary agricultural product that can be bought and sold. Moreover, it is a term that does not accept a direct translation; in fact it has been translated as ‘basic product’. For all these reasons, the use of this term commodity should be discouraged.

In principle, the terms *consumer product* and *consumer good* do not present significant differences; they could be used as quasi-synonyms; in common parlance: both of them refer to all everyday goods supplied for public consumption or use. However the glossary of the current international standards define consumer good as “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" [5]. This definition only encompasses items, such as smoke detectors and luminous dials into which radionuclides have deliberately been incorporated as well as ion generating tubes. It does not include goods such as building materials, ceramic tiles, spa waters, minerals and foodstuffs, and it excludes products and appliances installed in public places [e.g. exit signs]. This glossary definition precludes the use of the term consumer product as a synonym of consumer good for the purpose of the document.

In sum, in order to avoid confusion the document suggest to internationalize the use of the term *consumer goods* for referring to all items supplied for public consumption or use, including merchandise, edible and non-edible products, materials, goods and articles.

3.2. Foodstuff

Food is the quintessential consumer good and a main challenge is to share a common understanding of the concept of food. In modern English, food replaces the archaic term, *aliment*, which is derived from *alere*, meaning to nourish. The Codex Alimentarious, the collection of internationally recognized standards, codes of practice, guidelines, and other recommendations relating to foods, food production, and food safety, is an appropriate reference to understand the meaning of food. For the purpose of the Codex food means any substance, whether processed, semi-processed or raw, which is intended for human consumption, and includes drink, chewing gum and any substance which has been used in the manufacture, preparation or treatment of "food" but does not include cosmetics or tobacco or substances used only as drugs [5]. Namely, food comprehends any 'edible' nutritious substance that people ingest in order to maintain life and growth.

However, this straightforward understanding still presents some basic questions. Since water is a drink, …Should it be considered food according to the definition?...and, if this is the case…. Why food and water are regulated separately? Drugs are not the sole substance that people ingest. Are other edible substances that people eat for pleasure or vice [nor for nutrition] be also to be considered as food? Moreover, the meaning of 'edible' is somehow ambiguous and has cultural connotations; substances that are edible in some cultures are considered inedible in others. For instance, animal internals are a gourmet dish in some countries but are just used for instruments cords in others countries. Moreover, children and adults, women and men, have different food preferences. Some food is consumed primarily by infants and children, while others are consumed only by adults; some are preferred by woman and others by men. How these differences should be accounted for when deciding what concentrations of radionuclides in food may require regulatory control?

The Food and Agriculture Organization of the United Nations, the specialized agency that leads international efforts to defeat hunger and improve nutrition and food security, has a term portal to store, manage and update concepts, terms and definitions [6], but these basic questions are not addressed.

It seems therefore that a basic issue to be addressed for the regulation of consumer good is the precise definition of food.

3.3. Water

It seems that it should not be any thing simpler than the definition of water. However when water is considered a consumer good some issues arise. Water as a consumer good is regulated under the term *'drinking' water*. But the term is not absolutely clear. It has been translated as 'potable' water

given the impression that the intention was to refer to what is usually termed ‘tap’ water, i.e., supplied water. But what are termed *packaged waters* are regulated separately than ‘drinking’ water; these are packed waters 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. Moreover, what are termed *natural mineral waters* are also regulated separately in spite that they are the more common drinking water in many countries [in fact they are unregulated because there are not limit for their radioactivity content; these include: naturally carbonated natural mineral water; non-carbonated natural mineral water; de-carbonated natural mineral water; natural mineral water fortified with carbon dioxide from the source; or carbonated natural mineral water. It seems that this separation into various ‘waters’ does not help the regulation of consumer goods.

3.4. Contamination

But perhaps the more crucial concept for regulating consumer goods is that distincted with the term *contamination*. It has been formally defined as the *presence* of radioactive substances on surfaces, or within solids, liquids or gases [including the human body], where it is unintended or undesirable, or as the *process* giving rise to such presence [7]. In spite that the formal definition clearly indicate that the term gives no indication of the magnitude of the hazard involved, in practice the term has acquired a connotation that is not intended becoming a quasi-synonym of a dangerous situation.

In relation to consumer goods, contamination involves a particular connotation. Since it conveys the idea of danger, the use of the term ‘contaminated consumer good’ causes public concern, as people perceive it as a binary situation, namely either there is contamination, and some danger, or there is not. Moreover, applied to food it has a religious denotation since its primitive meaning (from Latin *contaminat-, contaminare*) is making a food religiously impure (e.g., ‘non-kosher’).
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As a result, the concept of ‘low levels of contamination in a consume goods’ has become incomprehensible for many people, namely or there are contamination and danger or impurity or there are no contamination. These undertones have caused anxiety to people, particularly after accidents [8], and confusion to the authorities when dealing with or discussing radioactivity in consumer goods. The use of the term is particularly unhelpful for consumer goods in which, in general, the content of radioactive substances is low.

4. REGULATORY SITUATION

The regulatory control of consumer goods presenting levels of radioactivity was not historically straightforward and continues to be ambiguous. Some separate international intergovernmental agreements exist, including basic safety standards and specific standards for foodstuff, ‘drinking’ water, other waters, and other goods, but they were and continue to be incoherent and inconsistent.

Historically the regulation of radioactivity in consumer goods was governed by the international Basic Safety Standards (BSS) [9]. The 1962 edition of the BSS 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 specified values, except to the intentional addition of radionuclides “in the manufacture of consumer goods such as foodstuffs, pharmaceutical goods, cosmetics and toys”, with the addition that, in order to limit radiation exposure through ingestion and inhalation, maximum permissible concentrations of single radionuclides in air and water were established. [10]. Essentially the same approach was maintained in the 1967 [11] and 1982 editions of the BSS [12].

By the end of the 1980s an international consensus on principles for the scope of regulatory control was being reached [13], and in 1988 a consensus was achieved 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 [14]. Thus, in the 1996 edition of the BSS, exemption values were developed using dose criteria [15]. Using a dosimetric criterion of 10 μSv in a year, conservative and uncertain models were employed to calculate values of activity concentration and of total activity below which compliance with the dose criterion was conjectured to be assured.

In 2000, the IAEA General Conference adopted a resolution requesting the development of radiological criteria for long-lived radionuclides in 'commodities' [4], but an agreement could not be achieved and instead, guidance on application of the concepts of exclusion, exemption and clearance was developed and published in 2004 [16]. In 2007, ICRP issued recommendations aimed at defining the scope of regulatory control [2], which suggested approaches to national authorities for their definition, through regulations, of the extent of radiological protection control measures including those for consumer goods.

Meanwhile, the control of foodstuff become regulated by the Codex Alimentarious Commission established by the The Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) [17]. The so-called 'drinking water' become implicitly regulated following WHO's drinking water guidelines [18], [19], although packaged water [20] and mineral water [21] are regulated separately by FAO. Thus, the 2011 Edition of the BSS summarize the status-quo of the situation by assembling all the criteria recommended but without homogenising them into a single approach for the regulatory control of consumer goods [22].

In sum, the relevant documents produced by the IAEA, the Codex Alimentarius Commission, FAO and WHO were considered inconsistent in relation to scope, radiation protection criteria and terminology [23]. Unsurprisingly, in the last years since 2016, the IAEA IAEA General Conference has been mandating the IAEA Secretariat to cooperate with relevant international organizations in developing a harmonized framework for the control of radioactivity in consumer goods.

5. VIEWS FROM STATES

In March 2017, the IAEA and ARN organized in Buenos Aires, Argentina, a Workshop of States' representatives, to discuss the application of current international standards for managing radioactivity in consumer goods. In November 2018, the IAEA organized a similar workshop in Xi'an, China. From these meetings, and other consultations, relevant views from States representatives were extracted.

Their views included the following: international standards ought to be harmonized; good from different exposure situations shall not be differentiated; natural values of radioactivity in the habitat, for food, drinking water and non-edible goods, should be used for reference; the Codex Alimentarius shall include levels for natural radionuclides in food.; the WHO total indicative dose of 0.1 mSv/y cause confusion vis-à-vis the reference level of 1 mSv/y in international safety standards [countries cannot comply with this value as they have higher values in their natural environment]; same criteria should apply to 'drinking' water, packed water and natural mineral water; bands of values for the regulation of activity in consumer goods shall not be used, since people and authorities usually believe that the minimum values are the safe ones.; it should be an international agreement on 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.; situations should be avoided where goods that are not regulated cannot be freely transported, and *vice versa*,

and, the regulatory control of consumer goods should be based on activity values due to the fact that making dose estimates can have a great deal of uncertainty due to parameters' variability.

6. CONCLUDING RECOMMENDATIONS

The document concludes with a Decalogue of recommendations as follows:

6.1. **Terms being used, such as 'commodities' and '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 radioactive consumer products should be used.

6.2. **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*.

6.3. **The quantity to be used for regulating consumer goods is the [radio]activity, and its derivatives, e.g., activity per unit volume or per unit weight or per unit surface area of the relevant good.** It is unreasonable, 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 not measurable in relation to the consumption or use of consumer goods and their estimation requires subjective modelling, often with substantial uncertainties.

6.4. **The presence of radionuclides in consumer goods should be regulated, regardless of the origin of the radionuclides, because radiation risks are independent of the origin of the activity**. I.e., specifically, consumer goods containing naturally occurring radionuclides and those containing artificial radionuclides should be regulated using the same criteria and regulations. Notwithstanding the above, regulations may also take account of the amenability of control, and possibly also the social expectations of those affected.

6.5. **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.

6.6. **National frameworks should be coherent and consistent with consensual international guidance established by the governing bodies of relevant international intergovernmental organizations**. This is essential due to the ubiquity and general global distribution of consumer goods.

6.7. **The regulation of consumer goods should neither be based on the exposure situation from which they are derived (e.g., planned, emergency or existing) nor on the type of exposure being incurred (e.g., occupational or public); namely, *all those affected by consumer goods should be considered members of the public undergoing an exposure situation without qualification*.** The reason is that it is not always possible to identify exactly either the radiation exposure situation that has generated the presence of radioactivity in consumer goods. For the consumer it is irrelevant which type of exposure situation has given rise to the presence of radioactivity in consumer goods.

6.8. **The control criteria for consumer goods should take into account conflicting views on *edibility*.** The separation of consumer goods between those that are edible and those that are considered inedible is not universal because the definition of edibility involves cultural attitudes. However, since consumer goods generally recognized as edible might

be of particular concern to people; in such cases, an *ad hoc* approach for dealing separately with edible and non-edible consumer goods need to be considered.

6.9. **Activity levels in consumer goods 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.** Criteria for controlling consumer goods that introduce differences among gender or age are difficult to implement in practice; and women and children are generally more sensitive to radiation than adult men

6.10. **National systems for controlling consumer goods could be framed on the following criteria: [i] 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 40K in the diet is normally excluded from regulatory control because of the fact that it is homeostatically controlled in the body)**, and [ii] 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.**

7. EPILOGUE

It is expected that the suggestions in the document will be helpful for 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. It seems to be crucial that the relevant intergovernmental international bodies to address and resolve the many issues referred to in the document.

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