



DOSES



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Specified doses

- ❑ Specified by the owner of the goods to be irradiated

- ❑ Two values required:

- ❑ A minimum value

- No part of the product shall receive less



- ❑ A maximum value

- No part of the product shall receive more



- ❑ Radiation processor is required to meet these dose specifications, not to obtain the desired effect (or absence of effect)

Specified minimum dose

1. Based on research

Postharvest Irradiation Treatment for Quarantine Control of *Drosophila suzukii* (Diptera: Drosophilidae) in Fresh Commodities

Peter A. Follett, Allison Swedman, Donald K. Price

Journal of Economic Entomology, Volume 107, Issue 3, 1 June 2014, Pages 964–969,

No first or second instars ... pupae, developed to the adult stage at a radiation dose of 40 Gy

2. Based on standard / regulation



ISPM 28
Annex 14

INTERNATIONAL STANDARDS FOR
PHYTOSANITARY MEASURES

ISPM 28:2007 PHYTOSANITARY TREATMENTS
FOR REGULATED PESTS

PT 14: Irradiation treatment for
Ceratitis capitata

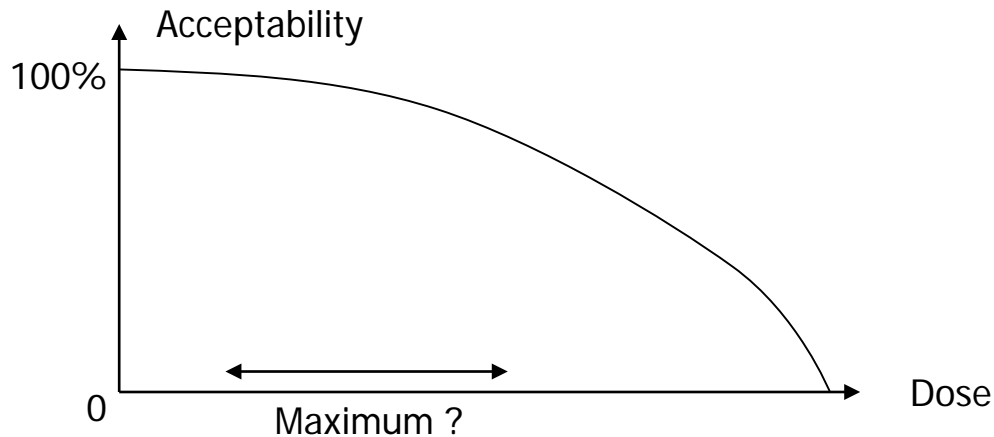
Treatment schedule:

Minimum absorbed dose of 100 Gy to prevent the emergence of adults of *Ceratitis capitata*

...[will result in] 95% confidence that the treatment prevents emergence of not less than 99,9970% of adults

Specified maximum dose

1. Based on tests to determine a threshold (sensory or nutritional)



2. Based on a standard / regulation

Australia New Zealand Food Standards Code
Standard 1.5.3 – Irradiation of food

1.5.3—3

Irradiation of fruit and vegetables



- F2017C00053

In force - Latest Version

[View Series](#)

- (1) Fruit and vegetables listed in subsection (2) may be irradiated for the purpose of pest disinfestation for a phytosanitary objective, if the absorbed dose is:
 - (a) no lower than 150 Gy; and
 - (b) no higher than 1 kGy.



The 1 kGy upper limit for fresh produce

1986: US FDA approves irradiation for preservation and disinfestation of fresh fruits and vegetables up to 1 kGy

In the US irradiation is regulated as a food additive

Chemiclearance concept was used.

Assumption: Up to 1 kGy, *unique radiolytic products* – if any - would be negligible or difficult to study.

No method available yet to chemically distinguish irradiated and non-irradiated produce

Hence the exemption from animal feeding tests

- Studies available **then** suggested about half of the fruit and vegetables irradiated for various purposes would maintain quality and half would not



The 1 kGy upper limit for fresh produce

1980: Joint WHO-FAO-IAEA Expert Committee on the Safety of Irradiated Food

Food irradiated up to 10 kGy is safe

1986: US FDA approves irradiation for preservation and disinfestation of fresh fruits and vegetables **up to 1 kGy**

1989: Joint WHO-FAO-IAEA Expert Committee on the Safety of Irradiated Food

Wholesomeness of food irradiated with doses above 10 kGy

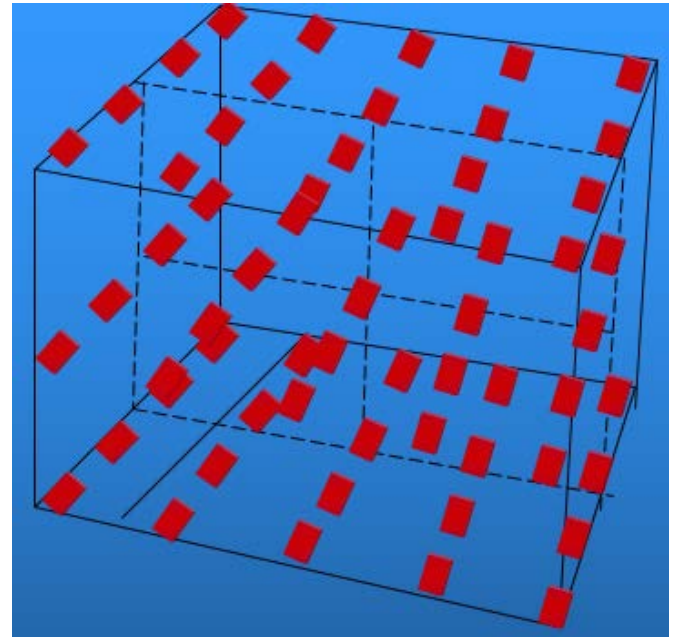
2003: Codex Alimentarius revised *General Standard for Irradiated Food* permits 10+ kGy but does not stipulate a maximum dose for fresh produce

2003: ISPM 18: Guidelines for the use of irradiation as a phytosanitary measure does not stipulate a maximum dose

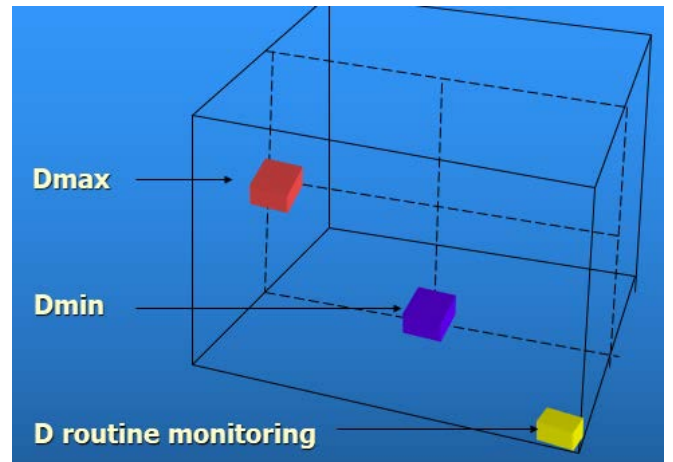
2008: FDA permits irradiation of fresh spinach and iceberg lettuce up to 3 kGy to control pathogens

Spotting Dmin and Dmax

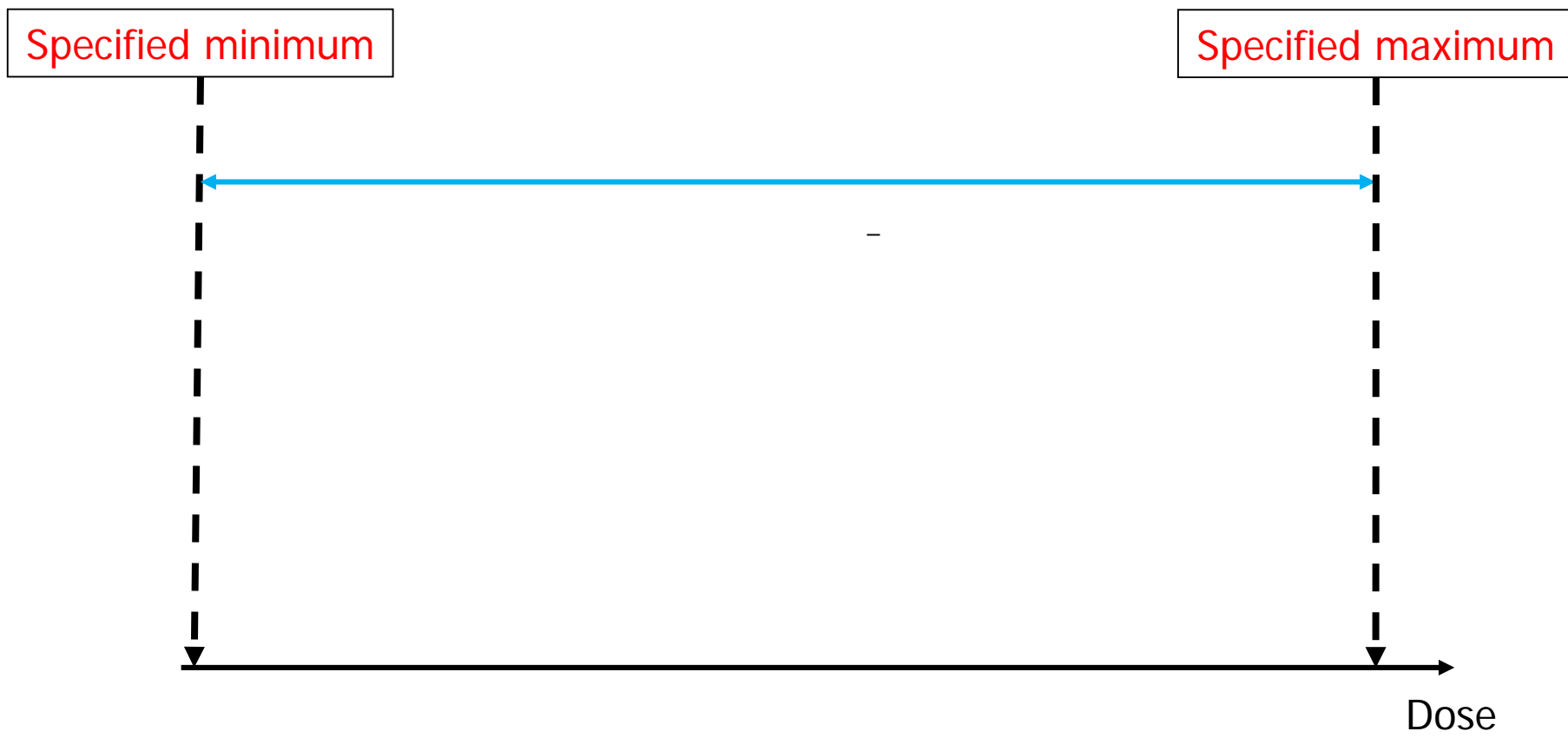
- By placing many dosimeters throughout the load the locations of the minimum dose and maximum dose are identified (dose mapping).
- In routine, these values are directly or indirectly monitored.



gamma



What is the Processing window?





What you get from a dosimeter

A measure of the dose in the dosimeter

From reading out one dosimeter one does not get THE dose but A POSSIBLE DOSE among a continuum of doses within a certain range

UNCERTAINTY

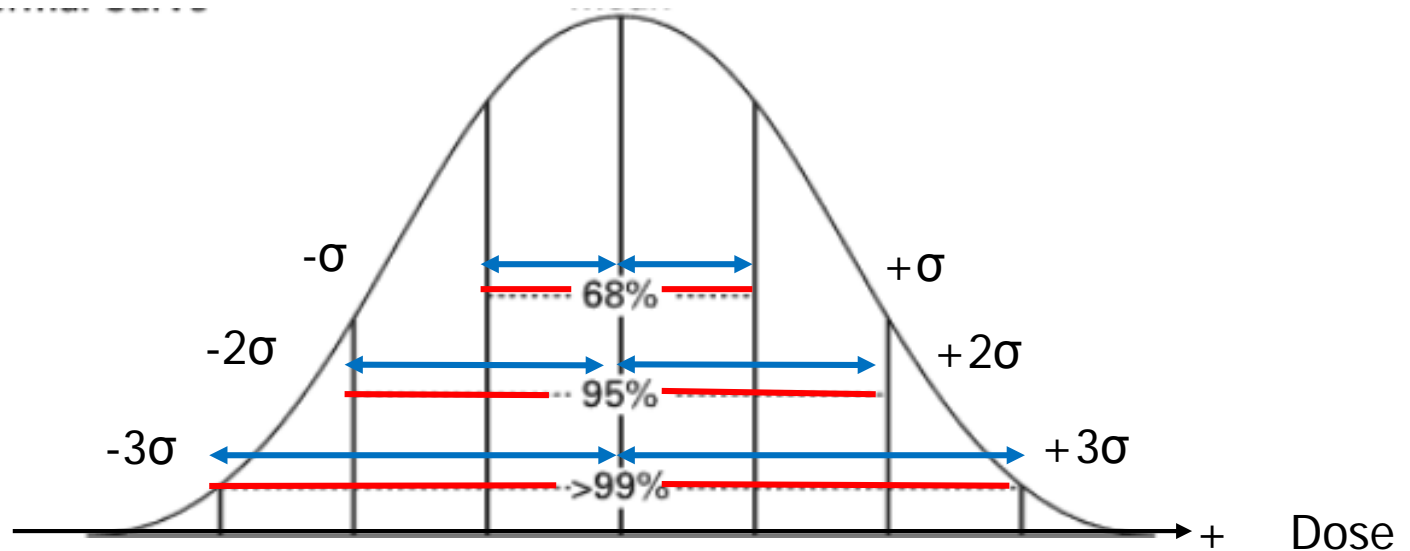
Reading: 400 Gy

If uncertainty is 7 % (compounded result of uncertainty on dosimeters and process related variability) the dose is

between 372 Gy and 428 Gy

Confidence level

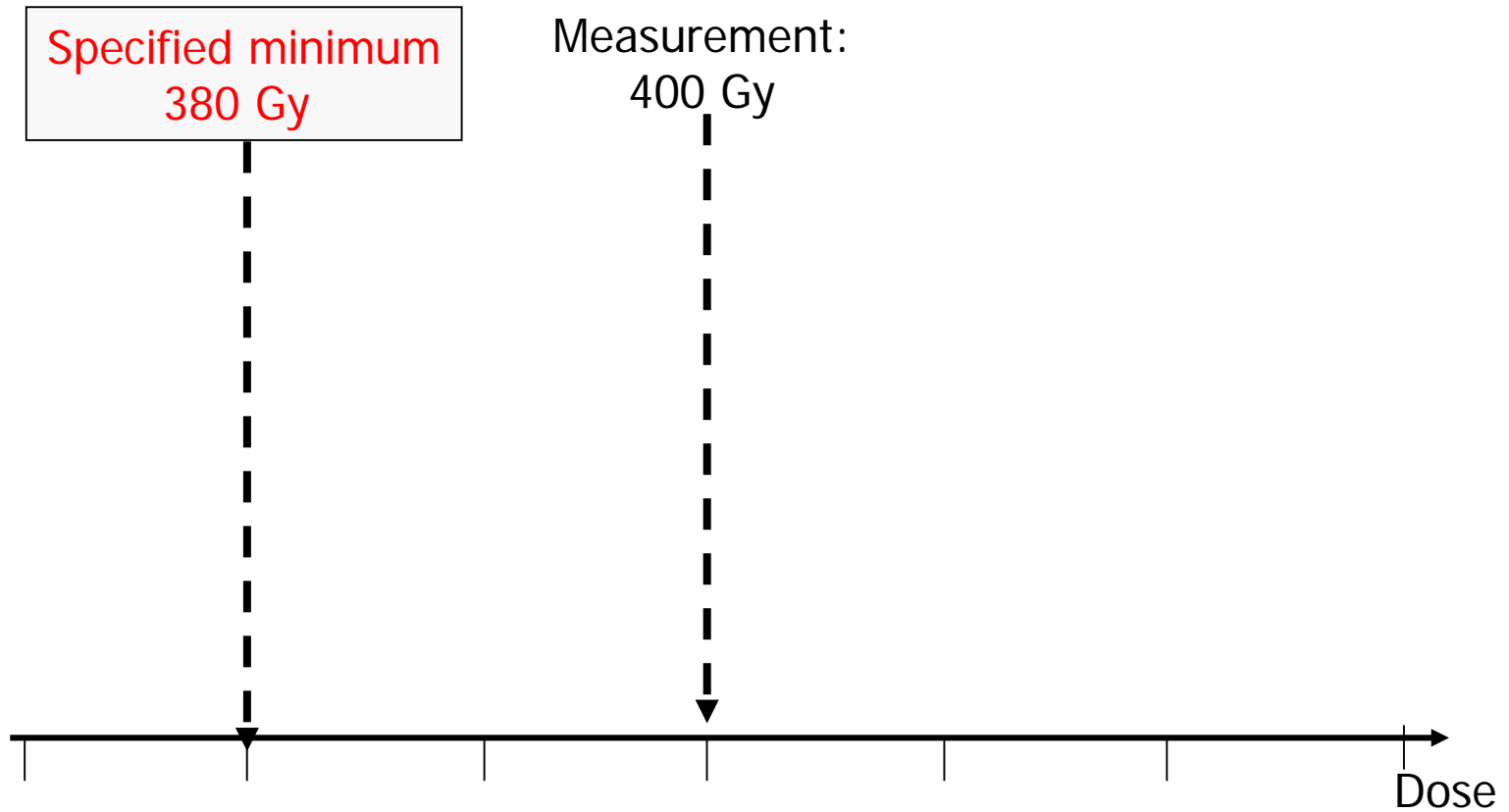
The *standard deviation* (σ) quantifies the (Normal) dispersion of a set of values



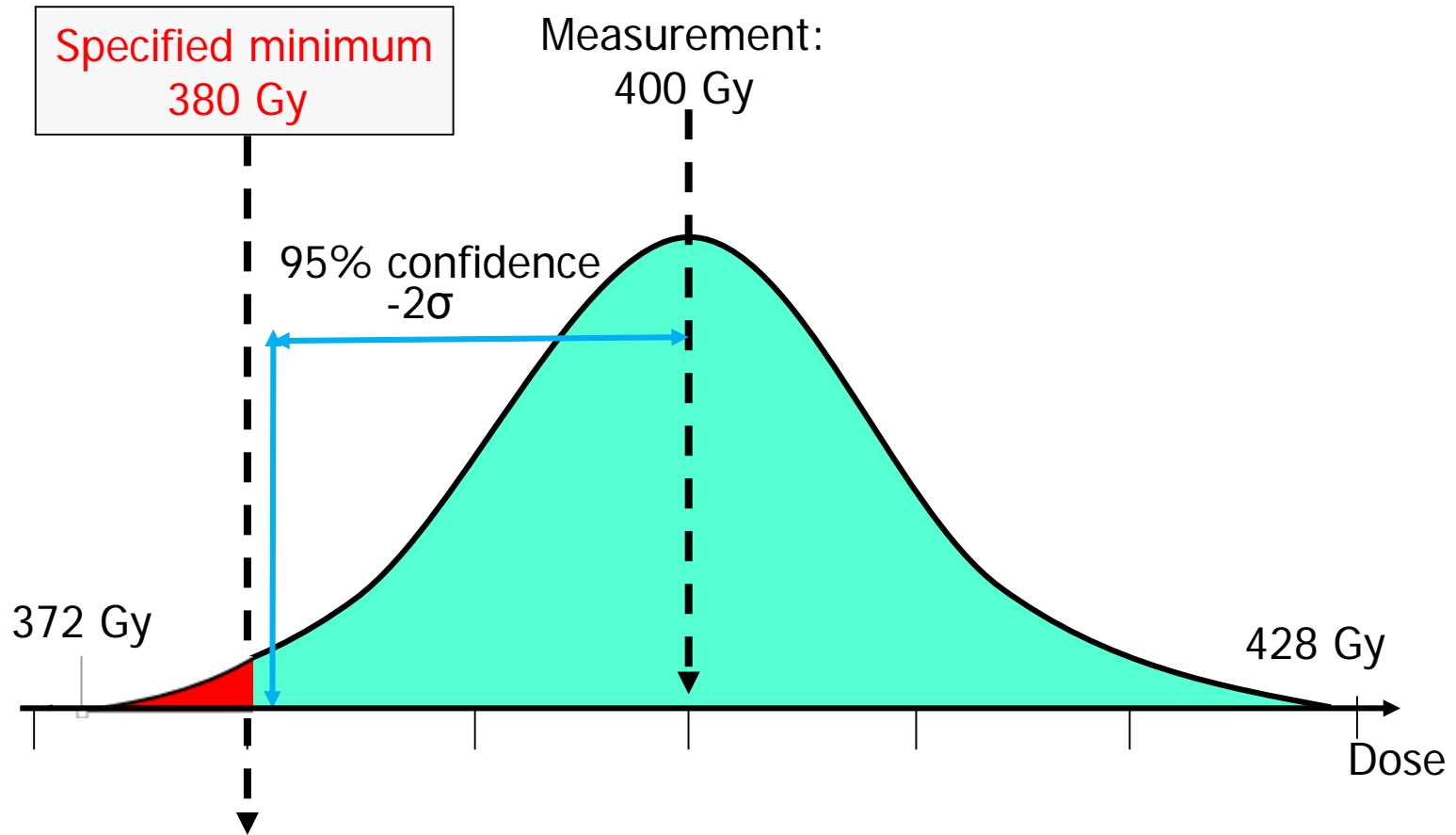
--- Confidence level ---
= probability of the dose being in the interval

No requirement on the level of confidence of **dosimetry** in ISPM 18 and treatment schedules in annexes of ISPM 28

Acceptability of measure

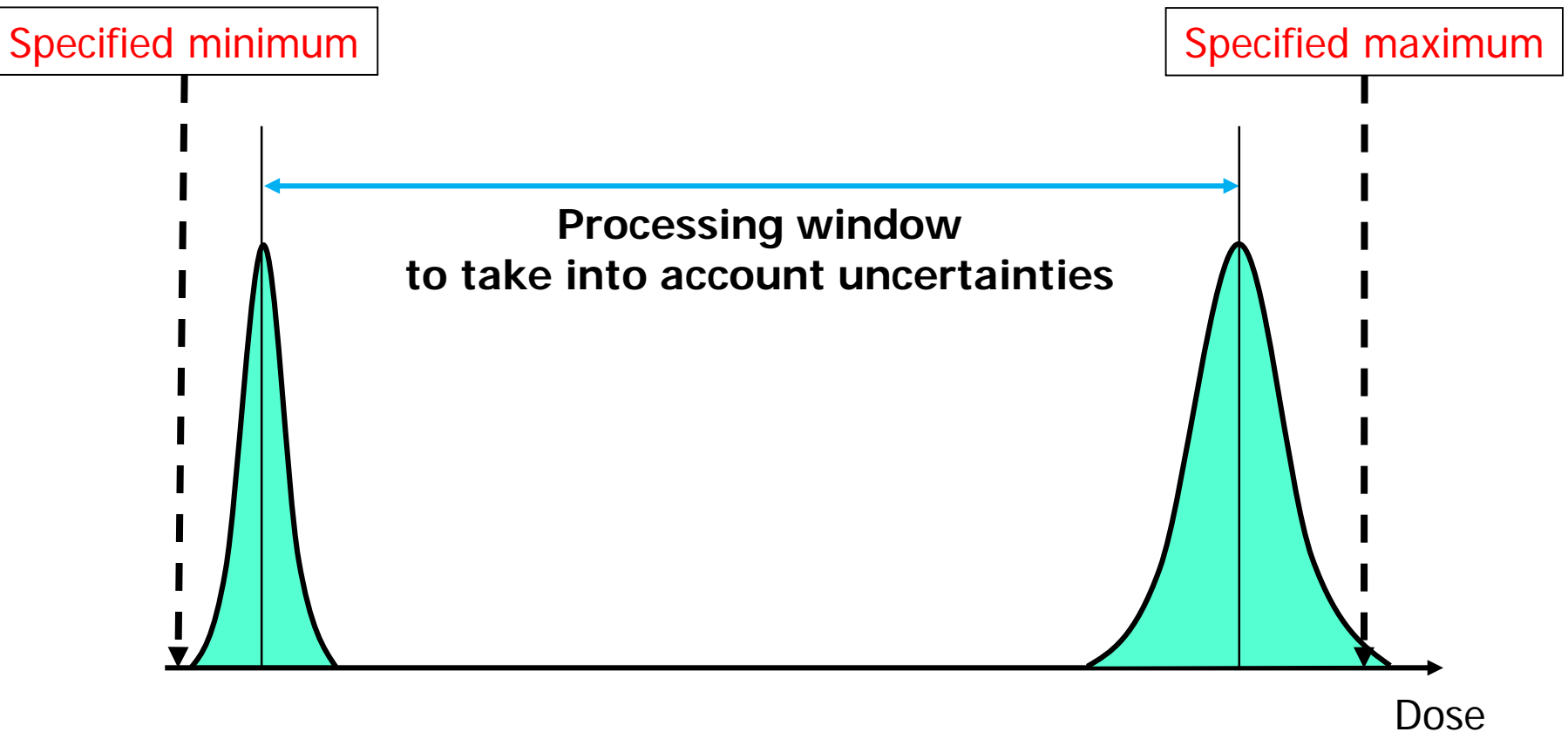


Acceptability of measure

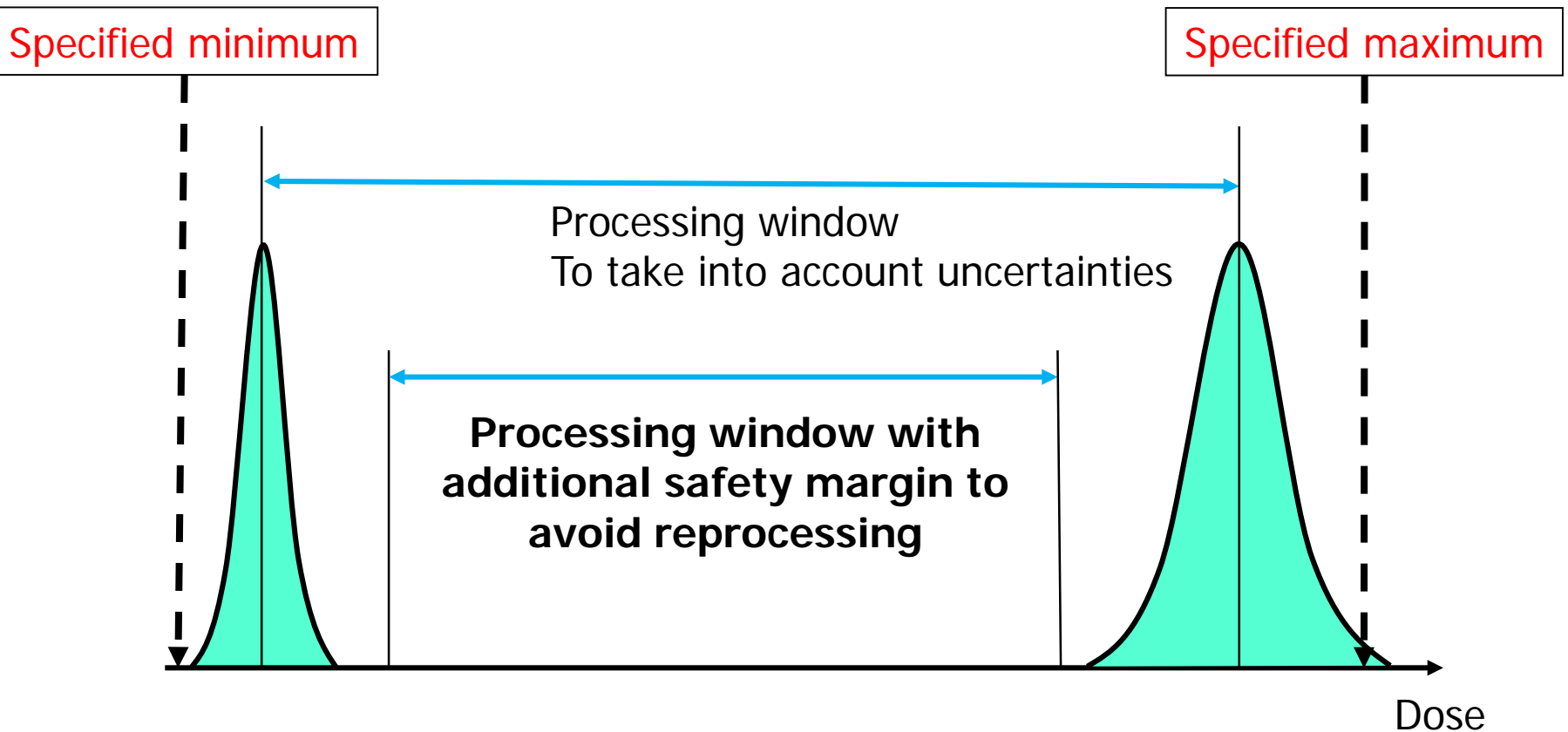


Out of the 95% confidence area

Narrowing processing window 1



Narrowing processing window 2



The 1 kGy upper limit for fresh produce

- The 1 kGy regulatory upper limit makes processing more challenging - and sometimes impossible - for radiation processors, especially with EB.

This limit restricts the potential for applications

- On the basis of new knowledge and experience gained, the 1 kGy upper limit for fresh produce no longer appears justified.
- Maximum dose to be dictated by quality and marketability (only)



Initiative of the International Irradiation Association to initiate a revision of the 1 kGy upper limit (and expand objective of treatment to pathogens)