



FOOD IRRADIATION SUBMISSION CHECKLIST

Submissions for amendment of Division 26, Part B of the Food and Drug Regulations

Please, provide all information in black ink. Where appropriate, place checkmarks (U) in the boxes to indicate the desired response.

We request that the completed and signed checklist accompany the submission package. The package, if less than 20 pages, may be sent electronically, using the words "Food Irradiation Submission" in the subject line of the E-mail: smiu-ugdi@hc-sc.gc.ca. Otherwise, a hardcopy and, if possible, a softcopy (e.g. CD-ROM, DVD) of the submission package should be mailed to the Submission Management and Information Unit, Food Directorate, Health Products and Food Branch, Health Canada, 251 Sir Frederick Banting Driveway, Postal Locator: 2202E, Ottawa, Ontario, Canada, K1A 0K9. For additional information on submission preparation, please refer to A Guide for the Preparation of Submissions on Food Additives.

FOR USE BY HEALTH CANADA ONLY: Date of receipt CHHAD Mailno

Petitioner Information

1. Name of petitioner (manufacturer, company, consultant, importation agent, etc.):

[Empty text box for petitioner name]

2. Full postal address:

No. and street [ ] City [ ] Country [ ] Postal code [ ]

3. Contact information:

Primary [Country code] [Area code] [Number] Alternative [ ] [ ] [ ] Fax [ ] [ ] [ ] Email [ ]

4. Alternative name and address for correspondence:

[Empty text box for alternative name and address]

Description of the Submission

5. Title:

[Empty text box for title]

6. Date of Submission :

Day [ ] Month [ ] Year [ ]

7. Please indicate the technical purpose of this application for the use of irradiation:

- Anti-microbial preservation
Anti-infestation
Quarantine
Sprouting Inhibition

Checklist of enclosed information and data

8. Cover letter

[ ] Yes [ ] No

9. Purpose and details of the proposed irradiation (B.26.005 a)

[ ] Yes [ ] No

10. Efficacy data of the proposed irradiation (B.26.005 b)

[ ] Yes [ ] No

11. Information pertaining to dosimeters and dosimetry (B.26.005 c)

[ ] Yes [ ] No

12. Effects of irradiation on the nutritional quality of irradiated food (B.26.005)

[ ] Yes [ ] No

13. Data demonstrating safety of applied irradiation (food chemical, physical and microbiological characteristics, B.26.005 e)

[ ] Yes [ ] No

14. Data demonstrating toxicological safety of applied irradiation (B.26.005 f)

[ ] Yes [ ] No

15. Recommended conditions of storage and shipment of irradiated food (B.26.005 g)

[ ] Yes [ ] No

16. Details of other technological processes applied to food (B.26.005 h)

[ ] Yes [ ] No

17. Any other relevant data and information (B.26.005 i)

[ ] Yes [ ] No

18. If you checkmarked "No" for any items listed above, please provide a rationale for not providing that information:

[Empty text box for rationale]

Summary of information pertaining to the irradiation technique

Please summarize the purpose and details of the applied irradiation; dosimeters and dosimetry; efficacy data pertaining to the dose applied; chemical / physical / microbiological / nutritional effects of the irradiation; details of pre- and post-irradiation; handling and storage of the food; specific toxicological end-points if applicable; status of other national jurisdictions; other important relevant information (e.g. any additional technological process applied).

[Empty text box for summary]