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REGULATION: Food Irradiation

Overview of Global Regulations

What do we mean?
Food irradiation regulations

- Rules that govern food irradiation and irradiated foods

Image by succo from Pixabay.com

Why do we need food regulations?

Legislation, laws, codes, standards

Photo by Dariusz Sankowski on Unsplash.com

Why do we need food regulations?

Legislation, laws, codes, standards

- Protect the health of consumers (food safety)
- Ensure good food quality (wholesomeness)
- Prevent fraud (fair practices)

Photo by Jan Simons on Unsplash.com

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Regulations are rules contained in a “collection of laws” (legislation) that govern food related practices.

Photo by Dariusz Sankowski on Unsplash

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Regulations are rules contained in a “collection of laws” (legislation) that govern food related practices.

Legislation also gives legal powers to authorities and a framework for food-control activities (enforcement)

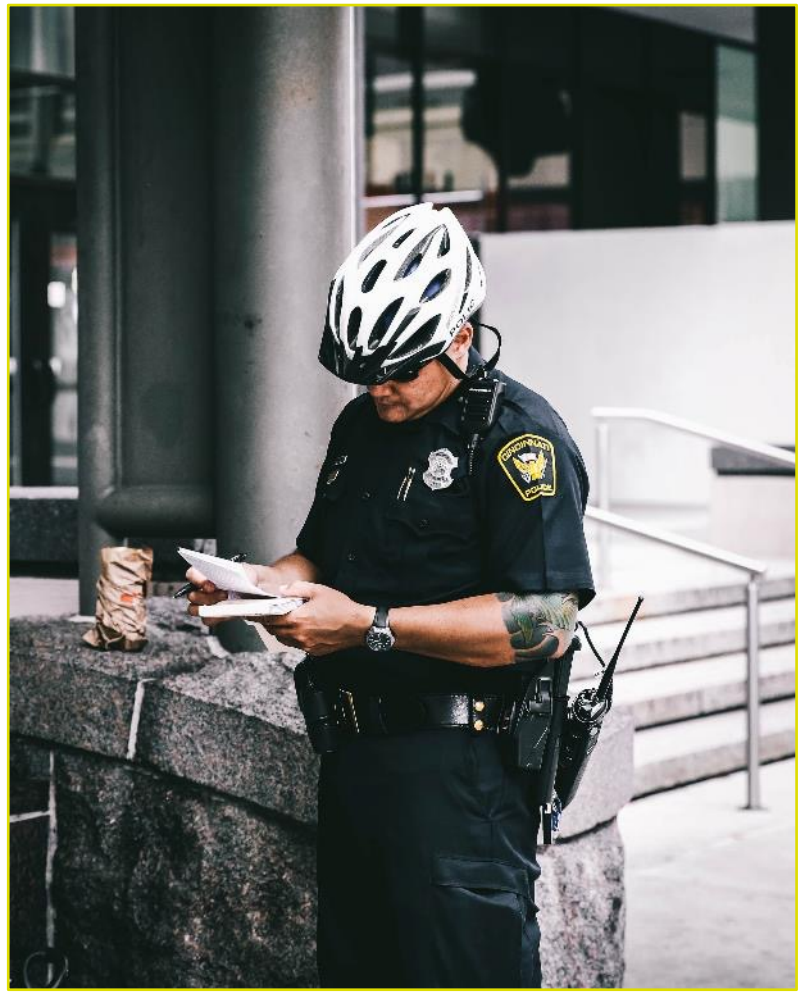


Photo by Jordan on Unsplash.com

Global regulations?

International agreements, declarations, conventions, standards, codes of practice,

International level

At the international level there are no global mandatory food irradiation regulations

There are accepted standardized rules that together can be used to give a framework for the regulation of food irradiation

International Standards give the baseline and regional or national authorities make use of these standards to harmonized trade.

Photo by CHUTTERSNAP on Unsplash.com

World Trade

International trade agreements

Bedrock of multilateral trading system

- Fairness – avoid arbitrary or unjustifiable discrimination.
- Prevent technical requirements being unnecessary barriers to trade

The WTO Agreement on Sanitary and Phytosanitary Measures (SPS Agreement, 1995) states that "to harmonize sanitary and phytosanitary measures on as wide a basis as possible, Members shall base their sanitary or phytosanitary measures on international standards, guidelines or recommendations"
www.wto.org

Photo by Roan Lavery on Unsplash.com

International standards

.. rules and obligations are the bedrock that channel the ebb and flow of trade….

Food, animal and plant health regulations

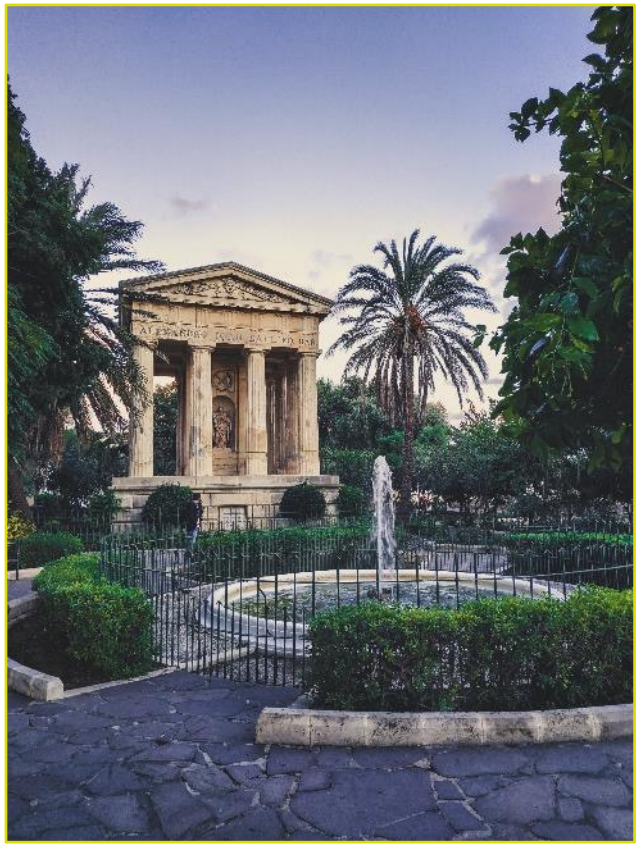
WORLD TRADE – Agreements, regulations, legislation
Sanitary and Phytosanitary Measures

Animal Health Standards

Plant Health Standards

Food Safety & Quality Standards

Photo by Pavel Neznanov on Unsplash.com



WORLD ORGANISATION FOR ANIMAL HEALTH
Protecting animals, preserving our future

International Plant Protection Convention

CODEX ALIMENTARIUS
INTERNATIONAL FOOD STANDARDS

Food irradiation regulations

Food Irradiation and irradiated food
Agreements, regulations, legislation

Plant Health Standards

International Plant Protection Convention

IPPC

www.ippc.int/en/

Food Safety & Quality Standards

CODEX ALIMENTARIUS
INTERNATIONAL FOOD STANDARDS

Codex

www.fao.org/fao-who-codexalimentarius/home/en/

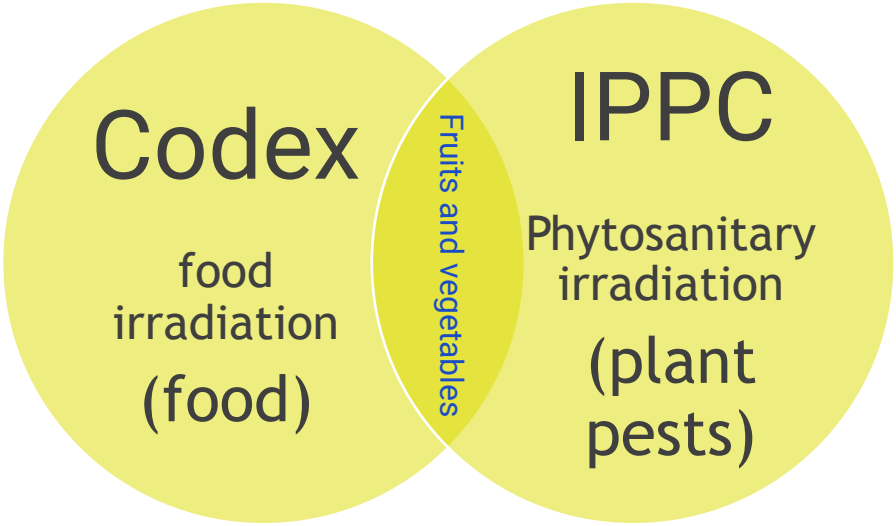
Purpose of food irradiation

- Food safety (Destroy foodborne pathogens)
- Maintain food quality and extend shelf-life
- Inhibit sprouting (potatoes, garlic, ginger)
- Prevent the spread of pests harmful to plant health (Phytosanitary irradiation)

Food irradiation rules that are harmonized and facilitate trade

Photo by Carl Blackburn

Photo by Yoal Desurmont on Unsplash.com



Overlap
Food
Phytosanitary

Codex Alimentarius (General standard and codes of practice)

- CXC 19-1979 Code of Practice for Radiation Processing of Food (last modified 2003)
- CXS 106-1983 General Standard for Irradiated Foods (last modified 2003)
- Codex STAN 1-1985 General Standard for the Labelling of Prepackaged Foods (last modified 2010)

IPPC International Standards for Phytosanitary Measures (ISPMs)

- ISPM 18: Guidelines for the use of irradiation as a phytosanitary measure (currently being rewritten as “Requirements for the use of irradiation as a phytosanitary measure”)
- ISPM 28: Phytosanitary Treatments for Regulated Pests (16 irradiation treatments in Annexes to ISPM28)

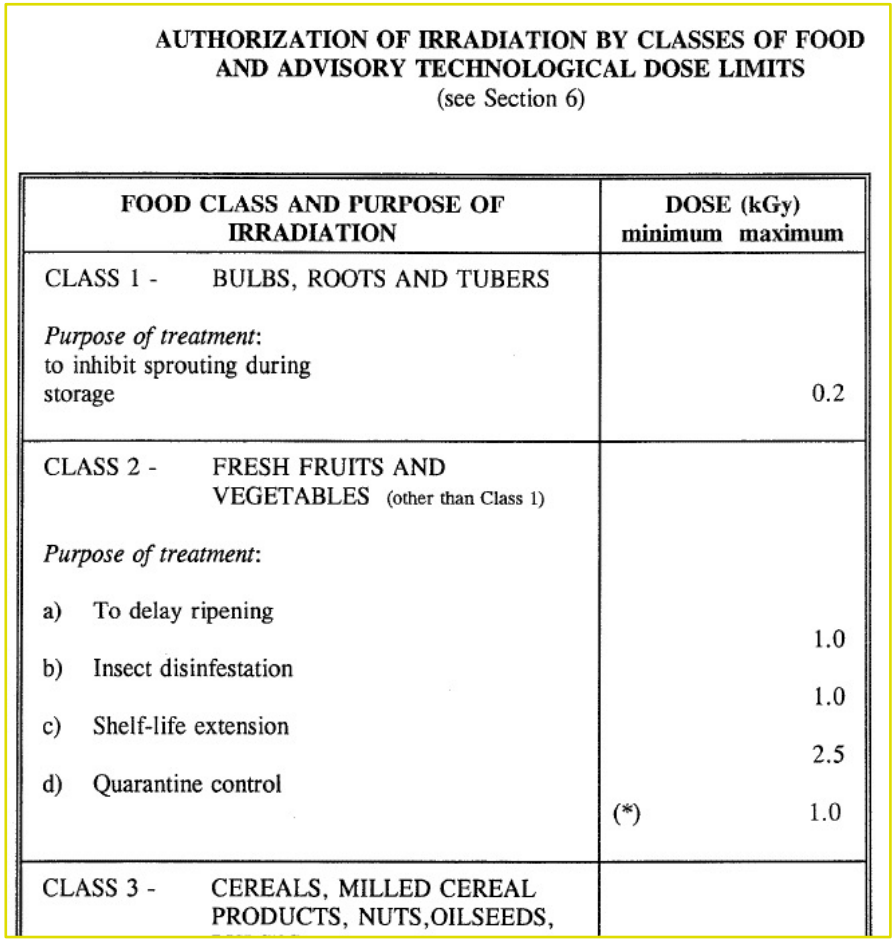
History – International Consultative Group on Food Irradiation (ICGFI)

FAO, IAEA, WHO and National Representatives

International Organizations plus nominated national experts - harmonization by providing information:

- made collections of national regulations
- Guidelines for authorization of food irradiation regulations: **ICGFI Doc 15 of 1994** (by class of food and based on the International standards at that time)
- Technical input to Codex and IPPC standards
- Compiled wholesomeness data
- Codes of practice for irradiation of different foods

From 1982 to 2004 when disbanded



AUTHORIZATION OF IRRADIATION BY CLASSES OF FOOD AND ADVISORY TECHNOLOGICAL DOSE LIMITS
(see Section 6)

FOOD CLASS AND PURPOSE OF IRRADIATION	DOSE (kGy) minimum	maximum
CLASS 1 - BULBS, ROOTS AND TUBERS		
Purpose of treatment: to inhibit sprouting during storage		0.2
CLASS 2 - FRESH FRUITS AND VEGETABLES (other than Class 1)		
Purpose of treatment:		
a) To delay ripening		1.0
b) Insect disinfestation		1.0
c) Shelf-life extension		2.5
d) Quarantine control	(*)	1.0
CLASS 3 - CEREALS, MILLED CEREAL PRODUCTS, NUTS,OILSEEDS,		

ICGFI Doc 15: Guidelines for the Authorization of Food Irradiation Generally or by Classes of Food

Echoes of history

India, 2012 and 2016

India – through trade agreements with USA recognized that legislation needed to be brought up to date – based revision on international standards and also ICGFI experience

- Using regulations (trade) makes for better legislation.
- Based on Codex and IPPC standards
- ICGFI experience (ICGFI Doc 15)
- Authorizations by class of food

Class	Food	Purpose	Dose limit (kGy)	
			Min	Max
Class 1	Bulbs, stem and root tubers and rhizomes	Inhibit sprouting	0.02	0.2
Class 2	Fresh fruits and vegetables (other than class 1)	Delay ripening	0.2	1.0
		Insect disinfestations	0.2	1.0
		Shelf-life extension	1.0	2.5
		Quarantine application	0.1	1.0
Class 3	Cereals and their milled products, pulses and their milled products, nuts, oil seeds, dried fruits and their products	Insect disinfestations	0.25	1.0
		Reduction of microbial load	1.5	5.0
Class 4	Fish, aquaculture, seafood and their products (fresh or frozen) and crustaceans	Elimination of pathogenic microorganisms	1.0	7.0
		Shelf-life extension	1.0	3.0
		Control of human parasites	0.3	2.0
Class 5	Meat and meat products including poultry (fresh and frozen) and eggs	Elimination of pathogenic microorganisms	1.0	7.0
		Shelf-life extension	1.0	3.0
		Control of human parasites	0.3	2.0
Class 6	Dry vegetables, seasonings, spices, condiments, dry herbs and their products, tea, coffee, cocoa and plant products	Microbial decontamination	6.0	14.0
		Insect disinfestation	0.3	1.0
Class 7	Dried foods of animal origin and their products	Insect disinfestation	0.3	1.0
		Control of moulds	1.0	3.0
		Elimination of pathogenic microorganisms	2.0	7.0
Class 8	Ethnic foods, military rations, space foods, ready-to-eat, ready-to-cook/minimally processed foods	Quarantine application	0.25	1.0
		Reduction of microorganism	2.0	10.0
		Sterilization	5.0	25.0

Government of India under Atomic Energy (Radiation Processing of Food and Allied Products) Rule, 2012 class wise clearance. Food irradiation rules and dose limits incorporated in Food Safety and Standards Authority of India (FSSAI) rules in 2016

Australia / New Zealand

Variation to food code

Food Standards Code - 1.5.3 - Irradiation of Food (17 January 2020)

- A mix of specific and generic authorizations for irradiation of different foods
- Recent application: replace list of 26 fruits/veg with category of “fresh fruits and vegetables” (Dec 2020).
- Being driven by trade (fruit and veg. trade Australia – NZ and increasing trade with Indonesia, Malaysia, Viet Nam, USA)
- SPS Agreement / phytosanitary measures should not be an unnecessary barrier to trade

Regulations are being used - makes for better legislation.

Food	Purpose(s)	Min and Max dose / kGy
Fruit and vegetables in this list: Apple, apricot, blueberry, bread fruit, capsicum, carambola, cherry, custard apple, honeydew, litchi, longan, mango, mangosteen, nectarine, papaya (paw paw), peach, persimmon, plum, rambutan, raspberry, rockmelon, scallopini, strawberry, table grape, tomato, zucchini (courgette)	pest disinfestation for a phytosanitary objective	0.15 – 1
Herbs and spices	Control of sprouting and pest disinfestation, including control of weeds.	< = 6
	Bacterial decontamination	2 – 30
Herbal infusions – fresh, dried, or fermented leaves, flowers and other parts of plants used to make beverages but does not include tea.	Control of sprouting and pest disinfestation, including control of weeds.	< = 6
	Bacterial decontamination	2 – 10

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	Bacterial decontamination	2 – 10

What foods can be irradiated according to international standards?

Codex General Standard on Irradiated Foods

- Neither the Codex General Standard nor the IPPC standards say what food can be authorized for irradiation.
- Technological need / appropriate doses

4. TECHNOLOGICAL REQUIREMENTS

4.1 General Requirement

The irradiation of food is justified only when it fulfils a technological requirement and/or is beneficial for the protection of consumer health. It should not be used as a substitute for good hygienic and good manufacturing practices or good agricultural practices.

4.2 Food Quality and Packaging Requirements

The doses applied shall be commensurate with the technological and public health purposes to be achieved and shall be in accordance with good radiation processing practice. Foods to be irradiated and their packaging materials shall be of suitable quality, acceptable hygienic condition and appropriate for this purpose and shall be handled, before and after irradiation, according to good manufacturing practices taking into account the particular requirements of the technology of the process.

Technological needs include

- Food safety (Destroy foodborne pathogens)
- Maintain food quality and extend shelf-life
- Inhibit sprouting (potatoes, garlic, ginger)
- Prevent the spread of pests harmful to plant health (Phytosanitary irradiation)

What is out of scope in international standards?

Codex General Standard on Irradiated Foods

- Foods exposed to radiation by measuring instruments and inspection purposes are out of scope (regulations usually exempt)
- Most regulations also exempt food for medical uses (e.g. patients supervised by a doctor)

Eagle brings out pipeline X-ray machine
27-Jan-2016 By Oscar Rousseau: Eagle Product Inspection has created a pipeline X-ray system that it claims can help firms optimise production rates, while complying with safety standards.
HTTPS://WWW.FOODNAVIGATOR-USA.COM/ARTICLE/2016/01/27/EAGLE-BRINGS-OUT-PIPELINE-X-RAY-MACHINE

What radiation sources are in international standards?

National/regional food irradiation mirror this

Food irradiation regulations worldwide

- Gamma (^{60}Co-60 but also ^{137}Cs)
- x-ray (5 MeV but some up to 7.5 MeV)
- E-beam (10 MeV)

Cobalt-60 source underwater - Carl Blackburn

2. GENERAL REQUIREMENTS FOR THE PROCESS

2.1 Radiation Sources

The following types of ionizing radiation may be used:

a) Gamma rays from the radionuclides ^{60}Co or ^{137}Cs;

b) X-rays generated from machine sources operated at or below an energy level of 5 MeV;

c) Electrons generated from machine sources operated at or below an energy level of 10 MeV.

Codex Alimentarius (General standard and codes of practice)

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Pasal 3

Iradiasi Pangan wajib menggunakan sumber radiasi berupa:

a. Iradiator Gamma dengan zat radioaktif kobalt-60 (^{60}Co) (Kobalt enam puluh) atau sesium-137 (^{137}Cs) (Sesium seratus tiga puluh tujuh);

b. Mesin pembangkit sinar-X dengan energi sama dengan atau dibawah 7,5 MeV (tujuh koma lima mega elektron volt); atau

c. Mesin berkas elektron dengan energi sama dengan atau dibawah 10 MeV (sepuluh mega elektron volt).

BADAN PENGAWAS OBAT DAN MAKANAN

REPUBLIK INDONESIA

- Regulations in 5 countries allow x-ray irradiation of food up to an energy of 7.5 MeV (international standards have 5 MeV)
- This is a case of the standards lagging behind technological developments
- 7.5 MeV x-rays have the same efficacy, and is safe for food
- 7.5 MeV x-rays give a better conversion efficiency and so is more economical and enables more throughput

X-Ray energy generally 5 MeV or less but if using a tantalum or gold converter can allow 7.5 MeV X-ray irradiation of food
(Canada, India, Indonesia, Republic of Korea and USA)

Codex and IPPC have been asked to consider a revision to the international standards

What doses of ionizing radiation according to international standards?

Codex General Standard on Irradiated Foods

- Up to 10 kGy (advisory "technological dose limit")
- But can use higher doses if necessary for a legitimate technological purpose*

*In regulations these include

- Dried herbs and spices – microbial decontamination (European Union 15 kGy maximum, Australia 30 kGy maximum)
- Microbial decontamination: Dried vegetables seasonings, spices, condiments, herbs, tea, coffee, cocoa and plant products (India 14 kGy maximum)
- sterilization e.g Space food. food military rations, ready-to-eat, ready-to-cook/minimally processed foods (rations) India 25 kGy maximum, food for astronauts, 42 kGy, USA.

2.2 Absorbed Dose

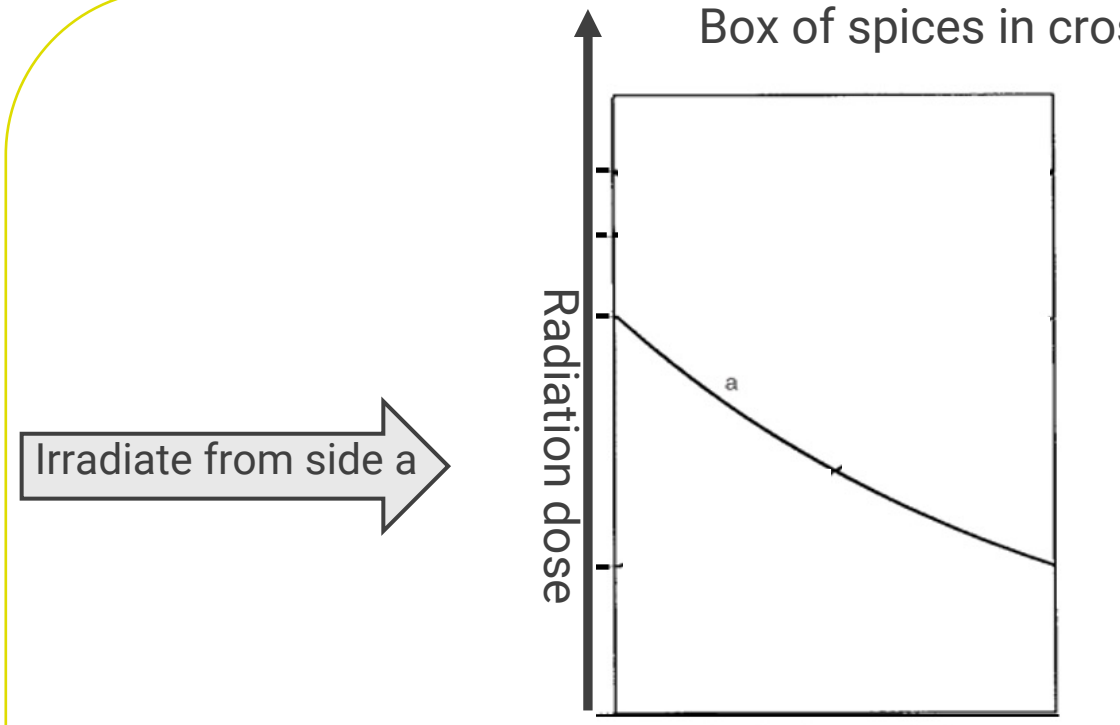
For the irradiation of any food, the minimum absorbed dose should be sufficient to achieve the technological purpose and the maximum absorbed dose should be less than that which would compromise consumer safety, wholesomeness or would adversely affect structural integrity, functional properties, or sensory attributes. The maximum absorbed dose delivered to a food should not exceed 10kGy, except when necessary to achieve a legitimate technological purpose.[1]

[1] High Dose Irradiation: Wholesomeness of Food Irradiated with Doses above 10kGy, Report of a Joint FAO/IAEA/WHO Study Group, Technical Report Series 890 WHO. Geneva, 1999; Safety and Nutritional Adequacy of Irradiated Foods, WHO, Geneva, 1994; and Wholesomeness of Irradiated Food, Report of Joint FAO/IAEA WHO Expert Committee, Technical Report Series 659, WHO, Geneva, 1981.

Doses of ionizing radiation in international standards?

Codex General Standard on Irradiated Foods

- IPPC and Codex now use minimum dose and maximum dose
- Old standards had concept of “overall average dose” (cannot be measured)
- Some regulations still have “overall average dose”



One side gamma irradiation

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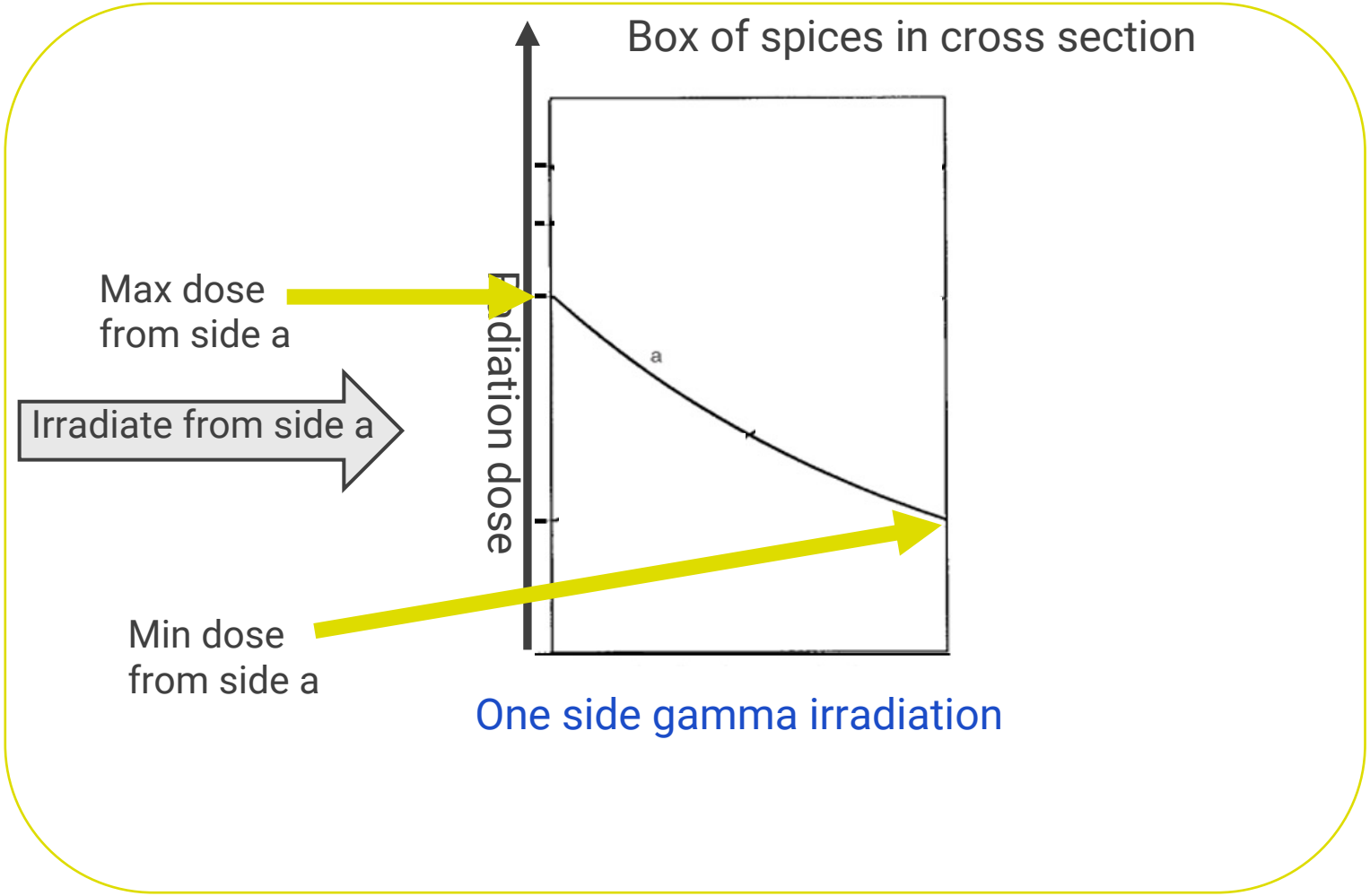

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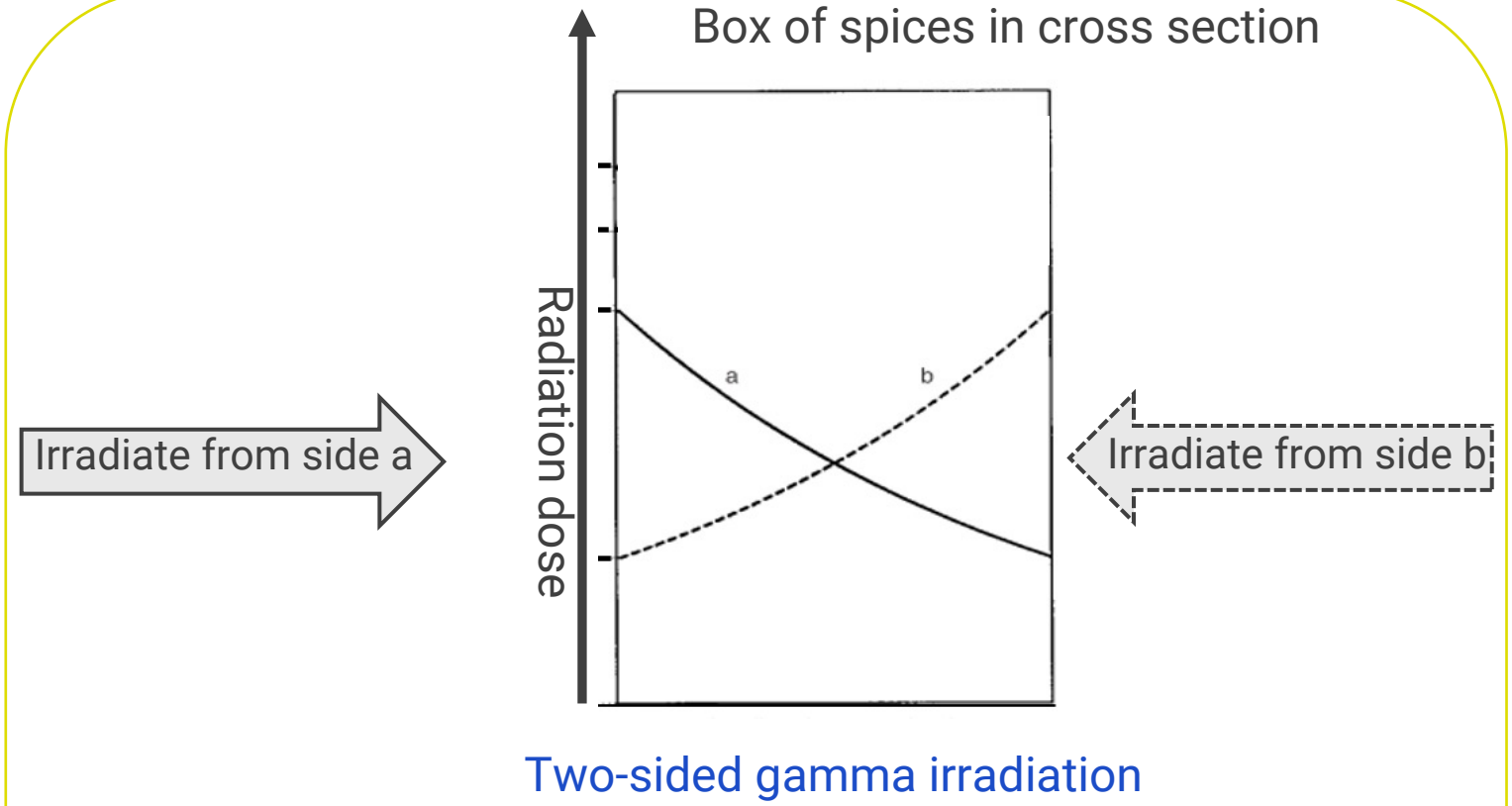

Two-sided gamma irradiation

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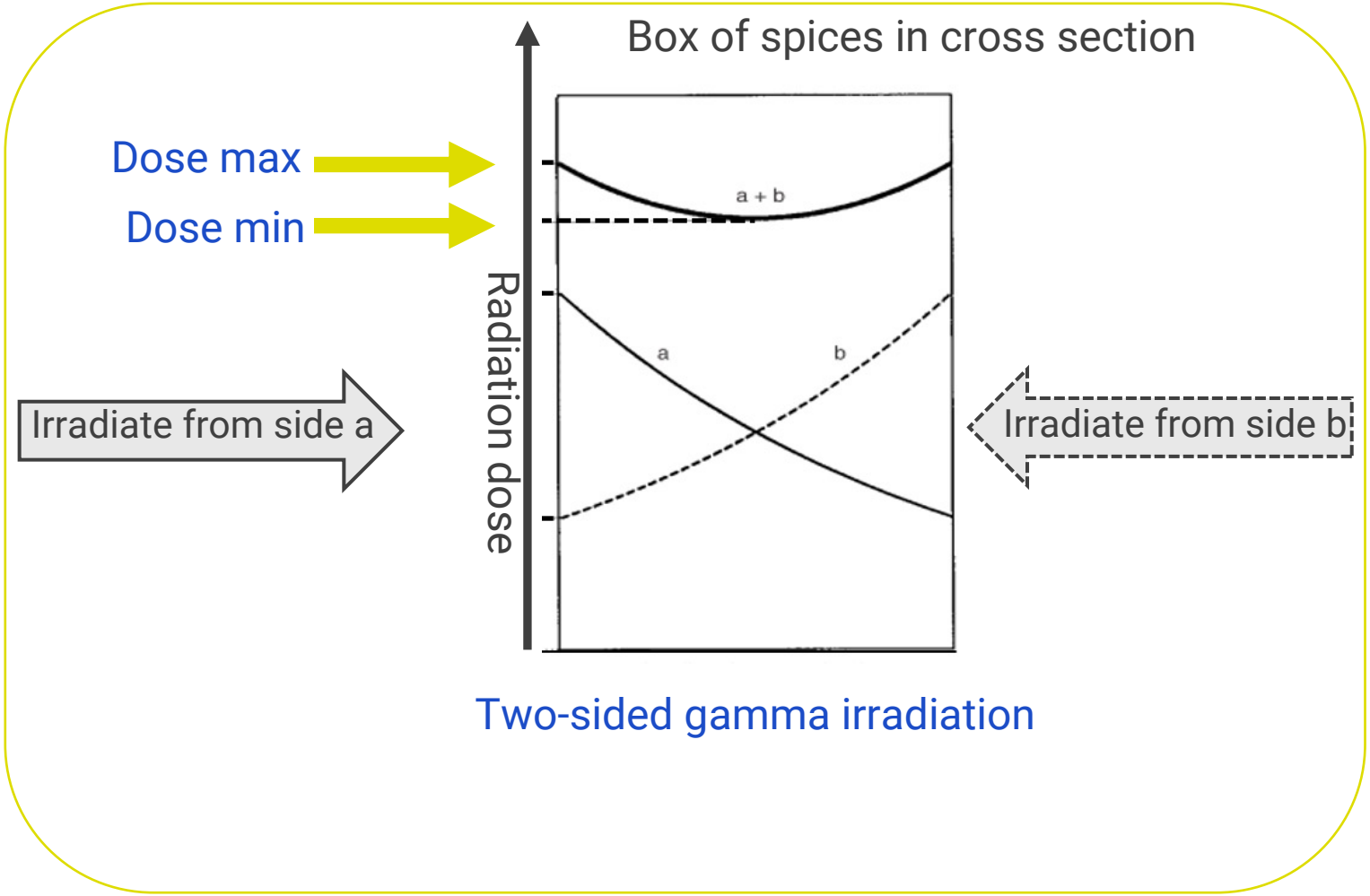

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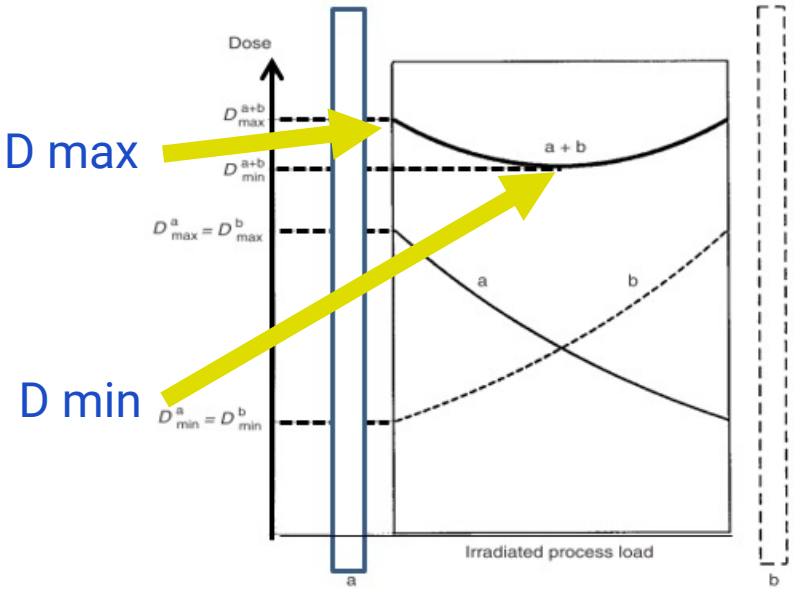

Two-sided gamma irradiation

Overall average absorbed dose

The overall average dose, D, is defined by the following integral over the total volume of the goods:

$$\bar{D} = \frac{1}{M} \int p\,(x,y,z)\ d\,(x,y,z)\ dV$$

where M = the total mass of the treated sample
p = the local density at the point (x,y,z)
d = the local absorbed dose at the point (x,y,z)
dV = dx dy dz, the infinitesimal volume element which in real cases is represented by the volume fractions.

The overall average absorbed dose can be determined directly for homogenous products or for bulk goods of homogenous apparent density by distributing an adequate number of dosimeters strategically and at random throughout the volume of the goods. From the dose distribution determined in this manner an average can be calculated which is the overall average absorbed dose.

If the shape of the dose distribution curve through the product is well determined, the positions of minimum and maximum dose are known. Measurements of the distribution of dose in these two positions in a series of samples of the product can be used to give an estimate of the overall average dose.

In some cases, the mean value of the average values of the minimum dose ($\bar{D}$min) and maximum dose ($\bar{D}$max) will be a good estimate of the overall dose: i.e., in these cases:

$$\text{overall average dose} \approx \frac{\bar{D}\text{max} + \bar{D}\text{min}}{2}$$

Doses of ionizing radiation in international standards?

Directive 1999/3/EC, initial list of foods that may be irradiated in the European Union

- IPPC and Codex now use minimum dose and maximum dose
- Old standards had concept of "overall average dose" (cannot be measured, has to be calculated)
- Some regulations still have "maximum overall average dose"
- This is an example of regulations lagging behind the standards

E.g. European union countries

"maximum overall average dose" = 10 kGy

The maximum dose allowed = 15 kGy

Overall average absorbed dose

FOODSTUFFS AUTHORISED FOR IRRADIATION TREATMENT AND MAXIMUM RADIATION DOSES

Category of foodstuff	Maximum overall average absorbed radiation dose (kGy)
Dried aromatic herbs, spices and vegetable seasonings	10

$$\text{overall average dose} \approx \frac{\bar{D}\text{max} + \bar{D}\text{min}}{2}$$

D min = 5 kGy,

D max = 15 kGy

Overall average dose = $\frac{5 + 15}{2}$ = 10 kGy

Labelling

Codex General Standard for Irradiated Foods

7. LABELLING

7.1 Inventory Control

For irradiated foods, whether prepackaged or not, the relevant shipping documents shall give appropriate information to identify the registered facility which has irradiated the food, the date(s) of treatment, irradiation dose and lot identification.

7.2 Prepackaged Foods Intended for Direct Consumption

The labelling of prepackaged irradiated foods should indicate the treatment and in all aspects should be in accordance with the relevant provisions of the *Codex General Standard for the Labelling of Prepackaged Foods* (CODEX STAN 1-1985, Rev.2-1999).

Codex General Standard for the Labelling of Prepackaged Foods

5.2 IRRADIATED FOODS

5.2.1 The label of a food which has been treated with ionizing radiation shall carry a written statement indicating that treatment in close proximity to the name of the food. The use of the international food irradiation symbol, as shown below, is optional, but when it is used, it shall be in close proximity to the name of the food.

5.2.2 When an irradiated product is used as an ingredient in another food, this shall be so declared in the list of ingredients.

5.2.3 When a single ingredient product is prepared from a raw material which has been irradiated, the label of the product shall contain a statement indicating the treatment.

Labelling in practice

Irradiated pre-packaged foods

- most countries require a statement e.g. “irradiated” or “treated by irradiation” etc. (generally same for unpackaged foods)
- some mandate use of the radura symbol, but this is optional in others.
- A few countries require the purpose of irradiation to be included

Ingredients

- Irradiation is generally declared on list of ingredients
  - No minimum cut off, e.g. in all EU countries irradiated ingredients must be labelled no matter how minor the ingredient
  - Other countries have a cut off - e.g. in Canada if irradiated ingredient is less than 10% of finished product no need to label
  - BUT, some countries don’t label ingredients as irradiated e.g. USA only requires labelling as irradiated when the whole product is irradiated

Small packets

- some countries don’t require ingredient labelling on small packages (e.g. <100 cm^2) but instead require labelling on wholesale packages.

Conclusions

Legislation, laws, codes, standards

- International framework exists - international trade agreements and standards
- Authorities ultimately decide their regulations based on these agreements/standards (but updates are needed e.g. - different food authorizations, max. and min Dose rather than “overall average dose”, labelling harmonization)
- Increasing trade helps improve regulations (e.g. irradiated fruits and vegetables and recent trade developments)
- Maximum dose limits indicate technological limit *NOT* food safety risk
  - Ensure good food quality (wholesomeness)
- Food safety relies on correct treatment (minimum dose applied, audits of facilities)
- Labelling – to enable consumer choice but is it necessary to label all minor ingredients?

New York, June 2019
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Thanks.

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